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Unused medication waste: respondent's opinion from current study in Malaysia.

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Abstract

There are a lot of effort have been employed to find out the major factor which increase the volume of medication waste. However, several survey reports were highlighted the key factors of medication waste like lack of knowledge on the serious impact of unused medication waste, neglected the proper disposal technique, not following the drug take bag system, pharmacy or dispensaries were not providing proper guideline or any materials to return unused medicines to the pharmacy, not enough campaign or community activities on medication waste, educational institute were not taking any responsibility like institution base extra seminar or lecturer on dangerous environmental impact and serious public health problem due to unused medications. However, this report will be encouraged to the government policy maker, social and welfare department and health facilities department to take an emergency necessary steps to reduce or resolved this problem.

Keywords: Knowledge, Attitude, Unused medications, Medication waste, Public health, Environment.

Introduction

Medication return program (MRP) was first introduced in year 2010 as an initiative from Pharmaceutical Service Division, Ministry of Health Malaysia. With its objectives to preserve the environment from hazardous pharmaceutical compounds and to prevent accidental ingestion, misuse and abuse of extra medication, the core function of MRP is to provide public a safe place to dispose unused medication [1]. Unused medication collected by pharmacies is managed as clinical waste and incinerated by waste management company. On the other hand, inappropriate disposal of unused medication has led to the traces of pharmaceutical waste like analgesic, anticonvulsant, antiepileptic, antibiotics accumulated in landfills and leached into freshwater environment [2]. This detrimental effect can be expected in countries where landfilling is the predominant method of managing municipal solid waste, such as Malaysia [3, 4].

More importantly, Malaysian's awareness on environmental hazard caused by unsafe medication disposal are largely unknown. Several international studies have shown that 48-75% of the population are aware that improper disposal of unwanted medication will lead to contamination of the environment [5-8].

From the previously published research reports which explored the opinion and practice regarding disposal of unused medication among patients and general medication consumers in Malaysia. This effort was conducted to elucidate unused medication disposal practice and their impact on environment as well as public health. Al-Nagar et al., (2010) performed an in-depth interview with 28 patients during the period from December 2009 until February 20. Majority of the participants were male, 15 (53.6%), older than 55 years old, 18 (64.3%), Malay, 20 (71.4%) and married, 24 (85.8%). The most common diseases reported among the participants were hypertension, 11 (39.3%) and diabetes mellitus type II, 6 (21.4%). There were three main frequent disposal methods practiced by the respondents, the majority of them threw unused medication into the trash, 16 (57.1%), followed by burning the unused medication, 4 (14.2%) and storing it in a refrigerator, 4 (14.2%). The majority of the participants, 17 (60.7%) mentioned that the best way to educate the public about disposal unused medication is through school, university and public campaign. The most used method to dispose unused medication among Malaysian patients is a throw of unused medication into the trash [9].

Azad et al., (2012) performed a descriptive cross sectional survey involving patients-based structured questionnaire format with answer sets; carried out at International Islamic University Malaysia (Health centre Gombak campus, Selangor) and the medical college of the International Islamic University Malaysia (Kuantan campus, Pahang). Although, 87% of the respondents had primary knowledge on medications waste and its impact on public health, majority of the respondents (93%) were not familiar with the drug-take-back system. However, only ~2% of the total respondents properly follow the drug-take-back system. Most of the participants reported disposing off in a manner that leads to more than 65% ending up in a landfill. In addition, 83% of the respondents added another disposal system that ultimately ended up in a landfill. A survey suggested that there is an urgent need to develop public awareness and dispensing policies & delivery to

collection bag which reduces the volume of medication waste [10]. There is a growing concern of unintended consequences of inappropriate medications disposal on the environment and public health.

Lim et al., (2016) conducted a cross sectional survey using a self-administered closed-ended questionnaire on information, medications disposal and views, awareness of medications take back program and reasons for their unwillingness to return the unused and unwanted medication to pharmacy or doctor. A convenient sample of 438 patients at Out Patient Pharmacy and Patient Registration areas in the hospital were collected which completed within three months. Only 44.5% had ever received information about medications disposal and were significantly more likely to return them to a pharmacy or doctor (29.2% versus 6.0%, $p < 0.001$). There were significant differences between tertiary and non-tertiary institutions with regard to not returning to pharmacy or doctor (22.8% versus 42.0 %, $p = 0.004$). Some common medications disposal methods were throwing medications away with household garbage, 38.3% (n = 168), returning to pharmacy or doctor, 35.1% (n = 154) and flushing medications down the toilet or sink 11.0% (n = 48). About 50.2% (n = 220) knew about medications take back program and were significantly more willing to return the medication to the assigned location (34.7 % versus20.1%, $p < 0.001$). The main reasons for unwillingness were availability of time, not convenient or a bother and out-of-vicinity location. There is a clear need to create public awareness about issues on safe medication disposal and medications take back program [11].

Azad et al., (2016) conducted a descriptive cross-sectional audit involving patients-based structured questionnaire format with set answers. The data was analyzed using partial least square method. The results revealed that excess supplied, expired medicine, changed treatment and side effects have a significant impact on unused medication. In addition, overall unused medication had a significant relationship with environmental effect. In contrast, although excess supplied and side effects had no significant impact on environmental effect, expired medicine and changed treatment had significant impact on environmental effect. The data therefore suggested that there are few factors which increased the volume of leftover medicine and this led to an enhanced international awareness of the potential detrimental effects on the environment. More effort are needed to raise public awareness as an initial step towards promoting behavioural change in connection to medication wastage [12].

Visually impaired individuals are particularly at higher risk of experiencing medication error. In a study to identify the problems encountered by the visually impaired population when handling their medication, cross-sectional survey was conducted using an interviewer-guided questionnaire with 100 visually impaired individuals. The questionnaire comprised of series of questions in medication management. All of the respondents perceived that self-administration of medication was a challenging task. A total of 89% of respondents were unable to read the prescription labels, 75% of respondents did not know the expiry date of their own medication, and 58% of respondents did not know the name of the medication. With regard to storage of medication, 72%

of respondents did not practice appropriate methods to store their medication, and 80% of respondents kept the unused medication. All of the respondents disposed leftover medication through household rubbish. A total of 64% of respondents never practice medication review. Most (96%) of them did not tell health-care providers when they faced difficulties in handling their medication. Most of the visually impaired individuals did not receive appropriate assistance regarding medicine use and having low awareness in medication management. This can lead to increased risk of medication errors or mismanagement among visually impaired population. Hence, effective strategies, especially in pharmaceutical care services, should be structured to assist this special population in medication handling [13].

Yang et al., (2018) conducted a cross-sectional study in 33 out-patient pharmacies in Sabah healthcare facilities. Quota sampling was used to recruit 244 subjects. Data collected from each facility was identified and trained prior to data collection. Self-reporting questionnaire captured data of socio-demographic, awareness on MRP and patient's knowledge and practice towards unused medication. Independent t-test and chi square test were performed to detect differences and association. Subject mean (SD) age was 45.1(15.5) years and almost two-third (60%) of the subjects were female. Majority (73%, 95%CI 67- 78%) knew that inappropriate disposal of medication will cause environmental hazard. Only 54% (95% CI 47-60%) had heard of MRP, 26% (95%CI 21-32%) had utilized MRP to return unused medication. Subject's awareness on environmental hazard and MRP were associated with their practice to return unused medication ($p=0.001$ and $p<0.001$ respectively). Mean years of education and median family income were significantly different between the aware and unaware group respectively [11.3(6.0) vs 8.9(4.5) yrs, $p=0.003$; RM2000 vs RM1260, $p<0.001$]. The most common unused medication were analgesics (27.1%), antihypertensive (24.4%), antiglycemic (14.7%) and supplements (12%). The two predominant methods to "dispose" unused medication at home were through garbage (47.8%) and return to healthcare facilities (30.0%). This study established the need for public awareness on MRP, environment awareness and disposal practice of Malaysian citizen. Creative and innovative recommendations have been made for MRP promotion and to improve public knowledge on safety disposal of unused medication [14].

CONCLUSION

To develop the public awareness about dangerous effect of medication waste on public health and environment is the most important target of this present report. This report will help facilitate an enhanced national or local and international awareness of the potential detrimental effects on the environment and public health of unused medication waste.

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CONFLICTS OF INTEREST

All authors declared no conflict of interest.

REFERENCES

1. Bahagian Perkhidmatan Farmasi. Garis Panduan Program Pemulangan Ubat. 3rd ed.; 2016.
2. Murray KE, Thomas SM, Bodour AA. Prioritizing research for trace pollutants and emerging contaminants in the freshwater environment. Environ Pollut. 2010;158: 3462-71.
3. Manaf L, Samah M, Zukki N. Municipal solid waste management in Malaysia: Practices and challenges. Waste Manag. 2009; 29:2902-6.
4. Paut KM, Tomas A, Sabo A. Disposal of Unused Drugs: Knowledge and Behavior Among People Around the World. In: Reviews of Environmental Contamination and Toxicology. 2016; 240:71-104.
5. Abdallah QMA, Al-Haddad MSM, Al-Khathami OHM, et al. Knowledge, Attitude and Practice towards Discarding Unwanted Household Medicines among Univerisity Students in Western Region, KSA. Int J Pharm. 2014; 4:14-21.
6. Wieczorkiewicz SM, Kassamali Z, Danziger LH. Behind Closed Doors: Medication Storage and Disposal in the Home. Ann Pharmacother. 2013; 47:4 82-9.
7. Kusturica MP, Sabo A, Tomic Z, Horvat O, Šolak Z. Storage and disposal of unused medications: knowledge, behavior, and attitudes among Serbian people. Int J Clin Pharm. 2012; 34: 604-10.
8. Kotchen M, Kallaos J, Wheeler K, Wong C, Zahller M. Pharmaceuticals in wastewater: Behavior, preferences, and willingness to pay for a disposal program. J Environ Manage. 2009; 90: 1476-82.
9. Al-Naggar, R.A. and Alareefi, A., 2010. Patients' opinion and practice toward unused medication disposal in Malaysia: a qualitative study. Thai J. Pharm. Sci. 34; 117-123.
10. Azad, M., Kalam, A., Akhter, M.A., Ansary, M.R.H., Al-Mamun, S.M., Uddin, M. and Rahman, M., 2012. Disposal practice for unused medications among the students of the International Islamic University Malaysia. J App Pharm Sci. 2012; 2:101-106.
11. Lim MT. Disposal practices of unused and unwanted Medications among patients in a Tertiary hospital. Edu Med J. 2016;8: 49-59.
12. Azad, A.K., Muhammad, K.R., Hossin, M.M., Robiul, I., Abdullahi, M.M. and Islam, M.A. Medication wastage and its impact on environment: Evidence from Malaysia. Pharmacologyonline. 2016; 3:114-121.

13. Zhi-Han L, Hui-Yin Y, Makmor-Bakry M. Medication-handling challenges among visually impaired population. Arch Pharma Pract. 2017; 8:8-14.

14. Yang SL, Tan SL, Goh QL, Liau SY. Utilization of Ministry of Health Medication Return Programme, Knowledge and Disposal Practice of Unused Medication in Malaysia. J Pharm Pract Commu Med. 2018;4(1); 7

Study on Short-term and long-term Quality of life in patients with acute musculoskeletal injuries undergone treatment

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Abstract

Introduction: This study aimed to investigate the quality of life in patients with acute musculoskeletal injuries was done during the short and long term.

Methods: This prospective study on 65 patients with acute musculoskeletal injuries in hospitals affiliated to University of Medical Sciences Iran. Data collection instrument was a questionnaire SF-36 quality of life. To evaluate changes in quality of life scores using paired t-test. For statistical analysis software SPSS version 21 was used.

Results: The quality of life score on admission time was in average of 74.4. This time was at the beginning tracking the quality of life of the people in the study were referred. After a month follow-up, the average quality of life score, has large drop (61.7). After 6 months of follow-up in the study, quality of life scores showed that 73.02 number. In this study, quality of life scores 86.07 in physical function, 76.53 in after limitations due to physical problems, 62.56 in after limitations due to emotional problems, 66.79 in after refreshing, 76.92 in social functioning 81.65 in pain and 72.53 in after public health shows.

Conclusion: Three-time pursuit of quality of life for patients with musculoskeletal problems undergone treatment revealed the second one-month period, significantly decrease quality of life and long-term period of six months is almost equal to the amount in the first period. In case of non-intervention and proper treatment may lead to a high probability of subjects, quality of life was worse.

Keywords: quality of life, acute musculoskeletal injury, questionnaire SF-36

Introduction

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Musculoskeletal injuries (*MSI*) are the most common type of injury in the world. According to the World Health Organization (WHO, 1985), musculoskeletal problems occur following a multi-agent etiology, such as working conditions, physical conditions, work-related organizational conditions, physiological conditions, and individual and sociocultural factors. Ergonomic mode of inappropriate working time, repetition of a motion during high intensity work, excessive activity and body placement under difficult conditions can be considered as a risk factor that leads to skeletal musculoskeletal disorders. Other reasons can be: lack of adequate rest, excessive work, inappropriate mode of handling when working with a computer, long working hours, physiological factors, etc. [1]. Musculoskeletal pain, as compared with other types of pain in the Primary Care Services system, is the most common type of pain which occurs over and over again and imposes more disability and financial burden [2]. According to a recent U.S. Bureau of Labor Statistics, Musculoskeletal disorders account for 44% of work-related injuries, costing $45-54 million a year. In Europe, chronic musculoskeletal disorders occur at an intermediate or severe level in 19% of adults, and these conditions can reduce their daily activities to a high degree and, as a result, reduce their quality of life [4]. The study of the global burden of diseases shows that most of the admissions to health centers caused by traffic accidents and various non-lethal injuries have been caused by musculoskeletal injuries. A total of about 50% of non-lethal injuries included fractures, and disorders and muscle soreness [2]. Quality of life is a mental concept of feeling good and satisfying life experiences which includes the positive and negative aspects of a person's life, and represents a way that a person understands the state of health and other aspects of his life and responds to that[5].

The mental image is one of the effective factors in the quality of life and health, research has also shown that people who have not had a positive mental image of their bodies have decreased their quality of life after the disease [6]. The World Health Organization considers quality of life as a concept that includes physical health, mental status, social communication and environmental conditions. In fact, quality of life is a patient-centered approach that evaluates the patient's condition and status rather than expert assessment [7]. While the world's people spend more years of life with disability, they have grown overall in terms of life expectancy. One of the major contributing factors in years of life with disability is chronic musculoskeletal conditions [8]. Pain is one of the main attributes of the survival experience of societies, which has a negative effect on physical performance and quality of life scores [9]. Musculoskeletal problems are a factor for pain and loss of function and complicated complications with high prevalence, resulting in high costs and physiological damage to the individual [10-11]. In a study on the quality of life of employed and unemployed women, it was found that the prevalence of musculoskeletal pain in employed women is slightly higher. Musculoskeletal pain and depression were recognized as an effective factor in the quality of life of both groups [12]. Working life can increase the quality of life, including the economic conditions, relationships with friends and family, career prospects, entertainment and lifestyle, educational opportunities, living conditions, expectations of the future, and standard living standards. Further, quality of life is related to working conditions, age and marital status, and the number of children [13]. Adolescent obesity is also one of the causes of musculoskeletal disorders, which limits their physical function and reduces

their quality of life [14]. Musculoskeletal pain clearly affects the quality of life associated with health [15]. Musculoskeletal disorders as one of the major causes of illness in the world have a severe negative impact on the quality of life associated with health [16]. It is also said that musculoskeletal disorders are associated with depression, stress and mental conditions [17]. For this reason, one of the goals of the Bone and Joint Decade is to provide health-related quality of life for people with musculoskeletal problems or those at risk for these disorders in a rapidly increasing world of awareness of Suffering and pain and cost. By empowering patients to participate in decision-making on how to care and provide services for them, early prevention and treatment can be improved by expanding the understanding of musculoskeletal characteristics and improving treatment and prevention through study [16]. In general, muscle damage leads to bone fractures, pain, decreased physical activity, functional imbalance, motor limitation, disability, permanent disruption to participation in sports activities, loss of working time, health costs, psychological problems And even death [18]. further, the assessment of quality of life in patients provides valuable information to doctors and nurses, because doctors and nurses as the most important members of the patient care team from the first moments after the onset of the disease have been associated with patients for years and undertaken emotional support of the patient and his family and the control of treatments [19]. Despite the importance of quality of life, the most relevant research has been conducted in developed countries. However, their findings may not be generalized to the Iranian community. In addition, the available research has not been accompanied by decisive results in this regard. Therefore, the present study aimed to determine the short-term and long-term quality of life in the patients with acute muscular damage requiring supportive care in the short term of one month and a long term of 6 months, perhaps, with its accurate identification in the planning of necessary health services care for these patients is useful.

Materials and methods

This research is a prospective before-after study conducted on Sixty-five patients with acute skeletal musculoskeletal injuries in need of supportive care referred to hospitals affiliated to the University of Iran, including Haft Tir Martyrs Hospital, Rasoul Akram, Firoozabadi and others. People over the age of 15 will be enrolled in the study. People who need surgery or physiotherapy will be excluded from the study. People who are not able to work together, such as those with mental retardation and people with cerebral palsy, will also be excluded from the study. For each patient, information about the type of musculoskeletal injuries and the time needed for complete recovery will be collected and the quality of life of the patients will be assessed and evaluated at three points in time, one month after injury, and six months after the injury. In the implementation of this plan, all provisions of the Helsinki Statement will be implemented. Descriptions are given to individuals for collaborative research and their consent to be included in the study is asked verbally. Researchers are committed to the Helsinki Treaty at all stages of their research, and the information of participants is used without disclosing their identities. Persons will be free to discontinue to cooperate in this research at any stage of the research and for any reason or even without any specific cause. Individual data is encoded to exclude their names. Data collection is done through SF-

36 quality of life questionnaire. The Quality of Life Questionnaire (36SF) has 36 questions and consists of 8 subscales and each subscale consists of 2 to 10 items. The eight subscales of this questionnaire are: physical functioning (PF), role impairment due to physical health (RP), role impairment due to emotional health (RE), energy/fatigue (EF), emotional well-being (EW), social function (SF), Pain (P) and General Health (GH). Further, the integration of sub-scales involves two subsamples with the names of physical health and mental health. In this questionnaire, lower scores represent lower quality of life and vice versa. Montazeri and his colleagues examined the reliability of this questionnaire for the Iranian society and obtained the standard coefficients of reliability of the scale of this questionnaire between 0.77 and 0.9, which indicates the suitability of questionnaire for use in the Iranian society. The results for quantitative variables are expressed as mean and standard deviation (mean ± SD) and for the qualitative variables, expressed as percentages. T-test was used to compare quantitative variables, and chi-square test was used to compare qualitative variables. Paired t-test is used to assess changes in the quality of life score. The significance level is considered less than 0.05. SPSS 21 will be used to analyze the data.

Findings and results

The ratio of male participants in this study was 58.5% and the female ratio was 41.5%. The average age of participants in this study was 35.71 years, the oldest in the study was 60 years old, and the youngest was 17 years old. The majority of participants in the study studied had a diploma (69.2%). Other participants were combined with 13.8% of the diploma and 13.8% of the diploma and 3.1% of the bachelor's degree. Short leg cast with 41.5%, and left short-leg cast, THUMP cast, Bandagh 8, hand volar cast, Short gypsum and Left-foot cast with the abundance of 1.5% are the largest and the least therapeutic procedures respectively (Table 4).

Table 1. Procedures

FREQUENCEY PERCENT	FREQUENCEY	VARIABLE
41.5	27	SHORT LEG CAST
1.5	1	THUMP cast
1.5	1	left short-leg cast
1.5	1	Bandagh 8
4.6	3	jones Bandagh
16.9	11	Short hand cast
13.8	9	LONG LEG CAST
9.2	6	LONG HAND CAST
3.1	2	gypsum
1.5	1	hand volar cast
1.5	1	SHORT gypsum
1.5	1	LEFT LEG CAST

100	65	SUM

After calculating the quality of life score, the average quality of life at admission was 74.4. After a month of follow-up, the average total quality of life in the study population was 61.7. After completing the 6-month follow-up period, the overall average of quality of life of the participants in the study was 73.02 (Table 2).

Table 2. Average score of quality of life at admission

VARIABLE	MINIMUM	MAXIMUM	MEAN	RANGE OF VARIATION	STANDARD DEVIATION
Quality of life at admission	25	97.43	74.4	72.43	19.2
Quality of life one month after admission	19.17	96.94	61.7	77.78	19.07
Quality of life six month after admission	22.92	97.65	73.02	74.73	17.47

Average quality of life one month after admission significantly decreased (p = 0.001). However, there was no statistically significant correlation between the mean of quality of life and its mean in return after 6 months and follow up (p = 0.24). That is, supportive care has been able to bring quality of life back to the time of visit. There was difference about 1.4 units of quality of life at 6 months after referral and during referral (Table 2).

Table 3. Changes at various dimensions of quality of life

quality of life	quality of life at admission	quality of life one month after admission	quality of life six month after admission
PHYSICAL FUNCTION	86.0769	63.8205	81.3846
PHYSICAL ROLE	76.5385	52.6923	74.2308
MENTAL HEALTH	62.5641	62.0513	65.1282
ENERGY	66.7949	56.1538	62.6042
EMOTIONAL ROLE	69.0462	63.3385	65.9219
SOCIAL FUNCTION	76.9231	61.5385	73.6538
PHYSICAL PAIN	81.6538	55.2308	75.6538

GENERAL HEALTH	72.5385	71.1346	76

The quality of life score (the physical function) decreased significantly after one month after the visit (p = 0.001). After 6 months follow up, the quality of life of the patient increased to one month and decreased to 4.69 after the first visit, which was statistically significant (p = 0.008). The average quality of life (physical function) showed decrease (23.84) one month after the visit (p = 0.001), which this difference reached to 23 units of difference after six month and this difference was not significant statistically (0.585 = p). The average quality of life (mental health) after one month (0.51 unit of decrease) and six months (2.56 unit of decrease) was not significant statistically. Dimension of quality of life (energy) decreased by 10.64 units (p = 0.001) after a month and decreased by 4.19 units after 6 months from the beginning of the visit, which both were statistically significant. In the emotional role, the difference was also observed with referrals 5.7 and 3.12, respectively, 1 month and 6 months after referral, both of which were statistically significant (p = 0.001) and (p=0.022). In the dimension of social function, the mean of quality of life in individuals was 15.38 units less (p = 0.001), which was 3.26 after 6 months, due to the relative improvement of patients. However, it was not significant (p = 0.062). The quality of life scores in the aspect of physical pain showed a decrease of 26.42 units after one month of follow-up, that is, the pain of patients was relatively high. After completing the 6-month follow-up period, the difference in the quality of life score in the study showed a decrease of 11 units, both of which were statistically significant (p = 0.001). Changes in quality of life in the general health dimension in the first month decreased by 1.4 units (which was not statistically significant: p =0.4) and showed an increase of 3.46 units 6 months after referral (p = 0.025).

Discussion

The present study aimed to determine one-month short-term quality of life and six-month long-term quality of life in patients with acute musculoskeletal disorders requiring supportive care. The participants in this study were 65, of which 38 (58.5%) were male and 27 (41.5%) were female. The majority of them (69.2%) had a post-graduate degree. Therapeutic procedures for these patients were Short leg cast, and left short-leg cast, THUMP cast, Bandagh 8, hand volar cast, Short gypsum and Left-foot cast. In general, they did not have severe and fatal injuries and were selected among those who came to hospitals affiliated to Iran University of Medical Sciences and had inclusion criteria for this study. Quality of life score of individuals during referral to take care was 74.4, that is, in the beginning of follow-up the individuals with quality of life score participated in the study. After one month follow-up, average score of quality of life declined. After 6 months of follow up, the quality of life score of individuals showed 73.02. In general, the present study shows that one month after the admission, people with musculoskeletal disorders experience a relative decline in their quality of life, and after 6 months with a recovery, the quality of life score is relatively higher than the acceptable level, but it does not return to its original state. In a study by MAC Van Son et al in 2015, 171 patients with lower limb fractures with an average age of 49.7 years, using the WHOQOL-BREF questionnaire and the musculoskeletal muscle performance

evaluation questionnaire during the follow-up period 1) at diagnosis, 2) One week after diagnosis and 3 months after the diagnosis, the results indicate that although significant improvements in patient's physical health score were achieved, patients did not return to the initial conditions before the injury. Based on the results of our study, it was found that after supportive treatment, physical function increased in the first month. Further, during follow up, it was found that after six months of follow-up, physical performance increased over a one-month period. But, like the study, the physical performance of patients did not return to its original state but was greatly improved, and physiological performance rates were largely close to pre-injury rates. In the study of M. A. C. Van Son et al., It was found that after the end of the follow-up period (6 months), the physiological function of patients was significantly worse compared to the time before the injury.

In our study, it was found that physical constraints after supportive care increased in the first follow-up month, but after 6 months, physical limitations were reduced and have almost equal scores with the physical constraints upon admission. Further, the results of the study by MAC Van Son et al.showed that the social function in the first week after diagnosis and treatment was improved relative to the social relationship, the scores of this area improved after 6 months compared to one week period. However, the privileges of this area are lower than the pre-injury period, which indicates that during the six months of follow-up, the social relationship of the participants has not yet fully recovered [20]. In the study of Antonio Ignacio Cuesta-Vargas et al in Spain, which evaluated the effect of 8 weeks of multi-model physiotherapy on general health status and quality of life in 224 patients with musculoskeletal disorders, the results showed that the results obtained from The assessment of physical condition is significant.

The results of this study also had relevant clinical changes in terms of relative improvement of baseline privileges. During the whole eight weeks of treatment using the multimodal physiotherapy program, it seems to improve the general health and improve the quality of life associated with health and quality of life in patients with musculoskeletal disorders. The results of this study show an average improvement in the quality of life of the participants in the study. If patients did not receive treatment, there was little chance of returning to the extent that they received the treatment before the injury. Therefore, it can be said that in the present study, the quality of life of individuals has increased, but it is not yet equal to the amount before the injury time [21]. Comparison of quality of life scores in the present study with the study of Sori and colleagues on 165 car assembly workers with musculoskeletal problems showed that the quality of life scores of 86.07 in terms of physical function, 76.53 in terms of limitation of Physical problems, 62.56 in The limitations of emotional problems, 66.79 in vitality, 76.92 in social performance dimension, 81.65 in pain dimension and 72.53 in general health. The quality of life scores of these dimensions were respectively in formal study, 38.2 for physical function, 95.2 for limitation due to physical problems, 44.2 for emotional problems, 40.6 for vitality, 40 for social function, 46.1 for pain dimension, 35.2 for health dimension Public shows. Comparing these results shows a very large difference between the quality of life scores in the various dimensions of these two studies, which can be due to differences in the type of musculoskeletal problem and due to the underlying population. Also, the overall score of the average quality of life in formal study and colleagues is 46.7, while the average quality of life in the study population is

74.4, which can be attributed to the following reasons [22]. The study by Heather K. Vincent et al., Which evaluates the quality of life and musculoskeletal pain after obesity, reveals a significant difference in the quality of life in various aspects of the lives of surgeons who have not been treated. The results of this study were approximately 11 increase units for physical dimension, 12 increase for social role dimension, 8 increase for physiological pain dimension, 12 increase for general health dimension, 12 increase for vitality dimension, 11 increase for performance, Social, 6 increase in emotional dimension and 6 increase in mental health dimension.

In the present study, after 6 months of follow-up, approximately 5 units were reduced for physical aspect, 2 units for social role, 6 for reduction in physical pain, 4 for general health, 4 for reduction in vitality dimension, 3 reduction units for social function, 3 units increase in emotional dimension and 4 units decrease in mental health. comparison of these two studies indicate differences in change of scores of mental dimensions which the reason can be due to difference in characteristics of population under study, difference in intervention type and difference in health problem in two studies. Results from study by Heather K. Vincent et al indicate that in quality of life at various dimensions reduces in obese people with basic problems after 3 months of study of scores, while as mentioned, in people underwent injury, quality of life scores in 3 months of follow-up increased in all dimensions[23].

Conclusion

At three periods of follow-up during referral and diagnosis, one month after supportive care and six months after supportive care, it was specified that quality of life at beginning of follow-up has become less than the normal rate due to musculoskeletal injuries. After one month follow-up, it was revealed that average quality of life decreases significantly, but after long-term six month period, quality of life scores approach to its rate at beginning of follow-up period. it should be noted that with regard to existing evidences, under lack of intervention and appropriate treatment with high probability, quality of life of people induced to worse conditions. With regard to reduced quality of life to conditions prior to injury, it can do the activities to improve quality of life in individuals with such problems using better interventions.

References

1. Peden M, Scurfield R, Sleet D, Mohan D, Hyder AA, Jarawan E, et al. World report on road traffic injury prevention. World Health Organization Geneva; 2004.

2. Kroenke K. Patients presenting with somatic complaints: epidemiology, psychiatric co-morbidity and management. International journal of methods in psychiatric research. 2003; 12(1):34-43

3. Denis D, St-Vincent M, Imbeau D, Jette C, Nastasia I. Intervention practices in musculoskeletal disorder prevention: a critical literature review. Applied Ergonomics. 2008; 39(1):1-14

4. Cheung K, Hume PA, Maxwell L. Delayed onset muscle soreness. Sports Medicine. 2003; 33(2):145-64

5. Ilechukwu ST. Psychiatry of the medically ill in the burn unit. Psychiatric Clinics of North America. 2002; 25(1):129-47.
6. Fauerbach JA, Heinberg LJ, Lawrence JW, Munster AM, Palombo DA, Richter D, et al. Effect of early body image dissatisfaction on subsequent psychological and physical adjustment after disfiguring injury. Psychosomatic medicine. 2000; 62(4):576-82.
7. Benavente-Aguilar I, Morales-Blánquez C, Rubio E, Rey J. Quality of life of adolescents suffering from epilepsy living in the community. Journal of paediatrics and child health. 2004; 40(3):110-3.
8. Tüzün EH. Quality of life in chronic musculoskeletal pain. Best Practice & Research Clinical Rheumatology. 2007; 21(3):567-79.
9. Furtado S, Grimer R, Cool P, Murray S, Briggs T, Fulton J, et al. Physical functioning, pain and quality of life after amputation for musculoskeletal tumours. Bone Joint J. 2015; 97(9):1284-90.
10. Sintonen H. The 15D instrument of health-related quality of life: properties and applications. Annals of medicine. 2001; 33(5):328-36.
11. Olaya-Contreras P, Styf J. Biopsychosocial function analyses changes the assessment of the ability to work in patients on long-term sick-leave due to chronic musculoskeletal pain: The role of undiagnosed mental health comorbidity. Scandinavian journal of public health. 2013:1403494812473380.
12. Baskan E, Yağci N, Telli Atalay O, Aslan Telci E. Quality of life, depression and musculoskeletal pain experience among employed women: A controlled study. Journal of back and musculoskeletal rehabilitation. 2016; 29(3):597-601.
13. GÜLMEZ H. Factors that Affecting Quality of Life of Employees. Turkish Journal of Family Medicine & Primary Care. 2013; 7(4):74-82.
14. Bout-Tabaku S, Michalsky MP, Jenkins TM, Baughcum A, Zeller MH, Brandt ML, et al. Musculoskeletal pain, self-reported physical function, and quality of life in the Teen–Longitudinal Assessment of Bariatric Surgery (Teen-LABS) cohort. JAMA pediatrics. 2015; 169(6):552-9.
15. Murray CJ, Vos T, Lozano R, Naghavi M, Flaxman AD, Michaud C, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. The lancet. 2013; 380 (7):219-223.
16. The burden of musculoskeletal conditions at the start of the new millennium. In: (Ed) WHO, editor. 2003.
17. Antonopoulou MD, Alegakis AK, Hadjipavlou AG, Lionis CD. Studying the association between musculoskeletal disorders, quality of life and mental health. A primary care pilot study in rural Crete, Greece. BMC musculoskeletal disorders. 2009; 10(1):143.
18. Margaritis I, Tessier F, Verdera F, Bermon S, Marconnet P. Muscle enzyme release does not predict muscle function impairment after triathlon. Journal of sports medicine and physical fitness. 1999; 39(2):133
19. Rafii F. design theory, nursing care of burn patients. Nursing Dissertation: Tehran University of Medical Sciences. 2004
20. Son M, Vries J, Roukema J, Gosens T, Verhofstad M, Oudsten B. The course of health status and (health-related) quality of life following fracture of the lower extremity: a 6-month follow-up study. Quality of Life Research. 2016; 25(5):1285-94.
21. Cuesta-Vargas AI, González-Sánchez M, Casuso-Holgado MJ. Effect on health-related quality of life of a multimodal physiotherapy program in patients with chronic musculoskeletal disorders. Health and quality of life outcomes. 2013; 11(1):19.
22. Souri A, Tahmasebizadeh A, Montazeri A, Jaafari M, Eyni E. The

relationship between quality of life and musculoskeletal disorders automaker's assembly line. Journal of Qazvin University of Medical Sciences. 2011; 15(1):34-8.
23. Vincent HK, Ben-David K, Conrad BP ,Lamb KM, Seay AN, Vincent KR. Rapid changes in gait, musculoskeletal pain, and quality of life after bariatric surgery. Surgery for Obesity and Related Diseases. 2012; 8(3):346-54.

Comparing the Effect of Morphine and Injecting Lidocaine on Reducing the Acute Pain of Limb Fracture: A Randomized Double-Blind Controlled Clinical Trial

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Abstract

Background: The first priority in the emergency ward of the hospitals is to control pain and provide patients comfort and then try to inhibit negative physiological responses.

Aim of the study: The aim of the present study was to compare the effect of injecting lidocaine and morphine on controlling the acute pain of limb fracture in patients referred to the emergency ward of a hospitals in Iran.

Methods: In the current randomized double-blind controlled clinical trial, 98 patients with the age range of 18-65 years and limb fracture pain were divided into two groups of lidocaine and morphine receivers. Patients with cardiovascular, renal and liver failures and the ones with known sensitivity to lidocaine and morphine or lack of consciousness were excluded from the study. The subjects in the groups received 1.5 and 1 mg/kg intravenous (IV) doses of lidocaine and morphine, respectively. Vital signs, pain scores and other signs and drugs side effects to the subjects were recorded at 5, 10, 15 and 30 minutes after taking analgesic drugs and the collected data were analyzed using SPSS ver. 21.

Results: The mean age of the subjects in the morphine and lidocaine receiver groups were 35.65±12.23 and 35.02±11.77 years, respectively. There was a significant relationship regarding

the mean of pain severity, heart rate, systolic and diastolic blood pressures and side effects between the groups (P<0.001).

Conclusions: Injecting lidocaine can be considered as a likely suitable agent to manage pain in the patients with limb fracture.

Keywords: lidocaine, morphine, acute pain, limb fracture, Iran, injection.

Introduction

Nowadays, trauma damages develop rapidly following different fractures and pains (1). Patients with trauma and limber injuries, referring to the emergency wards of hospitals need urgent treatment using an effective pain controlling method; pain management is one of the most important health care goals in the emergency wards. There are helpful attempts to control pain, but in some cases the level of pain management might not be satisfactory (2-4).

The main goal to control pain in the emergency ward is to provide patients comfort and then inhibit physiological negative responses (5, 6). There are suitable drugs with specific mechanisms to control pain such as changing pain perception in the central nervous system (opioids), inhibiting the production of local mediators (anti-inflammatory drugs) and/or preventing the transmission of messages through the spinal cord (neuraxial block) (7, 8).

Opioids are one of the most effective drugs to manage acute pains, but there are some complications regarding their use; for example, dependency and related side effects. Drug side effects cause emergency wards to prescribe lower doses of opioids, which may not provide the desirable level of pain relief (8, 9). Morphine is one of the most known and applicable analgesic opioids which newly introduced analgesics

are usually compared to it. The exclusive properties of morphine cause its easy penetration to the central nervous system (CNS), but its therapeutic effects occur slowly due to the low fat solubility. It means that morphine weakens respiratory system with lower probability compared to quick-acting opioids and also after the administration of common doses of analgesics as bolus. On the other hand, slow onset of morphine effect may increase the prescription of different doses which may result in drug toxicity. The main side effects of morphine are nausea, severe drowsiness, increased breathing rate and blood pressure drop. By increasing the dose of morphine, the effectiveness decreases due to drug tolerance (10-13). Using morphine solely cannot cause pain relief and physicians look for co-administration of morphine with other agents with different mechanisms.

Lidocaine is a local anesthetic considered as a suitable option to manage visceral and central pains when opioids are not helpful or cause complications. Lidocaine is used intravenously to control neuropathic pains such as diabetic neuropathy, post-surgery pains, pains caused by herpes simplex virus infection, headache and neurological malignancies (14, 15). Hence, considering the possibility of undesirable analgesia due to morphine prescription and the associated complications, and also similar to the analgesic effects of lidocaine with lower complications, it seems that lidocaine can be used as an analgesic drug to manage acute pains in patients with limb fracture. Therefore, the current study aimed to asess the effect of intravenous (IV) lidocaine, as an alternative for morphine, to create optimal analgesia with decreased complications in patients with limb fracture.

Materials and methods

The current randomized double-blind clinical trial aimed to compare the effect of IV lidocaine and IV morphine to manage acute pain in patients with limb fracture referring to the emergency wards of a hospital in Iran. The study was approved in the ethics committee of Iran University of medical sciences. This study was also registered in Iranian Registry of Clinical Trial (IRCT) with registration number IRCT2016060828342N1. All subjects signed the informed written consent and confident about confidentiality details of the patients. The study procedure is illustrated in Figure 1.

The study population included all patients aged 18-65 years referred to the emergency wards of hospital following the limb fracture; sampling was continued up to completing the sample size of the study. Since sampling from all patients was not possible due to different reasons, patients with the following criteria were excluded from the study: sensitivity to lidocaine and morphine, having renal, liver and cardiovascular (ischemic heart diseases and arrhythmia) disorders, being illiterate, lack of consciousness and speech ability and lack of interest to sign the informed consent to participate in the study. Patients were assured regarding the employment of standard methods and participation in the study did not interfere with the common treatment procedure.

The sample size was 96 subjects based on the study by Soleimanpour et al. (15), considering the power test of 80% and error of 5%. The subjects were randomly divided into the two groups of 48. The single doses of 1.5 mg/kg lidocaine and 1 mg/kg

morphine were administered to the subjects in groups 1 and 2, respectively.

To inject lidocaine and morphine similar syringes were used; a 10 mL of morphine solution and a 200 mg of 2% lidocaine (20 mg/mL lidocaine solution). The code and administered dose of drug was recorded on each syringe. The injection was done by a person who was unaware of the content of syringes and study groups. To consider the ethical principles in the current research, if other methods were used to relieve the pain in a subject and/or there was a case of subject exchange between the groups, the results were evaluated separately.

The drug administration was monitored and the vital signs, pain score and other symptoms and drug side effects were evaluated at 5, 10, 15 and 30 minutes of the injection and the results with the drug code were recorded in the checklists.

Data were analyzed using SPSS ver. 21. To compare the quantitative variables between the groups, the independent T-test and its non-parametric equivalent, and the Mann-Whitney test were used. To compare the qualitative variables between the groups, Chi-square and the Fisher exact tests were used. To compare the quantitative variables between the groups shortly before and after the study (evaluating the significance of the changes), the paired T-test and its non-parametric equivalent were used.

Results

Table 1 shows the comparison between the demographic personal data of the subjects in both groups. The mean age of the subjects in morphine and lidocaine receiver groups

were 35.65±12.23 and 35.02±11.77 years, respectively; there was no significant difference between the groups regarding the age (P= 0.799). Also there were no significant differences between the groups regarding the body mass index (BMI) (P= 0.833), gender (P= 0.486) and fracture site (P = 0.623).

The results of evaluating parameters affected by lidocaine and morphine injection are illustrated in Figure 2. Accordingly, there was a significant difference regarding the mean of respiratory rate (breaths/minute) in the studied time intervalin morphine and lidocaine receiver groups (P =0.0001 and P = 0.0001, respectively), but no significant difference was observed regarding the respiratory rate (breaths/minute) in the studied time interval between the groups (P= 0.167).

A significant difference was found in the heart rate (beats/minute) in the studied time interval in morphine and lidocaine receiver groups (P= 0.0001 and P= 0.0001, respectively). Significant differences were observed in the minutes 15and 30 of the study between the groups (P = 0.001 and P=0.001, respectively).

There was a significant difference regarding the mean of systolic blood pressure in the studied time intervals in morphine and lidocaine receiver groups (P = 0.0001 and P = 0.0001, respectively); the difference was significant in the same regard between the groups (P = 0.0001). The significant difference was observed regarding the mean of systolic blood pressure in the minutes 0 and 30 between the groups (P = 0.007 and P = 0.0001, respectively).

There was no insignificant difference regarding the diastolic blood pressure in the studied time interval in the morphine receiver group (P= 0.216), but a significant difference was observed in the studied time

interval in the lidocaine receiver group (P = 0.0001). There was also a significant difference regarding the same factor in the minutes 0, 5 and 30 between the groups (P = 0.0001, P = 0.02 and P= 0.002).

A significant difference was observed regarding the pain severity based on the visual analogue scale (VAS) between the studied time intervals in the morphine and lidocaine receiver groups (P = 0.0001 and P= 0.0001, respectively). Also, there was a significant difference in the same regard in the minutes 5, 10 and 30 of the studied time intervals between the groups (P = 0.0001, P = 0.001 and P = 0.0001).

Totally, 30 subjects showed no signs of drug side effects which 28 out of them were from lidocaine receiver group. The main side effects in the morphine receiver group were drowsiness (39.6%), nausea and vomiting (37.5%), and in the lidocaine receiver group the main side effect was nausea and vomiting (33.3%). More than half of the lidocaine receiver subjects showed no sign of drug side effects. There was a significant difference regarding the frequency of drug side effects between the groups (P< 0.0001).

Discussion

The current study aimed at assess the effect of lidocaine, as an alternative to morphine, on patients with limb fracture to create optimal analgesia and decrease drug side effects. Results of the study showed significant difference regarding the mean of pain severity based on VAS in the studied time interval in the morphine and lidocaine receiver groups.

Lidocaine applies the analgesic effects through the following mechanisms: blocking sodium channels and probably suppression of N-methyl-D-aspartate and G-protein receptors, which controls anatomic impulses in the dorsal horn and damaged peripheral nerves. Lidocaine makes changes in the sympathetic rhythm of smooth muscles through the reduction of crossing the afferent pathways (16-18). Wenderoth (2013) showed that patients who received lidocaine experienced longer and more desirable analgesia (18). In another study, Patanwala et al. reported that patients who underwent surgery and received lidocaine experienced longer and more desirable analgesia compared to the ones who received morphine (19). According to the study by Lin et al., patients with brain trauma also showed more desirable analgesia through receiving lidocaine (20).

Statistical analyses showed significant differences regarding the mean of pain severity in the minutes 5, 10 and 30 of the studied time interval and the mean of pain severity was lower among the subjects who received lidocaine compared to that of the ones who received morphine. In the study by Soleimanpour et al. (2012) conducted in Tabriz, Iran, the pain score in the lidocaine receiver group was significantly lower than that of morphine receiver group (15). Hence, it can be said that compared to morphine, lidocaine has more analgesic effects on the patients with limb fracture.

Subjects who received lidocaine had higher levels of systolic blood pressure in different time intervals compared to the ones who received morphine. This result was consistent with that of the Soleimanpour et al. (15), but inconsistent with the results of Lin et al., which reported that lidocaine and morphine both had the same effects on the

decrease of systolic blood pressure (20). These different results may be derived from different study population, pain severity, type and pattern of the pain, administered doses and also different affecting mechanisms of the two drugs on relieving the pain.

The level of diastolic blood pressure reduction was different in the groups; a significant different was observed between the minutes 1, 5 and 30 of the study time interval, in favor of lidocaine receiver group. Results of the studies conducted by Moharari et al. (2008) in Tehran, and Soleimanpour et al. (2012) in Tabriz showed that the effect of lidocaine on the reduction of diastolic blood pressure was more than that of morphine, which was consistent with the results of the current study. At the beginning of the treatment, the level of systolic and diastolic blood pressures in the patients who received lidocaine was higher than those of the patients who received morphine. Lidocaine induces its effects over the time and decreases systolic and diastolic blood pressures more, compared to morphine. Meanwhile, morphine has low effects on blood pressure changes (Figure 2).

There was a significant difference regarding the mean of respiratory rate (breaths/minute) in the studied time interval in the lidocaine receiver group. Lidocaine decreased the respiratory rate more than morphine in the minutes 0 to 30 of the study time interval which was consistent with the results of other studies (15, 22).

One of the most important results of the study was that the side effects observed in 95.8% of morphine receivers and 41.7% of the lidocaine receivers. It means that lidocaine receivers faced lower drug side effects. The type of drug side effects is different in the studies. For example, in the

study by Soleimanpour et al. (2012), the drowsiness was the most frequent side effect of lidocaine, but the prevalence of side effects was generally lower among lidocaine receivers (15). Hames et al. also indicated the lower side effects of lidocaine compared to morphine (23).

Due to the side effects and therapeutic window for these two drugs, different doses should be used for different people; in other words, lidocaine has lower limitations with increasing doses, but increasing the dose of morphine may cause side effects and toxicity. However, considering some side effects of the drugs it can be said that compared to morphine, IV lidocaine may have more desirable analgesic effects and lower side effects. Lidocaine is a low cost drug with low temporary side effects and short half-life of 2.5-3 hours (24); also, it promptly responds to the treatment. Therefore, IV lidocaine can be considered a safer drug to control acute pains in the patients with limb fracture.

The key limitations of the study were short time and limited resource to involving the high number patients in the study and unwillingness of some patients to participating in the study.

Conclusions

The current study showed that IV lidocaine has lower side effects and more desirable analgesic results to relieve the pains of limb fracture. Also, most of the vital signs had better statuses in lidocaine receivers. The current study suggests that IV lidocaine can be considered as a likely choice to relieve pain and cause optimal analgesia in the traumatic patients with limb fracture in the emergency ward of hospitals.

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Conflict of Interest

The authors report no conflicts of interest.

References

[1].Zargar M, Modaghegh M-HS, Rezaishiraz H. Urban injuries in Tehran: demography of trauma patients and evaluation of trauma care. Inj 2001;32(8):613-7.

[2]. Goodacre S, Roden R. A protocol to improve analgesia use in the accident and emergency department. J Accid Emerg Med 1996;13(3):177-9.

[3]. Jantos TJ, Paris PM, Menegazzi JJ, Yealy DM. Analgesic practice for acute orthopedic trauma pain in Costa Rican emergency departments. Annu emerg med 1996;28(2):145-50.

[4]. Rupp T, Delaney KA. Inadequate analgesia in emergency medicine. Ann emerg med 2004;43(4):494-503.

[5]. Kelly DJ, Ahmad M, Brull SJ. Preemptive analgesia I: physiological pathways and pharmacological modalities. Can J Anaesth 2001; 48(10):1000-10.

[6]. Yealy DM. Ketorolac in the treatment of acute pain: The pendulum swings. Annu emerg med 1992;21(8):985-6.

[7]. Flacke JW, Flacke WE, Bloor BC, Van Etten AP, Kripke BJ. Histamine release by four narcotics: a double-blind study in humans. Anesth Analg 1987;66(8):723-30.

[8]. McNicol ED, Midbari A, Eisenberg E. Opioids for neuropathic pain. Cochrane Database Syst Rev 2013;8:1-99.

[9]. Wibbenmeyer L, Sevier A, Liao J, Williams I, Light T, Latenser B, et al. The impact of opioid administration on resuscitation volumes in thermally injured patients. J Burn Care Res 2010; 31(1):48-56.

[10]. Lipp J. Possible mechanisms of morphine analgesia. Clin Neuropharmacol 1991;14(2):131-47.

[11]. Desbiens NA, Wu AW, Broste SK, Wenger NS, Connors AF, Lynn J, et al. Pain and satisfaction with pain control in seriously ill hospitalized adults: findings from the SUPPORT research investigations. Crit care med 1996;24(12):1953-61.

[12]. Al-Hasani R, Bruchas MR. Molecular Mechanisms of Opioid Receptor-Dependent Signaling and Behavior. Anesth 2011;115(6):1363-81.

[13]. DuPen A, Shen D, Ersek M. Mechanisms of opioid-induced tolerance and hyperalgesia. Pain Manag Nurs 2007;8(3):113-21.

[14]. Dix SK, Rosner GF, Nayar M, Harris JJ, Guglin ME, Winterfield JR, et al. Intractable cardiac arrest due to lidocaine toxicity successfully resuscitated with lipid emulsion. Crit car med 2011;39(4):872-4.

[15]. Soleimanpour H, Hassanzadeh K, Vaezi H, Golzari SE, Esfanjani RM, Soleimanpour M. Effectiveness of intravenous lidocaine versus intravenous morphine for patients with renal colic in the emergency department. BMC urol 2012;12(1):13.

[16]. Kurabe M, Furue H, Kohno T. Intravenous administration of lidocaine directly acts on spinal dorsal horn and produces analgesic effect: An in vivo patch-clamp analysis. Sci Rep 2016; 6: 26253.

[17]. Kim JE, Choi JB, Koo B-N, Jeong HW, Lee BH, Kim SY. Efficacy of Intravenous Lidocaine During Endoscopic Submucosal Dissection for Gastric Neoplasm: A Randomized, Double-Blind, Controlled Study. Med 2016;95(18).

[18]. Wenderoth BR, Kaneda ET, Amini A, Amini R, Patanwala AE. Morphine versus fentanyl for pain due to traumatic injury in the emergency department. J Trauma Nurs 2013;20(1):10-5.

[19]. Patanwala AE, Holmes KL, Erstad BL. Analgesic response to morphine in obese and morbidly obese patients in the emergency department. Emerg Med J 2014;31(2):139-42.

[20]. Lin C-C, Yu J-H, Lin C-C, Li W-C, Weng Y-M, Chen S-Y. Postintubation hemodynamic effects of intravenous lidocaine in severe traumatic brain injury. Am J Emerg Med 2012;30(9):1782-7.

[21]. Moharari RS, Khademhosseini P, Espandar R, Soleymani HA, Talebian M, Khashayar P, et al. Intra-articular lidocaine versus intravenous meperidine/diazepam in anterior shoulder dislocation: a randomised clinical trial. Emerg Med J 2008;25(5):262-4.

[22]. Bektas F, Eken C, Karadenız O, Goksu E, Cubuk M, Cete Y. Intravenous paracetamol or morphine for the treatment of renal colic: a randomized, placebo-controlled trial. Annu emerg med 2009;54(4):568-74.

[23]. Hames H, McLeod S, Millard W. Intra-articular lidocaine versus intravenous sedation for the reduction of anterior shoulder dislocations in the emergency department. Ca J emerg med care 2011;13(06):378-83.

[24]. Gordon D, Shroeder M. Intravenous lidocaine for postoperativ e analgesia: renewed interest in an old strategy. APS Bulleti. 2008;18(3):1-4.

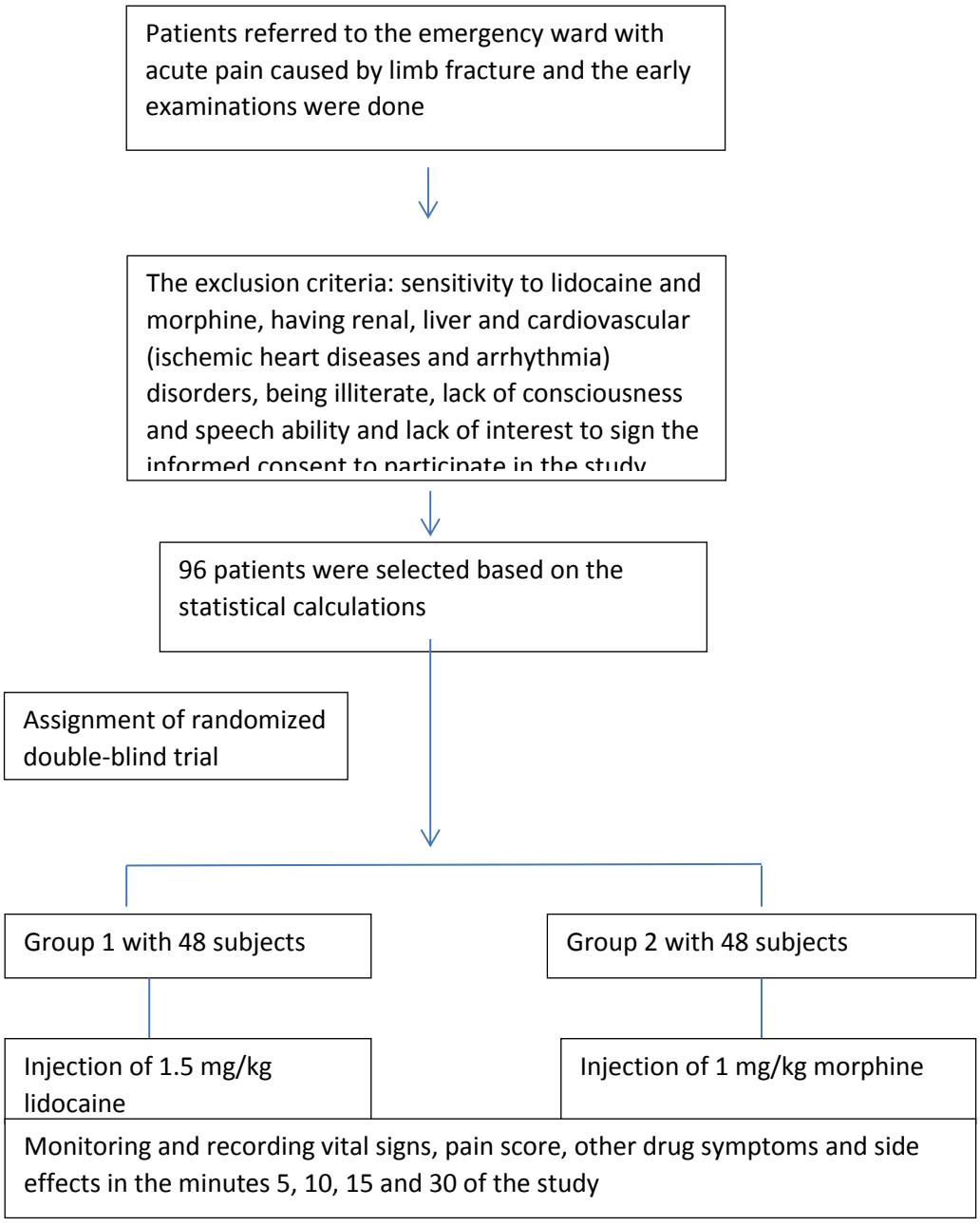


Figure 1. Study Procedure

Table 1. Comparing the Groups of the Study Based on Demographic Variables and Fracture Site

Variable	Group 1; Morphine Receivers Mean ± SD	Group 2; Lidocaine Receivers Mean ± SD	P-value
Age (year)	35.65±12.23	35.02±11.77	0.779
*BMI	25.4±3.25	25.55±3.61	0.833
	Frequency (%)	**Frequency (%)**	**P-value**
Gender			
Male	42 (87.5)	45 (93.8)	0.486
Female	6(12.5)	3 (6.2)	
Fractures site			
Right upper extremity	17 (14.6)	11 (22.9)	0.623
Right lower extremity	12 (25)	9 (18.8)	
Left lower extremity	12 (25)	14 (29.2)	

*BMI, body mass index

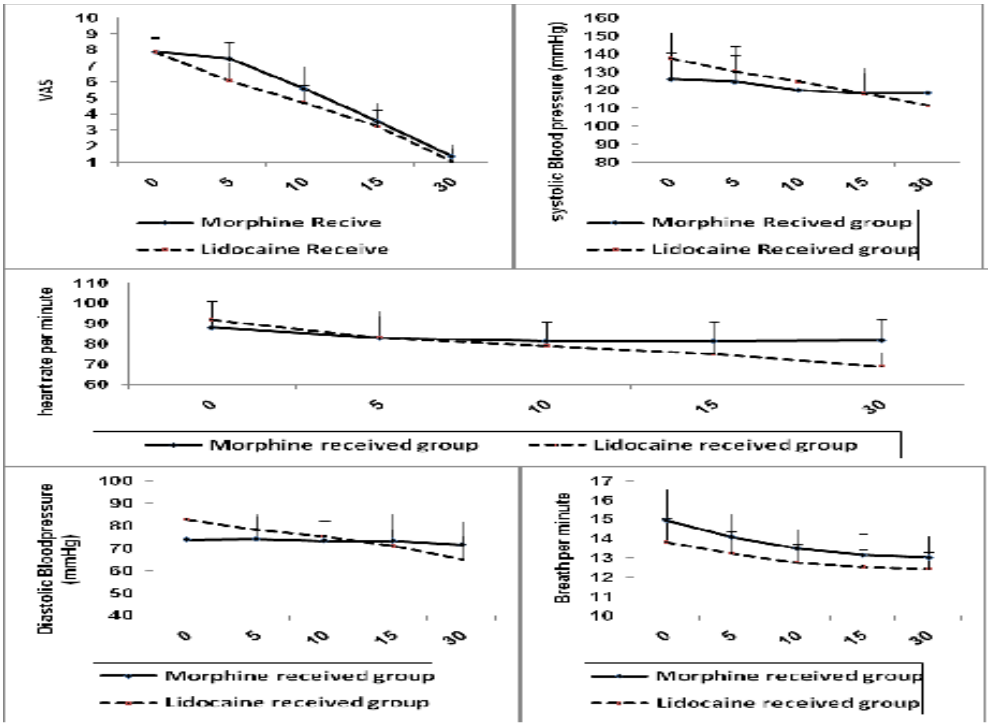
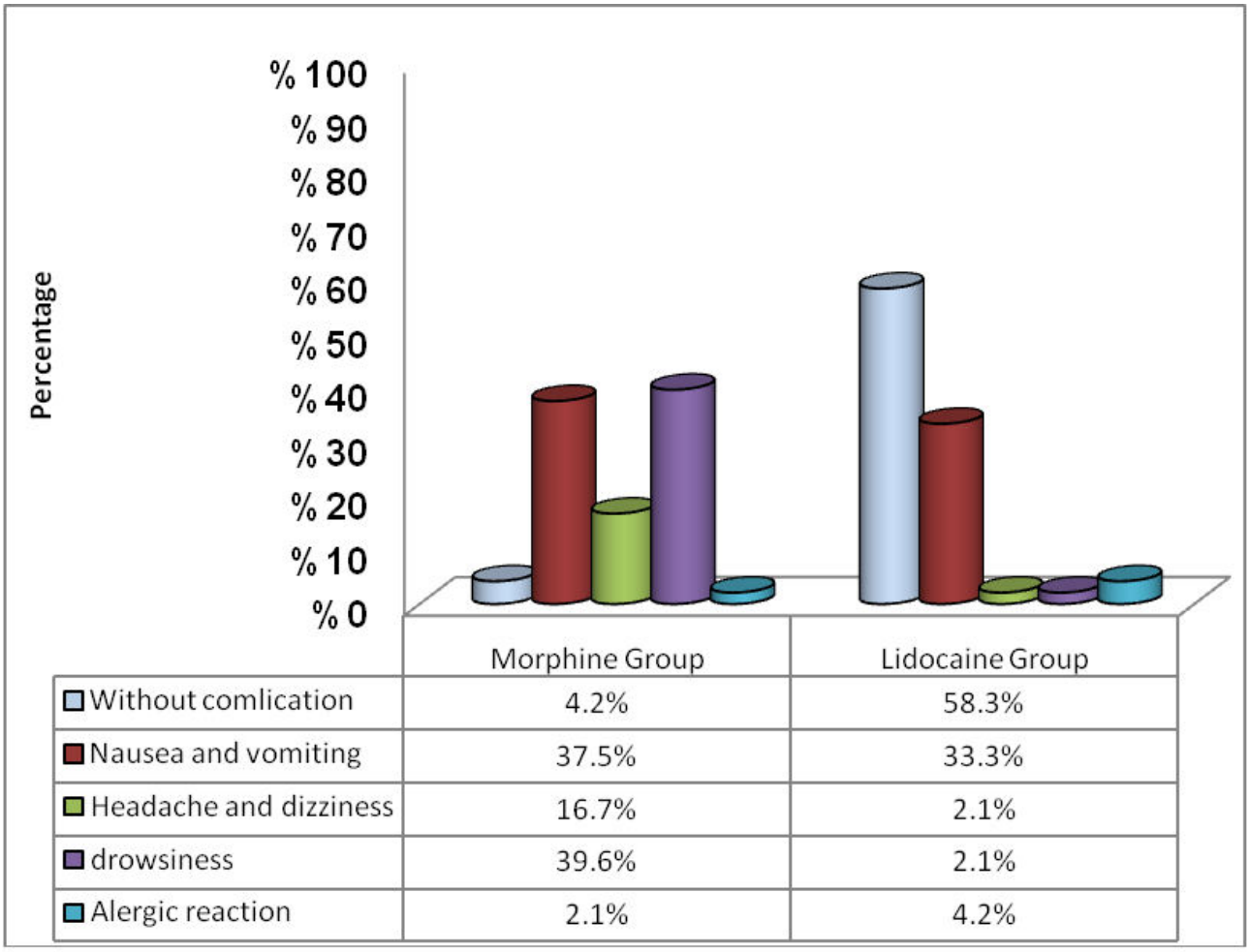


Figure 2. Comparison change of VAS, blood pressure, breathing rate and heart rate between morphine and lidocaine received groups duration time interval (minute 0, 5, 10, 15, 30)



	Morphine Group	Lidocaine Group
Without comlication	4.2%	58.3%
Nausea and vomiting	37.5%	33.3%
Headache and dizziness	16.7%	2.1%
drowsiness	39.6%	2.1%
Alergic reaction	2.1%	4.2%

Figure 3. Evaluating the frequency distribution of different drug side effects in the morphine and lidocaine receiver groups

Evaluation of the relationship between spiritual well-being, social dignity, and quality of life in elderly patients with cardiovascular disease

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Introduction: With respect to the growing elderly population, the need for attention to their quality of life (QOL) increases. Two of the factors affecting their quality of life (QOL) are spiritual well-being and social dignity. This study was carried out with the objective of evaluating the relationship between spiritual well-being,

Materials and Methods: One hundred fifty elderly patients with cardiovascular disease who were admitted to the only cardiac center in Ilam were evaluated in the present descriptive analytical research. The tools used included the Ellison and Paloutzian spiritual health questionnaires, the social dignity questionnaire for heart patients, and the sf-36 Quality of Life Questionnaire. Data were analyzed using descriptive & inferential statistics.

Results: The findings showed that most of the participants had moderate spiritual health, moderate social dignity, and a fairly good QOL. Patients' social dignity improved by improving their spiritual health and their QOL. Also, the elderly men had better spiritual health, social dignity, and QOL than did the elderly women.

Conclusion: With respect to the effects of social dignity and spiritual health on the QOL of patients with cardiovascular disease, interventions to improve their spiritual health and social dignity in order to increase their QOL are recommended.

Keywords: Spiritual health, social dignity, quality of life, Elder, heart disease

Introduction:

For decades, one's state of health was based on physical, mental, and social aspects. Suggestions about including spiritual health into the concept of health added a new aspect of individual and group life for healthcare experts (1). In fact, spiritual health is the newest aspect of health which has been placed next to other aspects of health (2). Some even believe that other aspects of health are not sufficient for enjoying perfect health without also incorporating spiritual health, and therefore, it is impossible to have a good quality of life (QOL) without spiritual health (3).Several studies have shown the connection between body, mind, and spirit; and the effect of one's beliefs and desires on one's physical health (4-7).

Health is a holistic concept, which includes physical, social, cultural, emotional, intellectual, spiritual, mystical, esoteric, communicational, and cognitive aspects. Spiritual health is a less understood concept among these mentioned aspects, and there are more challenges facing it (8).Spiritual health is neither limited to the effects of prayer nor psychological states on recovery, nor is it about replacing conventional medical treatment or medicine (1). It can be said that spiritual health is an important aspect of human health and palliative care that provides coordination and integration between internal forces, and it is characterized by stability in life, peace, balance, and harmony; as well as intimacy with self, God, society, and the environment (9). Religious practices may not treat a patient but they can help a person feel good, prevent health problems, and cope with disease and death (10).

Another essential component of specialized palliative care is respecting the dignity and rights of other people regardless of nationality, race, religion, color, age, gender, socioeconomic status, or political beliefs (11). Social dignity for patients includes their social concerns and social connections that can strengthen or weaken their dignity (12, 13). Identification and promotion of a patient's dignity can lead to patient satisfaction, confidence in their care, a reduced length of hospitalization, and improved patient health outcomes. On the other hand, reducing a patient's dignity can undermine the physical and mental aspects of the patient's health (14, 15). One of the diseases that reduce spiritual health and social dignity are heart diseases (16).

Heart diseases are considered the common chronic illness and the greatest cause of death among adults; and heart failure is known as the common final pathway of all cardiac disorders (17).Heart failure leads to many symptoms, such as shortness of breath, dizziness, angina pectoris, edema, and ascites. These symptoms lead to decreasing activities and changes in the patient's lifestyle that affect their satisfaction and QOL (18). The association of disability in elderly individuals with heart diseases leads to negative consequences as shown in several studies which reported that older people have a poor QOL. The objective of this study was to determine the

relationship between spiritual health, social dignity, and QOL in elderly patients with cardiovascular disease in Ilam with respect to growing trend of elderly population as well as the importance of cardiovascular disease.

Materials and methods:

One hundred fifty elderly patients with cardiovascular disease who were admitted to the only cardiac center in Ilam were evaluated in this descriptive analytical research in 2015 years. Inclusion criteria included being Muslim, being older than 65 years, having the ability to speak, having a cardiovascular disease (heart failure, hypertension, acute coronary syndrome, myocardial infarction, angina pectoris, or pericarditis), living in Ilam, and gave informed consent to participate in the study.

Tools used included the Ellison and Paloutzian spiritual health questionnaires (19-21), the social dignity questionnaire for heart patients (16) and the sf-36 QOL Questionnaire (22, 23). Paloutzian and Allison "spiritual well-being" with 20 questions, and the scoring was based on a 6-point Likert scale ranging from "completely disagree" to "completely agree". Negative questions were reverse-scored. The spiritual wellbeing score (20-120) was classified into three levels: high (100- 120), medium (41-99), and low (20-40). The content validity of the questionnaire was determined by the Hossein Bagheri and its reliability was processed (r= 0.99, a=0.97) (19-21). The Social dignity questionnaire has 77 questions related to communication and support (family relationships and support, social relationships and support, and relationship and support from the health care providers) and feeling like a burden to others (physically-psychologically-socially, economically). This questionnaire was based on a 6-point Likert scale (completely agree, agree, relatively agree, relatively disagree, disagree, or completely disagree) and the range of scores in each phrase varies from 1 to 6. Most items score one for completely disagree and six for completely agree, and only items 7-9, 13, 15, 17, 34-31, 40, 53-50, 59, 62, and 69-77 were reverse-scored. The overall score for the questionnaire is the average of the item scores with higher scores showing greater social dignity (16). The SF-36 index has 36 questions and eight health-related subscales related that measure quality of life factors. Each question has at least 2 and at most 6 options, and the score for each section or sub-scale ranges from zero to 100 with a higher score indicating a better QOL. QOL was classified as desirable (71-100), relatively desirable (31-70), or undesirable (0-30) (22, 23).

Participants were recruited from the CCU & Post-CCU wards in Shahid Mostafa Khomeini Hospital in Ilam, the specialized center for cardiology on a daily basis by identifying the cardiovascular failure

patients who were eligible and willing to participate in the study. Permission was first obtained from the Research Ethics Council in Ilam's University of Medical Sciences (with code 958030/81and 41.ir.medilam.rec.1395) and from the hospital administration. In addition, Also, the objectives and methods was explained to each participant, informed consent was obtained from patients to participate in the research, and was committed to the provisions of the Helsinki Declaration at all stages of research.

SPSS statistical software (version 16) was used to analyze the data. Data were described using frequency distribution tables, mean, standard deviation, and a t-test for independent groups and ANOVA test were used for data analysis. The significance level in this study was considered to be less than 0.05.

Results

The table 1 shows the distribution of mean and SD related to spiritual health, QOL.

The result showed implies that there is a statistically significant relationship between spiritual health and all aspects of social dignity in cardiac patients and that increased social dignity increases spiritual health ($P<0.05$). There is also a statistically significant relationship between quality of life and all aspects of the social dignity questionnaire except feeling supported by health care providers, being an economic burden, and the general feeling of being a burden ($P<0.05$).

Table 1: The distribution of mean and SD related to spiritual health, QOL, and social dignity of elderly people in terms of demographics

Variable	categories	percent)) number	Spiritual well-being (Mean ± SD)	quality of life (Mean ± SD)	Social dignity (Mean ± SD)
Gender	Man	84 (56)	107.02±11.12	55.95±6.69	3.80±1.04
	Female	66 (44)	85.22±21.98	46.95±9.26	3.10±0.94
	p-value		0.001	0.001	0.001
education	illiterate	99 (66)	99.27±19.05	55.12±8.98	3.58±0.94
	Diploma or under diploma	(26.7) 40	89.67±20.19	50.04±9.24	3.14±1.21
	Collegiate	11 (7.3)	109.1±8.68	57.88±7.20	4.07±1.1
	p-value		0.004	0.03	0.01
income	Less than 3Million	(67.3) 101	96.25±19.28	52.13±9.33	3.48±1.09
	Between 3 and 5 million	30 (20)	93.32±24.25	50.47±9.71	3.52±1.04
	More than 5 million	(12.7) 19	110.12±8.49	53.66±6.34	3.54±0.89
	p-value		0.009	0.47	0.96
job	Working	(85.3) 128	82.27±21.27	48.06±8.47	3.2±0.53
	Unemployed	(14.7) 22	100.03±18.57	52.66±9.04	3.55±1.11
	p-value		0.001	0.02	0.14
Any chronic disease	yes	36 (24)	112.25±7.26	58.88±8.84	4.31±0.94
	no	114 (76)	92.75±18.97	49.81±8.04	3.24±0.96
	p-value		0.001	0.001	0.001
History of hospitalization	No admission	(23.3) 35	103.28±16.19	54.44±7.61	3.69±0.98
	1 - 2 times	54 (36)	103.24±16.29	55.22±8.59	3.71±1.09
	3 - 4 times	(28.7) 43	91.74±23.11	49.77±9.42	3.48±0.98
	> 4 times	18 (12)	82.22±11.65	42.84±3.31	2.53±0.69
	p-value		0.001	0.001	0.001
Type of disease	Heart failure	36 (24)	110.58±8.75	56.68±8.29	4.01±1.05
	High blood pressure	(31.3) 47	101.80±10.91	55.42±6.77	3.41±0.94
	Acute Coronary Syndrome	(18.7) 28	95.14±20.37	51.90±9.18	3.69±1.32
	Myocardial infarction	(15.3) 23	83.26±18.72	44.25±6.10	2.95±0.68
	Angina	(10.7) 16	79.37±21.36	42.67±6.16	3.07±0.78
	p-value		0.001	0.001	0.001

Discussion

The results showed that most of the elderly patients with cardiovascular diseases in Ilam had a high level of spiritual health, similar to the previous research about older adults (12, 13, 24-26) and heart disease patients (27, 28). The current results are consistent to the results obtained by Elahe Bakhsian Farsiani and her colleagues, which

indicate a higher score on physical health than religious health for cancer patients, (29) but these results are inconsistent with the result of Reazaie et al, which indicated a higher score for religious health than physical health in cancer patients (24). Findings of the present study showed a statistically significant relationship between demographic characteristics and spiritual health. Statistically significant relationships have been observed in different studies between age, gender, and marital status and spiritual health, similar to the results of this study (13, 24, 30, and 31). In fact, religion and spirituality have been important sources of strength and support in all stages of life and help with crises and stressful situations (8). Religion and spirituality are important for a lot of individuals, and it is more important for elderly individuals than young individuals (11, 32).

Most elderly people in the present study had an average QOL which is consistent with earlier results (25, 33, and 34). There was a significant relationship between QOL and demographic characteristics such as gender, education, history of hospitalization, and type of heart disease, but there was no significant relationship between QOL and income. In a study of Nabavi et al on elderly people; age, gender, marital status, occupation, and education level were among the factors which affected QOL (35). In a study by Jadidi et al, significant relationship between QOL and marital status was reported, but no significant relationship was reported between other demographic characteristics, such as age and education, and QOL. Differences between the year of the research and population sample may be among the reasons for the difference in the results of this study and previous studies on elderly patients with cardiovascular diseases.

There was a significant relationship between social dignity and all demographic characteristics, except job and income level, which is consistent with the result of different studies that show age, gender, and education affects social dignity in patients with heart disease (16). This findings also showed that most elderly patients with cardiovascular diseases had average social dignity. We can refer to the research of Kokino et al (36) that evaluated the extent of threat to social dignity in patients in four physical, psychological, social and existential aspects where the dignity of patients was at a low level and was threatened. The population samples can be among the reasons for different results of the present study and the study of Kokino et al, since elderly patients with cardiovascular disease were evaluated in the present study but Kokino et al (36) evaluated patients with end-stage cancer. Also, elderly people in the present study may have more social dignity and respect due to the Islamic and Iranian culture. Another point is that different aspects of a

patient's dignity in the study of Kokino et al are physical, psychological, social, and existential aspects but the aspects of social dignity questionnaire in the present study are two aspects of communication and support (relation and support in family, relation and support in society, relation and support of health care providers) and being burden to others (physically-psychologically-socially, economically) and all of these factors are considered as factors affecting the difference between the results of this study and previous studies.

There was a relationship between QOL and spiritual health in the present study. Other studies also reported of relationship between spiritual health and QOL in various diseases. These studies include the study of Finkelestine et al on patients with renal failure (37), study of Bussing et al (2007) on cancer patients (38), study of ElaheBakhsian et al on patients with multiple sclerosis (29), study of Jadidi et al on elderly people (39), study of Finocchiaro et al on adults with paraplegia (40), the study of Jafaret et al on women with cancer (41), study of Catherine on people with a spinal cord injury (42), study of Mehrabi et al on infertile women (43), study of Jahani et al on patients with coronary artery disease (44), and study by Salsman et al on patients with colorectal cancer, (45) all of which are consistent with the results of this study. In fact, spirituality leads to relaxation and anxiety relief during hard and lonely times. In addition, religion and spirituality lead to hope and support in elderly patients with cardiovascular disease in difficult conditions (46).

Findings of the present study showed that there was a relationship between QOL and social dignity in the way that elderly people who had higher social dignity had a higher QOL. In the study of Sandes et al, social connections and supports were influential in the feeling of wellbeing in patients with heart failure, but if this supportive relationship did not exist, they felt like a burden to others (47). Based on the opinion of Falk et al, patients with heart failure tend to have the same connections and friends as they had before their illness and tend to maintain their values and be treated as a complete person and not a patient (48). Results of studies have shown that strengthening social dignity has positive effects on the dignity of patients (36, 49, and 50) which are in line with the results of this study.

With respect to the effect of social dignity and spiritual health on the QOL of patients with cardiovascular disease, interventions in order to improve their spiritual health and social dignity in order to increase their QOL are recommended.

Ethical clearance:

Ethics Council in Ilam's University of Medical Sciences (with code 958030/81 and 41.ir.medilam.rec.1395)

Conflicts of interests

There are no conflicts of interest

References

1. Marandi A, Azizi F. The position, based on the difficulties of defining and spiritual health of the population–Islam. J Medical Ethics. 2010; 4(14):11-21.

2. Assarroudi A, Jalilvand M, Oudi D, Akaberi A. The relationship between spiritual well-being and life satisfaction in the nursing staff of Mashhad Hasheminezhad Hospital (2011). Modern Care Journal. 2012; 9(2):156-62.

3. Rahimi N, Nouhi E, Nakhaee N. Spiritual health among nursing and midwifery students at kerman university of medical sciences. Journal of hayat. 2014; 19(4):74-81.

4. Miri M, HajiAbadi M, Soorgi Z, Qasemi K. Relationship between depression and level of reliance on God in Birjand university students. Journal of Birjand University of Medical Sciences. 2007; 14(4):9-15.

5. Baljani E, Khashabi J, Amanpour E, Azimi N. Relationship between Spiritual Well-being, Religion, and Hope among Patients with Cancer. Hayat. [Research]. 2011; 17(3):27-37.

6. Rawdin B, Evans C, Rabow MW. The relationships among hope, pain, psychological distress, and spiritual well-being in oncology outpatients. Journal of palliative medicine. 2013; 16(2):167-72.

7. Sadeghifar J, Bahadori M, Baldacchino D, Raadabadi M, Jafari M. Relationship between career motivation and perceived spiritual leadership in health professional educators: a correlational study in Iran. Global journal of health science. 2014; 6(2):145.

8. Daaleman TP, Perera S, Studenski SA. Religion, spirituality, and health status in geriatric outpatients. The Annals of Family Medicine. 2004; 2(1):49-53.

9. Rezaei M, Seyedfatemi N, Hosseini F. Spiritual Well-being in Cancer Patients who Undergo Chemotherapy. Hayat. [Research]. 2009; 14(4):33-9.

10. Baljani E, Khashabi J, Amanpour E, Azimi N. Relationship between spiritual well-being, religion, and hope among patients with cancer. Journal of hayat. 2011; 17(3):27-37.

11. Sadeghi M, Kazemi H. Prevalence of dementia and depression among residents

of elderly nursing homes in Tehran province. Iranian journal of psychiatry and clinical psychology. 2004; 9(4):49-55.

12. Saydshohadai M, Heshmat S, Seidfatemi N, Haghani H, Mehrdad N. The spiritual health of seniors living in sanitarium and home residents. Iran Journal of Nursing. 2013; 26(81):11-20.

13. Whelan-Gales MA, Griffin MTQ, Maloni J, Fitzpatrick JJ. Spiritual well-being, spiritual practices, and depressive symptoms among elderly patients hospitalized with acute heart failure. Geriatric Nursing. 2009; 30(5):312-7.

14. Lam K. Dignity, respect for dignity, and dignity conserving in palliative care. Hong Kong Society of Palliative Medicine. 2007; 3:30-5.

15. Walsh K, Kowanko I. Nurses' and patients' perceptions of dignity. International Journal of Nursing Practice. 2002; 8(3):143-51.

16. Bagheri H, Yaghmaei F, Ashktorab T, Zayeri F. Patient dignity and its related factors in heart failure patients. Nursing ethics. 2012:0969733011425970.

17. Rafii F, Shahpoorian F, Naasher Z, Azarbaad M, Hosseini F. The importance of learning needs of CHF patients from patients' and nurses' perspective. Iran Journal of Nursing. 2009; 22(57):19-30.

18. Dunderdale K, Thompson DR, Miles JN, Beer SF, Furze G. Quality-of-life measurement in chronic heart failure: do we take account of the patient perspective? European journal of heart failure. 2005; 7(4):572-82.

19. O'Connor M, Guilfoyle A, Breen L, Mukhardt F, Fisher C. Relationships between quality of life, spiritual well-being, and psychological adjustment styles for people living with leukaemia: An exploratory study. Mental health, religion and culture. 2007; 10(6):631-47.

20. Bastani F, Pourmohammadi A, Haghani H. Relationship between Perceived Stress with Spiritual Health among Older Adults with Diabetes Registered to the Association of Diabetes Prevention and Control in Babol, 2013. Hayat. [Research]. 2014; 20(3):6-18.

21. Hasanshahi M, Mazaheri MA. The Effects of Education on Spirituality through Virtual Social Media on the Spiritual Well-Being of the Public Health Students of Isfahan University of Medical Sciences in 2015. International journal of community based nursing and midwifery. 2016; 4(2):168.

22. López-Pérez P, Miranda-Novales G, Segura-Méndez N, Del Rivero-Hernández L, Cambray-Gutiérrez C, Chávez-García A. [Study of quality of life in adults with common variable immunodeficiency by using the Questionnaire SF-36]. Revistaalergia Mexico (Tecamachalco, Puebla, Mexico: 1993). 2013; 61(2):52-8.

23. Kielbergerová L, Mayer Jr O, Vaněk J, Bruthans J, Wohlfahrt P, Cífková R. Quality of life predictors in chronic stable post-stroke patients and prognostic value of SF-36 score as a mortality surrogate.

Translational stroke research. 2015; 6(5):375-83.

24. Rezaei M, Seyedfatemi N, Hosseini F. Spiritual Well-being in Cancer Patients who Undergo Chemotherapy. Hayat. 2008; 14.

25. Jadidi A, Farahaninia M, Janmohammadi S, Haghani H. The relationship between spiritual well-being and quality of life among elderly people residing in Kahrizak senior house. Iran Journal of Nursing. 2011; 24(72):48-56.

26. Bastani F, Pourmohammadi A, Haghani H. Relationship between Perceived Stress with Spiritual Health among Older Adults with Diabetes Registered to the Association of Diabetes Prevention and Control in Babol, 2013. Journal of hayat. 2014; 20(3):6-18.

27. MomeniGhaleghasemi T, Musarezaie A, Moini M. Survey of Relationship between spiritual wellbeing with Anxiety and Some Demographic Variables in Patients with Coronary Artery Disease2013.

28. SEYED FN, Rezaei M, Givari A, Hosseini F. Prayer and spiritual well-being in cancer patients. 2006.

29. Allahbakhshian M, Jaffarpour M, Parvizy S, Haghani H. A Survey on relationship between spiritual wellbeing and quality of life in multiple sclerosis patients. Zahedan Journal of Research in Medical Sciences. 2010; 12(3):29-33.

30. Motlagh M, Nouri F, Shirifnia S, Mohammadnejad E, Heydari B. Relationship between different dimensions of prayer and spiritual health of patients treated with hemodialysis. Journal of Critical Care Nursing. 2010; 2(4):7-8.

31. Zakavi AA, Marzband R, Moallemi M, Mohammadpour RA, Afzali MA, Laeini MBM. Level of Spiritual Health According to Islamic Teachings in Students Studying in Mazandaran University of Medical Sciences.

32. Koenig HG. Spirituality, wellness, and quality of life. Sexuality, Reproduction and Menopause. 2004; 2(2):76-82.

33. Lee TW, Ko IS, Lee KJ. Health promotion behaviors and quality of life among community-dwelling elderly in Korea: A cross-sectional survey. International Journal of Nursing Studies. 2006; 43(3):293-300.

34. HABIBI S, Nikpour S, Sohbatzadeh R, Haghani H. Quality of life in elderly people of west of Tehran. 2008.

35. Nabavi S, Shoja M, Mohammadi S, Rashedi V. Health-related quality of life in community-dwelling older adults of Bojnourd, 2014. Journal of North Khorasan University of Medical Sciences. 2014; 6(2).

36. Chochinov HM, Krisjanson LJ, Hack TF, Hassard T, McCLEMENT S, Harlos M. Dignity in the terminally ill: revisited. Journal of palliative medicine. 2006; 9(3):666-72.

37. Finkelstein FO, West W, Gobin J, Finkelstein SH, Wuerth D. Spirituality, quality of life and the dialysis patient. Nephrology Dialysis Transplantation. 2007; 22(9):2432-4.

38. BüssingA, Matthiessen PF, Ostermann T. Engagement of patients in religious and spiritual practices: confirmatory results with the SpREUK-P 1.1 questionnaire as a tool of quality of life research. Health and Quality of Life outcomes. 2005; 3(1):1.

39. Jadidi a, Marhemat F, Sara J, Hamid H. The relationship between spiritual well-being and quality of life among elderly people. Holistic nursing practice. 2015; 29(3):128-35.

40. Finocchiaro DN, Roth PA, Connelly CD. Spiritual Well-Being as Predictor of Quality of Life for Adults with Paraplegia. Rehabilitation Nursing. 2014; 39(6):285-93.

41. Jafari N, Farajzadegan Z, Zamani A, Bahrami F, Emami H, Loghmani A. Spiritual well-being and quality of life in Iranian women with breast cancer undergoing radiation therapy. Supportive Care in Cancer. 2013; 21(5):1219-25.

42. Wilson CS, Forchheimer M, Heinemann AW, Warren AM, McCullumsmith C. Assessment of the relationship of spiritual well-being to depression and quality of life for persons with spinal cord injury. Disability and rehabilitation. 2016:1-6.

43. Mehrabi T, alijanpooraghamaleki m, hosseinyrs, ziraki dana a, safaee z. a study on the relationship between spiritual well-being and quality of life in infertile women referred to Infertility centers in Isfahan. Journal of Nursing and Midwifery Urmia University of Medical Sciences. [Research]. 2014; 12(7):562-7.

44. Jahani A, Rejeh N, Heravi-Karimooi M, Hadavi A, Zayeri F, Khatooni AR. The relationship between spiritual health and quality of life in patients with coronary artery disease. Islamic lifestyle centered on health. 2012; 1(2):17-21.

45. Salsman JM, Yost KJ, West DW, Cella D. Spiritual well-being and health-related quality of life in colorectal cancer: a multi-site examination of the role of personal meaning. Supportive Care in Cancer. 2011; 19(6):757-64.

46. Johnson ME, Piderman KM, Sloan JA, Huschka M, Atherton PJ, Hanson JM, et al. Measuring spiritual quality of life in patients with cancer. J Support Oncol. 2007; 5(9):437-42.

47. Sundin K, Bruce E, Barremo A-S. Elderly women's experiences of support when living with congestive heart failure. International journal of qualitative studies on health and well-being. 2010; 5(2).

48. Falk S, Wahn A-K, Lidell E. Keeping the maintenance of daily life in spite of chronic heart failure. A qualitative study. European Journal of Cardiovascular Nursing. 2007; 6(3):192-9.

49. Chochinov HM, Hack T, Hassard T, Kristjanson LJ, McClement S, Harlos M. Dignity in the terminally ill: a cross-sectional, cohort study. The Lancet. 2002; 360(9350):2026-30.

50. Chochinov HM, Hack T, McClement S, Kristjanson L, Harlos M. Dignity in the terminally ill: a developing empirical model.

Social science & medicine. 2002; 54(3):433- 43.

Low-risks in MAP3K1 AC and LSP1 TT, not only influences the chance of developing breast cancer but also influences tumor characteristics

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Abstract

Genetic factors and numerous polymorphisms were related to breast cancer.

Breast cancer induce of multiple genetic or epigenetic molecular. SNPs was main to differentiation liability in breast cancer. The present study aimed at investigating the association of SNPs of two genes, MAP3K1 (mitogen-activated protein kinase kinase kinase1) and *LSP1* (lymphocyte-specific protein 1) with possibility of breast cancer in Iranian women.

Two polymorphic variants are association with breast cancer, rs889312 in Chromosome 5and rs3717198 in Chromosome 11.

Firstly, we assessed these polymorphisms included 126 breast cancer and 160 controls of peripheral blood for DNA extraction and then using Tetra-Primer ARMS –PCR technique. On the other side were histochemical pathology test as $HER2^-$, $HER2^+$, ER^-, ER^+, PR^- and PR^+ upon breast tumor tissue.

In the current study, LSP1 CT gene polymorphism of SNP variants had statistically significant association with breast cancer (41.26%)frequency, Odd Ratio; 3.466, CI; 0.202 - 4.733, P value; 0.001^{***}).On the other

hands, number of total test histochemical in MAP3K1 AC and then LSP1TT were highest positive in $HER2^{-}$, $HER2^{+}$, ER^{-}, ER^{+}, PR^{-} and PR^{+}.

Keywords: LSP1, MAP3K1 gene, polymorphism, breast cancer.

INTRODUCTION

Breast cancer is the high rates of cancer in women [1].it is a polyfactorial disease such as inner and outer factors [2]. MAP3K1 are members of signaling pathway and was known from GWAS of breast cancer genes. LSP1, encodes an intracellular F-actin binding protein adhesion to fibrinogen matrix proteins, and trans endothelial migration [3, 4]. The relationship between the *LSP1* rs3817198 T > C polymorphism and breast cancer risk were investigated, but will need to outworks. To this time, several study have assessed to play of LSP1 and MAP3K1 genotypes in breast cancer progress by rs3817198 and rs889312.

We look at LSP1 and MAP3K1 variants, breast tumor hormone in our population sample.

Several publications have reported a significant association of the *LSP1* rs3817198 T > C polymorphism with the risk of breast cancer [5,3,7] and other studies have failed any association [8,9].

Current study, is the first time, to examination of relation LSP1 (rs3817198) and MAP3K1 (rs889312) gene to risk of Breast cancer in Iranian population.

Rs3817198 in European populations showed a strongly relations to estrogen-positive than negative.

The MAP3K1 gene, codes serine/threonine protein kinase, and then it stimulates the JNK pathway.

The rs889312-C allele showed a risk factor of breast cancer in European and Asian, and not any in Africans populations.

Finally, it's possible a low-risk not only stimulate of emerging breast cancer but also guidance tumor characteristics carcinoma.

LSP1 (rs3817198)			bp
F- inner	ACCTGAATCCAGATTCAAACTCGCC	C	250
R- inner	CGGGCTGACTCTAGTGAAATGATCA	T	362
F- outer	CTCTCACCTGACCTCTTGGTCTCCTTT		562
R- outer	AGTAGGACCTAAGTTCCTGCCCCTCTAT		
MAP3K1(rs889312)			
F- inner	ATGCCCGGTACAGGAGAAAAGA	A	261
R- inner	AACTGATTTGCCATCTCTGTAATTGCACGTG	C	183
F- outer	TCAATTACATGTCACTCCAATGCAAATC		392
R- outer	TTCTTTGGCTTCAAAGATTTCCTCTTTT		

Table 1. Internal primers and external by Tetra-Primer ARMS –PCR technique.

SNP	Genotype	Controls (n=160)	%	Cases, overall (n=126)	%
MAP3K1(rs889312)	CC	22	(13.75%)	35	(27.77%)
	AC	84	(52.5%)	65	(51.58%)
	AA	54	(33.75%)	26	(20.63%)
LSP1 (rs3817198)	TT	9	(5.625%)	46	(36.50%)
	CT	118	(73.75%)	52	(41.26%)
	CC	33	(20.625%)	28	(22.22%)

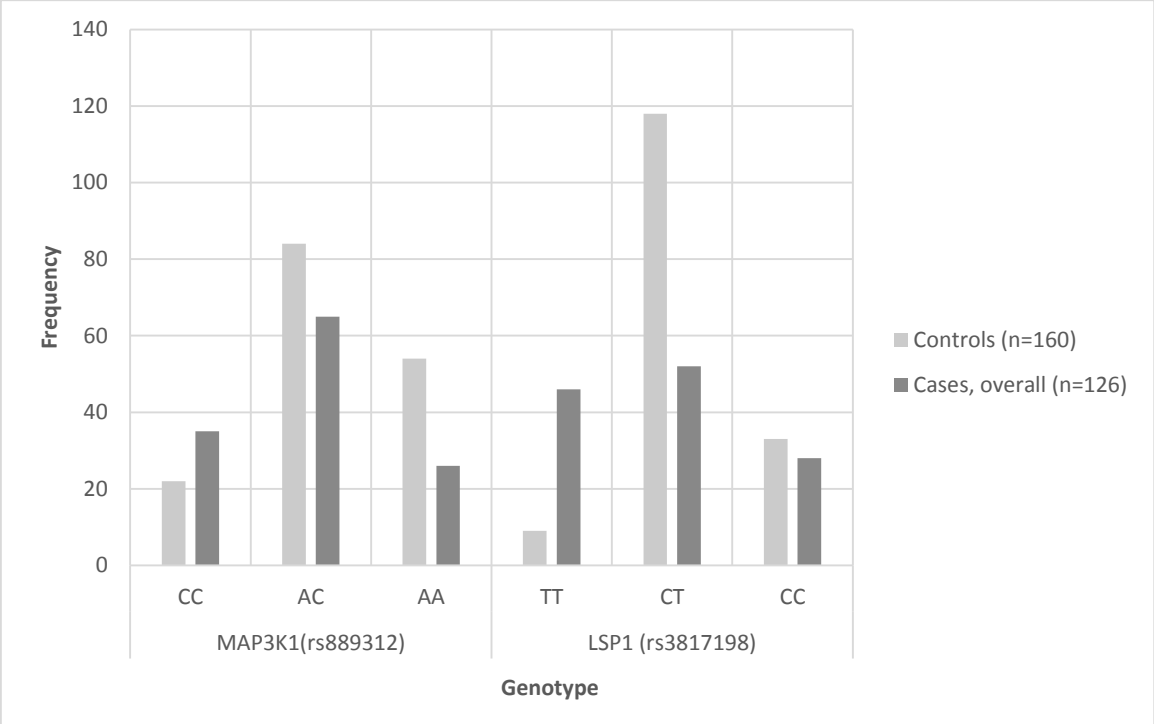
Table 2: MAP3K1 and LSP1 genotype frequencies [n (%)] for cases and control

SNP	Genotype	OR	95% CL	P value
MAP3K1(rs889312)				
	CC	0.019	0.037-0.198	0.38
	AC	0.14	0.021-0.42	0.09
	AA	1.086	0.040 - 0.198	0.026
LSP1 (rs3817198)				
	TT	1.321	0.172 - 0.446	0.108
	CT	3.466	0.202 - 4.733	0.001***
	CC	0.042	0.021-0.092	0.17

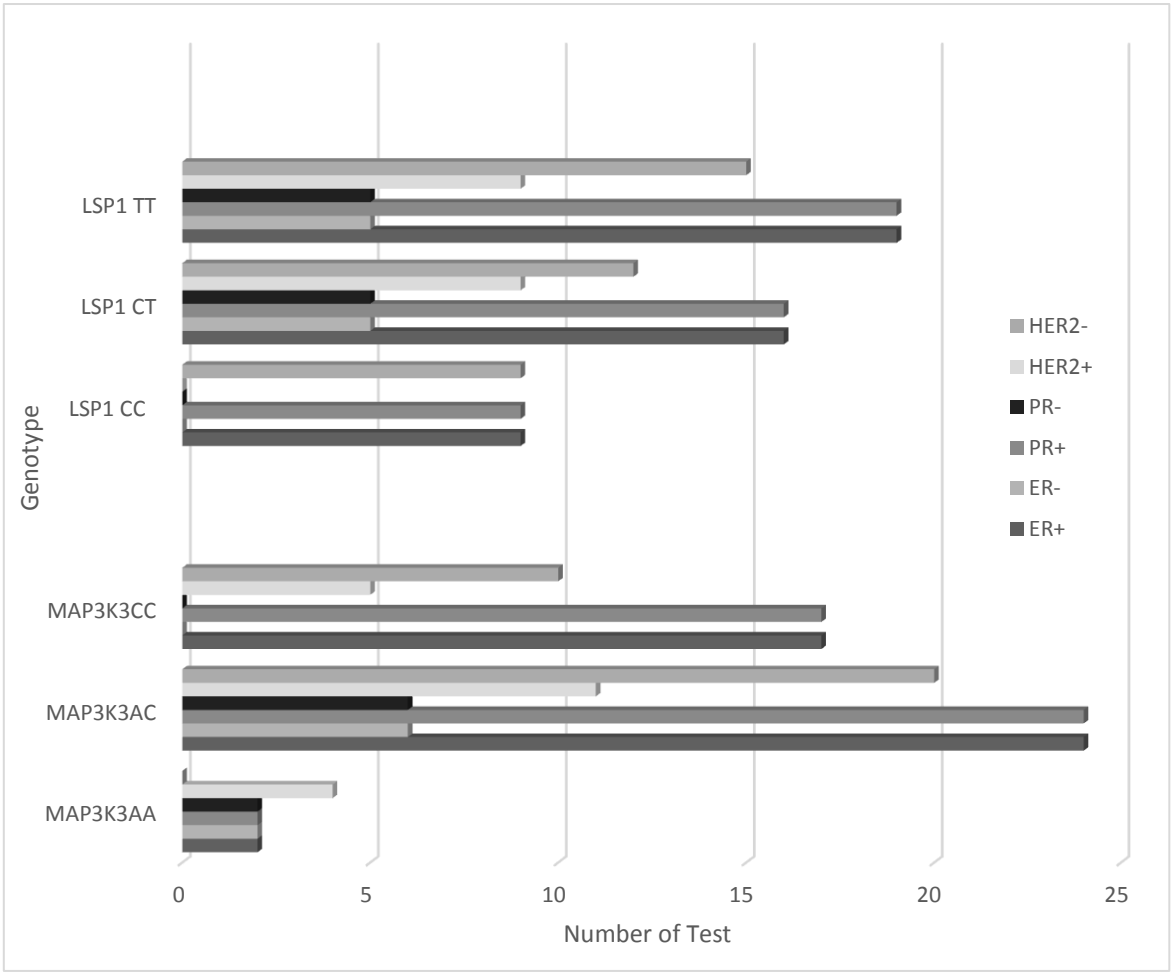
Table 3: Comparison between genotypes MAP3K1 and LSP1, odds ratio and p value, showed that P ***=P<=0.001, **=P<=0.05

MAP3K1(rs889312)	ER+	ER-	PR+	PR-	HER2+	HER2-	total
AA	2	2	2	2	4	-	12
AC	24	6	24	6	11	20	91
CC	17	-	17	-	5	10	49
LSP1 (rs3817198)							
CC	9	-	9	-	-	9	27
CT	16	5	16	5	9	12	63
TT	19	5	19	5	9	15	72

Table 4: Test histochemical in MAP3K1 AC and then LSP1TT were highest positive in $HER2^{-}$, $HER2^{+}$, ER^{-}, ER^{+}, PR- and PR^{+} tumor.



Graph 1: Column Chart genotype frequencies [n (%)] for cases and control: Analyses of 126 affected women and 160 controls: LSP1 (rs3817198) ;(TT, CT and CC) and MAP3K1 (rs889312) ;(AA, CC and AC).



Graph 2: Column Chart Test histochemical Tumor; in MAP3K1 AC and then LSP1TT were highest positive in $HER2^{-}$, $HER2^{+,}$ $ER^{-,}$ $ER^{+,}$ PR^{-} and PR^{+} tumor.

Materials and Methods

A) Patients data:

In this study 126 patients Carcinoma Breast Cancer in grade 4 and 160 controls patients of the Khas Medical Center and HAZRAT RASOUL MEDICAL COMPLEX, TEHRAN*, Iran* were conducted for the genotyped for IGF1 in ages 30-60 years.
This study was agreed by the Ethical Committee of Islamic Azad University from samples rights.

Clinical Laboratory data included age, cancer type, grade of tumor, lymph node, and family background. The blood and tissue tumor were collects from two groups. DNA Extracted of peripheral blood using FelxiGene Qiagen Germany extraction kit working on LSP1 (rs3817198) and MAP3K1 (rs889312) SNPs.

B) Genotyping

To design primers, an internal with external with different lengths for SNPs type. SNPs was examined by Tetra-Primer ARMS –PCR technique. (Table 1)

The genotypes of this polymorphisms in Patient and control groups were analyses by p value, Frequency and odd ratio tests by Hardy-Weinberg equilibrium.

Results

The intention of the present study relationship MAP3K and *LSP1* to risk of Breast cancer, Because It study was for first time upon our population.
We considered the joint effects of MAP3K1 and *LSP1* genotypes and hormone-related breast cancer risk factors. (Tables 4, 3 and Graph 1). However, we report statistically significant associations of MAP3K1 AC and LSP1 TT genotypes in ER+, PR+ tumors (Table 4). That it's opposite to has been significant LSP1 CT. (Table 4, Graph 2). It is possible that a low-risk allele not only influences the chance of developing breast cancer but also influences tumor characteristics such as breast carcinoma. There was a significant between *LSP1* CT polymorphism and breast cancer risk (41.26%) frequency, Odd Ratio; 3.466, CI; 0.202 - 4.733, P value; 0.001***) (Table 2, 3 and Graph 1)

Discussion

MAP3K1 AC and LSP1 TT genotypes were significantly associated with breast cancer in EA only in estrogen receptor-positive (ER1), progesterone receptor-positive (PR1) tumors Finally, we observed a significant interaction between LSP1 in CT but not TT women. These results approve that LSP1 CT was mediate in breast cancer liability but NOT any effects to ER and PR tumors.
Polymorphisms in the *LSP1* gene may perhaps lead to expression protein of signaling pathways, thus reducing breast cancer liability [10,11, 12].
Our results propose that the *LSP1* rs3817198 TC polymorphism is a risk factor for breast cancer.
Chen MB in 2011 considered the relationship between the *LSP1* rs3817198 TC polymorphism and breast cancer risk [7].
A number of new studies BY Butt S in 2012, Campa D in 2011, and Long J in 2010 were also resulted similar in our research [6,9,14]. Long J in 2010 discovered in Asian and Caucasian population a high risk of breast cancer with the *LSP1* rs3817198 TC [14].
we previously studied association FGFR2 to carcinoma breast [15] and so now we observed an increased risk with the *LSP1* rs3817198. On the other hands Timothy R. Rebbeck in 2009 reported that mutations in FGFR2 or MAP3K are associated with HER2 positive tumor [16], that, in current study no find any associated with HER2.
Therefore, MAP3K1 and LSP1 spatially LSP1 CT, associate to risk of breast cancer but not any depended to hormonal ER, PR and HER2.
So, there are a potential of LSP1 TT to developing Breast Carcinoma.

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REFERENCES

1-FERLAY J, SOERJOMATARAM I, DIKSHIT R. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN. Int J Cancer 2012; 136: 359-386.

2- MERSCH J, JACKSON MA, PARK M,Cancers associated with BRCA1 and BRCA2 mutations other than breast and ovarian. Cancer 2015; 121: 269-275.

3. Fanale D, Amodeo V, Corsini LR, Rizzo S, Bazan V, Russo A. Breast cancer genome-wide association studies: there is strength in numbers. Oncogene. 2012; 31:2121–2128.

4. Easton DF, Pooley KA, Dunning AM, Pharoah PD, Thompson D, Ballinger DG, Struewing JP, Morrison J, Field H, Luben R, Wareham N, Ahmed S, Healey CS, et al. Genome-wide association study identifies novel breast cancer susceptibility loci. Nature. 2007; 447:1087–1093.

5. Barnholtz-Sloan JS, Shetty PB, Guan X, Nyante SJ, Luo J, Brennan DJ, Millikan RC. FGFR2 and other loci identified in genome-wide association studies are associated with breast cancer in African-American and younger women. Carcinogenesis. 2010; 31:1417–1423.

6. Butt S, Harlid S, Borgquist S, Ivarsson M, Landberg G, Dillner J, Carlson J, Manjer J. Genetic predisposition, parity, age at first childbirth and risk for breast cancer. BMC Res Notes. 2012; 5:414.

7. Chen MB, Li C, Shen WX, Guo YJ, Shen W, Lu PH. Association of a LSP1 gene rs3817198T > C polymorphism

with breast cancer risk: evidence from 33,920 cases and 35,671 controls. Mol Biol Rep. 2011; 38:4687–4695.

8. Latif A, Hadfield KD, Roberts SA, Shenton A, Lalloo F, Black GC, Howell A, Evans DG, Newman WG. Breast cancer susceptibility variants alter risks in familial disease. J Med Genet. 2010; 47:126–131.

9. Campa D, Kaaks R, Le Marchand L, Haiman CA, Travis RC, Berg CD, Buring JE, Chanock SJ, Diver WR, Dostal L, Fournier A, Hankinson SE, Henderson BE, et al. Interactions between genetic variants and breast cancer risk factors in the breast and prostate cancer cohort consortium. J Natl Cancer Inst. 2011; 103:1252–1263.

10. Ripperger T, Gadzicki D, Meindl A, Schlegelberger B. Breast cancer susceptibility: current knowledge and implications for genetic counselling. Eur J Hum Genet. 2009; 17:722–731.

11. Fanale D, Amodeo V, Corsini LR, Rizzo S, Bazan V, Russo A. Breast cancer genome-wide association studies: there is strength in numbers. Oncogene. 2012; 31:2121–2128.

12. Fletcher O, Dudbridge F. Candidate gene-environment interactions in breast cancer. BMC Med. 2014; 12:195.

14. Long J, Shu XO, Cai Q, Gao YT, Zheng Y, Li G, Li C, Gu K, Wen W, Xiang YB, Lu W, Zheng W. Evaluation of breast cancer susceptibility loci in Chinese women. Cancer Epidemiol Biomarkers Prev. 2010; 19:2357–2365.

15- M Hosseini ,The Relationship Between Polymorphic Fibroblast Growth Factor Receptor (FGFR) Gene and Breast Cancer Risk .Archives of Breast Cancer 2014;1: 24-27.

16-Timothy R.Rebbeck, Angela DeMichele, Teo V.Tran, Hormone-dependent effects of FGFR2 and MAP3K1 in breast cancer susceptibility in a population-based sample of post-menopausal African-American and European-American women, Carcinogenesis, 2009,3(2) .269–274,

Effect of Local Cold Application before and after Subcutaneous Enoxaparin Sodium Injection in Injection Site Pain and Bruising

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Abstract

Background and Object: Subcutaneous enoxaparin injection very often leads to various reaction such as bruising and pain in the injection site. Therefore, this study aims to investigate the effect of local cold application on occurrence of bruising and pain on injection site resulting from enoxaparin sodium injection in patients.

Investigation method: The method employed in this study is clinical trial for which 100 hospitalized patients in the Coronary Care Unit of Ayatollah Roohani teaching hospital in Babol were selected through convenience sampling. Patients in the study were divided into 5 groups (4 case groups and 1 control group). Injections for control group were administered by standard procedure (i.e. 10-second injection without cold application) for case groups local cold (ice and cold water compress) were applied 5 minutes before injection, 5 minutes before and after injection, 20 minutes after injection, and 5 minutes before and 20 minutes after injection for which 10-second rule was observed. Data was collated using a researcher-made check list which consisted of two sections: personal information and a section for recording bruising and pain intensity measurements. Size of bruises were measure 24, 48 and 72 hours after injection using a transparent millimeter ruler and pain intensity was measured using VAS visual scale which was done immediately after injection. Descriptive and inferential tests (independent T test and Chi-squared test) of SPSS 16 were used to analyze collected data.

Findings: The results indicated that there is a significant difference between control group and case groups in pain intensity and width of bruise after 24, 48 and 72 hours after injections and this difference was more noticeable for the case group which receive local cold application 5 minutes before and after injection.

Conclusion: The current study showed that cold application before and after subcutaneous enoxaparin sodium injection helps reduce pain and bruise width in injection site.

Key words: enoxaparin sodium, pain, bruise, local cold, subcutaneous injection

Introduction

One of the essential skills and nursing intervention is administering safe injection for patients. Injecting anticoagulants, in particular, is one of common nursing intervention which are administered widely for treating thrombosis. Of all anticoagulants, injecting Low-molecular-weight heparins such as enoxaparin has received increasing attention (Dod A'een, 2013). Enoxaparin is used for treating various conditions and diseases such as deep vein thrombosis (DVT) with or without pulmonary embolism, preventing DVT in abdominal surgeries, hip replacement surgery which in acute cases patients have very limited mobility,

preventing unstable ischemic angina, myocardial infarction, and treating myocardial infarction which is treated medically and with the help of coronary interventions through skin (Chan, 2001). Therefore, enoxaparin is low-molecular-weight anticoagulant with a long half-life which is made through polymerization of heparin and is injected subcutaneously. Some medicine such as heparin are injected subcutaneously (Dehghani et al, 2012).

This type of injection causes bruises and pain in hospitalized patients. The pain from injection for long periods can cause fear of injection in patients and leads to their mistrust of nurses. Bruises in injections site creates some problems such as altering patients' body image and fewer available sites on their body for subsequent injection (Abdikour et al, 2011). Therefore, pain is an emotionally unpleasant experience which is related to possible severe tissue damage (Correl, 2007) which can vary depending on pace of injection, type of medicine and amount of injected medicine (Chan, 2001). Medical practitioners believe that bruising and pain in subcutaneous injection sites is one of the main concerns among patients who need them for their treatment (Dod A'een, 2013).

As members of medical team, administering safe and accurate injections is one nurses' duties and they not only need to be aware of side effects of medicine they use they should also use suitable strategies based on scientific proof in order to reduce potential injuries. Therefore, various methods have been investigated including tactile pressure to injection site prior to injection, apply cold to needle, injecting within a certain period of time, applying cold before injection and warming up the injection site after injection in order to reduce such side effects (Lili, 2010). Early studies in this area have started in 1991 and have continued until now. One such study is that of Chan which aimed to investigate the effect of duration of subcutaneous injection of heparin on pain intensity and bruising in injection site. Pain intensity was measured immediately after injection while bruising was measured 48 and 60 hours after injection. The findings of this study showed that pain intensity is low and size of bruises is smaller when 30-second injection method is applied (Chan, 2001).

A similar study done be Dehaghani et al (2012) showed that 30-second injection method reduces pain in injection site significantly. Dod A'een et al (2013) also found that enoxaparin injections administered in 30-second periods compared to 10-second injection method cause less pain and bruising. Zaybak et al (2008) investigated the effect of duration of subcutaneous heparin injection in 50 conscious patients over 20 years old who have been hospitalized in neurology, orthopedics and cardiology units of a hospital. The findings indicated that pain intensity and duration of pain was significantly reduced when 30-second injection method was employed. However, there was no different in these two variables between genders in two groups. Amanian (2013) found that applying cold prior to injection and warming up the injection site 12 hours after injection can help reduce pain. In another study which compared the effect of Emla Cream and cold compress 5 minutes prior to injection on pain intensity in enoxaparin injection, Farnia (2014) found that both interventions were effective in pain reduction. However, Rahmani Anaraki et al (2014) found that there was no significant difference in bruise width between control group and case group 24, 48 and 72 hours after injection. Chenick (2004) also showed that there was no significant difference between two methods of injecting enoxaparin (i.e. 10-seond and 30-second methods) in terms of pain intensity.

Considering importance and necessity of prescribing anticoagulants for various patients, inevitable effect of side effects of such medicines in patients' cooperation in continuing treatment, a large number of previous studies found contradictory results and mainly investigated various methods of reducing side effects of subcutaneous injections and few studies focused on amount of pain and bruising from enoxaparin injections and also the fact that previous studies on investigating the duration of cold application have not determined a standard period of time of applying cold before or after injection and these studies have not investigated the effect of cold application, which reduces blood flow in injections site, pain and bruising resulted from injection.

Research methodology

This study was a clinical trial which consisted of five groups (1 control group and 4 case group) of patients conducted in Ayatollah Rouhani teaching hospital in Babol in 2015. Patients of the study were selected

through convenience sampling and random allocation in various groups. Inclusion criteria consisted patients under 65 and over 18 years of age who were not pregnant or breastfeeding, received no injections 12 hours prior to test and were completely conscious and were able to clearly describe their pain. They need not to have any coagulation disorders and the amount of enoxaparin (6000 units) was the same for all of them. The number of sample group was decided to be 100, which was divided into 5 groups of 20 people, and was determined based on statistics consultant and using the formula for determining the size of sample population.

The researcher started sampling based on inclusion criteria and analyzed the side effects 24, 48 and 72 hours after injection. Injections for control group were administered without intervention using standard procedure in which injection was administered on left or rights side of the abdomen within 5 centimeters surrounding the navel on where 10-second method without massaging after injection was applied. j training was provided for the patients as not to manipulate the injection site. Cold compress (ice and water pack) were applied 5 minutes before injection, 20 minutes before injection, 5 minutes before and after injection and 5 minutes before and 20 minutes after injection in intervention groups 1 to 4 respectively. Data related to injections were recorded in a researcher-made check list by researcher's trained colleague which consisted of age, gender, type of disease in the first section of check list and measurements of pain using VAS visual scale (ranging from 0 to 100 milimeter) ranging from painless to very painful. Pain intensity was measured immediately after injection using the visual scale of pain and 24, 48 and 72 hours later bruise width was measured and findings were compared. In order to measure bruise width, the nurse assigned for measurement used a transparent ruler and largest diameter of bruise width was determined by millimeter. It is clear that patients who were reluctant to cooperate and/ or were discharged earlier than 72 hours were excluded from the study. Precision of pain intensity measurement based on visual scale, validity and reliability and sensitivity of this measurement tool were confirmed by intense, chronic and cancer-related pain in various studies (Dehghani 2012). Giveh'ee quoted from Boonstra that level of validity of this scale is around 76 to 86 per cent and its reliability is estimated from 60 to 77 per cent (Giveh'ee). Data was analyzed using descriptive statistics (mean and standard deviation) and inferential tests (T test and Chi-squared test) of SPSS 16 with significant level lower than $p<0.05$. It should be noted that this study was conducted with a permit from Office of research with project number () and security section of the hospital and prior to carrying out the study purpose of the study and its harmless nature was explained to all participants and their informed consent was obtained.

Findings:

Based on the findings descriptive statistics, the youngest participant was 26 years and the oldest was 65 years old. Average age of sample population was 54.66 and standard deviation was 8.603. Gender distribution of participants was equal at 50 per cent.

Based on the findings of Chi-squared test (600/3=2χ, Sig= 0.463) it can be said that zero can be assumed meaning gender distribution in two groups is equal. This means that there is no difference among the five groups in terms of number of male and female patients and they are identical (table 1)

Findings of ANOVA variance analysis showed that level of significance (Sig= 0.562) is higher than 0.05 and therefore there is no significant difference in 5 groups in terms of average age of participants (table 2)

ANOVA variance analysis was also used in order to compare pain intensity in five groups of the study. Findings show that there is a significant difference in pain intensity in 5 groups (F=2.255, Sig= 0.044). This means that assuming zero which means equal level of pain intensity in five groups is refuted and difference in this variable is significant among five groups (tables 1 and 2).

Table 1 - Descriptive statistics of pain intensity in 5 groups of the study

	No.	minimum	maximum	mean	standard deviation
without intervention	20	0	4	1/40	1/602
5 minutes before injection	20	0	5	1/15	1/496
20 minutes after injection	20	0	7	1/05	2/038
5 minutes before and 20 minutes after injection	20	0	2	0/6	0/882
5 minutes before and 5 minutes after injection	20	0	2	0/2	0/615

Table 2 – Items in ANOVA analysis test (differences in pain intensity in 5 groups)

	sum of squares	degree of freedom	mean square	F	level of significance
between groups	18/26	4	4/565	2/255	0/044
within groups	192/3	95	2/024		
total	210/56	99			

Using ANOVA variance analysis and with repeated measurement of bruise width after 24, 48 and 72 hours after injection a significant difference between bruise width in group 2 (with cold application 5 minutes before injection) and group 5 (cold application 5 minutes before and after injection) because level of significance is lower than 5 per cent. In other groups, however, this difference is not significant (table 3 and 4).

Table 3 – descriptive indexes of bruising after 24, 48 and 72 hours in each group

group	variable	No.	minimum	maximum	mean	standard deviation
without intervention	bruising time	20	0	20	4/25	6/164
	bruising time	20	0	50	6/1	11/79
	bruising time	20	0	50	6/1	11/719
5 minutes before	bruising time	20	0	0	0	0
	bruising time	20	0	5	0/7	1/417
	bruising time	20	0	10	¼	2/722
20 minutes after	bruising time	20	0	5	0/6	1/569
	bruising time	20	0	5	0/75	1/517
	bruising time	20	0	50	3/75	11/428
5 minutes before and 20 minutes after	bruising time	20	0	4	0/2	0/894
	bruising time	20	0	10	0/55	2/355
	bruising time	20	0	15	1/05	3/363
5minutes before and after	bruising time	20	0	5	1	1/622
	bruising time	20	0	10	2/55	3/332

	bruising time	20	0	20	5/35	7/4

Table 4 – Items in GLM Repeated Measures Analysis of variance (GLMRM) for bruising after 24, 48 and 72 hours

group	source		Type III Sum of Squares	degree of freedom	mean square	F	level of significance
without intervention	bruising	Greenhouse-Geisser	45/633	1	45/633	1/313	0/266
5 minutes before		Greenhouse-Geisser	8/1	1/039	7/796	4/726	0/041
20 minutes after	bruising	Greenhouse-Geisser	99/633	1/064	93/644	1/825	0/192
5 minutes before and 20 minutes after	bruising	Greenhouse-Geisser	7/3	1/047	6/795	2/285	0/146
5minutes before and after	bruising	Greenhouse-Geisser	211/093	1/146	187/217	8/385	0/007

Discussion:

Findings of this study indicated that there is a significant difference between two groups of men and women (t= 3.039, p<0.05). Based on the data on pain intensity in women (1.43) and men (0.42) in can be said that pain intensity in women is higher compared to men; however, there is no significance difference in amount of bruising in two genders. Therefore, it can be concluded that women's group have lower pain tolerance compare to men but bruising is not related to gender.

Findings of ANOVA variance analysis, used to compare pain intensity in 5 groups, showed that there is a significant difference in average pain intensity in 5 groups (F=2.25 , sig= 0.004). Pain intensity in control group was by far the highest. These findings are consistent with those of Rahmani et al (2014).

In their study, titled "Effect of Local Cold and Subcutaneous Enoxaparin Sodium Duration on Pain Intensity and Bruise at the Injection Site", Rahmani et al (2014) reported 27.55 - + 38.66 pain intensity for control group and 16.17 - +55.30 for intervention group with a 1.8 difference in pain intensity which is statistically significant. However, average pain intensity in intervention group is lower compared to control group and highest level of reported pain in control group is 100 while the highest in intervention group was 56 which is clinically a significant difference. This indicates that applying cold reduces pain in patients receiving subcutaneous injections. In current study the difference of pain intensity between control group and intervention group was statistically significant. In general, it can be said that two case groups receiving cold application (i.e. one with cold application 5 minutes before and 20 minutes after injection and the other with cold application 5 minutes before and 5 minutes after injection) equally experienced the lowest level of reported pain. These findings are consistent with those of Kuzu et al (2001) who investigated the effect of cold application on pain intensity and bruising in injection site of subcutaneous low-molecular-weight heparin in 63 patients. The findings of their study done on 63 patients for whom 4 different injection methods were used showed that applying cold before and after injection significantly reduces pain in injection site. It seems that the reason for contradicting results of the two studies mentioned above is in the use of cold compress before and after injections which resulted in longer painless experience. Therefore, current study confirms this by using both cold applications.

Repeated measurement of bruising of injection site 24, 48 and 72 hours after injection in variance analysis also revealed that there is a significance difference in average bruising in intervention groups (the ones using cold application 5 minutes before and after injection, and 5 minutes before injection) but this trend was not observed in other groups. However, in the study by Rahmani et al (2001), highest average bruising in intervention group was observed in the second 24-hour period and was almost equal to that of third 24-hour period and there was no statistically significant

difference in bruise width between two groups in the second and third 24-hour. However, the findings of a study done by Varghese et al (2006) on 100 patients to investigate the effect of local cold application on pain intensity and bruising resulted from heparin injection showed that bruising trend gradually decreased starting from 12 hours and up to 48 and 72 hours after injection and this is also consistent with the findings of the current study. Another study done by Silvain et al (2012) done to investigate the effect of cold 5 minutes before subcutaneous injection of heparin on bruising and size of Hematoma found that there is a significance difference in size of Hematoma in injection site seen before applying cold between control group and intervention group and this is consistent with findings of Rahmani Anaraki et al (2014). It seems that contradiction between the findings of the studies and the current study is in the size of sampe population (36 patients). Therefore, the researchers attempted to eliminate this restriction by increasing the size of sample population.

Conclusion:

The current study showed that local cold application reduces the size of bruises and pain associated with injection. Based on the results of this study, it seems that level of pain and bruising associated with injection in intervention groups receiving cold application 5 minutes before and after injection were the lowest. Therefore, in order to improve the quality of clinical care and minimizing unpleasant and stressful experiences the findings of this study can be used a guideline for reducing unpleasant side effects associated with subcutaneous enoxaparin and for training healthcare staff. These findings can also be used for clinical nursing in order to improve the quality of nursing performance and increase patients' satisfaction and cooperation. There were some restrictions in conducting this study including the effect of patients' cultural background and beliefs and everyday life on how they perceive and described their pain which cannot be controlled or measured.

References:

- Rahmani Anaraki Hossein, Farhang Ranjbar Mehri, Kovoosi Ali, Nasiri Hossein, Shariati Alireza. (2014) Effect of Local Cold Application on Bruising and Pain associated with Subcutaneous Enoxaparin Sodium Injection in Injection Site. Developing Research in Nursing and Midwifery. 2014. 11 (2): 15-21
- Farnia Farahnaz, Zayghamian Somaie, Dehghani Khadije, Lotfi Hassan. (2014) Comparison of effect of Emla Cream and cold compress on level of pain associated to enoxaparin. Salamte Jame'e, 2014. Period 8. No. 2.
- Dehghani Khadije et al (2012) Investigating the effect of duration of subcutaneous injection of enoxaparin on pain intensity of injection site in patients with acute coronary syndrome in intensive care unit of Afshar Hospital in Yazd. 2011. Science and Research Magazine of Shaheed Sadooghi Medical Science Unversity of Yaz; Period 20, No. 4. September and October.
- AbdiKor,JouybariL,SanagooA,ShiafcanA.BatyarMM,NasiriE,HekmatAfsharM.AStudy on the Effect of the Duration of Subcutaneous Heparin Injection on Bruising and Pain of panjeAzar Hospital hnGorgan ,2008 Journal of GorganBouyeh Faculty of Nursing &Midwifery 2011;8(19):11-9.[Persian]
- Chan H. Effects of injection duration on site-pain intensity and bruising associated with subcutaneous heparin. J Adv Nurs 2001; 35(6): 882-92.
- Correl D. The management of pain: objectifying the subjective. In: Waldman S, editor. Pain management. Philadelphia: Sunders Elsevier; 2007.p. 197-99.
- Crooke B.Fatalhaemorrhage associated with enoxaparin.Journal compilation 2007 Royal Australasian college of Physicians: 207-8.
- DehghaniK,DehghaniH,NajariZ.Effect of Subcutaneous Enoxaparin Injection Duration on Site-pain Intensity in Acute coronary syndrome patients Hospitaized in ccuAfshar Hospital,Yazd,2011.Iranian journal of nursing

and midwifery research 2014;19(6):564-8.[Persian]

- GhamariGiviH,ShareiSJ,MohammadypoorN,AbolghasemiA,Naderpilehroud M.A investigation into the effect of employing relaxation and Attention DevationMetods on alleviating pain in children hospitalized in state hospitals.counsel cult psychother 2011;3(10):101-15.[Persian].
- Lilley LL, CollinsSR, HarringtonS, SynderJS. Pharmacology and the nursing process.6thed.Louis, Missouri: Mosby Elsever, 2010 Februrary 5.
- nir Y,pazA,SaboE,PotasmanI,Fear of hnjections in young adult:prevalence and associations.Am J Top Med Hyg2003;68:341-4
- Rahmani AnarakiH,FarhangRanjbarM,AbdollahiAA,BehnampoorN,Effect of local cold and subcutaneous Enaxaparin sodium duration on pain intensity and bruise at the injection site.Journal of Research Development in Nursing &Midwifery16/spring and summer 2013,vol 10,no1.
- Senaran H, AcaroE, EzdemirHM, AtillaB.Enoxaparin and heparin comparison of deep vein thrombosis prophylaxis in total hip replacement patients.Archorthopthraumasurg 2006; 126(1):1-5.
- Zaybak A, Khorshid L. A study on the effect of the duration of subcutaneous heparin injection on bruising and pain. J Clin Nurs 2008; 17(3): 378-85.

A prediction model based on personality traits and domestic violence against women and child abuse history spouses in Isfahan

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Abstract

Background: In recent decades, violence against women, as the most serious social problem beyond cultural, social and regional remembered.

Objective: The aim of this study is to predict the pattern of domestic violence against women based on personality traits and history of child abuse in Isfahan wives.

Methods: The research method was descriptive-correlation. The study sample included all women about domestic violence, the number of 159 students were selected by convenience sampling method domestic violence against women, child abuse history questionnaire between personality traits and a questionnaire was distributed. Data correlation and multiple regression analysis were used.

Results: The results showed that personality traits and child abuse, domestic violence against women and wives predictor of personality trait neuroticism and child abuse, domestic violence against women, there is a significant positive relationship (P<0.0001). This is despite the fact that the other personality traits includes extroversion, openness to experience, agreeableness and conscientiousness with domestic violence against women, there is a significant negative correlation (P<0.0001).

Conclusion: It can be said that personality traits and child abuse, domestic violence against women and wives predict the personality trait neuroticism and child abuse, domestic violence against women, there is a significant relationship. These results indicate the relationship between personality traits and child abuse, spouse that should be considered by researchers.

Keywords: domestic violence, personality traits, child abuse, women .

INTRODUCTION

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In recent decades, violence against women has been seen as the most serious social problem that exists beyond cultural, social, and regional boundaries. Violence against women refers to any kind of gender-based violence that leads to physical, sexual, or psychological harm (or increases the likelihood of these harms), creates suffering for women, or leads to coercive deprivation of personal or social freedom. The most common form of violence against women is the violence committed by a partner, which is called domestic violence or partner violence (1). Women can also be violent against men, but various studies have shown that women are prone to partner violence 7 times more than men. In addition, various surveys around the world have shown that 10% to more than 50% of women have been subject to some form of violence by their partners, and in about one-third to half of the cases, physical mistreatment has been accompanied by psychological violence (2). Different factors, such as poverty, psychiatric disorders, and alcohol dependence have been implicated for domestic violence (3). Because domestic violence against women is an important factor in many physical harms, psychological disorders, and other unpleasant outcomes, it is not only seen as a major problem for women, but also a continued, hidden epidemic in society (4). In 2008, a study on domestic violence that was conducted by the cooperation of the World Health Organization (WHO) indicated that the prevalence of domestic violence against women varied from 15% in Japan to 71% in Ethiopia, and the prevalence of physical-sexual violence in the previous year had been 4% to 54% (5). Domestic violence against women is a phenomenon that is seen all over the world; it not only endangers the health, well-being, rights, and personality of the victim women, but also is regarded as a serious threat to the society. Although physical harm and death are the most evident and urgent outcomes of domestic violence against women, a wide spectrum of psychological complications (such as chronic physical complaints, reproductive health problems, and high-risk behaviors, like drug and alcohol abuse) resulted from couples' personality traits, can lead to domestic violence (3). Personality refers to stable tendencies and characteristics that determine differences and similarities in people's thoughts, emotions, and actions. These characteristics continue over time, and cannot be regarded as simply the outcome of social and biological pressure in a certain time (6). Various theories have been proposed in the field of personality psychology among which the trait approaches have been an important progress. The Big 5 personality traits model is one the most prominent personality theories in recent years that was created through development of personality theories and progress in the measurement methods and statistical analyses. This model maintains that human being is a rational being that can explain its personality and behavior. According to this theory, human being can perceive its way of life, and analyze its actions and reactions (6). The five factors of personality include Neuroticism, Extraversion, Openness to experience, Agreeableness, and Conscientiousness. Childhood is a stage of life characterized by a high level of vulnerability, in which personality traits are stabilized. Child abuse that, despite significant progress in science and technology, still continues to exist as a major problem, not only have a negative impact on children and their families, but also harms the whole society, because today's abused children could be tomorrow's abusers, and this vicious cycle can continue over and over again (7). It has been found that violent people have been subject to violence in their childhood. Therefore, domestic violence is not limited to one person, and the victim utilizes the violent behaviors learned during childhood to solve domestic conflicts and tensions during adulthood and in marriage life (4). Child abuse has been defined from legal, medical, and social perspectives, and includes any form of physical, sexual, and emotional harm, and neglect imposed on a child (under 18 Years of age) by an older person (above 18 years of age). Physical child abuse involves intentionally inflicting harm on the child's body by an adult (2). Sexual abuse refers to any kind of sexual activity with an underage child who cannot have legal consent. Child neglect involves the failure to meet the child's basic needs, including food, clothing, support, and educational facilities (5). Emotional abuse refers to any kind of child maltreatment that is regarded harmful based on social criteria and experts' opinions, that is, any behavior that affects the behavioral, cognitive, physical, and emotional functioning of the child, such as continued belittling, insulting, and swearing (6). Based on what was said, the present study aims to answer the following question:

Can partner's personality traits and history of abuse during childhood significantly predict domestic violence against women?

METHODS

This was a descriptive-correlational study. The statistical population included all women under domestic violence and their husbands with open cases in the Dispute Settlement Council of Isfahan, Iran in 2015; their total number was estimated to be 270. Using a convenience sampling method and according to Krejcie & Morgan table, a total of 159 individuals were selected from this population as the study sample.

The NEO Five-Factor Inventory (NEO-FFI): This is a personality test developed using factor analysis. It is one of the newest personality scales that was developed by McCrae & Costa (1985). In the present study, the short form of the inventory was used. The items of NEO-FFI are rated on a 5-point Likert-type scale ranging from totally disagree to totally agree (7). It has been validated in various countries. In Iran, Garoosi, Mehryar, and Tabatabaei (7) found a Cronbach's alpha of .92 for the total scale. In addition, Cronbach's alphas of .68 to .86 have been reported for the subscales (7).

The History of Child Abuse Questionnaire (HCAQ): This 22-item questionnaire was developed by Yousefi and Shamaei (8). The items are rated on a 5-point Likert-type scale. The developers found a Cronbach's alpha of .86 for their questionnaire; they also found good validity for the HCAQ. In the present study, Cronbach's alphas of .81, .85, .79, .80, and .81 were found for the Emotional abuse, Physical abuse, Sexual abuse, and Negligence subscales and the total score, respectively.

The Violence against Women Questionnaire (VAWQ): This 71-item questionnaire was developed by Tabrizi (9). The items are rated on a 4-point Liker-type scale. The scoring process has two parts: The sum of scores is calculated and multiplied by 10. Tabrizi (9) reported a Cronbach's alpha of .83 for the VAWQ indicating the acceptable reliability of the questionnaire and its different items and subscales. In the present study a Cronbach's alpha of .82 was found for the questionnaire.

The data were analyzed using descriptive and inferential statistics. At the descriptive level, means, standard deviations, etc. and at the inferential level, Pearson correlation coefficient and stepwise multiple regression analysis were used. All analyses were performed using SPSS software v.21.

RESULTS

The mean (SD) age of the study participants was 29.23 (5.23) years. The youngest and oldest partners with a history of aggression toward women were 26 and 37 years old. Among the participants, 90 (56.6%) had middle-school education or lower, 36 (22%) had high-school education, and 33 (20%) had a high-school diploma or higher.

Table 1. Descriptive statistics for the study variables.

Variable	Mean	Standard deviation
Neuroticism	23.9	4.8
Extraversion	21.7	3.4
Openness to experience	22.2	3.9
Agreeableness	19.8	2.5
Conscientiousness	20.3	3.1
Emotional abuse	14.7	1.4
Physical abuse	15.9	2.7
Sexual abuse	17.2	2.69
Negligence	16.3	2.4

Table 2. Stepwise regression analysis of domestic violence against women on personality traits.

Predictive variables		R	R^2	Adjusted R^2	F	P	Beta	t	P
tep 1	Neuroticism	.80	.64	.63	281.09	.0001	.80	16.76	0.0001
tep 2	Neuroticism,	.81	.66	.66	155.87	.0001	.72	14.34	0.0001
	Conscientiousness						-.17	-3.40	0.001
tep 3	Neuroticism,	.82	.67	.66	107.16	.0001	.83	11.27	0.0001
	Conscientiousness,						-.20	-3.89	0.0001
	Openness to experience						.15	1.97	0.05

As you can see in Table 2, in the first step, Neuroticism (R^2=.80) could enter the model in the presence of predictive variables, and predict 64% of the total variance of the criterion variable. In the second step, Neuroticism and Conscientiousness (R^2=.81) could enter the model in the presence of predictive variables, and predict 66.2% of the total variance of the criterion variable. Finally, in the third step, Neuroticism, Conscientiousness, and Openness to experience (R^2=.821) could enter the model in the presence of predictive variables, and predict 66.8% of the total variance of the criterion variable.

Table 3. Stepwise regression analysis of domestic violence against women on child abuse variables.

Predictive variables		R	R^2	Adjusted R^2	F	P	Beta	t	P
Step 1	Physical abuse	.86	.74	.74	450.47	0.0001	.86	21.22	0.0001
Step 2	Physical abuse,	.89	.79	.79	299.62	0.0001	.65	13.156	0.0001
	Emotional abuse						.31	6.26	0.0001
Step 2	Physical abuse,					0.0001	.56	10.58	0.0001
	Emotional abuse,						.24	4.94	0.0001
	Negligence						.18	3.65	0.0001
Step 4	Physical					0.0001	.52	9.37	0.0001

abuse,	.23	4.66	0.0001
Emotional abuse,	.17	3.54	0.001
Negligence,	.09	2.20	0.029
Sexual abuse			

AS you can see in Table 3, in the first step, Physical abuse (R^2=.86) could enter the model in the presence of predictive variables, and predict 74% of the total variance of the criterion variable. In the second step, Physical abuse and Emotional abuse (R^2=.89) could enter the model in the presence of predictive variables, and predict 79.1% of the total variance of the criterion variable. In the third step, Physical abuse, Emotional abuse, and Negligence (R^2=.90) could enter the model in the presence of predictive variables, and predict 80.6% of the total variance of the criterion variable. Finally, in the fourth step, Physical abuse, Emotional abuse, Negligence, and Sexual abuse (R^2=.90) could enter the model in the presence of predictive variables, and predict 81.1% of the total variance of the criterion variable.

DISCUSSION

The study results showed that personality traits and partner's history of child abuse could significantly predict domestic violence against women, and there was a positive relationship between Neuroticism and domestic violence against women, but there were negative relationships between domestic violence against women and other personality traits, including Extraversion, Openness to experience, Agreeableness, and Conscientiousness. This finding could be explained by the fact that partners with neuroticism experience conflicts and paradoxes in their feelings, beliefs, and behaviors. They are unable to make decisive and appropriate decisions. Inconsistency in behavior and personality, psychosomatic disorders, like shortness of breath, chronic indigestion, severe headaches etc. all can be signs of neurotic conflicts in them that may lead to domestic violence (1). Because of these internal conflicts, an honest neurotic partner may suddenly become a downright liar, or turn into a ruthless person after being nice and kind, and show impulsive behaviors due to not paying attention to consequences of actions (10). Neurotic people tend to have dominant personalities that can lead to aggressive behavior and tension in the family. When comparing their ideal self to their actual self, neurotic people see their actual self as inferior, therefore, they may doubt their personality and identity. In other words, discrepancy between ideal and actual self may lead to severe internal tension in neurotic people (11). But sometimes the neurotic person gets closer to one of these two, in this case, if they get closer to their ideal self and see themselves more like that, their behaviors match the ideal self, that is, they become dominant, arrogant, ambitious, and abuser, and expect others to obey them and admire them, and if their partner refuses to obey them, they become aggressive (12). Neurotic partners do not tolerate the requirements and prerequisites of competent functioning, delay their tasks with feeble excuses, and try to find faults in the works of those they are attached to, and show aggression toward them. However, they never want to get rid of such relationships that are based on attachment. These people lack assertiveness and do not express their needs and demands clearly. They cannot ask appropriate equations about what other people expect from them (13). Therefore, if they are forced to do something, they use their typical defense that is directing their anger toward themselves, and during interpersonal relationships, try to put themselves in a dependent position, but other people often consider their passive and masochistic behavior as kind of punishment and deceit against themselves. In other words, neurotic people keep complaining and asking others to be fair and honest with them to the point that their friends and therapists may involve themselves in the problems of the neurotic person, hoping that they can reduce their violence and aggression. Neurotic people are not happy in their intimate relationships. They are more focused on their own annoyances and resentments, and tend to direct their anger at other people and objects at home. These people do not have confidence in themselves, are often pessimistic about the future, and always abuse their partners, physically, psychologically, and emotionally (14).

Neuroticism is accompanied by a wide spectrum of negative emotions, such as anxiety and anger that can lead to domestic violence against women. Men who are violent at home, usually live in socio-cultural environments in which men's dominance on women is considered a normal thing, and aggression and violence are regarded as manly characteristics and obedience is seen as a feminine quality. In such societies, when order is in danger, the use of aggression and violence to restore order in both the society and the family is regarded as a legitimate solution (15). Men who use physical punishment to discipline their children, usually act in the same way to create order at home, and physically punish their wives if they do anything wrong (16). Men who treat their children with verbal and non-verbal abuse, blaming or insulting, swearing, mocking, severe and unreasonable control, repeated threatening the child with physical punishment, using the child to satisfy their own emotional needs, and showing unpredictable behavioral responses along with cognitive instability, act in the same way toward their wives (17). Men who have experienced negligence during their childhood, in their adulthood, may become negligent toward their wives. Negligence most often occurs in low-income families where lack of proper food, dressing, housing, sanitation, medical care, and education may be present; men who have been raised in such conditions may show negligence and carelessness toward the emotional needs of their wives. Me who have been subject to sexual abuse during their childhood, may abuse children in their adulthood. In fact, their past experiences, psychological and physiological problems, etc. may be generalized to their marital life. It can be argued that men who show sadistic tendencies and aggression when having intercourse with their wives, have been subject to sexual abuse during their childhood, or have numerous physiological, psychological, and behavioral problems (18).

It can be concluded that partner's personality traits and history of abuse during childhood can predict domestic violence against women. The results indicate a link between partner's personality traits and child-abuse, an issue that needs to be further explored by the future studies.

References

1. Ali TS, Mogren I, Krantz G. Intimate partner violence and mental health effects: A population-based study among married women in Karachi, Pakistan. International journal of behavioral medicine. 2013 Mar 1; 20(1):131-9.
2. Tinglöf S, Högberg U, Lundell IW, Svanberg AS. Exposure to violence among women with unwanted pregnancies and the association with post-traumatic stress disorder, symptoms of anxiety and depression. Sexual & Reproductive Healthcare. 2015 Jun 30; 6(2):50-3.
3. Anderson J. Effects of Partner Violence on Mental Health and HIV Disease Progression in Women in Baltimore. InSigma Theta Tau International's 27th International Nursing Research Congress 2016 Jul 25. STTI.
4. Alesina A, Brioschi B, Ferrara EL. Violence against women: A cross-cultural analysis for Africa. National Bureau of Economic Research; 2016 Jan 21.
5. Devries KM, Mak JY, García-Moreno C, Petzold M, Child JC, Falder G, Lim S, Bacchus LJ, Engell RE, Rosenfeld L, Pallitto C. The global prevalence of intimate partner violence against women. Science. 2013 Jun 28; 340(6140):1527-8.
6. Shedler J, Westen D. Dimensions of personality pathology: an alternative to the five-factor model. American Journal of Psychiatry. 2014 Dec 22.
7. McCrae RR, Terracciano A, Costa P, Brant L. Hierarchical Linear Modeling Analyses of the NEO-PI-R Scales in the Baltimore Longitudinal Study of Aging. Psychology and Aging. 2016; 20(3).
8. Shamaeizadeh N, Yousefi Z, Shaygan Nejad V. The relationship between a history of child abuse, five factors of personality and family connections and the prevalence of multiple sclerosis in Isfahan. Second National Conference on Research and Treatment in Clinical Psychology. 2014.
9. Mohseni Tabrizi A, Kaldi A, Javadian Zadeh M. The situation of domestic violence among married women referred to forensic centers and

well-being of Yazd city in 1389. Journal of Yazd health sunrise.
10. Roelens K, Verstraelen H, Van Egmond K, Temmerman M. A knowledge, attitudes, and practice survey among obstetrician-gynaecologists on intimate partner violence in Flanders, Belgium. BMC public health. 2006 Sep 26; 6(1):1.
11. Audi CA, Segall-Corrêa AM, Santiago SM, Andrade MD, Pèrez-Escamila R. Violence against pregnant women: prevalence and associated factors. Revista de saude publica. 2008 Oct; 42(5):877-85.
12. Sargent KS, McDonald R, Vu NL, Jouriles EN. Evaluating an online program to help children exposed to domestic violence: results of two randomized controlled trials. Journal of family violence. 2016 Jul 1; 31(5):647-54.
13. Howard LM, Oram S, Galley H, Trevillion K, Feder G. Domestic violence and perinatal mental disorders: a systematic review and meta-analysis. PLoS Med. 2013 May 28; 10(5):e1001452.
14. Howarth E, Moore TH, Shaw AR, Welton NJ, Feder GS, Hester M, MacMillan HL, Stanley N. The effectiveness of targeted interventions for children exposed to domestic violence: measuring success in ways that matter to children, parents and professionals. Child Abuse Review. 2015 Jul 1; 24(4):297-310.
15. Pallitto CC, García-Moreno C, Jansen HA, Heise L, Ellsberg M, Watts C. Intimate partner violence, abortion, and unintended pregnancy: results from the WHO Multi-country Study on Women's Health and Domestic Violence. International Journal of Gynecology & Obstetrics. 2013 Jan 31; 120(1):3-9.
16. Oram S, Trevillion K, Feder G, Howard LM. Prevalence of experiences of domestic violence among psychiatric patients: systematic review. The British Journal of Psychiatry. 2013 Feb 1; 202(2):94-9.
17. Tavoli Z, Tavoli A, Amirpour R, Hosseini R, Montazeri A. Quality of life in women who were exposed to domestic violence during pregnancy. BMC pregnancy and childbirth. 2016 Jan 26; 16(1):19.
18. Allen CT, Swan SC, Maas CD, Barber S. A comparison of the structural factors of the propensity for abusiveness scale for women and men in a domestic violence treatment program. Journal of interpersonal violence. 2015 Aug; 30(13):2326-43.

The relationship between aggression and self-efficacy and coping strategies among involuntary patients of detention center

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Objective: The purpose of this study was determining the relationship between aggression and self-efficacy and coping strategies among involuntary patients of detention center.

Methods: the statistical population of the study was all the male involuntary patients of detention center of CHESHMEH SEFID of KERMANSHAH city in 2016. This is a correlational study. Sampling method was purposive sampling based on the Cohen (1970) table, and 80 people were selected as a sample. The study data was collected using an aggression and self-efficacy and coping strategies questionnaire and it was analyzed using descriptive statistics, Pearson correlation and stepwise regression and ANOVA with SPSS-21 software.

Results: The results showed that there is a negative and significant relationship between aggression and emotion-oriented and avoidance coping strategies and self-efficacy variable but there is positive and significant relationship between problem-focused coping strategies and self-efficacy variable ($P<0.05$).

Conclusions: It can be concluded that strengthening psychological factors lead to aggression and crime reduction.

Keywords: Aggression, Coping strategies, Self-efficacy, Patients

Introduction

Crime has a history as old as humanity and issues of criminals and prisoners in particular its relationship with psychological problems is one of the most challenging and the most active areas of research (1). A look at the prisons condition and the growing number of prisoners in recent years shows the reduction of patients' mental health. Although the tendency to commit crime is caused by several factors, some are rooted in internal personality and some has social roots, personality characteristics and coping strategies and their efficacy in coping with stressful situations and stress has an effective role in aggression and delinquency and incarceration (2).

Today aggression has risen sharply in the community and in personal and social behavior in different age groups (3). Aggression is done as a visible behavior intended to damage or harm, and include: causing damage not only unjustifiable in the eyes of viewers, but only has meaning in the ethical and legal framework of a given society (4). As it was reported more than one fourth of the population experienced some of these psychological problems during their life (5). In

some cases, the type and severity of the problem reaches to the extent that causes the legal harassment and intimidation of other members of society and as a result, causes a patient's conflict with the law and penal authorities (6).

The tendency to aggressive behavior on several hypotheses have been mentioned, but none alone cannot explain it. The role of coping styles, (7); and self-efficacy, (8, 2) are of particular importance among these aspects and factors. Coping strategies is another psychological variables that in general plays a major role in mental health (9). Coping is a process of psychological, cognitive and behavioral efforts to resolve those stressful conditions. Coping is including action-oriented efforts and intra-psychological, for managing environmental demands, internal conflicts between them, and there are two types of coping style for mental pressure; Problem-focused coping style and emotion-oriented coping style (10). In problem-focused coping styles, the person focus on the pressing factor and tries to do constructive actions to change or remove the overwhelming conditions but in emotion-oriented coping style the person tries to control emotional consequences of overwhelming event (11). Our character and the ability to control life affairs affect the assessment of the situation and thus the coping style (12).

Since Bandura (1997) introduced the concept of self-efficacy for the first time, this structure has attracted many researches in various fields. Researches have shown that self-efficacy and behavioral changes and consequences are highly correlated and self-efficacy is an important predictors of behavior (13). In Bandura (1997) system self-efficacy means; "competency, competence and ability to cope with life that meet and maintain standards performance increase that. According to this model, self-efficacy plays a central role in the psychological states. When people feel that they are unable to gain valuable outcomes they will have psychological disorders (13).

Recent researches of Bandura (13) have shown that feelings of low self-efficacy is related with greater mental pressure. On the contrary, a sense of high self-efficacy is correlated with less environmental stress and responses to stress, power to adapt more and more interest in health programs and mental health. Low self-efficacy is related with depression, anxiety and hostility (14). Thus, according to conducted researches, the lack of compatible coping styles in an effective relationship of mutual influence and can be a driving factor for the disorder and emotional behaviors such as aggression and help its consistency. The results of Lehmann and Ittel (7) studies showed that there is a significant relationship between the amount of aggressive behavior (physical and verbal) and psychological disorders. Also results showed that social support can have a moderating role to play in reducing aggression and psychological disorders. Grella and Messina (15) also showed that self- efficacy variable can be a mediator in the development of psychological disorders subsequent to the particular disorder, post-traumatic stress for the addicted prisoners experienced traumatic events and addicted inmates without this experience. Sygit-Kowalkowska et al (16) showed that there is a significant statistical relationship between the amount of experienced stress by poor self-control and using maladaptive coping styles and emotional avoidance ($P<0.05$).

Today, many societies is believed that in every society, instead of relying solely on punishing there is a need for places to keep incompatible and criminals apart from society for a while and thought that their arrangements were modified and get back into society. Thus, the goal of keeping them in prison is the correct implementation of correctional practices to reduce re-offending prisoners (1). The findings of various studies show that between 10 to 15 percent of prisoners are suffering from mental disorders. Also, the prevalence of the disorder samples of criminals and prisoners is much higher than other people in society (17). Also it was observed that patients with mental health problems, not only commits more offense in prison, as a result, it will increase the length of the sentence, but more likely to be victims of violence and abuse and harassment of other inmates (6). Clinical observations of Mc Shane (1989) show that patients with mental illnesses, 5 times more than other inmates attack the staff and other patients. These figures show that the detention and prison centers need to provide conditions that prisoners can be under more precise study and individual and group psychological treatments. Thus the purpose of this study is providing some evidence of the

relationship between aggression and coping styles and self-efficacy among the patients of detention center of CHESHMEH SEFID of KERMANSHAH city.

Materials and Methods

This is descriptive and correlational research.

Sampling method was purposive sampling based on the Cohen (1970) table, and 80 people were selected as a sample. The study data was collected using;

A) Aggression Questionnaire (AQ): it is one of the most successful self-report questionnaires aggression, aggression questionnaire by Buss and Perry (1992); the questionnaire has 29 questions with 4 subscales, including verbal aggression (5 items), physical aggression (9 items), anger (7 questions) and hostility (8 items). These factors are classified into three motor components or tools (physical and verbal aggression), emotional (anger) and cognitive (hostility). The questionnaire items are arranged in a manner to place the person on each question on a scale of 5 degrees, Likert scale, from 1 (completely describes me) to 5 (does not completely describes me). Buss and Perry (1992) Psychometric analysis has shown a high internal consistency (0.89). Furthermore, the correlation subscales of the questionnaire with each other and with the scale ranges 0.60 to 0.78, represent the appropriate reliability. Mohammadi (2006) reported the coefficients to retest reliability of the questionnaire for the whole questionnaire 0.78 and its 0.61 – 0.74 for variable subscales. Also, concurrent validity of the questionnaire using a scale of psychological damage was reported generally favorable. In Rustayi et al (6) study, Aggression Questionnaire reliability coefficients were calculated using Cronbach's alpha which is for the whole scale of verbal aggression, physical aggression, anger, and hostility, respectively are 0.79, 0.81, 0.82, 0.83 and 0.80.

B) Coping Inventory for Stressful Situations (CISS): This questionnaire was designed by Endler and Parker (1994), which includes 48 questions which measures three coping styles, problem-focused coping, emotion-focused coping and avoidance -oriented coping. Each question is graded with 5 degrees Likert scale (never to very much) grading and each category contains 16 questions. It means it measures 16 questions of problem-oriented behaviors; 16 questions of emotion-focused behaviors and16 questions of avoidance -oriented behaviors. The questionnaire designers have reported a very high level validity and reliability of both scales for adults and adolescents (18). In Iran Shokri et al (18) have reported Cronbach's alpha for the total scale and subscale 0.83 problem-focused coping, emotion-oriented and avoidance, respectively; 0.86, 0.81 and 0.79.

C) Self-Efficacy Questionnaire (SES): This 10-item scale has been developed by Schwarzer and Jerusalem (1979). The results of many studies have shown that there is a negative relationship between this scale and positive emotions, optimism and positive relationship between job satisfaction and the scale of depression, anxiety, stress, exhaustion and complaints related to health (19). Now it is used to predict the compatibility of life changes and evaluate the effectiveness of clinical practice and change in behavior. Participants should answer in a 4-point scale from 1 (not true at all) to 4 (very true) to determine the correct amount of each item on their own. The items should be added together to obtain the overall score and the higher the score, the higher a person's public sense of self. 10 is the minimum score and 40 is the maximum score of the scale (19). The high internal consistency and test-retest reliability has been reported for this scale ranges (0.0 – 82.93). Cronbach's alpha coefficient was established in Iranian samples 30 adolescent fatherless girls (0.850) have been reported. Test-retest reliability of self-efficacy scale run on five different samples, are obtained in a period of 6 months, within one year 0.55- 0.70 and within two years 0.47 – 0.63 (19).

For research data analysis, in addition to using descriptive statistics (mean and standard deviation), the Pearson correlation coefficient, stepwise regression and one-way analysis of variance (ANOVA) were used using SPSS-21 software.

Results

Table 1. Descriptive data of research variables

Research variables	Mean	Standard deviation
Verbal aggression	22/11	8/15
Physical aggression	18/05	6/19
Anger	13/72	4/02
Hostility	20/56	8/68
Total score of aggression	36/28	10/45
Self-efficacy	46/34	9/03
Problem-focused coping	15/75	2/12
Emotion-focused coping	22/30	3/01
Avoidance-focused coping	28/19	2/04

As shown in Table 1 in aggression variable the highest and lowest mean (and standard deviation) belongs to the components of verbal aggression (8.22 ± 11.15) and component of anger (4.13 ± 2.72). Also, the mean (standard deviation) of total score of aggression in male patients prisoner (10.36 ± 45.28) and their self-efficacy score (9.46 ± 3.34). Descriptive statistical analysis of coping strategies variable in general are among subjects in Table 1.

Table 2. Correlation coefficients between aggression and coping strategies with self-efficacy

Predictive variables	Self-efficacy	P-value
Aggression	-**0/454	0/001
Verbal aggression	-**0/474	0/002
Physical aggression	-**0/460	0/011
Anger	-**0/456	0/008
Hostility	-**0/518	0/004
Problem-focused coping	**0/688	0/013
Emotion-focused coping	-**0/594	0/001
Avoidance-focused coping	-**0/517	0/042

Findings of Table 2 shows that there is negative and significant relationship between aggression and its four sub-scales, also the emotion and avoidance oriented coping style with self-efficacy variable but there is a significant positive relationship between problem focused coping style and self-efficacy variable ($P<0.05$).

Table 3. Results of multivariate stepwise regression analysis based on the self-aggression

Model		Non-standard coefficients		Standard coefficients	T	P-value
		B	N Standard error	Beta		
1	Fixed	690/27	0/325	-	85/236	0/001
	Physical aggression	-0/919	0/032	-0/518	-5/995	0/001

As can be seen in Table 3, among the predictive variables of the analysis, the only significant component was physical aggression and operating verbal aggression, anger and hostility were not significant in this model. This variable, physical aggression in predicting the self-efficacy variable of patients of detention center of CHESHMEH SEFID of KERMANSHAH city is important and its contribution to the variance of self-efficacy among male patients is set based on R is 26.4.

Table 4. Results of multivariate stepwise regression analysis of self-efficacy based on coping styles

Model		Non-standard coefficients		Standard coefficients	T	P-value
		B	N Standard error	Beta		
1	Fixed	13/072	1/377	-	9/496	0/001
	Problem-focused coping style	00/542	0/058	0/688	9/391	0/001
2	Fixed	16/796	1/575	-	10/665	0/001
	Problem-focused coping style	0/480	00/056	0/610	8/607	0/001
	Emotional-focused coping style	-0/242	0/060	-0/287	-4/056	0/001

As can be seen in Table 4 of the predictor variables entered in the analysis, just coping style of problem-focused and emotion-focused coping styles were significant and avoidance- focused coping styles was not significant (P> 0.05). Problem-focused coping style and emotional-focused coping style were important in prediction self-efficacy of patient men. The share of these variables in explaining the variance in self-efficacy based on the R-set table is 0.541.

Table 5. The results of the correlation coefficient of aggression and coping strategies

Variable	Problem-focused coping styles	Emotion-focused coping styles	Avoidance-focused coping styles
Aggression	0/850**	0/797**	0/589*
Verbal Aggression	-0/666**	-0/576*	-0/531*
Physical Aggression	-0/683**	-0/602*	-0/550*
Anger	-0/652**	-0/539*	-0/525*
Hostility	-0/702**	0/587*	-0/532*

Based on the results of Table 5, the hypothesis that there is a relationship between aggression and coping strategies were approved and all the relationships were meaningful.

Discussion

The purpose of this study was to investigate the relationship between aggression and self-efficacy and coping strategies among involuntary patients of detention center of CHESHMEH SEFID of KERMANSHAH city. Research findings showed that using Pearson's correlation coefficient that there is negative and significant relationship between aggression and its sub-scales as well, emotion-oriented coping style and avoidance-oriented and self-efficacy variable but there is positive and significant relationship between problem-oriented and self-efficacy variable (P<0.05). These findings were consistent with previous studies, including; Grella and Messina (15), Bogaerts et al (20), Lehmann and Ittel (7), Wolff et al (21).

Yamamoto et al (8) in a study investigate the relationship between the self-efficacy and crime in Japan. The results showed that the crime rate in 144 patients participating in the study are closely related with self-efficacy scores. The more self-efficacy scores were lower, crime has increased more.

Other findings showed that among the components of aggression as verbal aggression, physical aggression, and anger and hostility only physical aggression component can explain the changes of self-efficacy in patients of detention center of CHESHMEH SEFID of KERMANSHAH city. This findings of this study was consistent with previous studies, including; Yamamoto et al (8), Hansen et al (22), and Fadakar, Gablo et al (23).

Another finding of the research showed that problem-focused and emotion-oriented coping styles can define the changes of self-efficacy variable in detention center. Among the predictive variables of the analysis, only the problem focused coping and emotion-focused coping styles were significant and avoidance focused coping style was not significant (P>0.05). The problem focused coping and emotion-focused coping styles are important in the prediction of self- efficacy variable of male prisoner. This finding is consistent with previous studies of Bogaerts et al (20), Wolff et al (21), and Sygit-Kowalkowska et al. (16).

The results showed that there is a significant difference between two groups in terms of self-regulation and the use of problem-focused emotional and avoidance coping styles (P<0.05). There was also a significant between the early maladaptive patterns and emotion-oriented and avoidance coping style and addiction potential (P<0.005). Also, this study showed that there is a relationship between aggression and coping strategies. This findings was consistent with results of number 8, 11, 15 and 20 studies.

To explain the findings of this study, it should be mentioned that the efficacy means a person belief about his ability to cope in certain situations and

patterns has effect on thought, behavior and excitement in different levels of human experience (13). Accordingly, self-efficacy plays a central role in mental health issues, including control of aggression and emotional behaviors. Low self-efficacy is related with depression, anxiety, low self-esteem and inefficient problem-solving methods, such as emotion-oriented style, on the contrary high efficacy is related with the ability of problem-solving and analytical thinking and improves the performance (19). People with high self-efficacy with respect to analytical thinking and confidence in stressful situations have less emotional behaviors such as verbal aggression and anger or being shy and compared with those with lower self-efficacy have less aggression and unhealthy behavior and criminal act.

Recent research based on the theory of "rational action / social-cognitive theory of planned behavior" demonstrated that self-efficacy component always have a strong predictor for starting, maintaining and continuing health behaviors in individuals at different ages (3). This component affect the behavior of people in two different ways: first, people who have a strong sense of self-efficacy to perform a particular behavior, is likely to make greater efforts to do that behavior. Second, studies show that people with low self-efficacy show up greater physiological responses such as heart rate and blood pressure frequently in stressful situations (13). This severe anxiety reactions may cause people with low self-efficacy do less efforts to change behavior in comparison with those with high self-efficacy and do physically aggressive behavior and physical action in frustrating situations. Finally, and perhaps most important of all, people with high self-efficacy, between cognition and behavior show more unity and more likely to act on their knowledge (3); so that they use more adaptive coping styles such as problem-focused coping style in stressful situations and have high self-control to express the aggressive impulses for their language and unlike people with low self-efficacy have higher understanding and control over their emotions. Thus in frustrating situations instead of anger and hostility use more productive behaviors such as problem solving and finding and less damaging solutions.

Conclusion

Several studies indicate that due to higher levels of testosterone in men, aggressive behavior is statistically higher compared to women and also considering that prisoners have educational problems, arbitrary parenting and inadequate learning experiences and personality problems, thus despite the self-efficacy of these people still we can see the physical type of aggressive behavior because they experience severe physiological reactions and high pressure at the time of the failure and sympathetic part of these people in response show more severe reactions to stimuli and vague anxiety. Also, given that at the time of activation of the brain's anxiety and risk the possibility of rational behavior is lowered thus people react with staying in their place for attacks or escape. Therefore the physical aggression behavior and dysfunctional coping styles used by patients is justifiable. This study similar to other studies in humanities has some limitations. Because of single gender study due to the subjects of the study precautions must be considered in generalizing the results to the other gender (women) and also lower age groups. Also, it is possible that the multiplicity and variety of variables and consequently the number of questionnaires and research questions has caused fatigue and reduce its accuracy in responding the questions.

It is recommended to use these same variables and conduct a comparative study between female and male patients. Also it is recommended to study the relationship between variables of men study with other psychological problems such as anxiety disorders, personality disorders and drug abuse

References

1. Johnson ME, Kondo KK, Brems C, Ironside EF & Eldridge GD. (2016). Mental Health Research in Correctional Settings: Perceptions of Risk and Vulnerabilities. Ethics Behav. 26(3):238-251.

2. Pont J, Stöver H, Gétaz L, Casillas A & Wolff H. (2015). Prevention of violence in prison - The role of health care professionals. J Forensic Leg Med. 34:127-32.

3. Snderson CA. Health Psychology. 2nd 2013. Translated by; Farhad Jomehri & et al. Tehran Publication Sarafraz. 2015.[Persian]

4. Sadock BJ, Sadock VA & Ruiz P. Kaplan and Sadock's, Synopsis of Psychiatry)Behavioral Sciences/Clinical Psychiatry). 1Volume. 11th ed, 2014. Translated by: Farzin Rezaei. Tehran: Publication Arjmand. 2015. pp; 477-580.[Persian]

5. Lantta T, Kontio R, Daffern M, Adams CE & Välimäki M. (2016). Using the Dynamic Appraisal of Situational Aggression with mental health inpatients: a feasibility study. Patient Prefer Adherence. 28(10):691-701.

6. Rostaei A, Abolghasemi SH, Mohammadi Aria A, Saedi S. Compare the effectiveness of anger management and drug therapy on aggressive prisoners. New findings in the journal Psychology. 2012; 6(21):19-31.

7. Lehmann A & Ittel A. (2012). Aggressive behavior and measurement of psychopathy in female inmates of German prisons-a preliminary study. Int J Law Psychiatry. 35(3):190-7.

8. Yamamoto M, Mori T & Ushiki J. (2013). Relationship between recidivism and self-efficacy among inmates of drug-related offences. Nihon Arukoru Yakubutsu Igakkai Zasshi. 48(6):445-53.

9. Shamlo S. Mental Health. Tehran: Publishers Roshd. 2014.

10. Kwarta P, Pietrzak J, Miśkowiec D, Stelmach I, Górski P, Kuna P & et al. (2016). Personality traits and styles of coping with stress in physicians. Pol Merkur Lekarski. 40(239):301-307.

11. Bahadori khosroshahi J, Khanjani Z. Relationship of Coping Strategies and Self-Efficacy with Substance Abuse Tendency among Students. Knowledge & Research in Applied Psychology. 2014; 14 (53):80-90.

12. Panthee, B., Kritpracha, C & Chinnawong, T. (2011). Correlation between Coping Strategies and Quality of Life among Myocardial Infarction Patients in Nepal. 1(2):187-194.

13. Bandura, A. (2006). Adolescent development from an agnatic perspective. In F. Pajares and T. Urdan (Eds.). Self-efficacy beliefs of Adolescent. Greenwich: Information age publishing. 5:143-146.

14. Murris, P. (2002). Relationship between self-efficacy and symptoms of anxiety disorders and depression in a normal adolescent sample. Pers Individ Dif. 32(2):337-48.

15. Grella CE & Messina NP. (2016). Continuing Care and Trauma in Women Offenders' Substance Use, Psychiatric Status, and Self-Efficacy Outcomes. Women Crim Justice. 26(2):99-121.

16. Sygit-Kowalkowska E, Weber-Rajek M, Porażyński K, Goch A, Kraszkiewicz K & Bułatowicz I. (2015). Emotional self-control, coping with stress and psycho-physical well-being of prison officers. 66(3):373-82.

17. Pettigrew M. (2016). Deterioration and the long term prisoner: a descriptive analysis of Myra Hindley. Int J Prison Health. 12(2):115-26.

18. Mahmod Alilo M, Esmoeili A, Vahedi H, Rezaei R. The relationship between personality characteristics (personality disorders) and problem-solving methods in criminal prisoners. Journal of Behavior. 2008; 16(34):61-69.

19. Moradi A. The effect of self-esteem, self-efficacy and achievement motivation on quality of life and entrepreneurial behavior of young women, a model for people with physical disability movement. Psychology doctoral thesis. Faculty of Education and Psychology, University of Isfahan. 2011.

20. Bogaerts S & van der Laan AM. (2013). Intracolleague aggression in a group of Dutch prison workers: negative affectivity and posttraumatic stress disorder. Int J Offender Ther Comp Criminol. 57(5):544-56.

21. Wolff N, Morgan RD, Shi J, Huening J & Fisher WH. (2014). Thinking styles and emotional states of male and female prison inmates by mental disorder status. Psychiatr Serv. 62(12):1485-93.

22. Hansen AL, Waage L, Eid J, Johnsen BH & Hart S. (2011). The relationship between attachment, personality and antisocial tendencies in a prison sample: a pilot study. Scand J Psychol. 52(3):268-76.

23. Fadakar P, Yonesi J, Mosavi Panah S. The mediating role of public health, aggression and risk-taking in predicting driving behavior. Journal of Management Studies Rahvar. 2015; 12(3):55-74

Examining Response Time to Emergency Cases and Causes of Delay in Missions of 115 Prehospital Emergency Center in Khorramabad

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Abstract

Introduction: pre-hospital emergency is an important department in healthcare service system. Immediate, efficient and effective healthcare services save lives of many people and reduce the severity, length of illness and side effects.

Methods: This was a descriptive, cross-sectional study on 5431 missions in five urban centers in Khorramabad in the first six months of 2016. Mission duration (dispatch time and response time interval from call receipt to ambulance arrival at the accident scene) and causes of delay in missions were analyzed.

Findings: findings showed that 74.8% of missions were performed in less than 8 minutes (at the standard time). Dispatch of ambulance from areas other than nearby centers (29.2%), route crowdedness (traffic) (25%), long distance (22%), etc. were high frequency causes of delay in response to emergency cases.

Conclusion: given the importance of 115 prehospital emergency care centers in reducing response time to emergency cases, the Ministry of Healthcare and Medical Emergency Department and other relevant organizations (e.g. Traffic Police) should allocate more funds to this sector and perform an accurate need

assessment for required number of ambulances, emergency equipment and centers based on population density and public demand in every urban area.

Keywords: prehospital emergency, standard dispatch time, medical emergency

Introduction

The government decided to launch the pre-hospital emergency system in 1997 in Iran after collapse of the roof at Mehrabad airport terminal that killed many people. Nowadays, prehospital care is a vital issue in treatment of emergency patients. If all departments in this system function properly, the ambulance will be immediately dispatched to the accident scene in a timely manner, which will reduce mortality and disability rates. Successful performance of this department depends on various factors including capability of the authority, trained personnel, equipment, coordination and communication system. Currently, prehospital emergency is the first unit in contact with critical patients in any urban health care system. The more accurate, more precise and faster the EMS care, the lower the rate of mortality and disability. This also increases public trust in the prehospital emergency care system (1-3).

Emergency is the most important department in every health system (4). Hospitals cannot deliver proper healthcare services to the patients unless a medical emergency center is designed in every hospital. Although this department is always neglected by the authorities, it requires substantial reforms and planning. Efficiency of this department was discussed in both public and private sectors in Iran for many years. This department is tied with societal healthcare service delivery (this department is essential in provision of immediate care services to critical patients in any society). Since prehospital emergency care is the first aid services given to the patients, efficiency of the system directly affect the patients and their families and friends. Timely arrival of the ambulance at the accident scene is also an important issue in this department. Immediate, efficient and effective emergency care services could save lives of many people and reduce both severity and length of the disease. Emergency patients require immediate attention and treatment. Resuscitation is also vital for these patients in emergency and crucial situations because it keep them alive so that they can reach hospital for specialized treatment that cannot be provided at the accident scene. Immediate and proper treatment can save injured people and help them to do their usual daily activities sooner in case that the injury is not fatal. Delayed and inefficient treatment would keep the patients from their usual lives for a longer period. In some cases, delayed and inefficient treatment might result in costly long periods of healing process rehabilitation for the patients that will keep the patients to

go back to work for long periods of time. Thereby, the emergency department should refrain from any delay in delivery of healthcare services (5). In this regard, high speed of service delivery in health centers (especially, prehospital emergency department) reduce mortality and morbidity rates.

Various scholars have shown that response time interval to emergency cases is one of the most important assessment criterion in emergency centers (6). Emergency medical service system guidelines and principles were compiled in California in 1993, which were used to determine standard response time interval in order to make plan, organize and assess local emergency systems in emergency centers (7). There are different criteria for calculating standard response time intervals including the time of the first call by the caller, the time the phone was picked up by the operator, the time the authorized person for dispatching the ambulance spoke to the caller and the time the collected data was recorded in a computer to dispatch an ambulance. The first factor (the first call by the caller) is determined as the best starting point for response time interval (8).

Skinner (2008) stated that emergency service department is responsible for saving the patients in less than the standard time (less than eight minutes) before transferring the patient to the hospital. Emergency Centers (115 Medical Emergency Center) are responsible for transferring injured people and patients to the nearest healthcare service center and hospital from roads, houses, etc. (9). Patient transfer is an important factor in the cycle of provision of health care services to patients (transfer from the accident scene, house, etc. to either a hospital or a healthcare center). Patient transfer system requires proper management and monitoring including ambulance, human resources and equipment (10). Given the importance of emergency center in delivering immediate and urgent care services to the patients and since time management is a key element in service delivery to these centers, proper response and efficient time management in emergency department are important factors in successful high-quality patient care in order to improve patient care and health care system (11). Nowadays, timely patient transfer to medical centers by ambulances is an important issue because well-equipped and prepared ambulances greatly save injured people and decrease mortality rates (12). Therefore, the present study assessed delay in response time interval to emergency missions and causes of delay in 115 prehospital emergency center in Khorramabad.

Methods

This was a descriptive, cross-sectional study in 115 emergency department with five centers in Khorramabad. One ambulance was

studied as a research environment in each center. All emergency missions in the first six months of 2016 (n = 5431) were selected as the statistical population in order to calculate mean response time interval to emergency mission in 115 emergency center in Khorramabad and causes of delay in missions (missions lasting longer than the standard time). Accordingly, response time interval and causes of delay were assessed. Standard response time interval was determined as eight minutes according to previous studies.

The collected data was encoded using SPSS. According to the research objectives, causes of delay in missions were extracted from the software. The collected data was analyzed at three time intervals, namely less than eight minutes, between 8 and 10 minutes, greater than eight minutes. Response time interval to emergency cases was calculated within the interval from the first call to the center for requesting an ambulance (as the starting point) to technician arrival at the accident scene (as the end). In this process, the mission time interval was originally recorded by ambulance technicians. Then, the data was delivered to the operator via a wireless device. The operator entered initial data in the software designed for 115 emergency center. The mission was recorded in this software. Causes of delay in mission was also identified by the individuals authorized for dispatching the ambulance since they are fully aware and infirmed of the missions. Causes of delay in mission were recorded per shift. These cases were assessed and confirmed by the quality control unit in the next day.

Findings

Of 5431 patients, 3042 (56%) were females and 2389 (44%) were males. Mean age of the patients was 39.5 + 13.5. In addition, 4063 missions (74.8%) were carried out in less than 8 minutes, 939 missions (17.3%) from 8 to 10 minutes and 429 (7.9%) in greater than 10 minutes (Table 1). The content of Table 2 show various causes for delay in response time interval to emergency cases. In this study, frequency of causes of delay in missions were calculated.

The most frequent causes of long response time interval was dispatch of ambulance from areas other than nearby centers due to inadequate number of ambulances and route traffic. The less frequent cause of long response time interval was delay in sending the code by the operator (refer to Table 2).

Table 1 – response time interval and frequency of missions in urban centers affiliated to 115 Emergency Center in Khorramabad

Response time interval	Less than 8 minutes	Between 8 and 10 minutes	Greater than 10 minutes
Frequency (percent)	4063 (74.8)	939 (17.3)	429 (7.9)
Total	5431 (100)		

Table 2 - causes of delay in response and frequency of delayed missions in the centers affiliated to emergency department in Khorramabad

Cause	The number of missions	Percent
Dispatch of ambulance from areas other than nearby centers due to inadequate number of ambulances	1585	29.2
Going to the wrong address	66	1.2
Delay in dispatch of an ambulance	11	0.2
Not dispatching the ambulance	5	0.1
Giving the wrong address by the caller	191	3.5
Unfavorable weather	314	5.8
Long distance	1194	22
Route traffic	1357	25
Unsuitable route (not well-asphalted and full of peddles)	56	1
Other causes	622	12
Total	5431	100

It should be noted that the exact time of the mission was not available to the author. Therefore, mission interval was reported in frequency and percent.

Discussion and Conclusion

Since pre-hospital emergency care department is tied with societal healthcare service delivery (this department is essential in provision of immediate care services to critical patients in any society), immediate,

efficient and effective care services save lives of many people and reduce both severity and length of illness and side effects of accident injuries. Therefore, time management is a gold standard in this department.

Given the importance of time management in pre-hospital emergency centers, a high percentage (25.2%) of missions were carried out in the interval greater than standard time interval (less than 8 minutes) although most of the missions were carried out within the standard time interval (in less than 8 minutes) in this study. These delayed missions were clinically significant. Jack Campbell (2007) also reported a mean response time interval greater than the standard time interval (9.8 minutes) (13).

Kleindorfer (2003) also reported that 93% to 97% of emergency missions were carried out within 10 minutes (14).

Jack Campbell and Timothy Gridley (2009) also reported that response time interval was 8.2 minutes in 1059 of total 1945 missions (15). However, the standard response time to emergency missions was 8 minutes. Since early hours and minutes of response to emergencies are called golden hours, any decrease in response time interval increases survival rate of the patients and consequently reduces mortality rate (16). Therefore, it is essential to address causes of delay in mission or increase in standard response time interval. The most important cause of delay in mission was dispatch of ambulance from regions other than nearby centers. This constituted a high percentage of causes of delay in missions.

Given that dispatch of the closest ambulance to emergency mission is one of the main strategies to improve emergency system (17), strategic distribution of ambulances and emergency service centers (based on the number of ambulance and received calls in a center) reduces the risk of dispatch of an ambulance from areas other than nearby centers, which ultimately reduces response time interval (18). Mohammad Rakei and Farouz Nader (2000) addressed that response time interval was greater than standard time due to inadequate number of ambulance and long distance between the accident scenes and emergency centers (19). Farzad Panahi also reported to Assembly Health Committee in 2008 that unsuitable geographic distribution of emergency centers is involved in response time interval to emergency cases. Accordingly, the emergency center can respond to an emergency case at the shortest possible time by increasing the number of emergency centers and ambulances in a center (20). Jarrell *et al.* (2007) also addressed the importance of ambulance distribution in emergency centers and reported that poor management in ambulance distribution leads to long response time interval to emergency cases (21).

Response time interval was greater than standard in densely populated areas due to crowded passages. This also increased the risk of dispatch of ambulance from centers other than

nearby places. Therefore, it is recommended that the number of emergency centers and the number of ambulances in these centers be increased to overcome crowdedness in densely populated areas.

Route traffic is the second cause of greater than standard response time interval. Population density has increased and the culture of calling EMS has been promoted in modern society. Unfortunately, the number accidents have also increased dramatically in modern society. However, traffic and relevant problems have decreased efficiency and speed of ambulances in response to emergency cases. Therefore, traffic has increased standard response time interval to emergency cases in modern societies (22).

Ayrik Cuneyt (2006) reported that traffic is a cause of delay in transferring cardiac patients to the hospital (23). Shabghare (2008) reported that 39.6% of emergency missions lasted greater than standard response time (greater than 8 minutes) due to traffic (24). A report in an emergency center in Tehran in 2008 showed that heavy traffic causes failure of the emergency center to meet citizen demands in a timely manner (25). Alavi (2008) also reported that traffic affects standard response time interval to emergency cases (26).

Long distance is the third cause of greater than standard response time interval to emergency cases. Patient transfer should be monitored by the emergency system and the patients should be transferred to the nearest suitable medical center (27). Each emergency system should locate those medical centers well-equipped with diagnostic devices and excellent care services (including critical care) in order to transfer the patient to the nearest suitable center as soon as possible. This highlights the importance of distance in reducing response time interval to emergency missions (28). Shabghare (2008) reported that 34% of missions lasted longer than standard response time interval (21). Rakei (2000) also reported long distance as the cause of greater than standard response time to emergency cases (19).

Lynn Eaton (2007) studied the effect of distance on response time to emergency cases and reported 94.2% survival rate in distances from 0 and 10 km, 92.3% survival rate in distances from 11 to 20 km and 91.2% survival rate in distances greater than 21 km. The greater the distance the lower the survival rate (28). Ayrik Cuneyt also reported that distance is an important factor in response time interval to emergency cases. He reported that distance was involved in delayed transfer of cardiac patients to the hospitals (23). On the other hand, several strategies can be suggested to decrease response time interval considering causes of delays in emergency missions and the contribution of each cause in increasing standard response time interval.

Inadequate number of ambulances, abnormal distribution of emergency centers in urban areas, poor need assessment for the number of ambulance based on population

density and public demand in every urban area, obsolete ambulances and equipment can be mentioned as the causes of delay in response due to dispatch of ambulance from areas other than nearby emergency centers and long distance.

Several strategies are proposed to resolve this issue.

a. Allocate adequate funds to Medical Emergency Department in the Ministry of Health for purchase of new ambulances and equipment.
b. Need assessment by experts to calculate the number of required ambulances in each center based on population density.
c. Division of densely populated and broad centers to several small centers
d. Standard emergency center distribution to reduce distance between neighboring centers and allocate more ambulances to densely populated areas and those areas with high requests for ambulance

Several strategies were also proposed to resolve traffic issue and timely response time interval to emergency cases.

a. Familiarity of emergency technicians with shortcuts, satellite GPS, radar, GIS, high-frequency waves and Trunking (automatic radio system) systems to find the best and most suitable route in emergency cases
b. Public training through mass media to cooperate with the emergency unit and ambulance.
c. Taking into account specific passages for ambulance in streets with heavy traffic.
d. Replacing ambulances with motor lances in old or crowded streets
e. Reforming old and destroyed routes with the help of civil engineers or reconstruction of old roads

Decrease in response time interval to 115 emergency missions require proper planning by policy makers in the Ministry of Health and Medical Emergency Department in Iran. Accordingly, more funds should be allocated to medical emergency department. Accurate need assessment should be performed for the number of required ambulances and emergency equipment and centers based on population density and public demand in every urban area.

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References

1. Blachwell T. Principle of emergency medical services system. In: Rosen's Emergency Medicine. 5 ed. Philadelphia: Mosby. 2002: PP: 2616-25.
2. Lilja GP. Emergency medical services. In: tintalli j. Kelen G: Stapezynski j. emergency medicine a comprehensive study guide. 5 ed. New York mcgraw-hill. 2004: PP: 1-5.
3. Farahmand F. *Physical Resource Management in Emergency Room base on Standard*, Abstract in Tehran Resource Management congress: 6,2002.
4. Abedi T. Vaezzade F, Baghbanian A, Bahreini F. *Managing Hospital. First Edition. Rasht:* 2003,218.
5. Zohoor A. Pilevarzade M. *Survey the Speed of Emergency Care in Bahonar Hospital in Kerman*. Esfahan University of Medical Sciences, 2000, 5(4):21-15.
6. EMS Medical Directors Association of California, EMS Response Intervals , position paper, 1998:54-57
7. Goldfrank L, Henneman PL., Ling LJ., Prescott JE., Rosen C., Sama A., Emergency center categorization standards Reeves MJ, Arnora S, et al Acute stroke care in us: results from. Acade Emerg Med 1999, 17(8): 638
8. Azmak, M. *Survey the Cause of Refferall Patients From Imam Khomeini and Zeinabie Hospital to higher level,* Thesis for BS in Health Care Management, School of Management in Shiraz

University of Medical Sciences 1385:55-59.

9. Etminani, R. Fathi H. *Standardize Emergency Medical System's Ambulances.* Abstract of Quality Improvement in Disaster Management, 2002:33.
10. Skinner, Ric. *Improving ambulance estimated time of arrival (ETA) at hospital emergency department*. Health GIS guy, 2008, 6:78-79.
11. Bidari A, Abbasi S, Farsi D, Saeedi H, Mofidi M, Radmehr M, et al: Performance assessment of prehospital emergncy at transported patients to the Rasoole Akram hospital. Medical Journal of Tabriz University of Medical Sciences, Volume 29, Number 3, 2008, p: 46-43.
12. Campbell Jack P, Kroshus Kathy S, Lindholm Daniel J, Watson William A. *Measuring the Call-Receipt-to- Defibrillation Interval: Evaluation of Prehospital Methods*. 2007, 8:5-8.
13. Kleindorfer D, Schneider A, Kissela BM, Woo D, Khoury J, Alwell K, Miller R, Gebel J, Szaflarski J, Pancioli A. *The effect of race and gender on patterns of rt-PA use within a population*. Journal of Stroke and Cerebrovascular Diseases. 2003; 12:217–20. , available at PUB MED
14. Campbell J, Gridley P., Timothy S., Robert L**.** *Measuring Response Intervals in a System With a 911 Primary and Emergency Medical Services Secondary Public Safety Answering Point*.2008; 18:15.
15. Nichol G, Detsky AS, Stiell IG, O'Rourke K, Wells G, Laupacis A. *Effectiveness of emergency medical services for victims of out-ofhospital cardiac arrest: a meta analysis.* Ann Emerg Med. 1996; 27(6): 700-10.
16. Dean SF, *Why the closest ambulance cannot be dispatched in an urban*

emergency medical services system. Prehosp Disaster Med. 2008; 23(2): 161-5.

17. Polland N, .Beck JK, Rhonda. J., Stephen R. *Intermediate health emergency care and transportation of the sick and injured*. MA 01776, 978-443- 5000. 2006: 4-5.
18. Rakei M. Nader F. *Mean Arrival Time for Patients with Head Injury in Mobasher Kashani Hospital in2001*. Journal of Shiraz University of Medical Sciences, 2002, 9 (2): 107.
19. Peyravi MR, Tubaei F, Pourmohammadi K. *The Efficiency of Motorlance in Comparison with Ambulance in Shiraz*, Southern Iran, Iranian Red Crescent Medical Journal IRCMJ 2009; 11(3):330-333
20. Jarrell B, Tadros A, Whiteman C, Crocco T, Davis SM. *National health line responses to a stroke scenario: implications for early intervention. Stroke.* 2007, 38: 2376–2378.
21. Esenberg MS, Bergner L, Hallstrom A, *cardiac resuscitation in the community importance of rapid provision and implication for program planning*. JAMA.1989; 241:1905-7.
22. Ayrik C, Ulku E , Ozan K , Cem N, Belgin N, Oklay E. *Factors influencing emergency department arrival time and In-hospital management of patients with acute myocardial infarction*. Advances in therapy J: 2006. 23:2.
23. Shabghare M, Dehghanian A. *Mean Time from Calling to EMS till Arrival at Hospital and its Causes*. PhD Thesis, Shiraz University of Medical Sciences. 1387:35-43

24. Dehghanpour R. *Factors in the emergence of infectious diseases*[cited 2008]; 1(1) . Available at: URL: http://www. *ems115.behdasht.gov.ir*

25. Alavi E. Pilevardy Z. Bahrami M. *Emergency Helices 'standards for patient*

Transmission in City. Journal of Tehran University of Medical Sciences.2009, 66(3):146-157.

26. Hamedi, M. Hamedi Seresht E, Khoramnia S. *Middle Emergency Pre Hospital Medical System*.2006, 20(15): 17-23.
27. Mrandi AR, Azizi F. *Health in Iran*. UNICEF, WHO and Beheshti University of Medical Sciences. Tehran. 2001
28. Eaton L**.** *Longer ambulance journeys raise mortality in patients with life threatening conditions,* 2007, available at PUB MED.

Auditing Professional Code of Ethics by Nurses who work at Psychiatric Wards in University Hospitals in Tehran in 2016

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Abstract

Background and Purpose: Ethics is a branch of the humanities whose object is to determine the value, in accordance with professional ethical standards in any group or profession. The ethical issues in psychiatric wards are higher due to care of patients with mental disorder. This study was designed to determine codes of professional ethics compliance in nurses with standards in psychiatric wards.

Methods: In this descriptive study (auditing), 100 electro convulsive therapies, 100 medication, and 100 cases of physical restraints was observed by sampling event in psychiatric wards of hospitals affiliation university of Tehran in 2016. Data were gathered through a researcher made checklist (codes of professional ethics compliance in psychiatric wards).Data analyzed using descriptive statistics and SPSS software version 19.

Results: Codes of professional ethics conformity rate with standards was 53.1% that evaluated the breakdown of compliance with codes of professional ethics in treatment by electro convulsive therapy 51.6%, in medication 49.3% and physical restraint 49.8%.
Conclusion: Codes of professional ethics conformity rate is far from the standards in psychiatric wards, and in order to improve it, recommended to apply the guideline codes of professional ethics and supervision by managers on its implementation.

Keywords: Professional ethics, nurse, auditing, psychiatric ward

Introduction

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In today's world, ethics is again located in the spotlight of health-related professions (1). Ethics is a branch of the humanities that its object is to determine values (Right or wrong) in accordance with ethical standards in each group or profession (2). Although having the appropriate level of ethical development is important for all people, this issue is particularly important for health care personnel, including nurses (3) because they are the largest group that providing the services in the health care system (4), have a significant impact on the quality of health care (4,5) And certainly we can be said that the nursing profession is based on ethics principles (6).

Townsend explains: Ethical problems in psychiatry ward and psychiatric nurses is more due to care of patients with mental disorders (7). Studies indicate that two-thirds of psychiatric nurses experience a variety of ethical issues in Canada(8).At the moment, about 30 percent of the world population has been affected by a mental disorder that more than two-thirds of them did not get the care they need(9). Taking care of patients with mental disorders is very specialized and also requires obligation. Ethical complexity in the care of these patients have several reasons that the most important of them is that patient affected by experience and self-imagination and Suffering from psychiatric hospitalization due to stigmatization and loss of social rights (11). Psychiatric nurses daily encounter with various ethical issues and it is important to be able to evaluate fields and conditions that creating the unethical behavior (9). The codes of ethics help the psychiatric nurses to provide daily care to patients with considering the boundary between the independence and treat (12). Codes of professional ethics are the set of principles and standards that determine the behavior of individuals and groups and should be explained in any professional working during a rational process to provide a common understanding of the values that should be preserved and promoted in each organization (13).

Studies show different results in the field of regarding the professional ethics in psychiatric wards. The study of Rezai stated that some of the principles and terms of clinical care is not accurate in patients with psychiatric disorders and these principles are not covered enough by usual ethical considerations (14). In a research conducted in India, 67.8% of psychiatric nurses that have enough information in the field of professional ethics, , and 66.7% of them that have degree in ethics from well-known college, faced with various ethical issues(15). Psychiatric nurses have many influence in using the ethics and laws during admission, discharge, appointments, providing the emotional and cognitive needs, and explain the problems to the patient, protecting the confidential information of patient and informed consent (16). In a study that was conducted in Jaipur of India, Only 10 percent of psychiatric nurses had enough knowledge in relation to ethical issues in the fields of psychiatry (15). Performing the professional ethics in relation with patients with mental disorders has been a social problem of the human society for a long time (14) that control and evaluation of this matter is the main tasks of managers so that the follow up of the evaluations will improve the quality of health care (17). Auditing is one of the best way to evaluate Codes of Professional Ethics in psychiatric wards.

Auditing is one of the important components of clinical governance program (18) and is a method of

improving the evaluation of patient care quality (19). Auditing of patient care is a type of control that demonstrate current situation of the patient care that we can recognize the problems and dilemmas and implement the necessary planning in order to resolve it (20). Therefore the present research has been designed to determine codes of professional ethics compliance in nurses with standards in psychiatric wards.

Method

This descriptive study, is an auditing research that was conducted in the psychiatric wards of hospitals affiliation university Tehran (Razi, Iran, Imam Hossein, Taleghani, Ruzbeh and Rasul akram hospitals) in 2016. All nursing care related to electro convulsive therapy, medication and physical restraint in the psychiatric hospitals organize the samples. By taking into account the p=0.5, α=0.05 , d=0.1 and using the formula $n = \frac{Z^2_{1-\alpha/2} \times P(1-P)}{d^2}$, the required sample size calculated 100 cases. Sampling was performed from April to September 2016 by event sampling method with an observer (researcher), and by referring to the psychiatric wards in mentioned hospitals in three shifts, morning, evening and night. During sampling of the event, which dependents on the knowledge of observer about the special situation of the event, the observations happen in certain situation, thus observer should be present in that situation to record her observations(21).By considering that the number of referrals to psychiatric hospitals were different and by considering the number of active beds in each of these hospitals, observation were allocated to 38 events in Razi Hospital, 26 events in Ruzbeh Hospital, 18 events in Iran hospital, 8 events in Imam Hossein Hospital, 5 events in taleqani hospital and 5 events in Rasul hospital. Observations continued from the beginning steps of all three dimension (electro convulsive therapy, medication and physical restraint) to the end of work and documenting.

Collection data tool was the researcher made checklist that was designed by using the valid Persian and English articles and protocols and guidelines as well as nursing and psychiatry reference books published between 2006 and 2016. Demographic information such as number of patients, type of ward, and the number of personnel, work shift and gender is also studied. Checklist includes 45 phrases in three parts. The first part contains 17 phrases on professional ethics in the electro convulsive therapy. The second part consists of 13 phrases about professional ethics in medication and the third part contains 15 phrases about professional ethics in the Physical restraint. Each part evaluated the five ethical axis that include; respect, education, conscientiousness, commitment to justice and improve the quality of patient care. Scoring methods consist of two parts: 1. Yes, which consists of two parts: (A) Done right "(this part was scored when the care was done completely correct). (B) Do not right (this part was scored when the care was not done completely correct). 2. No, this part was scored when the care was not performed. The scoring is as follows: Not done (score 0), do not correctly (due to the low number: score 0) done right (score 1). Score range of checklist was determined from 0 to 100. To check the validity of the checklist, we used the content and nominal validity index. For this purpose, the phrases of the checklist were studied by 10 specialists, nurses and nurse faculty members to control relevance, clarity and simplicity content

of the questions. To evaluate the reliability of the tools, we used Inter-rated coefficient method and ICC = 0.87 was obtained.

To perform this research, the ethics approval was taken from International Branch of Beheshti University of Medical Sciences with ethical code of IR.SBMU.RAM.REC.1395.63 and a referral was received from the Beheshti University of Medical Science and also the required coordination with the Training Unit of the university and head nurses of the psychiatric wards in mentioned hospitals was performed. Authorities were assured about confidentiality of information and trusteeship about using of the references. In order to analyze the data, we used the descriptive statistics of central indexes and distribution of SPSS v.19 software.

Results

In this research 100 events were observed in each dimension of study that half of the nurses were female and the remain of them were men. Codes of professional ethics conformity rate in men's ward, 5.56% and in women's ward 60.8% was desirable. Since this study has been provided on all shifts, the findings will be reported as follows; the codes of ethics conformity rate is 50% desirable in the morning shift, 30.3% in the afternoon shift and 6.4% in the night shift. In this research, findings showed that conformity rate in codes of professional ethics in psychiatric wards compared with the ethical standards is as follows;51.6% in electro convulsive therapy, 49.3% in medication and 49.8% in physical restraint that in all dimensions of the evaluation was just average. The highest conformity level is recorded for the registration and documentation of events in all three dimensions of research that was evaluated desirably. The lowest conformity level have been reported as follows: In electro convulsive therapy related to the statement (it explains to the patient about possible occurrence of side effects) that was not observed in 75% of cases, In the medication related to the statements(it explains to the patient about potential drug side effects with simple words) that was not observed in 81% of cases, and in physical restraint related to the statements (it refuses the intimidating and threating the patient during physical containment) that was not observed in 73% of cases.

In this research, any dimension is studied based on five ethical axis, the first axis is to respect for the patient, the second axis is to improve the quality of patient care, the third axis is patient education, the fourth axis is the responsibility, and fifth axis is justice. The findings based on mentioned five axis shows that the most conformity rate was in the fourth axis (responsibility) that reported desirable and the lowest of that, was in the third axis (training the patient) that reported poorly. Results of all axis conformity are available in table one.

Generally, based on the table 2 , it can be said that in all three dimensions , electro convulsive therapy, medication, and physical restraint, the codes of professional ethics conformity rate with standards was 53.1% that reported as an average of score

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Table 1: frequently distribution of the implementation of standards of regarding for the professional ethics codes in psychiatric wards, based on five axis professional ethics codes in psychiatric hospitals of Affiliation University of medical sciences and health services of Tehran in 2016

Axes	Dimensions of research	Done right Number(percentage)	Do not right Number(percentage)	Not done Number(percentage)	condition
First axis (respect to patient)	First dimension	256 (42.67)	28 (4.67)	316 (52.67)	Average
	Second dimension	143 (47.67)	2 (0.67)	155 (51.67)	Average
	Third dimension	149 (37.25)	2 (0.5)	249 (62.25)	Average
	total	548 (42.15)	32 (2.46)	720 (55.38)	Average
Second axis (Improving the quality of patient care)	First dimension	199 (66.33)	6 (2)	95 (31.67)	Fine
	Second dimension	107 (53.50)	1 (0.50)	92 (46)	Average
	Third dimension	346 (69.20)	0 (0)	154 (30.80)	Fine
	total	652 (65.20)	7 (0.7)	341 (34.10)	Average
Third axis (patient education)	First dimension	134 (33.50)	9 (2.25)	257 (64.25)	Average
	Second dimension	63 (21.00)	0 (0)	237 (79.00)	Weak
	Third dimension	29 (29.00)	3 (3.00)	68 (68.20)	Weak
	total	226 (28.25)	12 (1.50)	562 (70.25)	Weak
Fourth axis (responsibility)	First dimension	153 (79.50)	3 (1.50)	44 (23.00)	Fine
	Second dimension	218 (72.67)	4 (1.33)	78 (26.00)	Fine
	Third dimension	230 (76.67)	2 (0.67)	68 (22.67)	Fine
	total	601 (75.13)	9 (1.12)	190 (23.75)	Fine
Fifth axis (Justice)	First dimension	135 (67.50)	6 (3.00)	59 (29.50)	Fine
	Second dimension	122 (61.00)	3 (1.50)	75 (37.50)	Average
	Third dimension	107 (53.50)	0 (0)	93 (46.50)	Average
	total	364 (60.67)	9 (1.50)	227 (37.83)	Fine

Table 2: code of professional ethics conformity rate with standards in the psychiatric hospitals of university of medical sciences and health services of Tehran in 2016

	Compliance(y/x)	Current situation(y)	Setting the standard(x)	Not done	Done
Codes of professional ethics compliance	53.13	2391	4500	2109	2391

Discussion and conclusion

In the present research, the conformity of professional ethics were evaluated as average (score 53.1). In recent years, numerous studies have been performed in this field. Among these present studies the result of Kumar et al. (2011) and Ghobadi Far and Mosalanejad (2013) were agree with this study.

In a study that performed by Kumar et al in 2011, that was evaluated to assess the knowledge of nurses about ethical and legal responsibilities in the field of Psychiatric (15), 90% of nurses had average knowledge that is agree with the evaluations of the present study. In the study of Ghobadi Far and Mosalanejad in 2013, that provided in order to determine the conformity of professional ethics codes in the medical staff of Jaron University of Medical Sciences, the professional ethics codes were estimated average (22). This study is also agree with current research.

Since the purpose of this study is to determine the conformity of professional ethics codes with standards in psychiatric wards, the results were compared to similar studies which investigated the conformity of the professional ethics codes from view of patients and staff. It is not agree with the results of Liang Su et al. (2012), Maarefi et al. (2014), Dehghani and Mohammad Khan Kermanshahi (2012), Tefagh et al. (2004). It seems that the reasons of the inconsistency is difference in research method. In this research, conformity of standards were observed directly that could be more objective and provide more credible data, while other studies were investigated view of participants.

Study of Su Liang et al in 2012, which have been provided to evaluate the attitude of the personnel about ethics and rights of patients in psychiatric hospitals in China's Shanghai, revealed that 87% of personnel feel the need of Ethics Committee. Only 11% of personnel were familiar with ethical codes (23).In the Maarefi et al 2014 study, which have been examined to determine conformity with codes of professional ethics of nursing, in the field of clinical service from view of patients, the average conformity with codes of ethical was reported 68.20% that is at a good level. In this study, it was not observed significant relation between demographic data of patients and their performance of professional ethics codes of nurses (13).

The results of study of Dehghani and Mohammad Khan Kermanshahi (2012),

which have been provided to determine the observance of professional ethics codes in the performance of nursing in their view in Tehran University of Medical Sciences, Revealed that the majority of nurses (72.5%) have conformity performance with Code of Ethics (24).

In relation to the observance of professional ethics in the execution of medication orders by nurses, Tefagh et al have provided a study in 2004 that showed that highest percentage of nurses (49.6%) had poor performance in medication (25).

In the part of medication in this study , the observance of codes of professional ethics reported average that is agree with the study of Tefagh et al.

Probably, the reason of the result difference of this research with other research could be due to the difference in the research environment. Previous research was provided in all wards of the hospital while present study was provided specifically in psychiatric wards. In addition,the time of research could explain the difference in results, partly because, over the time, awareness of ethical issues of both medical staff and patients has risen and also approaches associated with the implementation of ethical codes (such as clinical governance and accreditation) have been implemented in the health care system. Results of some research suggest that despite the fact that health managers have an increasing emphasis on the importance of the codes of professional ethics, yet the conformity with the professional ethics codes is not an ideal. It seems that the cause of this problem have more important aspects of care and treatment of professional ethics codes like lack of control system for perspective of the health care personnel performance, heavy workload, low number of personnel and the high number of patients (26).

Moreover, the studies showed that receive appropriate health care services and providing health services based on respect for patient privacy and the principle of the confidentiality are the most important, and after that, achieving an efficient system of complaints Providing appropriate and adequate information for the patients, respect for patients' rights in deciding freely to receive the health services are important in health care recipients. (27).

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References

1. Hekmat afshar M, Juybari L, Sanagoo A, Kalantari. (2012).Investigate the factors affecting nurses' ethical distress: A review of previous studies. Journal of Ethics in Education, vol. 1 (1)22-28

2. Zirak M, Moghadasian S, Abdollah Zadeh F, Rahmani A. (2012). Ethical development of nurses working in teaching hospitals of Tabriz University of Medical Sciences. Journal of Qom

University of Medical Sciences, Vol (3) 32-39

3. Ghurchiani F, Barati M A, Abolghasem G H, Khatami F A M, Haghani H, Goldust M F.(2013). Compliance with nursing code of ethics for nurses and patients in one of teaching hospital in Tehran University of Medical Sciences, (2013) Journal of Medical Ethics, vol.2(3) 63-79

4. Dehghani A, Shamsi zadeh M. (2013). Effective strategies to improve the professional ethics: provide the best practical strategy. Journal of Nursing Education and Ethics, vol.2 (4) 13-19

5. Dehghani A, Eslami A R, Parvinian Nasab A M, Shamsi Zadeh M, Shamsi A.(2014). Determining factors management related professional ethics in nursing practice. Journal of Nursing Education and Ethics, vol.2 (3) 53-60

6.Varasteh Moghadam Y, Sadegh Fard M, Mohammadi S H, Ahanjan P. (2013). Stressors and compatibility modes in psychiatric nurses.Journal of Psychiatric Nursing, vol 3(3) 64-61

7. Maarefi F, Ashktorab T, Abas Zadeh A, Alavi M M, Eslami A R. (2014). Evaluation ethical codes of nursing professional compliance in the field of providing clinical services in the view of patients. Journal of Nursing Education and Ethics, vol.3 (1) 27-33

8. Rezayee H. (2009). Evaluation factors related to the ethics of nursing based on theory of rational behavior in nurses in psychiatric university hospitals in Tehran. The thesis for a master's degree in nursing, School of Nursing and Midwifery shahid Beheshti University of Medical Sciences and Health Services.

9. Khadem H M, Khoshnevis M A, Mokhtari N J, Alaf J M. (2006). Nursing performance evaluation. Journal of Nursing and Midwifery shahid Beheshti, vol 15(48) 1-24

10. Hoseini M. (2012). Principles of nursing management. Boshra, (p 351)

11. Ghobadi Far M A, Mossala Nejad L. (2014). Codes of professional ethics Compliance in medical staff of Jahrom University of Medical Sciences. Journal of Ethics in Education, vol 6 (3) (1-2)

12. Dehghani A, Kermanshahi S. (2013). Compliance with standards of professional ethics in nursing practice from the viewpoint of nursing staff Tehran University of Medical Sciences. Journal of Nursing and Midwifery of Birjand University of Medical Sciences.vol (3) 208-216

13. Tefagh M R, Nikbakht N A, Abbas M, Dinmohammadi M. (2005). Evaluation of professional ethics in the execution of medication orders by nurses. Journal of Life, vol 23(77-85)

14. Ghamari Z, Alizadeh B, Sadegh A H S, Esmaeli M, Romoozi M. (2014). Investigate the barriers professional ethics in the performance of nurses from the viewpoint of nursing managers in Qom in 2013. Journal of Nursing Education and Ethics, vol 1 (3) 57-63

15. Nasiryani Kh, Farnia F.(2007). Evaluation of patient rights of nurses in the hospital in Yazd. Journal of Forensic Medicine. Vol 13(1) 33-37

16. Shives L R (2012) Basic Concepts of Psychiatric Mental Health Nursing, 8th edition, Philadelphia. Lippincott Williams and Wilkins Co.

17. Townsend M C (2014), Essentials of Psychiatric Mental Health Nursing, 5th edition, Philadelphia. F.A Devis CO.

18. Eren N (2014), Nurses' attitudes toward ethical issues in psychiatric inpatient settings, Nursing Ethics, Vol. 21(3) 359–373

19. Yambo, T., Hamilton, R. and Johnson, M. (2014). Ethical Considerations in the Recruitment of Military Partners in Combat-Related Posttraumatic Stress Disorder Research. Nursing Forum 25, 355-365

20. Parihar A, Vyas H and Sharma NK (2013) Knowledge of the nursing personnel regarding ECT in a view to develop an informational booklet, IOSR Journal of Nursing and Health Science, vol2(6) 45-49.

21. Schadle-deininger, H. (2014). Subjective Glance in Ethics and Attitude in psychiatric Nursing. Psychiatrische Praxis, 20, 110-118.

22. Kumar R. Mehta S and Kalra R (2011). Knowledge of staff nurses regarding legal and ethical responsibilities in the field of psychiatric nursing. Nursing and Midwifery Research Journal, Vol.7 (1) 1-11.

23. Kontii, R., Pitkanen, A., Joffe, G., Katajisto, J and Valimaki, M. (2014). E-Learning Course May Shorten the Duration of Mechanical Restraint among Psychiatric Inpatients: A Cluster-Randomized Trial. Nordic Journal of Psychiatry, 68, 443-9.

24. Jairus R, Walia I (2011), Nursing adult, Nursing journal of India, 102(7): 157-160

25. Lancaster M (2013), Nursing issues in leading and managing changes, London, Mosby co.

26. Poilit D F.Beck C T (2013). Study Guide for Essentials of Nursing Research: Appraising Evidence for Nursing Practice. 7th edition. Philadelphia. Lippincott Williams and Wilkins Co.

27. Liang SU, Jingjing Huang, Weimin Yang, Huafang Li, Yifeng Shen and Yifeng Xu (2012), Ethics,patient rights and staff attitudes in Shanghai's psychiatric hospitals, BMC Medical Ethics 1-7

Evaluation of DNA Damage in Blood Lymphocytes of Iranian Silica Miners using Comet Assay

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Abstract
Background and objectives: Occupational exposure to silica dust in the silica mines is several times more than other mines. Silica dust can cause different complications in body tissues. One of damages caused by exposure to silica is the effects of oxidation that can lead to DNA fragmentation. The aim of this study was to assess the extent of damage DNA in blood lymphocytes of Iranian silica miners using Comet assay.
Material and methods: 70 Iranian silica miners with at least five years history of exposure to silica and 48 healthy administrative staff with non-exposure to silica and other chemicals were randomly selected. The DNA damage levels were determined using the Comet assay under fluorescence microscope and Comet score software. The obtained results were analyzed using SPSS version 19, t-test and Pearson's correlation coefficient.
Results: The age of subjects exposed to silica and control were respectively 44.5±7.6 and 41.3±10.3 years and Work experience of exposed and control was 22.5±7.6 and 18.2±10.3 and there were no significant differences in parameters including age, height, weight, work experience, BMI and blood pressure between two groups. The tail length (µm) was 3.2±0.98 and 11.52±5.2 in the exposed and control groups, respectively. The tail DNA% was 1.8±0.52 and 4.2±1.92 in the exposed and control groups, respectively. The tail moment (µm) was 0.81±0.21 and 1.9± 0.9 in the exposed and control groups, respectively. The DNA damage was significantly different for all three parameters between the two groups ($p<0.001$). In addition, there was a significant linear relationship between the level of DNA damage and work experience in the exposed group ($p<0.001$).
Conclusion: The silica dust can increase DNA damage in blood lymphocytes of exposed workers and this fragmentation enhances by prolonging exposure.

Key words: DNA damage, lymphocyte, comet assay, silica mine worker

Introduction

Different chemical, physical and biological factors are of genotoxic agents in the living environment and the workplace that induce various DNA damage such as single-stranded and double-stranded DNA fragmentation, mutagenesis and chromosome fragmentation; if the cells are not able to repair these damages, they will lead to varied mutations in the genes that cause various diseases including cancer (1-5). The silica dust is considered as a possible factor in developing genetic effects in humans that can be seen in many professions such as mining, construction industries and foundry as well as industrial ceramic, tile and cement (6).The silica effects on DNA have been investigated in many studies. For example, a research on foundry and pottery workers revealed that the level of DNA damage in these workers was higher than the control group. The study also found that smoking could trigger DNA damage(7) . The silica dust particles can cause lipid peroxidation and DNA fragmentation during oxidative process(8). Shi et al. indicated the silica damages on DNA and lipid peroxidation caused by the release of radicals that could lead to the appearance of fibrosis and cancer(9). In a study conducted by Carl Fanizza et al. in Canada, human lung cells were exposed to different concentrations of 25, 50 and 100 µg silica per ml. They found a significant relationship between the level of oxidation by silica and the rate of DNA fragmentation in all concentrations within 2 and 4 hours(10).

In a study on the construction workers exposed to the silica in India, there was a significant difference for DNA fragmentation between the exposed and control groups .The amount of DNA fragmentation was higher in smokers of case group compared to control smokers (11) . In another study on micronucleus in the nasal cells and lymphocytes of workers exposed to silica, the micronucleus created in nasal cells was three times higher, and in lymphocytes was two times more than the control group (12). Another investigative on coal workers showed a significant increase in DNA fragmentation in the case group(13).

The Comet assay, among various methods to determine the levels of DNA damage, is a rapid, sensitive and suitable technique, which provides the possibility of direct observation of DNA damage in individual cells. The Comet assay is a very sensitive test to identify the types of damage to DNA. This method is able to direct assessment of DNA single-strand and double-strand breaks in individual cells. In several *in vivo* and *in vitro* studies, the Comet assay has been used to investigate genotoxic effects of compounds and protective impacts of natural compounds on DNA(1-4) . This method can assess the effects of environmental genotoxic substances,

the rate of repair and the repair kinetics of DNA damaged by several agents. One of the applications for this approach is to evaluate DNA damages in subjects exposed to genotoxic agents due to occupational or environmental conditions. The aim of this study was to determine the level of damage DNA caused by silica among Iranian silica miners

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Material and methods

In the present study, 70 Iranian silica miners with at least five years history of exposure to silica and 48 healthy administrative staff with non-exposure to silica and other chemicals were randomly selected. They completed a questionnaire on demographic information and also the form of inclusion criteria, including questions such as the lack of infection, no history of exposure to chemicals or recent exposure to matters and radioactive devices. Then morning and fasting blood samples were obtained from subjects having inclusion criteria and willing to participate in this research. Individual degrees of exposure to the total and respirable silica dust in exposed workers were determined using NIOSH 7601 standard method(14).

To estimate the genotoxicity of silica dust, we used alkaline comet assay. The protocol was carried out according to Singh et al(15) The collected blood lymphocytes were separated using ficoll (Sigma Co. by centrifugation at 3300 rpm for 15 minutes. The separated lymphocytes were washed with PBS at 4°C and were precipitated by centrifugation at 1400 rpm for 15 min at 4°C. After collecting the blood samples and isolating the lymphocytes, the cell viability was determined using the Trypan Blue dye exclusion method (16) .The sample with cell viability higher 97% was observed. The cells placed on slides and a layer of common gel after dissolving the cells in PBS and mixing with agarose gel with low melting point. Finally, they were covered by a layer of agarose gel with low melting point and were placed at 4°C for 1 hour in lysis solution for elimination of the membrane and proteins. The electrophoresis solution was used to break the hydrogen bonds between the two strands for 20 min at 4°C, and then electrophoresis was performed for 20 minutes at a voltage of 0.65 V/cm length of the tank. The samples were transferred to a neutral buffer solution for 10 minutes, fixed by methanol, and stained with ethidium bromide at a concentration of 20µg/ml for 10 minutes; and after washing with water and putting cover slip, images were taken from the samples using a fluorescence microscope model Nikon 50i, Japan. Two slides were prepared for each sample; and altogether, 100 cells were examined, and the DNA damage levels were determined using the Comet score version 1.5 software.

Results

The age was 44.5±7.6 and 41.3±10.3 years as well as the mean work experience were 13.7±4.2 and 15.2±3.4 years in subjects exposed to silica and control, respectively. There were no significant differences in parameters including age, height, weight, diet, work experience, BMI and smoking in the exposed and control groups. Table 1 shows the demographic characteristics related to silica exposure and control groups.

Table 1 - Demographic characteristics of miners and administrative staff of silica mines

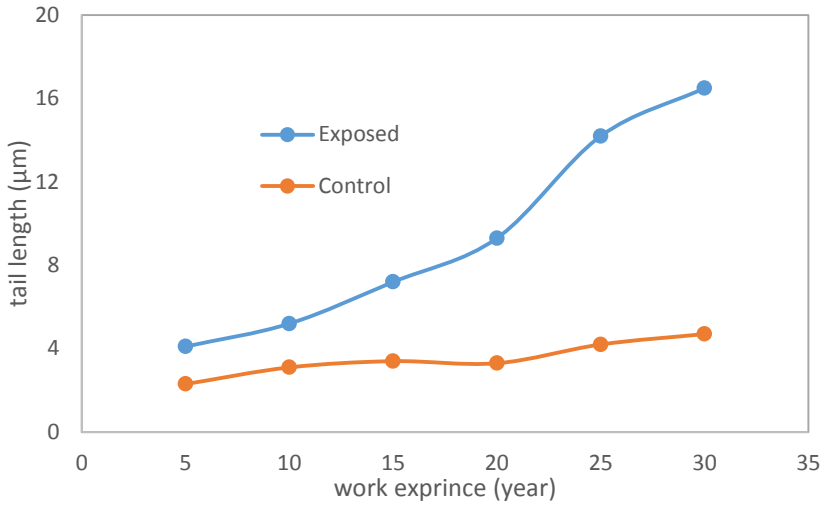
Demographic characteristics	Exposed group	Control group	p-value
Age (y)	44.5±7.6	41.3±10.3	0.088
Height (m)	1.67±0.72	1.67±0.67	0.555
Weight (kg)	74.6±3.03	76.5±3.9	0.708
Work experience (y)	22.5±7.6	18.2±10.3	0.099
BMI (kg/m^2)	26.6±2.8	27.4±2.5	0.457

Table 2 - Total and respirable dust and content of silica in dust in silica mines of Iran (mg/m^3)

	Number of sample	**Min**	**Max**	Mean ± SD
Total dust	**33**	**2.8**	**20.2**	**11.7±5.5**
Respirable dust	**33**	**1.2**	**8.9**	**4.9±2.7**
Silica content of total dust	**33**	**0.34**	**2.98**	**1.74±0.76**
Silica content of respirable dust	**33**	**0.2**	**2.09**	**1.17±0.57**

Table 3- Parameters of DNA damage in blood lymphocytes of miners and administrative staff of silica mines

Parameters of DNA damage	Tail length (µm)	Tail DNA (%)	Tail moment (µm)
Control group	0.98±3.2	0.52±1.8	0.81± 0.21
Exposed group	11.52 ± 5.2	1.92±4.2	1.9± 0.9
p-value	<0.001	<0.001	<0.001



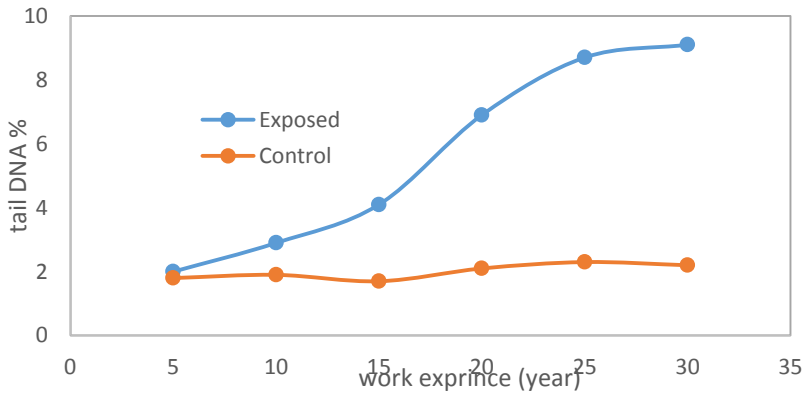


Figure 1- Relationship between the level of DNA damage and duration of exposure to silica dust in the silica mine workers

Discussion

The silica dust is one of the pollutants existing in many workplaces, especially in the mines. Most of the studies on workers exposed to silica have emphasized on the assessment of its effects on the respiratory system (17-20). Some studies have also been done on the effects of silica dust on the DNA (4, 21, 22). The results of this study indicated that the silica dust could lead to DNA fragmentation in lymphocytes of workers exposed to silica, which the level of damage elevated with prolonged exposure. In this study, the Comet assay was used to determine the level of DNA damage in the workers exposed to silica that among the methods to determine the levels of DNA damage is a rapid, easy sensitive and low-cost technique to measure DNA fragmentation in individual cells. Some in vitro investigations have examined the DNA damage caused by silica. For example, a study that was conducted on epithelial cells of mice exposed to silica showed that DNA fragmentation was observed along with the increase of OH group in these cells(23) .In a study carried out on human lung cells within 2 and 4 hours, DNA fragmentation was seen in these cells and there was a significant relationship between oxidation and DNA fragmentation in these cells(10) .These *in vitro* studies can be a good indicator to determine the oxidation effect of silicon and developing DNA fragmentation. Although the study design varies with the present study, but its results are consistent with the findings of the present study and confirm the results of our study.

The in vivo study by evaluating the effects of silica dust in small casting industries on DNA fragmentation revealed that DNA fragmentation in exposed cases was significantly different from the control group and the results of discussed study are in line with the present study (7). In addition, in a study on the workers of asbestos and cement industry, indexes of DNA fragmentation showed significant differences between case and control groups, consistent with the present study(24) .

In another research on coal miners, DNA fragmentation in the exposed group showed significant difference with the control group that is consistent with the current study, however, the difference is that the workers in our study were exposed to almost pure silica(13) . In another study on the construction workers in India, the silica dust in the workers was higher than exposure limit and DNA fragmentation in the workers showed significant differences with the control group. The results of this study are consistent with this study(11) . Considering that the present study has been conducted in the silica mines of Iran and

confounding effects of other minerals in the development of DNA fragmentation in this study was lower than in the similar studies, so it can be said that the silica could have major contribution in influencing in the studied worker's breath air that was over 98 percent. While in similar studies mentioned, because minerals other than silica also exist in the air, so these substances can contribute to the DNA fragmentation.

Conclusion

The results of present study showed that the silica dust available in silica mines of Iran can increase DNA fragmentation in blood lymphocytes of exposed workers and this fragmentation enhance by prolonging exposure. Considering the fact that many workers (in mines and in industries that consume processed silica) are exposed to silica dust, it seems necessary to use methods of dust control.

References

1. Møller P. Assessment of reference values for DNA damage detected by the comet assay in human blood cell DNA. Mutation Research/Reviews in Mutation Research. 2006;612(2):84-104.
2. Faust F, Kassie F, Knasmüller S, Boedecker RH, Mann M, Mersch-Sundermann V. The use of the alkaline comet assay with lymphocytes in human biomonitoring studies. Mutation Research/Reviews in Mutation Research. 2004;566(3):209-29.
3. Menke M, Chen I-P, Angelis KJ, Schubert I. DNA damage and repair in Arabidopsis thaliana as measured by the comet assay after treatment with different classes of genotoxins. Mutation Research/Genetic Toxicology and Environmental Mutagenesis. 2001;493(1):87-93.
4. Poli P, de Mello M, Buschini A, de Castro V, Restivo F, Rossi C, et al. Evaluation of the genotoxicity induced by the fungicide fenarimol in mammalian and plant cells by use of the single-cell gel electrophoresis assay. Mutation Research/Genetic Toxicology and Environmental Mutagenesis. 2003;540(1):57-66.
5. Gichner T, Patková Z, Száková J, Demnerová K. Cadmium induces DNA damage in tobacco roots, but no DNA damage, somatic mutations or homologous recombination in tobacco leaves. Mutation Research/Genetic Toxicology and Environmental Mutagenesis. 2004;559(1):49-57.
6. Yamano Y, Kagawa J, Hanaoka T, Takahashi T, Kasai H, Tsugane S, et al. Oxidative DNA damage induced by silica in vivo. Environmental research. 1995;69(2):102-7.
7. Başaran N, Shubair M, Ündeğer Ü, Kars A. Monitoring of DNA damage in foundry and pottery workers exposed to silica by the alkaline comet assay. American journal of industrial medicine. 2003;43(6):602-10.
8. Kamal A-AM, Gomaa A, El Khafif M, Hammad AS. Plasma lipid peroxides among workers exposed to silica or asbestos dusts. Environmental Research. 1989;49(2):173-80.
9. Shi X, Mao Y, Daniel LN, Saffiotti U, Dalal NS, Vallyathan V. Silica radical-

induced DNA damage and lipid peroxidation. Environmental health perspectives. 1994;102(Suppl 10):149.
10. Fanizza C, Ursini CL, Paba E, Ciervo A, Di Francesco A, Maiello R, et al. Cytotoxicity and DNA-damage in human lung epithelial cells exposed to respirable α-quartz. Toxicology in vitro. 2007;21(4):586-94.
11. Sellappa S, Prathyumnan S, Balachandar V. DNA damage induction and repair inhibition among building construction workers in South India. Asian Pac J Cancer Prev. 2010;11:875-80.
12. Demircigil GC, Coskun E, Vidinli N, Erbay Y, Yilmaz M, Cimrin A, et al. Increased micronucleus frequencies in surrogate and target cells from workers exposed to crystalline silica-containing dust. Mutagenesis. 2010;25(2):163-9.
13. Atabay MM. The Cytotoxic and Haematological Effect of Coal Dust to Underground Miners. American Journal of Biochemistry. 2011;1(1):4-8.
14. Eller PM. NIOSH manual of analytical methods: Diane Publishing; 1994.
15. Tice R, Andrews P, Hirai O, Singh NP. The single cell gel (SCG) assay: an electrophoretic technique for the detection of DNA damage in individual cells. Biological Reactive Intermediates IV: Springer; 1991. p. 157-64.
16. Tice R, Agurell E, Anderson D, Burlinson B, Hartmann A, Kobayashi H, et al. Single cell gel/comet assay: guidelines for in vitro and in vivo genetic toxicology testing. Environmental and molecular mutagenesis. 2000;35(3):206-21.
17. Gholami A, Fani MJ, Sadeghi N. Occupational exposure determination of silica dust in an iron-stone ore and comparison with standard. International Journal of collaborative Research on Medicine and Public Health. 2012;4(6):1141-9.
18. Kakooei H, Gholami A, Ghasemkhani M, Hosseini M, Panahi D, Pouryaghoub G. Dust exposure and respiratory health effects in cement production. Acta Medica Iranica. 2012;50(2):122.
19. Lumens ME, Spee T. Determinants of exposure to respirable quartz dust in the construction industry. Annals of Occupational Hygiene. 2001;45(7):585-95.
20. Elci OC, Akpinar-Elci M, Blair A, Dosemeci M. Occupational dust exposure and the risk of laryngeal cancer in Turkey. Scandinavian journal of work, environment & health. 2002:278-84.
21. Lin W, Huang Y-w, Zhou X-D, Ma Y. In vitro toxicity of silica nanoparticles in human lung cancer cells. Toxicology and applied pharmacology. 2006;217(3):252-9.
22. Schins RP, Knaapen AM, Cakmak GD, Shi T, Weishaupt C, Borm PJ. Oxidant-induced DNA damage by quartz in alveolar epithelial cells. Mutation Research/Genetic Toxicology and Environmental Mutagenesis. 2002;517(1):77-86.
23. Knaapen AM, Albrecht C, Becker A, Höhr D, Winzer A, Haenen GR, et al. DNA damage in lung epithelial cells isolated from rats exposed to quartz: role of surface reactivity and neutrophilic inflammation. Carcinogenesis. 2002;23(7):1111-20.
24. Afaghi A, Oryan S, Rahzani K, Abdollahi M. Study on genotoxicity, oxidative stress biomarkers and clinical symptoms in workers of an asbestos-cement factory. EXCLI journal. 2015;14:1067.

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Effectiveness of Mindfulness-based Cognitive Therapy and Conscious Group Yoga on Depression, Anxiety, and Stress of female caregivers of elderlies with Alzheimer

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Abstract

Background: continuous caregiving for patients with Alzheimer is the most difficult type of caregiving which can cause psychological disorders and reduction in life quality of caregivers. Present study aims to examine the effectiveness of mindfulness-based cognitive therapy and conscious group yoga on depression, anxiety and stress of female caregivers of the elderlies with Alzheimer who referred to the Alzheimer Association of Iran.

Methodology: the study was conducted based on a semi-experimental, a controlled random experiment with baseline testing after intervention and a two-month follow-up with control group. Twenty-four female caregivers for patients with Alzheimer who referred to the Alzheimer Association of Iran in city of Tehran were selected based on availability and were randomly assigned to experiment (n=12) and control (n=12) group. All the participants filled the Depression, Anxiety and Stress Scale (Dass-21) at three stages of baseline, post-intervention and follow-up. Experiment group participated in 8 sessions 2-hour of mindfulness-based cognitive therapy and conscious group yoga while control group did not receive any intervention. Collected data of both groups were analyzed using repeated measurement repeated-measures MANOVA.

Findings: findings of the study showed that mindfulness-based cognitive therapy and conscious group yoga caused a significant difference in experiment group compared to control group in terms of depression and stress after the end of intervention sessions and 2-month follow up. Depression and stress had significant reduction compared to pre-test while there was no significant difference in terms of anxiety.

Conclusion: mindfulness-based cognitive therapy and conscious group yoga resulted in depression and stress reduction in female caregivers of elderlies with Alzheimer after the treatment sessions and 2-month follow up. However, there was no change in anxiety.

Keywords: mindfulness-based cognitive therapy, conscious group yoga, depression, anxiety, stress, caregivers of patients with Alzheimer.

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Introduction

Alzheimer's disease has been described as a major health problem following increased age in recent decades (1). Alzheimer's disease is a chronic progressive and debilitating brain disorder that has a profound effect on memory, intelligence and the ability for personal care (2). As this disease has serious consequences for the patients and their family, it is one of the most serious disorders at present time which is often described as “an endless funeral” (3). Individuals with Alzheimer's have difficulty meeting their needs because of cognitive and behavioral disorders and require constant (4). Studies on caregivers of Alzheimer's patients with neurological problems have shown that these caregivers experience some levels of stress, depression, and lack of satisfaction in life (5). About one quarter of the caregivers of patients with Alzheimer suffer from anxiety (6). Also, studies have shown that 20% of caregivers are treated for psychiatric disorders such as depression (7). The study of Cheng et al. on the effect of the burden of caregiving on the health of family caregivers of patients with chronic illness indicated that caregiving burden has a significant impact on the physical and psychological health of caregivers and the time spent on caregiving and the amount of need for patient's physical support are the predictors of caregiving burden (8). Therefore, designing some interventions to help and strengthen them against the problems and difficulties of caregiving becomes more important regarding the increasing number of people with dementia, along with an increase in the number of elderly people. In the field of treatment for psychological problems such as anxiety, stress and depression, various approaches have been used, including medication therapy and combined therapies (9). This field of cognitive-behavioral therapy is introduced since 1970s. However, following some criticisms on this approach, other combinational approaches were also introduced for this problem (10). For example, mindfulness-based cognitive therapy was developed and has significant effect on treatment and prevention of recurrence of anxiety and depression (11). Mindfulness is usually defined as being conscious and focusing on present time. Scholars have shown that increased mindfulness is accompanied by consequences such as pain reduction, anxiety, depression, eating sickness, stress and other diseases (12). Yoga is form of mindfulness and if it is done on a regulated base, it will be a unique pattern for mind and body of those who desire to reach higher level of health (13). Conscious moves are done slowly and an individual is conscious of his breathing and feelings every moment. These practices are basically used in Hatha Yoga (14).

The conscious yoga involves discovering the limits of self and not having to go beyond the borders of these limits. Instead, they tried to stay on the border and breathe. This entails respect for the "message" that the body gives to the person (15). Regarding how much we can sustain this elongation, where and how to change the moves or when to stop the exercise, when to refrain from exercising because of our specific condition or when to avoid it completely (16), mindfulness can help to free individuals from automatic thoughts, habits and behavioral patterns and so they play an important role in behavioral regulation (17). Studies of Hou (18), Kogler et al (19), Epstein-Lubow et al (20), Paller (21) and Whiteboard (22) and Seyed Esmaili (23) examined the effectiveness of mindfulness on health variables of caregivers for patients with chronic illness, elderlies and mentally retarded children. According to what mentioned above, present study examines the effectiveness of mindfulness-based cognitive therapy and conscious group yoga on depression, anxiety and stress of female caregivers of the elderlies with Alzheimer who referred to the Alzheimer Association of Iran.

Methodology

This is a quasi-experimental study where in a controlled random clinical experiment, after taking the informed consent of Alzheimer Association of Iran, some caregivers of patients with Alzheimer referring to this association were selected as the participants of the study and were randomly divided into two groups of control and experiment under weekly sessions of mindfulness-based cognitive therapy and conscious group yoga (experiment group) and no intervention (control group). All the participants signed a written consent for participation. All the caregivers of elderlies with Alzheimer referring to Alzheimer Association of Iran in Tehran in 2017 were regarded as the population of the study. Participants of the study included 24 who were randomly assigned into experiment group (n=12) and control group (n=12). The inclusion and exclusion criteria of the study were: the main role in caregiving the patient, being literate, not having chronic physical and psychological illness, and having no experience of participation in the mindfulness therapy program for drug abuse, the ability to attend group therapy sessions, willingness to participate.

The exclusion criteria for the experimental group: absences for more than two sessions of intervention, unwillingness to continue attending intervention sessions, during a study of people who leave for any reason, including the specific disease, are not able to take care of the elderly with

Alzheimer or death of patient with Alzheimer during the study.
The mindfulness-based cognitive therapy and conscious group yoga were hold by two psychology experts with master degree who were well acquainted with intervention method based on ethical considerations of the study such as informed participation and confidentiality of personal data. Research instruments were filled by the participants in experiment and control group in three stages of before intervention (pre-test), after intervention (posttest) and two month follow-up. This treatment was done in group during 8 session. The participants in experiment group received 8 intervention sessions based on mindfulness-based cognitive therapy and conscious group yoga (24) once week for two hours while control group did not receive any intervention. Due to ethical consideration, the participants in control group received a CD of yoga exercises at the end of the sessions. A sum of instructions for implementing sessions of reducing stress by mindfulness-based cognitive therapy are provided in table 1.

Table1. Summary of functional instruction sessions of mindfulness-based cognitive therapy

Session	Topic
First session: Automatic Pilot	The introduction of automatic guidance system/knowing how to use present moment awareness of bodily sensation, thoughts and emotions in reducing stress/practicing eating raisins[1],giving feedback and discussion about the practice/three - minute breathing, giving assignment for next week and distributing leaflets of the first session and CDs of meditation
Second session: facing obstacles	Re-examining body workout/ giving feedback and discussion about examining body workout/ practicing breathing mindfulness meditation/ /distributing leaflets of the second session and CDs of meditation
Third session: Kindness with breathing, body and awareness about breathing and body movement	Having conscious sitting with awareness of breathing(the sitting meditation)/ practicing three -minute breathing /distributing leaflets of the third session and video tape of yoga practices
Fourth session: learning how to answer	Re-examining body workout / (in the hospital chapel)/5-minute practicing of "seeing or hearing"/ re-practicing conscious session with awareness of breathing and body/ distributing leaflets of fourth session and CDs of meditation
Fifth session: slowly cope with difficulty (attendance)	Practicing breathing /re-practicing conscious session(awareness of breathing ,body, sounds and thoughts)/explaining the stress and identifying participants' reactions to stress/examining awareness of pleasant and unpleasant events on feeling ,thoughts and bodily sensations/ practicing 3-minute breathing /distributing leaflets
Sixth session: thoughts are not facts	practicing sitting meditation (mindfulness of sounds and thoughts)/distributing leaflets of the sixth session and number4 video tape to participants
Seventh session: self-care	Practicing mountain meditation/sleep hygiene/ repeating exercises of the previous session/making a list of enjoyable activities/distributing leaflets of the seventh session
Eighth session: going beyond fear	Examining body workout /overview of program/examining and discussing programs /practicing stone, beads and marbles meditation

[1]Object attention training

Research Instrument

Demographic Information Questionnaire

A demographic questionnaire containing was developed by the researcher based on the effect of underlying factors and biological characteristics on the patients' mood and quality of life. Demographic questionnaires included including items of age, education, economic status, beginning and duration of caregiving, history of mental illness and history of suicide.

Structured Clinical Interview (SCID)

Was adapted by Frist et al (1997) (First, Spitzer, Gibbon, Williams, 1997). It is a tool for diagnosis based on four criteria of Diagnostic and Statistical Manual of Mental Disorders. This tool has two main versions: 1- Form SCID-I which assesses major psychiatric disorders (axis l in the DSM-IV) deals. This form have been translated and adapted by Sharifi et.al (1384). This interview has good validity and reliability for the diagnosis of mental disorders. For example, Zanaryny (2000), in examining diagnostic reliability between raters, for most diagnoses has reported more than 70 percent alpha. Bakhtiari's study (1379), Clinical psychology professionals and professors has confirmed the validity of this tool. Test-retest reliability with an interval of one week was 0/95 (Bakhtiar, 2000) 2 - Form SCID-II also assesses personality disorders (axis II DSM-IV). This test has been designed based on branching plan and includes some openended questions and one rule-out question which provide opportunity for interviewer to be guided in the new fields, based on previous answers of respondents (Marnat, 2003). Bakhtiari (1379; as quoted by Kabirnezhad et al, 1388) has translated and adapted this form (Kabirnzhad, Aliloo, Hashemi, 2000).Semi-structured clinical interview is used for personality disorders to assess the 10 DSM-IV personality disorders of axis ll and was set in 1997. Content validity is approved by using experts' opinions and test-retest reliability coefficient. Reliability and validity of this tool has been accepted in various studies (Kabirnzhad, Aliloo, Hashemi, 1388). In Bakhtiari's study (1379), the content validity of the translated version of the interview was confirmed by three professors of psychology, and test-retest reliability coefficient of the tool with an interval of one week was % 87

Anxiety, depression and stress questionnaire (DASS-21)

The short form of this questionnaire with 42 questions has been examined by Leviband (1995) to assess depression ,anxiety, and stress (30).Confirmatory factor analysis results has confirmed the existence of the 3 factors of depression ,anxiety and stress. Retest coefficient of 3 subscales of this questionnaire was mentioned with sample consisted of 20 patients between 71%-81% at an interval of two weeks (31).Reliability and validity of this questionnaire were studied on a number of subjects in England (32).Retest reliability for depression,

anxiety and stress are reported respectively 80%,76% and 77% and Chronbach's alpha for them are reported respectively 81%,79% and 78%.Validity of this scale was examined by confirmatory factor analysis and in main components method .

Findings

Standard deviation and mean age of control group and experiment group were 32.25± 3.07 and 32.33± 2.77. The standard deviation and mean for beginning and duration of caregiving for control and experiment group were 6.41± 2.96 and 5± 2.13, respectively. 66.7 percent of control group and 58.3 percent of experiment group had a high school degree. Further, results of the analysis showed that both groups were at average level in terms of income.

Table 2. Average and standard deviation of age, duration of care for patients with Alzheimer's for control and experiment group

	Group	Mean	SD
Age	Control	32.25	3.07
	Experimental	32.33	2.77
duration of care for patients with Alzheimer's	Control	6.41	2.96
	Experimental	5	2.13

Table 3. Mean and standard deviation of Depression, Anxiety, stress of separate tests in groups

	Control(n=12)			Experimental(n=12)		
	pre-test	post-test	follow	pre-test	post-test	Follow
Depression	1±13.50	1.15±12.33	0.93±12.83	2.13±14.75	1.43±6.66	1.26±10.83
Anxiety	1.78±3.50	1.35±3.25	1.82±3.66	3.02±4.41	2.49±4.25	1.96±3.66
Stress	0.90±16.08	1.50±14.50	1.78±14.50	1.97±15.50	1.80±9.16	1.64±10.83

As it is shown in table 3, the mean score of depression and stress at posttest significantly changes compared to pre-test while the mean score of control group had no significant change at three stages. Regarding the results of M box for stress variable (Sig=0.214, F=1.391) and also (Sig=0.265 F=1.276) for depression variable, the null hypothesis is not rejected and covariance matrices for dependent variables are equal among various groups. While, for anxiety (Sig=0.018 F=2.55) it was shown that observed covariance matrices of dependent variables was not equal among various groups.

Table 4. Results of repeated measures variance analysis

	Sum of squares	DF	Squared mean	F	significance level	Eta square
Depression	47.227	1	47.227	17.362	0.0001	0.441
Anxiety	1.185	1	1.185	0.673	0.421	0.030
stress	100.042	1	100.042	78.839	0.0001	0.782

As shown in table 4, the mindfulness-based cognitive therapy and conscious group yoga resulted in significant reduction of depression (F=17.361 Sig=0.0001) and stress (F=78.83, Sig=0.001) in female caregivers of the elderlies with Alzheimer. While the results of repeated measurement MANOVA for anxiety at three stages (F=0.421 Sig=0.67) showed that there was no significant difference in groups.

Results and Conclusion

Present study aimed to examine the effectiveness of mindfulness-based cognitive therapy and conscious group yoga on depression, anxiety and stress of female caregivers of the elderlies with Alzheimer who referred to the Alzheimer Association of Iran. Results of the study showed that this therapy was effective compared to before treatment, after two-month follow-up and compared to control group after treatment and follow up. Caregiving for a patient with Alzheimer and other types of dementia is associated with a range of challenges (5). Changes in the disease require these people to attain high levels of personal care and supervision, which causes many caregivers to experience high levels of stress and experience their negative effects on their health, their jobs, their income, and their financial security. Post-test results did not show a significant difference in stress and depression of control group. In the intervention group, mean of depression and stress after intervention significantly decreased. Considering that the two experiment and control groups are similar in demographic characteristics, it can be concluded that the changes in the mean scores of stress and depression in the experiment group can be due to mindfulness-based cognitive therapy. Results of the study were in line with findings of the studies by Hou (18), Kogler et al (19), Epstein-Lubow et al (20), Paller (21) and Whiteboard (22) and Seyed Esmaili (23). In study of Hou (18), mindfulness-based cognitive therapy caused reduction in depression and anxiety symptoms for patients with chronic disease. However, there was no significant difference for stress at present study. Findings of Kogler et al (19) on effectiveness of mindfulness-based

cognitive therapy by unofficial caregivers of relieving patients showed that mindfulness was a significant predictor of psychological suffering, meaning of life and quality of life in the post-intervention phase. The study of Epstein-Lubow et al also showed that mindfulness-based cognitive therapy results in reduction of depression symptoms, perceived stress and caregiving load in caregivers of weak elderlies (20). Paller also concluded that mindfulness training resulted in increased life quality, reduced depression symptoms and better sleeping quality in patients with cognitive impairment and their caregivers (21). The study of whiteboard showed that the mindfulness-based cognitive therapy to reduce stress resulted in reduced stress and depression in caregivers of patients with dementia (22). Study of Seyed Esmaili also showed the effectiveness of mindfulness-based cognitive therapy on reducing the mental pressure on mothers of mentally retarded children (23). Another study also examined the effectiveness of mindfulness-based cognitive therapy on samples except caregivers, all of which indicated the positive effectiveness of this therapy on psychological health variables of individuals. For example, the study of McKenzie which examined the effect of mindfulness-based cognitive therapy on nurses and nursing assistance in long-term care centers for the elderly and highlighted the effectiveness of this intervention on the prevention and treatment of stress related problems and the promotion of nurses' health and nursing care (32). Also, the study of Whiteboard found that mindfulness-based cognitive therapy for girls at school age increased the ability to adapt and reduce their stress by increasing their awareness of stressful situations (22). Further, the study of Rahmani and Talepasand, mindfulness-based cognitive therapy in clinical samples caused a reduction in stress level and improved their physical and mental health (33). In fact, it seems that mindfulness-based cognitive therapy and yoga are effective on reducing stress and anxiety by increasing the individuals' awareness of present time, through techniques such as meditation (by focusing on the breathing and focusing consciousness here and now) and yoga (regular exercises) on body control and, consequently, mind control (34). This study has some specific limitations. First limitation is the small sample size. Although the study is not affected by the decline in number of participants, the small sample size is one of the limitations which prevents exact estimation of effect size. Second limitation is related to self-reporting instrument. These instruments have some internal problems (measurement error, lack of self-control and …). The third limitation is related to the lack of control for the domain and individual factors. It is likely that participants will have overestimated

the effects of the program due to some underlying factors. Another possible assumption is that participants are more likely to overestimate the effect of treatment due to their individual tendency, optimism, and similar factors. It is also suggested that the future studies use placebo on control group to control the effect of waiting. It is also suggested that larger sample size are used to achieve the actual effect size of treatment. The strategies for prevention and relieving the caregiving burden of these people are considered as a priority in health care community. It is certain that caregivers of the elderly with Alzheimer have many stresses that put their physical and mental health in a threatening state, and this can influence on the patient's care and support process. Therefore, it is suggested that researchers can use effective supportive and interventional approaches such as mindfulness to reduce various difficulties of Alzheimer and elderlies in the community and also health of caregivers.

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References

1. Wimo A, Jonsson L, Bond J, Prince M, Winblad B, Alzheimer Disease I. The worldwide economic impact of dementia 2010. Alzheimers Dement. 2013;9(1):1-11 e3. DOI: 10.1016/j.jalz.2012.11.006 PMID: 23305821.
2. Association As. 2011 Alzheimer's disease facts and figures. Alzheimer Dementia J Alzheimer Assoc. 2011;7(2):208. PMID: 21414557.
3. Chang HY, Chiou CJ, Chen NS. Impact of mental health and caregiver burden on family caregivers' physical health. Arch Gerontol Geriatr. 2010;50(3):267-71. DOI: 10.1016/j.archger.2009.04.006 PMID: 19443058.
4. Mansouri T, Dehdari T, Seyedfatemi N, Gohari MR, Barkhordari M. [The effect of communication skills training on perceived stress of caregivers of elderly with Alzheimer's disease referral to Iranian Alzheimer Association in 2012]. Razi J Med Sci. 2014;21(121).
5. Breiddal SMF. Palliative care: A place for caregivers to thrive. Illness, Crisis, & Loss.2011; 19(2):111-24.
6. Abdollahpour I, Noroozian M, Nedjat S, Majdzadeh R. Caregiver burden and its determinants among the family members of patients with dementia in Iran. International Journal of Preventive Medicine. 2012; 3(8):544.

7. Mohammadi F, Babaie M. [The effect of participation in family support groups on the caregiving strain and spiritual wellbeing among family caregivers of elders with Alzheimer's disease]. Salmand. 2011; 6(19):29-37 (Persian).
8. Alzheimer Association. Alzheimer's disease facts and figures. 2010. Accessed: 26 May 2010; Available: http://www.alz.org/documents_cus-tom/report_alzfactsfigures2010.pdf.
9. Mansouri T, Dehdari T, Seyedfatemi N, Gohari MR, Barkhordari M. [The effect of communication skills training on perceived stress of caregivers of elderly with Alzheimer's disease referral to Iranian Alzheimer Association in 2012]. Razi J Med Sci. 2014;21(121).
10. Crane R and Kuyken W. The implementation of mindfulness-based cognitive therapy: Learning from the UK health service experience. Mindfulness 2012. DOI 10.1007/s12671–012–0121–6.
11. Kuyken W, Watkins E, Holden E et al. How does mindfulness-based cognitive therapy work? Behaviour Research and Therapy 2010;48:1105–12.
12. Health and Social Care Act. Health and Social Care Act. c7, 2012. Available at: www.legislation.gov.uk/ukpga/2012/7/enacted (accessed 26/06/12).
13. J. R.Vittengl, R. B. Jarrett, E. S.Weitz et al., "Divergent outcomes in cognitive-behavioral therapy and pharmacotherapy for adult depression," American Journal of Psychiatry, vol. 173, no. 5, pp. 481–490, 2016.
14. P. Cuijpers, E. Weitz, J. Twisk et al., "Gender as predictor and moderator of outcome in cognitive behavior therapy and pharmacotherapy for adult depression: an "individual patient data" meta-analysis," Depression and Anxiety, vol. 31, no. 11, pp. 941–951, 2014.
15. K. Bluth, S. Gaylord, K. Nguyen, A. Bunevicius, and S. Girdler, "Mindfulness-based stress reduction as a promising intervention for amelioration of premenstrual dysphoric disorder symptoms," Mindfulness, vol. 6, no. 6, pp. 1292–1302, 2015.
16. A. Omidi and F. Zargar, "Effect of mindfulness-based stress reduction on pain severity and mindful awareness in patients with tension headache: a randomized controlled clinical trial," Nursing and Midwifery Studies, vol. 3, no. 3, Article ID e21136, 2014.
17. S. G. Hofmann, A. T. Sawyer, A. A.Witt, and D. Oh, "The effect of mindfulness-based therapy on anxiety and depression: a meta-analytic review," Journal of Consulting and Clinical Psychology, vol. 78, no. 2, pp. 169–183, 2010.

19. Kogler M, Brandstatter M, Borasio GD, Fensterer V, Kuchenhoff H, Fegg MJ. Mindfulness in informal caregivers of palliative patients. Palliat Support Care. 2015;13(1):11-8. DOI: 10.1017/S1478951513000400 PMID: 23768947.
20. Epstein-Lubow G, McBee L, Darling E, Armey M, Miller IW. A pilot investigation of mindfulness-based stress reduction for caregivers of frail elderly. Mindfulness. 2011;2(2):95-102.
21. Paller KA, Creery JD, Florczak SM, Weintraub S, Mesulam M-M, Reber PJ, et al. Benefits of Mindfulness Training for Patients With Progressive Cognitive Decline and Their Caregivers. Am J Alzheimer Dis Other Dementias. 2014:257-67. DOI: 10.1177/1533317514545377 PMID: 25154985.
22. Whitebird RR, Kreitzer M, Crain AL, Lewis BA, Hanson LR, Enstad CJ. Mindfulness-based stress reduction for family caregivers: a randomized controlled trial. Gerontologist. 2013;53(4):676-86. DOI: 10.1093/geront/gns126 PMID: 23070934.
23. Seyed Esmaili N, Kazemi F, Pezeshk S. The Effectiveness of Stress Reduction Program Training Based on Mindfulness on the Stress Levels of Mothers with Intellectually Disabled Children. Psychol Except Individ. 2015; 5(17):133-48.
24.Seagal ZV, Williams JMG and Teasdale JD (eds). Mindfulness-Based Cognitive Therapy for Depression: a new approach to preventing relapse. Guilford Press: New York, 2002.
25. First M, Spitzer R, Gibbon M, Williams J. Structured Clinical Interview for DSM-IVAxis I Disorders (SCID-I), Clinical Version. Washington,DC: American Psychiatric Association 1997.
26. Sharifi Vandad, Asadi S. Yadmohammad, Mohammadi Mohammad Reza, Amini Homayoun, Kaviani Hossein, Semnani Yousef and colleagues, Reliability and Capability Implementation of the Persian version of the Diagnostic Structured Interview for 10-22, 6, Cognitive Science Reports, 1383, (SCID) DSM-IV
27. Zanarini M, Skodol A, Bender D, Donald R., Sanislow C, Schaefer E, et al. (2000).The collaborative longitudinal personality disorders study: Reliability of axis I and II diagnoses. J Personal Disord, 2000; 14 (4):297- 99.
28. Alaghband-rad J, Ahmadi-Abhari A, Sharifi V, CIDI Validation Group. Reliability, validity and feasibility of a Persian translation of the composite international diagnostic interview (CIDI). In: Mental health effects of Iraqi invasion of Kuwait on a wartorn population of Iran: Final Report, Tehran, Iran, 2003
29. Bakhtiar M. Psychiatric disorders in patients with body

dimorphic disorder. Master's thesis in clinical psychology. Iran University of Medical Sciences, Tehran Psychiatric In statute. 1379.
30. Lovibond SH, Lovibond SH. The structure of negative emotional states: comparison of depression anxiety stress scale (DASS) with the Back Depression and anxiety inventories. Behav Res Ther, 1995; 33(3):335-43.
31. Taouk M, Lovibond PF, Loube R. Psychometric of a chine's version of the DASS. Journal of Abnormal Psychology 1997; 107(13): 520.
32. Kuzu N, Beser N, Zencir M, Sahiner T, Nesrin E, Ahmet E, et al. Effects of a comprehensive educational program on quality of life and emotional issues of dementia patient caregivers. Geriatr Nurs. 2015; 26(6): 378-86.
33. Rahmani S, Talepasand S. The effect of group mindfulness - based stress reduction pro- gram and conscious yoga on the fatigue severity and global and specific life quality in women with breast cancer. Med J Islam Repub Iran 2015 (8 February). Vol. 29:175.
34. Segal ZV, Williams JMG, Teasdale JD. Mindfulness-based cognitive therapy for depression: Guilford Press; 2012.

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A Descriptive Study on Utilization of Fresh Frozen Plasma in University of the East Ramon Magsaysay Memorial Medical Center Incorporated (UERMMMCI)

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Abstract

This study investigated the utilization of fresh frozen plasma in University of the East Ramon Magsaysay Memorial Medical Center Incorporated.

I. Introduction and Significance of the Study

Over the years, the significant role of blood component in treating certain diseases or conditions has been recognized. Component therapy has a profound impact in the practice of transfusion medicine. The extraction of various constituents, including plasma, from the whole blood has led to increase efficacy and economic utilization of blood supply. [1]Fresh frozen plasma is frequently prescribed blood product; its use continues to rise despite the fact the supply of plasma derived from allogeneic blood donation is finite. [1,2]In clinical practice, fresh frozen plasma is widely used despite its indications being limited to a few. Conditions such as treatment of bleeding tendency combined with disseminated intravascular coagulation, clotting factor deficiencies and some rare bleeding disorders. [1,2,3] Various adverse effects including non-hemolytic febrile reactions, allergic reaction due to plasma protein incompatibility and transfusion-related lung injury after fresh frozen plasma transfusion. It is capable of transmitting viruses like Human Immunodeficiency Virus, Hepatitis B and Hepatitis C viruses. [1,2]

The appropriate use of fresh frozen plasma requires understanding of the

properties of fresh frozen plasma and its inadequacies, as well as an appreciation of the complications of fresh frozen plasma usage. [1]

Literature search revealed audits of fresh frozen plasma in the Philippines are scarce.

In order to avoid inappropriate use of the fresh frozen plasma in our institution, we have to establish Hospital Transfusion Guidelines based on the existing local guideline, which is The Philippine Clinical Practice Guidelines For Rational Use of Blood and Blood Products. Appropriate indications should be incorporated in the request forms to remind the clinicians.

Our institution is a tertiary hospital in Metro Manila with 229-bed capacity, with a broad range of medical and surgical specialties and our blood bank caters all services.

A retrospective audit on the hospital's fresh frozen plasma usage with specific aims of assessing the pattern and rate of usage will help us recognize the appropriate utilization of fresh frozen plasma and setting up policies to improve the utility and reduce the wastage of this important blood products.

II. Review of Related Literature

Plasma consists of the non-cellular portion of blood that is separated and frozen after donation. It may be prepared from the whole blood or collected by apheresis. This is separated from the whole blood and frozen at -25 degrees celsius or colder within 6-8 hours of donation in order to preserve its labile coagulation factors (factors V & VIII) [3,4,5]

Fresh frozen plasma is frozen at - 18 degrees celsius or colder within 6-8 hours of collection and contains functional quantities of all coagulation factors. Plasma frozen within 24 hours (FP24) and thawed plasma may contain variably reduced level of Factor V and Factor VII. Despite the differences between FP24, thawed plasma and fresh frozen plasma, they are generally used for same indication. [3,4,5,6]

Plasma transfusion must be ABO-compatible with the patient's red cell. (Grade A; Level 2) [4]

Fresh frozen plasma is indicated for multiple coagulation factor deficiencies associated with severe bleeding or disseminated intravascular coagulation (DIC) with bleeding, single coagulation factor deficiencies when no virus-safe fractional product is available, bleeding due to hemorrhagic disease of the newborn (HDN), neonates with coagulopathy who are bleeding or about to undergo invasive procedure, for neonatal exchange transfusion AB or type specific PRBC (AABB), severe bleeding due to warfarin or patients taking warfarin who will undergo emergency surgical procedure, medical situation like open-heart surgery with more than 6 units PRBC transfused; and for trauma casualties with 30% or more blood loss and who will be requiring massive transfusion. [1,4]

Massive transfusion protocols involve administration of red blood cells and plasma initially, then adding platelet units or cryoprecipitate later. The purpose is to prevent coagulopathy rather than wait for coagulopathy to develop then treat it. Transfusion with more than five units of RBC together with crystalloid inevitably leads to dilutional coagulopathy as shown in some modeling studies. The benefits administering blood products in the absence of laboratory tests usually outweigh the risk of transfusion in trauma patient in hemorrhagic shock and with ongoing bleeding.[4]

When used to correct isolated coagulation factor deficiencies like hemophilia A, B, or C for which no concentrated preparation is available (e.g. Factor V or XI) or hemophilia the type of which is not determined, the dosing depends on the half-life of the specific factor, the pre-transfusion level of the factor, the desired post-transfusion level and the duration of raised levels required. [4]

The volume of fresh frozen plasma unit is approximately 250 mL but variation may be expected. The volume may vary from 180-300 mL. [3,4]

There are risks involved in transfusion thus use of fresh frozen plasma is not indicated in the following situations like reversal of warfarin anticoagulation in the absence of severe bleeding (BSH, 126) (Grade A, Level 3) [4] , hypovolemia, plasma exchange, the reversal of prolonged INR in the absence of bleeding, prevention of intraventricular hemorrhage in preterm infant, treatment of neonates with polycythemia, wound healing and treatment of immunodeficiency states. [2, 3. 5] Prophylactic fresh frozen plasma transfusion may not further reduce bleeding incidence, but carries the risk of acute lung injury. [7]

Several audits and studies were done in different countries on fresh frozen plasma utilization. During the two-year retrospective study of Sameer, et al., they looked into the usage of fresh frozen plasma and used the guidelines published by College of American Pathologists (CAP), National Health and Medical Research Council (NHMRC) and Australasian Society For Blood Transfusion (ASBT). It was identified that 53.19% represent inappropriate use of fresh frozen plasma and the most common reason is transfusion in pregnant female with active labor suffering from severe anemia with shock. Disseminated intravascular coagulopathy and chronic liver disease represents the appropriate reasons for transfusion.[8] In the clinical audit of Garg, et al., they noted that 30% of the fresh frozen plasma were transfused

inappropriately for the purpose of volume expansion or circulating volume replacement. Also disseminated intravascular coagulopathy and prolonged prothrombin time are most common appropriate indications. [6] Another is a three-month study was done in South Africa by Visser, et al., and revealed a staggering 39.5% inappropriate use of fresh frozen plasma transfusion due to reason of circulatory volume expansion.[9] The evaluation of fresh frozen plasma usage conducted by Kulkarni, et al., which retrospectively done in Medical College Hospital, showed 52% were inappropriately transfused for absence of bleeding or surgical intervention. It was identified that disseminated intravascular coagulopathy was the most common appropriate indication for fresh frozen plasma transfusion[10]

On the other hand, Shinagare, et al., conducted a retrospective study and assessed the appropriateness in the usage of fresh frozen plasma in a tertiary hospital in India. In this study, like the others, disseminated intravascular coagulopathy was clearly appropriate reason for transfusion. They reported a 39.4 % of inappropriate utilization of the said blood product. The use of fresh frozen plasma for volume expansion was the most frequent cause of inappropriate fresh frozen plasma usage. [5] Pervaiz, et al., surveyed the trends of use of fresh frozen plasma at a tertiary hospital in Pakistan, showed disseminated intravascular coagulopathy was the appropriate reason for requesting fresh frozen plasma, and 81% of transfusions were inappropriately used, as requested for circulatory volume replacement of burn patients, accidental trauma hematological malignancies in adult patients, which was alarmingly high. [11]

III. Objectives

General Objectives

To describe the utilization practices of fresh frozen plasma in the different specialties in the University of the East Ramon Magsaysay Memorial Medical Center Incorporated from January 2011 to December 2011.

Specific Objectives

1. To identify the percentage of the usage of fresh frozen plasma of different specialties in University of the East Ramon Magsaysay Memorial Medical Center Incorporated from January 2011 to December 2011.
2. To describe the fresh frozen plasma transfusion indicators of various specialties in University of the East Ramon Magsaysay Memorial Medical Center Incorporated from January 2011 to December 2011.

IV. Materials and Methodology

A. Research Design

The study was a descriptive study.

Population

The study included all patients in the pay floors and charity ward that were admitted in the University of the East Ramon Magsaysay Memorial Medical Center Incorporated, and were requested for transfusion with fresh frozen plasma, in January 2011 to December 2011.

B. Data Collection and Analysis

All blood requisition forms of admitted patients, requested for fresh frozen plasma transfusion, submitted at the blood bank section from January 2011 to December 2011 were reviewed. Patients who were requested with fresh frozen plasma along with other supplements, such as whole blood, packed red blood cell and platelet, were also included in

the study, as well as, patients in all age groups. The following data were collected: patient's demographic data including age, gender and blood group, date, department of the requesting physician, number of fresh frozen plasma units requested and issued. The clinician's indication or reason for fresh frozen plasma transfusion was noted.

Data were encoded and tallied in IBM SPSS version 22 for Microsoft Windows. Descriptive statistics are generated to report the proportion of patients who received fresh frozen plasma and the proportion of patients in different specialties who were transfused with fresh frozen plasma. For nominal data, frequencies and percentages were generated. For numerical data, mean ± SD were computed

.

V. Results

A total of 386 units of fresh frozen plasma were issued by the blood bank section to 130 patients that were requested for transfusion from January 2011to December 2011. In this study, 68 (52.3%) males and 62 (47.7%) females were included with mean age of 51 years (SD 19.70, range of 1 day to 88 years). Fresh frozen plasma was commonly requested in patients with age group 30-60 years old. Maximum patients (65 or 50%) have O+ blood group, followed by B+ (31 or 23.8%) blood group. Thirty or 23% had blood group A+ and 4 patients or 3.2 % belonged to the AB+ blood group.

Of the 386 units of fresh frozen plasma that were given or issued, the breakdown of these, the most units (230 or 59.5%) were distributed to the Department of Internal Medicine, 75 (19.4%) to the Surgery Department and 43 (11.1%) to the Neurosurgery

Department. The Department of Pediatrics were given 22 or 6.0%, 8 units or 2.0% for Obstetrics and Gynecology Department and the other remaining 2.0% to Urology and Neurology Departments, as shown in Figure 1.

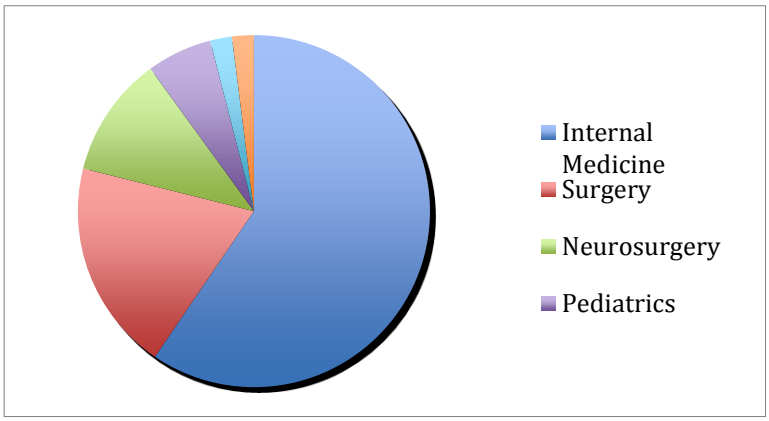

FIGURE 1. FRESH FROZEN PLASMA DISTRIBUTION ACCORDING TO DIFFERENT DEPARTMENTS

The clinical indications for which the 130 patients given with fresh frozen plasma were reviewed in the data collected from the blood bank and the most common reason for requesting the blood component was for surgical use (40%), followed by deranged prothrombin time (17%) as PT >1.5 from the midpoint of normal range which is usually 18 seconds. Active bleeding from gastrointestinal tract and dengue hemorrhagic fever represent 15.4 % of fresh frozen plasma use, and then followed by cases of sepsis (11.5%). Also, anemia of chronic disease like in chronic kidney disease and hepatic disease comprises 10.8% and 3.1 % to cases with disseminated intravascular coagulation. The least common reasons recorded were coagulopathy, from single coagulation factor and thrombocytopenia. This was shown on Table 1.

TABLE 1. CLINICAL INDICATIONS OF DIFFERENT SPECIALTIES OF UERMMMCI FOR FRESH FROZEN PLASMA UTILIZATION

	DEPARTMENT						
INDICATION	MEDICINE (n=77)	PEDIATRICS (n=7)	SURGERY (n=24)	NEUROSURGERY (n=13)	NEUROLOGY (n=1)	OBGYN (n=5)	GU (n=3)

SURGERY	13 (16.9%)	3 (42.9%)	20 (83.3%)	9 (69.2%)	0	4 (80.0%) 3 (100%)
DERANGED PT	21 (27.3%)	1 (14.3%)	0	0	1 (100%)	0 0
BLEEDING	15 (19.5%)	1 (14.3%)	1 (4.2%)	3 (23.1%	0	0 0
SEPSIS	13 (14.9%)	0	2 (8.3%)	0	0	0 0
ANEMIA	11 (14.3%)	1 (14.3%)	1 (4.2%)	1 (7.7%)	0	0 0
DIC	4 (5.2%)	0	0	0	0	0 0
COAGULOPATHY (SINGLE COAG FACT)	0	1 (14.3%)	0	0	0	0 0
THROMBOCYTOPENIA	0	0	0	0	0	1 (20.0%) 0

VI. Discussion/Conclusion

Transfusion practice is now a complex therapeutic discipline. The transfusion of a blood component can never be taken lightly and should be given for a proper indication after careful evaluation of the clinical situation. Blood components have been in use for many years. In the developing world, there is a shortage of blood and blood components, and to meet the needs for these, our blood bank requires more than 200 donors per

month. Fresh frozen plasma is a frequently used blood product and evaluation of its usage is very important.

Clinical transfusion auditing is valuable in identifying current trends and patterns of fresh frozen plasma usage, as well as, areas requiring improvement. The risks of transfusion and non-availability of blood components make it crucial to optimize fresh frozen plasma transfusion and reduce wastage. This study was done to evaluate the utilization of fresh frozen plasma in our institution. In this study, the indications were identified in reference with the local guideline, The Philippine Clinical Practice Guidelines For the Rational Use of Blood and Blood Products, since our institution does not have its own blood bank manual, stating the appropriate use of blood and blood products.

Overall, the Internal Medicine Department accounted for most fresh frozen plasma requisition for about 59.9% and these findings are similar to the studies of Sameer et al., Garg et al., and Visser et al., from India and a study of Pervaiz et al., of Pakistan. Only 19.4% from the Surgery Department and the rest are from other departments.

It is shown in this study that 40% of the requests for fresh frozen plasma units were for prophylactic transfusion in adult patients with normal coagulation profile but will undergo major invasive surgical procedure, with the potential for hemorrhage or massive blood loss. This result is similar to the inappropriate use of fresh frozen plasma units, stated in the studies of Kulkarni, et al., and most other studies. This study also reported 17% of the requests had an appropriate indication of deranged prothrombin time, which is slightly lower than the study by Garg, et al. Other common indications identified for fresh frozen plasma transfusion that were clearly appropriate include active bleeding from gastrointestinal tract and dengue hemorrhagic fever, sepsis, anemia and disseminated intravascular coagulopathy. These situations could

have multiple coagulation factors deficiencies that needed transfusion.

In this study, it was observed that the inappropriate requests were for prophylactic use for surgical operation and could be secondary to overestimation of risk of massive bleeding during the procedure, thus the tendency to transfuse.

With the increased demands of fresh frozen plasma units and less number of people donating, there was shortage of this blood – derived product in our institution. This has a significant impact on medical costs and patients' morbidity and mortality. It is essential to have institutional guidelines and policies on fresh frozen plasma transfusion, and indications should be reflected on the requisition forms for proper assessment, reducing wastage of this blood product. Guidelines were to be developed to help clinicians in deciding to request and not to replace their clinical judgment.

The study is limited to the acquiring information from blood bank requisition and it was not the patients were analyzed. Wastage of fresh frozen plasma units was not properly measured because data weren't obtained if all units' released by the blood bank were transfused to the patients. Also, our blood bank has no issued institutional fresh frozen plasma transfusion guidelines and policies for better assessment of proper usage of this blood product.

VII. Recommendation

After evaluating the usage of fresh frozen plasma, there were cases of irrational use of the said blood product among specialists. To properly use and reduce the wastage of fresh frozen plasma, it is recommended to make an institutional policies and guidelines regarding transfusion of blood and its blood product, here includes the fresh frozen plasma. Since the study is limited to blood bank requisition form, it is suggested in the forms to mention regularly the appropriate indication of fresh frozen plasma transfusion. Also,

proper education of medical stuff and regular auditing programs about the use of blood and its component is needed. A periodic reinforcement on proper use of blood and blood products, during clinicopathologic conferences, surgical tumor board conferences and gynecologic surgicopathologic conference, should be done. Further studies to improve the utilization of fresh frozen plasma are recommended.

VIII. References

1. Muller, M., et al. Transfusion of Fresh Frozen Plasma in Critically-Ill Patients With A Coagulopathy Before Invasive Procedures: A Randomized Clinical Trial. Transfusion. 2011; 55: 26-35.
2. Duguid, J., et al. Guidelines For The Use OF Fresh Frozen Plasma, Cryoprecipitate and Cryosupernatant. The British Society For Hematology. 2004. 126: 11-28. 10. 1111/j.1365-2141.2004.04972
3. Wong, M., et al. Guidelines for frozen plasma transfusion. BC Medical Journal. 2007; 49: 311—319.
4. Philippine Clinical Practice Guidelines for the Rational Use of Blood and Blood Products and Strategies for Implementation. Chapter 2 Clinical Practice Guidelines for Blood Transfusion. 2009. 42-25
5. Shinagare, S.A., et al. An Audit of Fresh Frozen Plasma Usage and Effect of Fresh Frozen Plasma On The Pre-transfusion International Normalized Ratio. Asian Journal Of Transfusion

Science. 2010; 4(2): 128-132.10.4103/0973-6247.67024.

6. Garg, S., Shashikal, P., Nandyal, S. The Trends Of Fresh Frozen Plasma Usage In Adults At A Tertiary Hospital With An Insight Into Transfusion Guidelines. International Journal Of Scientific Research / IJSR. 2011; 2 (5): 452-454.
7. Muller, M., et al. Transfusion of Fresh Frozen Plasma In Non-bleeding ICU Patients – TOPIC TRIAL: Study Protocol For Randomized Controlled Trial. Trials. 2011; 12 (266). 1-2. 10.1186/1745-6215-12-266.
8. Sameer, M.A., et al. Appropriate and Inappropriate Fresh Frozen Plasma Use In Coagulation Disorders. IOSR. Journal Of Dental and Medical Sciences / IOSR-JDMS. 2011; 13 (4): 89-92.
9. Visser, A., Geldenhuys, A., du Preez, S., van de Vyvers, A. Fresh Frozen Plasma Use In a South African Tertiary Hospital. South African Medical Journal/SAMJ. 2010; 102 (6): 366-367.
10. Kulkarni, N., et al. Evaluation of Fresh Frozen Plasma Usage At A Medical College Hospital – A Two-year Study. International Journal of Blood Transfusion and Immunohematology/ IJBTI. 2010: 16-20. 10. 5348 / ijbti – 2010 – 9-04-4.
11. Pervaiz, A., Naseem, L. The Trends Of Use Of Fresh Frozen Plasma At A Tertiary Care Hospital. International Journal of Pathology. 2009; 7(2): 88-93.

Structural Relationships of Psychological Well-Being and Life Expectancy in Psychological Hardiness by Mediating Social Support in Women with Breast Cancer

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Abstract

Introduction: Breast cancer endangers many aspects of mental health; it exacerbates mental stress and confronts one's mental health due to the disturbance in a person's mental image of his body. These cases can also affect the psychological well-being of these individuals. Method: the research is an applied one in terms of application of the results. It is descriptive-correlation type in the form of structural equation model In terms of implementation. AMOS 18 software was used to investigate the main purpose of the research in order to analyze the data in addition to descriptive indexes related to each scale. Data were analyzed by SPSS-22 software. 246 ones were selected as the sample size according to Cochran formula and model components by random sampling method. Measurement tools: Miller's Life Expectancy Questionnaire (MHS), Reef Psychological Well-Being Questionnaire (RSPWB), Ahwaz Psychological Hardiness Questionnaire (AHI), and Social Security Questionnaire of Berlin were used as the research tools. Results: Direct standard coefficients of conceptual model of psychological hardiness relationships with psychological well-being and life expectancy by mediating social support, women with breast cancer. The model indices are (GFI = 0.984, AGFI = 0.952, CFI=0.956, RMSEA =0.077, CMIN = 2.2, P<0.000); the indices values of model have a favorable fitting. RMSEA value is 0.077 and less than 0.08 and the indices GFI, AGFI and CFI are all greater than 0.90. Therefore, the model is well-fitted and approved. Therefore, considering the importance of maintaining and improving the quality of life of patients with breast cancer, it is recommended studying the mental hardiness and social support and hope to psychological well-being and intervention to increase the mental health of these patients in order to improve and adapt to the disease. Conclusion: In the present study, there was a significant positive relationship between psychological hardiness and psychological well-being and hope with direct mediation of social support; patients with better psychological hardiness had better health and better quality of life.

Keywords: Structural Relationships, Psychological Well-Being, Life Expectancy, Psychological Hardiness, Social Support, Breast Cancer

Introduction

Despite many advances in the field of medical science and the development of human knowledge in the management and treatment of various diseases, cancer is still considered as one of the most serious and in many cases incurable diseases that unfortunately threatens the life of many people and there is a risk of it for a significant part of human society (Lotfi Kashani et al. 2013).

Types of cancers are a widespread range of diseases, each of which has its own etiology, therapeutic profile and prognosis. Most people with cancer experience a stressful period. In some patients, this psychological stress goes away on its own and does not lead to long-term mental problems; it can be considered as a natural adaptation reaction but some patients experience more severe psychological problems that decrease their quality of life and their daily functioning 9Pedram et al. 2010). After cardiovascular diseases and accidents, cancer is the third leading cause of death in Iran. Annually more than 30,000 Iranians die from cancer. It is estimated that more than 70,000 new cases of cancer occur annually in the country. With an increase in life expectancy and an increase in the percentage of aging in the country's population, the incidence of cancer is expected to increase twice in the next two decades. In this regard, breast cancer is the most common cancer and the most common cause of death in Iranian women (V. Larence, 2001). Breast cancer which affects one in nine women and the second deadly cancer after lung cancer among women and a major push factor in several levels is life-threatening. Surgical interventions often cause body wrecking (Eping et al. 2004 quoted from Sarafino 2009).

Fortunately, this cancer is premature and recognizable. It can reduce late referral and provide effective treatment to increase survival, reduce mortality and improve the patients' quality of life by providing specific strategies. The prevalence of this cancer is due to the process of developing breast cancer tissue in several stages and is classified as a multi-factorial disease. This is due to the development of cancer because of infectious, environmental and genetic factors in individuals (Rahimi & Heydari, 2012; Behzadi & Zamaniyan 2012).

Cancer endanger the various aspects of mental health and it exacerbates the individual's mental stress and confronts his mental health because of disturbance in the mental image of own body. These issues can also affect the psychological well-being of these individuals (Crook and Abolinin, 2004). Extensive researches have shown that people with better psychological well-being, certainly have the attributes of

happiness, pleasure of life, proper social communication and, in general, higher satisfaction with life and their quality of life is better than those who have low psychological well-being (Bahrami, 1995). Peg et al. (2006) research also shows that unpleasant life events can affect psychological well-being and lead to mental problems such as depression and anxiety (Peg et al. 2006). In general, the threat of self-esteem, loss of feeling freedom, physical comfort, denial, anger, depression, uncertainty, loneliness and a reduction in psychological well-being are the outcomes of cancer (Demato, 2004). Disappointment can threaten the physical health and psychological well-being of patients and affect the process of recovery and rehabilitation (Grossi et al., 2010). Therefore, one of the most important factors affecting health and longevity is the hope to recovery and continuity of life (Wilson, translated by Bajlan Farrokhi, 2009). Hope has biological effects and can have a positive effect on the control of pain and physical impairment of patients. Hope and expect activate the brain circuits and the release endorphin and enkephalin and thus reduce the pain in the body (Snyder et al., 2005; Seligman et al., 2000). Future orientation, positive expectations, purposefulness, realism, goal setting and internal communication are some of the most important features of hope (Benzin and Seyman, 1998).

The psychological hardiness is one of the factors contributing to the formation of compatibility and its levels (Kobasa 1979 and Medi 1973, quoted by Ismail Khani, 1998). The notion of strict character has been described as an explanation for the relationship between stress and illness in some people. They have assumed that hardiness prevents harmful effects of stress and thus, having a tough character protects a person from stress-related illnesses.

Kobasa (1983), using existential theories in personality, defines tenacity as a combination of beliefs about self and the world which consists of three components of commitment, control and struggle. A person who has a high commitment believes in the importance, value and meaning of who is and what activities he is doing. On the basis of this, he can find meaning for all what he does and provoke his own curiosity. People who are strong in the control component believe that life events are predictable and controllable, and believe that they are able to influence what is happening around them. Fitting people believe that change is a feature of the natural routine of life and the anticipation of transformation is a stimulus for growth and development, rather than a threat to real security. Different studies and researches have shown the positive role of social contacts in psychological and health adjustment. Physicians believe that social contacts affect the well-being of the individual and his improvement. In general, adaptation and coping with chronic diseases such as cancer in people with many facilitators such as flexibility, ability to solve a problem,

hope, courage, religious spirit, and social support are happening faster. The largest volume of hope therapy researches in the last few decades belongs to Seligman (2000), the father of positive psychology and Snyder (1994-2006). To them, frustration causes physical and mental illness. The results of Snyder's research on mental patients and some physical patients, such as cancer, show that many mental illnesses and some physical illnesses occur in response to loss of hope and hope therapy can improve the patients' mental health and quality of life. He notes that the use of hope can turn a patient center into a health center due to the tremendous effects on the emergence and treatment of major physical and psychological disorders in human health centers. Snyder believes that everyone has hopeful thinking capacity and it can be increased in people (Snyder, Averying, Anderson, 1991).

Ryff pattern was based on studying the mental health literature and stated that the components of the model are positive mental health criteria and this dimensions help to measure the level of well-being and the person' positive s performance (Biyabangard et al. 2004). Psychological well-being requires understanding the existential challenges of life. The psychological well-being approach examines the evolution observed against the existential challenges of life and heavily emphasizes human development. For example, it is so important the pursuing meaningful goals, transforming and advancing as an individual and establishing quality relationships with others. An extensive collection of research literature in 1950s and 1960s focused on analyzing the challenges and basic problems of life (Yasmine Nezhad, 2002).

Method

The research is an applied one in terms of application of the results. It is descriptive-correlation type in the form of structural equation model in terms of implementation. AMOS 18 software was used to examine the main purpose of the research. Data were analyzed by SPSS version 22 software. The statistical population of this study is all breast cancer patients in Sari City. Sample size was selected according to Cochran formula and 246 model components by random sampling method. Müller (1999) uses proportion of sample size to free parameter for estimation to determine the sample size. He estimates this ratio 5 to 1, the average 10 to 1 and the maximum limit 20 to 1. However, in the current study, considering the maximum limit of sample size to the number of variables observed and free parameters, the complexity of the model, the method of estimating free parameters (estimating the maximum correctness (needing a high sample volume), the amount of missing data (less than 5%), and the relationship between normality and sample size,

the principle is that the sample size (236 people) is sufficient to implement structural equation modeling. (Sharifi, Research Method, 2005).

$$n = \frac{\frac{z^2 pq}{d^2}}{1+\frac{1}{N}\left(\frac{z^2 pq}{d^2}-1\right)} = 246$$

Measurement Tools: Miller's Life Expectancy Questionnaire (OHS) was created by Miller and Powers in 1988. The initial questionnaire had 40 questions, which in the next versions increased to 48 questions. The purpose of this questionnaire is to measure the amount of hope in individuals. Validity: Miller reports that the questionnaire is desirable (Hosseini, 2006). The standard question score was used to determine the validity of this questionnaire; in this way, the total score of the questionnaire has correlated with the score of the standard question and it was determined that there is a significant positive relationship between two. Two questionnaires were used to determine the reliability of the questionnaire. The coefficients were 90.8 and 0.89, respectively. Also, in the research (Gholami et al. 2009), the reliability coefficients of life expectancy questionnaire were calculated using Cronbach's alpha Which for the whole scale is 0.95 and 0.94; it indicates the desirable reliability of the questionnaire (Gholami et al. 2009).

Ryff Psychological Well-Being Questionnaire (RSPWB)

Description of the Questionnaire: This scale was created by Carroll Reyff in 1989. The original form has 120 questions, but in later studies, shorter forms with 84 questions, 40 questions, and 18 questions have been prepared. In this research, the form with 84 questions was used. Validity: Validity of psychological well-being scales have been reported in several studies. Riff performed this questionnaire on an example of 331 people In order to standardize the psychological well-being scales. He has reported the coincidence coefficient of sub-scales of this questionnaire as follow: Autonomy = 0.76, environment control= 0.90, individual growth = 0.87, positive relationship with others = 0.91, purposeful life = 0.90 and self-acceptance = 0.93. The validity of sub-scale re-test method was also was in a 117-member sample and in 6-week interval between 0.81 and 0.85 (Hoomani, Kushki and Sa'emian, 2014). Bayani and Koochaki (2008) in a study, performed it on a sample of 145 students of Islamic Azad University in order to standardize the psychological well-being scales in Iran. Coefficient of validity was 0.82 using re-test method of Reef Psychological Well-being Scale and its acceptance subscales and subscales of self-acceptance, positive relationships with others, autonomy, environment control, purposeful life

and personal growth were gotten 0.71, 0.77, 0.78, 0.77, 0.77 and 0.78 respectively. They were statistically significant (p <0.001).

Ahwaz Psychological Hardiness Inventory (AHI)

Description of the questionnaire: This questionnaire was prepared and validated by Kiyamarsi (1998). The Ahwaz Psychological Hardiness Questionnaire is a 27-item pencil-paper self-report scale. Validity and reliability: To assess the reliability of this questionnaire, four standard tests such as anxiety, depression, self-development and structural definition of psychological hardiness have been used. The questionnaire of psychological hardiness has the significant relationship with anxiety questionnaire (r = -0.55), depression questionnaire (r = -0.62) self-fulfillment questionnaire (r = 0.55) and with structural definition of psychological hardiness (r = 0.51); this indicates the satisfactory credibility.

Berlin Social Support Questionnaire: This self-report questionnaire is designed primarily to examine the social support of cancer patients who have undergone surgery. It is prepared by Schwarzer and Schulz (2000) and has 52 phrases and evaluates 5 realm of perceived support: the need for support, searching support, received actual support and the supporter. This questionnaire was first translated into Persian and then corrected and verified by three professors of English and also was examined and finalized by 6 faculty members of Surgery and Psychiatry. Reliability: To test the reliability of the test-re-test questionnaire, 40 questionnaires were submitted to medical and paramedical students. Then, the questionnaire was again completed within 3 weeks by the same students; people were asked to use a 6-digit code instead of mentioning the name at both times of the completion of the questionnaire In order to avoid interrupting the results. Then, determination of the subjects' scores was analyzed by SPSS and the reliability of the questionnaire was confirmed at level 90% (Taghavi, 2006). Also, Cronbach's alpha coefficient for perceived support elements and need for support, support searching, supporter and received actual support were 0.78, 0.75, 0.79, 0.75 and 0.77 respectively.

Findings

A total of 246 patients with breast cancer participated in the study. Their average age was 53 ± 75 years old, range from 35 to 75 years old. Most female patients were married (72%).

Table 1: Mean and standard deviation of test scores in the psychological hardiness scale

factors	mean	Standard deviation	minimum	maximum
commitment	53.8	79.8	23	76
challenge	62.22	8.76	39	58
Control	63.28	9.49	43	81
Psychological hardiness	177.3	27.04	105	215

Table 2: Mean and standard deviation of tests scores on social support scale

factors	mean	Standard deviation	minimum	maximum
Parental social support	53.8	8.79	23	75
Friends' support	61.22	8.76	39	81
Perceived support	64.28	8.49	43	81

Marital Status

The results of studying the respondents' frequency of marital status of (Table 3-4) show that the majority of people, who account for 72% of the total sample, are married and 82% are single.

Table 3: Respondents' Frequency Table of Marital Status

marital status	Frequency	Frequency percentage
Married	150	72
Single	30	28
Total	180	100

Birth Place

The results obtained from the frequency table of the birth place indicate that half of the respondents (37%) were born in Sari City and 63% in other cities.

Living Place

According to the results of table 4, 35% of respondents reside in Sari City and the surrounding and 65% in other towns around Sari.

Table 4. Frequency table of respondents' living place

marital status	Frequency	Frequency percentage
Sari	85	35
Other towns	166	65
Total	246	100

Table 5 Values of Kolmogrov-Smirnov test for evaluation of variables normality

Variable	Statistics	Significance level
Commitment	1.16	0.132
Challenge	1.32	0.062
Control	1.31	0.065
Psychological Hardness	1.15	0.141
Positive attitude to oneself	1.20	0.114
Feeling of being valued	1.27	0.081
Hope	1.26	0.084
Helplessness	1.27	0.079
Life expectancy	1.29	0.072
Perceived Social Support	1.24	0.089
An important person's support in life	1.29	0.070
Family support	1.26	0.084
Friends' support	1.30	0.069
social support	1.26	0.095
Self-acceptance	1.34	0.068
Positive relationships with others	1.16	0.132
Environment control	1.32	0.062
Purposeful life	1.31	0.065
Individual growth	1.15	0.141
Psychological well-being	1.20	0.114

Table 6. Mean, standard deviation and matrix of correlation coefficients among research variables and their components

Variable	Psychological hardiness	Psychological well-being	Hope	Motivation	Life quality	Social support	Motivation
Psychological hardiness	1						
Psychological well-being	0.56**	1					
Hope	0.48**	0.34	1				
Social support	0.59**	0.43**	0.42**	0.35	0.37**	1	
mean	44.23	33.32	31.55	24.31	14.15	11.12	7.32
Standard deviation	5.53	4.43	0.42	0.35	0.37	1	

*P<0/05 **P< 0/01

** Significance at 99% confidence level (P <0.01)

* Significant at 95% confidence level (P> 05.05)

According to Table 6, the correlation matrix of the research variables was significant at 99% confidence level (P <0.01). The strongest significance

is assigned to the variables: psychological hardiness, psychological well-being and hope as the obvious variables of the research. The highest levls of correlation among hidden variables are assigned to the variables: social support, quality of life and motivation. The correlation coefficients of these variables are given in the following table and the significance of these correlation coefficients is determined by one or two stars. (Sarmad, 1997).

The results indicate that social support has a significant effect on psychological hardiness (P<0.5).

That is, social support has been able to play a significant role in mediating between psychological well-being and psychological hardiness. The severity of the effect of social support on psychological hardiness in the first phase is 0.221. In the second stage, the effect of social support on psychological well-being is 0.132 and is significant (P<0.5). The role of full mediation of social support is confirmed due to the significance of the impact of social support on hope, in the third stage. It is significant at p<0.5 level.

Table 7. The Effect of Mediation of Social Support on Psychological Hardiness and Psychological Well-being

Relationship type		B level	Standard error b	Standard coefficient (Beta)	T level	Significance level
Phase 1	Social support on psychological hardiness	0.221	0.47	0.149	2.32	0.023
Phase 2	Social support on psychological well-being	0.132	0.36	0.125	2.34	0.015
Phase 3	Social support on hope	0.134	0.038	0.124	2.35	0.013

Table 8. Estimation of Indirect Impact Factors and Total Intermediary Model of Relationships among Social Support Psychological Hardiness, Hope and Psychological Well-being

Variable		Impact	
Default	Criterion	indirect	total
Psychological hardiness	Psychological hardiness	-	0.72
Psychological hardiness	Social support	0.36	0.72
Hope	Social support (mediator variable)	0.34	0.35
Psychological well-being	Social support (mediator variable)	0.43	0.33

The estimation of the indirect impact factors and the total mediator model of the relationship among social support and psychological hardiness, psychological well-being and life expectancy represent the prediction of the existing relationships in the model directly and indirectly; that is, 0.72% Hardiness can be explained by social support, 0.35 % of life expectancy can be explained by the social support mediator and 0.33% Psychological well-being can be explained by the social support mediator.

Table 9. Indices related to psychological hardiness model and social support with hope of psychological well-being in breast cancer patients

index	coefficients β	Standardized coefficients β	T-ratio	P-level	Fitting index of RSMEA
Psychological Hardiness to Social Support	0.72	0.21	5.35	$P \leq 0/05$	$RSMEA \leq 0/0001$
Social support to psychological well-being	0.33	0.59	7.50	$P \leq 0/05$	$RSMEA \leq 0/0001$
Hope to social support	0.33	0.47	6.95	P≤0/05	$RSMEA \leq 0/0001$
Social support to psychological well-being	0.72	0.40	7.5	$P \leq 0/05$	$RSMEA \leq 0/0001$

According to table 9, indices of psychological hardiness and social support with life expectancy and psychological well-being of breast cancer patients, the strongest values of β coefficients belong to psychological hardiness to social support. Each of them is significant at level P<0.05.

Hypothesis: Default of mental hardiness and social support with psychological well-being and life expectancy

Table 10. Multivariate correlation coefficients along with coefficients of determination and changes of the coefficients of default variables psychological hardiness and social support with psychological well-being and life expectancy

Model	Multiple correlation coefficient	determination coefficient	modified determination coefficient	Default Standard Error	Changes of determination coefficient	Standard coefficients
First step	0.72	0.32	0.32	14.11	0.33	57%
Second step	0.73	0.43	0.42	13.02	0.10	43%
Third step	0.74	0.46	0.45	12.70	0.03	35%
Forth step	0.69	0.48	0.49	12.45	0.02	36%
Fifth step	0.73	0.51	0.50	12.17	0.02	33%
Sixth step	0.79	0.52	0.51	12.06	0.01	36%

In Table 10, the multi-variance correlation coefficients along with determination coefficients and changes in determination coefficients of the default variables of mental hardiness and social support with psychological well-being and hope as the default of model variables, these factors ultimately explain the psychological hardiness variance; Because the value of multiple correlation from the first step to the sixth step has risen. The results of stepwise regression represent default variables of research. Step-by-step regression is used when the researcher has several independent variables and wants to show its effects on the dependent variable.

Path Analysis

The table below shows the scope of index domain and the good fitting.

fitting Index	good fitting	Acceptable fitting
P-value	P<0.05	0.05≤P≤0.1
χ^2/df	0≤ χ^2/df≤2	2≤ χ^2/df≤3
RMSEA	0≤RMSEA≤0.05	0.05≤RMSEA≤0.08
GFI	0.95≤GFI≤1	0.9≤GFI≤0.95
AGFI	0.9≤AGFI≤1	0.85≤AGFI≤0.9

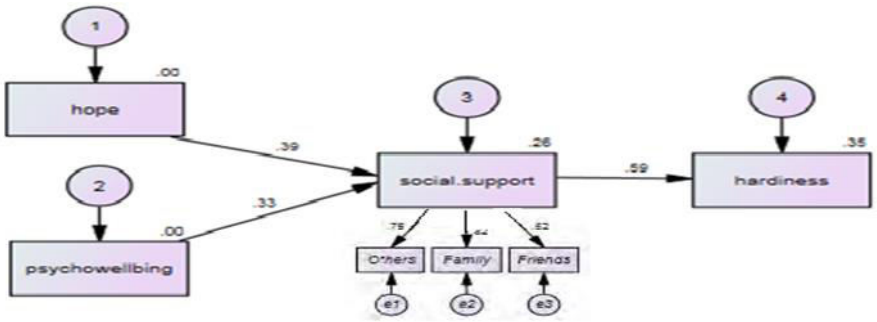

Diagram 1: path analysis and coefficients of the mediator variable and dependent variable and explicit research variables

There is a significant relationship between psychological well-being and psychological hardiness with the mediating role of social support

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Table 12. Examining the standard coefficient and significance of forth hypothesis

	Coefficient of path	P-value	Result of test
psychological well-being---> social support	0.33	0.000	significant
social support---> psychological hardiness	0.59	0.000	significant
well-being--->hope	0.46	0.000	significant

According to P value at 0.05 level, the research hypothesis is confirmed and impact factor of psychological hardiness on the basis of psychological well-being with mediating of social support is 0.59.

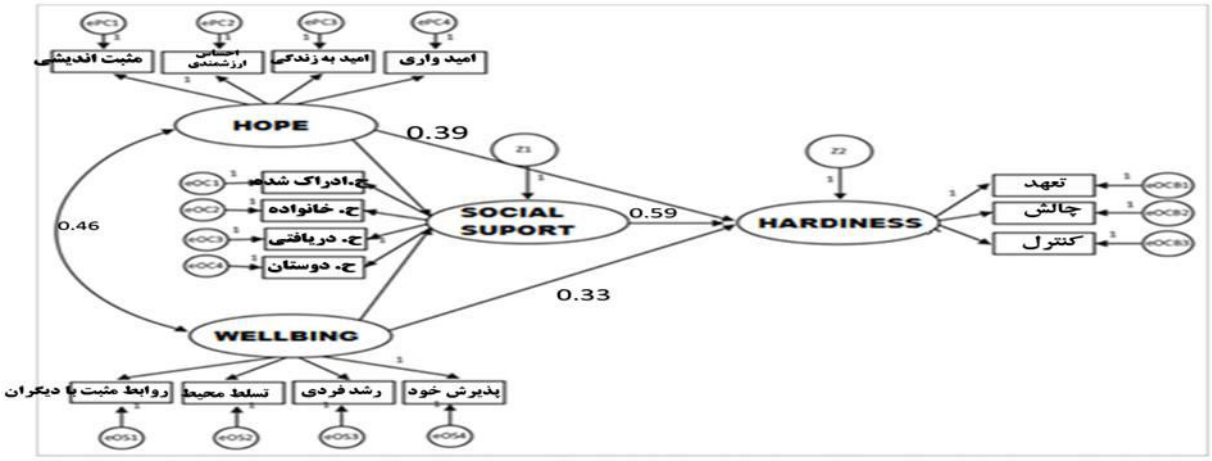

Diagram 2. Final model of the research with mediating of social support

Table 13. Direct standard coefficients of conceptual model of relationships between psychological hardiness and psychological well-being, social support and hope.

CHI-SQUARE	DF	CHI-SQUARE/df	P-VALUE	RMSEA	GFI	AGFI
8.3	3	2.76	0.000	0.077	0.984	0.952

Fitting Model

The purpose of fitting the model is to what extent a theoretical or conceptual model is adapted to the data obtained from the statistical society of consistency.

Examining the fitting model: using indices RMSEA: Mean Squares Root of Approximation Error (Less than 0.80 Acceptable), chi-square: (not significant), chi-square /df (less than 3), GFI: (greater than 0.90), AGFI: (greater than 0.90), NFI: (greater than 0.90), NNFI: (greater than 0.90), CFI: (greater than 0.90), P-value index: (less than 0.05), RMSEA index is between 0.05 and 0.08. GFI index is between 0.95 and 1. AGFI is between 0.9 and 1.

Table 14. Indices of examining fitting model

Indices	values
chi-square	8.3
df degree freedom	3
chi-square/ df	2.76
RMSEA	0.077
GFI	0.984
CFI	0.956
AGFI	0.952
CMIN	2.2
P-value	0.000

Verification factor analysis and total model estimation:

According to the laser output of x2 value, the chi-square to the degree freedom is 3, which is the appropriate value. The low level of this indicator indicates a slight difference between the conceptual model of the research and the observed data of the research.

Also, the output of RMSEA equal to 0.077, for the model, shows that it is less than 0.08. In addition to x2, RMSEA index is lower, the model has a better fitting.

Model Verification

Corresponding to the indices values of Table 14, the model has a favorable fitting. The value of chi-square to df is less than three. Also, RMSEA value is 0.077 and less than 0.08. Indices (GFI, AGFI, CFI), it means the variance values and models covariance are all greater than 0.90. Therefore, the model is well-matched and approved.

Conclusion

The present study aims to explain the psychological hardiness using social support variables, hope and psychological well-being of patients with breast cancer through structural equation modeling.

In this research, it was tested a conceptual model of psychological well-being, psychological hardiness, mediation of social support and hope in women with breast cancer. The results indicated the fitting of the suggested conceptual model with the data. In general, it can be said that in women with breast cancer, psychological hardiness is explained through direct impact and the role of mediator of social support (direct and indirect impact of psychological well-being and hope). This model explains 59% of psychological hardiness variance through social support and 33% of psychological well-being through social support mediation (P <0.05). Social support as the main variables affects the hope of women with breast cancer (Kuman & Goldman, 2003). Hence, it can be said that the social support is a mediator of psychological hardiness and social support leads to adapted strategies to tolerate suffering and pain from patients; because, according to some reports, life-threatening illnesses like cancer, cause disappointment and loneliness as well as changing the way patients and families' life and social support can greatly help to cope with illness (Medi et al., 1990). A total of 246 patients with breast cancer participated in the study.

A total of 246 patients with breast cancer participated in the study. Their average age was 53 ± 75 years old, range from 35 to 75 years. Most female patients were married (72%). 28 percent were single. the table of frequency of people's place of birth shows that half of the respondents (35%) were born in Sari City and the towns of Mazandaran Province and (65%) in other cities. On the other hand, along with the positive role of spiritual well-being on social

support, the findings suggest that stubborn people are more active and resolute in interpersonal communication and tend to be close to those who have a high hardiness (Medi et al., 1990). Thus, it can be said that psychological hardiness based on social support l05eads to a rise in the level of positive thinking and interpretation based on the challenge (not the threat) of stressful situations and hence the individual may be more likely to seek the support of others, and especially other hardliners, in finding efficient solutions. The significance of this finding is that, according to reports, receiving support from others among cancer patients is such as a protection against the negative outcomes of illness and treatment. Psychological hardiness and psychological well-being in patients with breast cancer, therefore, have a strong relationship with patient's psychological function (Helgeson et al., 1996). Psychological hardiness and psychological well-being in patients with breast cancer have a strong relationship with patient's psychological function (Helgeson et al. 1996).

The results of Table 11 show that there is a positive and significant relationship between psychological hardiness with psychological well-being and social support. Social support with all components of hope and hardiness has a significant relationship with psychological well-being and is positive for all relationships (P> 0.05).

The results of this research are based on the researches done by Benson Ward (2010), Kazemi (2011), Wye and Williams (1992), Walt and August Dieter (1984), Watzinger et al. 2003), Genes et al. (2002) Kobasa, Medi and the priest (1982).

The results of Table 9 and 10 show that there is a significant and positive relationship between the components of psychological hardiness and social support; it means that social support tests, especially the support of family and friends, have been predicted direct and positive through psychological hardness tests. The most correlation between the components of social support and psychological hardiness belong to family support, the challenge 0.155 and perceived support 0.174. Therefore, there is a significant relationship between social support and psychological hardiness (significance at 95% confidence level).

Social support is more effective in maintaining health when it is high in psychological hardiness. Psychological hardiness directly affects social compatibility through social support.

Previous research on cancer has emphasized the negative psychological experiences of cancer, including anxiety (Hill, Helcombe, Clarke, Boot Bay, Heinx, Fisher and Associates, 2011), depression (Mousavi and Mehdikhah, 2008; Mashhadi, Shakiba and Zakeri, 2013) and distress (Firoozi, Basharat, Rahimian Booger, 2013). Studies have also shown that a high proportion of patients with cancer have reported positive changes in the

disease and most cancer patients described some of the benefits of their cancer experiences when faced with death. Individuals may re-evaluate goals and priorities and then come out with more pleasure with life, spirituality, and relationships (Rinaldez, Peak Ham and Lynch, 2010; Cordova, Cunningham, Carlson and Andricowski, 2001). Tedsky introduced the term "post-traumatic development" to illustrate the positive psychological development in the post-experiential life-challenge (Tedsky and Calhoun, 2004).

The direct standard coefficients of Tables 12, 14 and 13 and diagrams 1 and 2 of the conceptual model of psychological hardiness relationships with psychological well-being and life expectancy through mediation of social support, women with breast cancer (GFI=0.984, AGFI=0.952, CFI=0.956, RMSEA=0.077, CMIN=2.2 P<0.000) corresponding to the values of the indicators in Table 4-25, has a good fitting.

The value of chi-square is less than three. Also, the RMSEA value is 0.077 and less than 0.08 and indices GFI, AGFI and CFI are all greater than 0.90. So this model is well-fitted and approved. Regarding the output of the laser, the value x2, the chi-square to the degree of freedom is 3, which is the appropriate value. The low level of this index indicates a slight difference between the conceptual model of the research with the observed data of the research. In addition to x2, the RMSEA index is lower, the model has a better fitting. The study of Bagheri et al. (2007), which was conducted on the quality of cancer patients' life, showed that social support significantly increase the quality of patients' life (P <0.05). This result is consistent with the results of the present study, which shows that the emotional dimension of social support is effective on psychological hardiness and life expectancy.

The results of Table 9 and10 show that there is a significant relationship between life expectancy and psychological hardiness with the role of mediator of social support; because the standard social support coefficients to hardiness is 0.59 which is significant at the P-value level (0.000); the standard life expectancy coefficients to social support is 0.39 which is significant at P-value level (0.000). Considering the value of P at the significance level of 0.05, the research hypothesis is confirmed and the coefficient of the effect of psychological hardiness on the basis of life expectancy with the mediation of social support is equal to 0.59. The results of this study are based on the results of researches done by Levy et al. (1999), Turner Couber et al. (2008), Mantig et al. (2005), Barker et al. (1995), Berman et al (2006), Piterung and Barker (2010) Alferi et al. (2001).

In women with breast cancer, the positive effect of psychological hardiness and hope with psychological well-being can be explained through the role of social support mediation. Also, using the model of this research can be

recommended as a training-therapeutic subject for physicians and nurses.

This model is effective for health promotion and coping with the disease in breast cancer patients and has acceptable fitting. In the treatment process, social team work, especially the health psychologists, are committed with supportive psychotherapy of breast cancer patients. Therefore, considering the importance of maintaining and improving the quality of life of patients with breast cancer, it is recommended studying of mental hardiness, social support, hope with psychological well-being and intervention to increase the mental health of these patients to improve and adapt to the disease. In the present study, there was a significant positive relationship between psychological hardiness, psychological well-being and hope with direct mediation of social support. The patients with better psychological hardiness had better health and better quality of life.

References

- Azad, H. (2012). Psychopathology. Twelve Edition, Tehran, Besat Publishing, (2012). Support: The most basic need of cancer patients when confronted with a diagnosis of the disease. Journal of Mazandaran University of Medical Sciences, Vol.2, No. 89, pp. 21-30

- Bahari, F. (2011). The foundations of hope and hope therapy. Tehran: Dangeh Publishing

- Besharat, M.A. Pourhossein, R. Karimi K. (2005). Studying the Effect of Hard Work on Mental Health and Academic Achievement. Journal of Psychological Sciences, No. 13, Volume 3, Pages 106-122

- Pedram, M. Mohammadi M. Nazari Q. Rita, N. (2010). The Effectiveness of Cognitive-Behavioral Therapy Group for therapy of Anxiety Disorders, Depression and Hope in Patients with Breast Cancer. Journal of Research-science in Women and Society, Volume 1, Issue 4, Pages 61-75

- Pourafkari, N. (1994). Comprehensive culture of psychology and psychiatry. Tehran. Roshd

- Taghaddosi, M. H. Abdi, N. Shahsavari S. (2011). Promoting health in cancer patients using a scientific learning method. Journal of Health Research. Seventh Year. No. 4.

- Hosseinian, E. Sudani M. Mehrabizadeh Honarman M. (2009). Effectiveness of Group mean Therapeutic on Life expectancy in Cancer Patients. Journal of Behavioral Sciences, Vol. 3, No. 4, Pages 287-292

- Damothe, M. Robin (2008). Health Psychology. (Translated by Kaviyani M. et al. under the supervision of Hashemian, Kianoush). Volume 1, Tehran. Samt Publication

- Saduk, B. Saduk V. (2003). Kaplan Medical Summary. Translated by Raza'i (2014). Tehran. Arjomand

- Sarafino, Edward P. (2012). Health Psychology. Translated by Elahe Mirzai, Tehran, Roshd Publishing

- Sobhani, S. (2011). studying the Effectiveness of Cognitive-Behavioral Group Therapy on Life expectancy and Resilience in Cancer Patients. Master's Degree in Public Psychology, Islamic Azad University, Sari

- Sanderson, C. A. (2013). Health Psychology. (Translated by Hossein Jahromi). Karaj: Sarafraz Publication

- Kaplan, H. Sadook, V. (2008). Summary of psychiatry. (Translated by Farzin Rezaee). Tehran. Arjmand Publications

- Lotfi Kashani F. Vaziri, S. Zain o-Abedini N. Zain El Abedini N. (2013). The Effectiveness of Group Therapy in Reducing Psychological Distress in Women with Breast Cancer. Journal of Applied Psychology, Vol. 7, No. 4, Pages 58-45

- Loongo, F. Casper H. Gemyson L. (2012). Harrison Principles of Internal Medicine 2012: Oncology Diseases. (Translated by Mehdi Azimi et al.) (2012), Tehran: Arjmand Publications

- Lahsaie Zadeh, A. Moradi G. (2007). the relationship between social capital and mental health in immigrants. Research-science Journal of Social Welfare, No. 26, pp. 161-180

- Milani Far B. (2007). Psychology of exceptional children and adolescents. Tehran, Gomes publishing house

- Mardanihamuleh M. Shahrakvahed A. (2010). Relationship between mental health and quality of life in cancer patients. Journal of Shaheed Sadouy University of Medical Sciences, Yazd, Volume 18, Issue 2, pp. 111-117

- Mehri Nejad A. Rajabi Moghadam S. (2012). Examining the Effectiveness of Therapy on Increasing the Life of Addicts with Short-Term Quit. Quarterly Journal of Clinical Psychology, Vol. 2, No. 8, pp. 30-41

- Mohammadian A. I. Asgari P. Hasanzadeh R. Ahadi H. Naderi F. (2016). Effectiveness of cognitive-behavioral group therapy on increasing the life expectancy of people with gastric cancer. Journal of Babol University of Medical Sciences. Vol. 18, No. 6, Pages 42-46

- Mohabat Bahar S. Golzari M. Akbari M. E. Moradi Jo M. (2015). The Effectiveness of mean Therapy in a Group Method in Reducing Despair in Women with Breast Cancer. Iranian Journal of Breast Disease, Issue 1, pp. 51-59

- Naderi F. Hosseini M. (2010). The relationship between life expectancy and psychological hardiness in male and female students of Islamic Azad University of Gachsaran. Journal of Women and Society (Former Women's Sociology), Volume 1, Issue 2, Pages 123-141

- Nasri S. Baraheni M. T. Kayhani M. (2001). The Effect of Cognitive-Behavioral Interventions on Reducing the Psychological Side Effects in Cancer Patients and Improving their Coping Strategies. Journal of Psychological Research, Vol. 6, No. 3

- Navabinejad S. (2005). Consultation with the Spiritual Approach. Proceedings of the Institute of Psychiatry, Tehran, Iran

- Wilson P. (2009). Little Hope Book: Learning Thoughts for the New Millennium. (Translated by Vina Bajlan Farokhi). Tehran: Farsan publishing

- White K. A. (2010). Cognitive-Behavioral Therapy for Chronic Medical Diseases. A Practical Guide to Evaluation and Treatment. (Translated by Molody Reza, Fatahi Katayoun). Tehran: Arjmand Publication (Original Publication 2001)

- Hallinger, R. (2003). Psychopathology. Volume II, translated by Yahya Seyyed Mohammadi (2011), Tehran. Ravan publication

- Poursardar N. Poursardar F. Panahandeh A. Sangari A. A. & Abdi Zarrin S. The Effect of Optimism (Positive Thinking) on Mental Health and Life Satisfaction, a Psychological Model of Wakim's Well-Being, 2013, Volume 16, Number 1, pp 42-49

- Rahimian Booger I. (2012) "The role of the prediction of happiness, optimism and demographic status in the behavior of health related behaviors", Volume 8, Issue 1, 2012, 17-23

- Khanlarzadeh, F. Asgari K. & Amini (2015). Evaluation of psychiatric functions in patients with type 2 diabetes. Journal of the Faculty of Medicine, Mashhad University of Medical Sciences, 58 (8), 459-465

- Shafiei H. Hossefi A. (2012). Effect of natural optimism on the bias of attention to emotional faces. Magazine of Principles of Mental Health, 14 (56), 13-302

- Alizadeh, G. Kurd Noghabi & Nazari (2014). The Effect of Optimistic Education in Storytelling Method on Increasing the Optimism of Students. Journal of Clinical Psychology, 6 (1), 103-112

- Lashani, Shaieri, Asghari Moghaddam & Golzarian (2012). Effect of thanking Strategies on Positive Affection, Happiness and Optimism. Iranian Journal of Psychiatry and Clinical Psychology, 18 (2), 157-166

- Mahmoudian H. Safarian H. Hashemzadeh Vaez, H. Mir Mohammad Tabar S. Rezvani Far, & Shirin (2015). Studying the relationship between the orientation of life and the goals of progress with the satisfaction of students' life. Educational Psychology, 11 (35), 118-129

Validi Pak A. Azar, Khaledi, Shadyeh and Moienimanesh (2015), the Effectiveness of Mindfulness Training on Increasing Optimism in

Diabetic Pregnant Women. Research-seientific Journal of Psychological Health, 4 (14), 40-55

- Seligman M. (1997). Learned Optimism. Translated by Karimi and Afraz (2015). Tehran. Green Spring Publishing 2. Seligman Martin (2004). Inner happiness. Translated by Tabrizi, Karimi and Niloufari (2014), Tehran, Danjeh Publishing House. 3. Schultz, Devon (2004). Theories of personality. Translated by Seyyed Mohammadi (2008). Tehran. Publish ed. 4. Karimi, Ramin (2009). The theory of learned helplessness. Tehran. Danjeh Publishing House

- Schultz D. Psychology of Perfection: Healthy Personality Patterns, translated by Khatidel Githi, Tehran, Pikan, 2009

- Curtis, Anthony James, Health Psychology, translated by Ali Fathi Ashtiani et al. Tehran, Besat Publishing House, 2003

- Cohen Thomas S. structure of world scientific revolution, translation: Ahmad Aram, Tehran, Soroush, 1990

- Gerdie, F. et al. "The relationship between mental health and irrational thoughts in students of Shahid Beheshti University", Psychological Research, vol. 16, winter 2004, p. 45-61

- Brieger GH.(1997). The development of surgery.Historical aspects important in the origin and development of modern surgical science. In: Sabiston DC, Lyerly

- Baykal U, Seren S, Sokmen S.(2009). A description of oncology nurses' working conditions in Turkey.Eur J OncolNurs; 13(5): 368 -375.

- Brooks, M.V. (2003). Health-related hardiness and chronic illness. Nursing Forum, 38,11-20.

- Biyabangard E, Javadi F. (2004). Psychological health among the young and adolscences]. Social Welfare, 1(4): 52-68 (Persian).

- Banson W. (2006). The role of hope and study skills in predicting test anxiety level of university students highschool and psychological health, self-esteem, positive thinking and social communication. These is for degree of master

- Kobasa,S.C, Maddi, S.R,& Kahn,S. (1982).Hardiness and health: A prospective study. Journal of Personality and Social Psychology,42,168-177.

- Kobasa SC.(1979). Stressful life events, personality, and health: an inquiry into hardiness. J Pers Soc Psychol;37(1):1–11.

- Kubler- Ross, E. (1969). On death and duing. New York: Macmillan.

- Keyes, C.L.M. & Shapiro, A. (2004). Social well-being in the U.S.:A Descriptive epidemiology. University of Chicago Press.

- Kruk J,Aboul-Enein HY. (2004). Psychological stress and the risk of breast cancer: a case–control study.

Cancer detection and prevention. 31;28(6):399-408.

- Keyes, C.L.M. (1998). Social well-being. Social Psychology Quarterly, 61, 121-140.

- Keyes, C.L.M. (2002). The mental health continuum: From languishing to flourishing in life. Journal of Health and Social Research, 43, 207-222.

- Keyes, C.L.M. (2003). Complete mental health: An agenda for the 21st century, Ryff & Ronald Publication.

- Lazarus RS.(1999). Stress and emotion: A new synthesis. London, UK: Free Association Books.

- Lechner SC, Antoni MH, Lydston D, et al.(2003).Cognitive–behavioral interventions improve quality of life in women with AIDS. J Psychosom Res; 54(3): 253-261.

- Levy M. (2008). Cancer fatigue: A review for psychiatrists. Gen Hosp Psychiatry; 30(3): 233-244.

- Lucas, R.E., & Diener,E, (2004). Well-being In C. spielberger (Ed). Encyclopedia of Applied Psychology. New bury Park. CA .

- Levy,S.M. Herberman, R.B. Maluish, A.M. Schlien, B & Ippmak, M. (1985). Prognostic risk assessment in primary brimary breast cancer by behavioral and immunological parameters. Health Psychology, 4, 99-113.

- Lee, V., Cohen, S. R., (2013). Meaning-making intervention during breast or colorectal cancer treatment improves self-esteem, optimism, and self-efficacy. Social Science & Medicine,V.62, Is12, P.3133-3145.

- Lee, E.N.(1991).The relationship between hardiness and psychosocial adjustment of persons with colostomies. Kanho-Hakhoe-chi, 21,218-229. Abstract.

- Levy,E.M, Cottrell,M.C,& Black,P.H.(1989).Psychological and immunolo -gical associations in men with AIDS pursuing a macrobiotic as an alternative therapy Brain. Behavior and Immunology,3,175-182.

- Lee EH. (2001). Fatigue and hope: relationships to psychosocial adjustment in Korean women with breast cancer. Appl Nurs Res; 14(2): 87-93.

- Laszelo, J. (1987). Understanding cancer. New York: Harper & Row.

- Lopez, S.J. Snyder, C. R & Pedrotti, J. T. (2003). Hope: Many definitions, many measures, In C. R. Snyder & S. J. Lopez (Eds), Positive psychological

- Ruini C, Vescovelli F, Albieri E.(2013). Post-traumatic growth in breast cancer survivors: new insights into its relationships with well-being and distress. J Clin Psychol Med Settings;20(3):383–91.

- Ruini, C. Ottlini, F. Rafanelli, C. Toosani, E. Ryff, CD & Fava, GA. (2003). The Relationship of

Psychological well-being to distress and personality. Psychother Psychosom, 72: 268-275.

- Raleigh, H.(1992). Sources of hope in choronic illness. Oncol Nurs Forum; 19(3):443 – 448.

- Rahimi F, Heidari M. (2012). Time trend analysis of stomach cancer incidence in the west of iran. J Health Dev; 1(2): 100-11. [In Persian]

- Rustoen T, Cooper BA, Miaskowski C.(2010). The importance of hope as a mediator of psychological distress and life satisfaction in a community sample of cancer patients. Cancer Nurs; 33(4): 258-67.

- Ryff, C.D., Singer, B.H., & Love, G.D., (1998). Positive health: Connecting Well-being With Biology, Philosophical Transactions of the Royal Society of London, 359: 1384-1394.

- Ransom S, Jacobsen PB, Schmidt JE and Andrykowski MA.(2008). Relationship of problem focused coping strategies to change in quality of life following treatment for early stage breast cancer. J Pain Symptom Manag; 30(3): 243-253.

- Rayan, R.M. & Deci. E.L. (2001). on happiness and human Potentials: A review of research an hedonic and eudemonic Well-being. Annual Review of psychology 52.

- Reeve, J. (2005). Understanding motivation and emotion. New York:Wiley.

Richardson, G. E. (2002). The metatheory of resilience and resiliency. Journal of clinical psychology, 58(3), 307-321

-Rhode Walt, F, & Agustsdottir, S (1984) .On the relationship of hardiness to type A behavior pattern, Journal of Research in Personality,18,212-223.

- Ryff, C. D. (1989). Happiness is everything or it is explorations on the meaning of psychological well-being. Journal of personality and social psychology, 57, 1069-1081.

Ryff, C. D., Singer, B., Love, G. D., & Essex, M. J. (1998). Resilience in adulthood and later life: 30. Cornman JC, Goldman N, Glei D, Weinstein M, Chang M. Social ties and perceived support: Two dimensions of social

relationships and health among the elderly in Taiwan. Journal of Aging and Health 2003; 15(4): 616-644.

- Selye, H. (1956). The stress of life. New york: Mc graw-hill.

- Scligman M.(2000).positive psychology. An Introduction American psychologist ; 221-278.

- Seligman M. walker ,E ,F, & Rosenhan ,D ,L.(2002). Relaxtion psychology. New York: W.W. Norton & company.

- Seo M, Tamura K, Shijo H, Morioka E, Ikegame C, Hirasako K. Telling the diagnosis to cancer patients in Japan: attitude and perception of patients, physicians and nurses. Palliat Med 2000; 14(2): 105-110.

-Shojakazemi M, Saadati M. Examine the impact of logotherapy dimensions education (Responsibility, freedom, value, etc.) to reduce hopelessness in women with Cancer. Iranian Journal of Breast Diseases 1389; 3(1,2):40-8.

-Seligman, M.., & Csikszentmihalyi, M. (2000). Positive psychology: An introduction. American Psychological Association, 55, 5-14.

- Sheard, M., & Golby, J., (2007). Hardiness and Undergraduate Academic

Study: The Moderating Role of Commitment, Journal of Personality and Individual Differences,Vol. 43, No. 35, pp. 579-588.

- Spillers RL, Wellisch DK, Kim Y, Matthews BA, Baker F. (2008). Family caregivers and guilt in the context of cancer care. Psychosomatics; 49(6): 511-9.

- Seo M, Tamura K, Shijo H, Morioka E, Ikegame C, Hirasako K. (2000). Telling the diagnosis to cancer patients in Japan: attitude and perception of patients, physicians and nurses. Palliat Med; 14(2): 105-110.

-Shoae Kazemi M, Saadat M. (2010). The effect of education Logotherapy (responsibility, freedom, value, etc.) to reduce the disappointment of women with breast cancer. Quarterly breast disease Iran, 2:24-84.

- Simpson M.R. (2001). " God Healed Me": Religious Responses to Events in the Cancer Trajectory of Breast Cancer Survivors in Central Appalachia: University of Kentucky.

- Staudinger, U. M., Dörner, T., & Mickler, C. (2005). Wisdom andpersonality. In R. Sternberg, J., Jordan(Eds), A‹handbook of wisdom. Psychological perspectives (pp. 191-219). New York: Cambridge University Press

Review the Spatial Distribution Pattern of Diabetes in Hashtrood based on Geographic Information System (GIS)

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Abstract

Introduction: In recent years, Geographic Information Systems (GIS) to discuss functionality such as collecting, display, management and spatial analysis, potential for Disease Control and Prevention and planning in the health care field have. GIS helps health plan, prevent and treat the different regions of the country should be developed. For better control of diabetes, as one of the most common diseases in the country, in this paper, spatial distribution pattern of diabetes in Hashtrood be discussed. The spatial pattern of the disease in the city Hashtrood through spatial statistical methods is one of the objectives of this study.

Methods: Data and data from Statistics diabetes in Hashtrood health centers were prepared. And then based on address records of people with diabetes through the GPS coordinates recorded through geographic information system (GIS) was applied.

Findings: In this study, patients with diabetes research community in the city Hashtrood is examined. The results of this study showed that patients diagnosed diabetes in different years show a significant trend. Twenty percent of diabetics in urban areas with high concentrations is Hashtrood. Northern and eastern regions of Hashtrood Health Network, respectively distribution patterns diabetics are dense and weak. The percentage of peoples with diabetes in urban and rural areas were equal to 2.51 and 0/58, respectively.

Conclusion: The cumulative pattern of diabetes in the northern city Hashtrood could be due to the high population density in the area. GIS spatial database for use as an effective system for patients. According to the results obtained from the use of GIS in the Department of Health

Keywords: Diabetes, geographic information systems (GIS), spatial statistics, spatial database

Introduction

Studying regional geography has special importance in review the diseases, as occurrence of some depend on geographical situations of the region. On one hand, the presence of natural barriers such as mountains and seas and on other hand dependency of some disease factors on environmental and climate condition have restricted some diseases to specific regions of the earth [1].

The geographic information system allows to provide and image spatial and thematic data in frame of plan, table and diagram, edition and updating of data as well as possibility of using available data in different objects trend and based on diverse demands of users in addition to accurate and fast approach to required data in broad mass. Also, it pave the way for introduce and present capabilities and different potentials as well as, recognize the research the research gaps of different geographic regions. GIS is an information system that process source spatial data and geographic data and obtains data related to phenomenons which correlated with spatial situation [2].

Unfortunately, there wasn't found any study on conducted research level in field of analysis and organization of patient's medical data in health centers based on GIS system, Yet, researchers, whether in inside or outside of country, exploited it in medical research which will be referred them at the following. John Snow, applied mapping issue of patients in capital of England, in London practically. The present study could and determine and situations of individuals suffering from Cholera on city level, then found through study and review that it corresponds with fixed sections of city which use potable water. He could determined the origin of pollution related with Cholera which transfer through potable water, thus counteracted it's effect [3].

Green and his colleagues, reviewed the incidence of disease in urban regions and analyzed the relationship between disease and parameters such as living level, education, addition, income by GIS [4]. They found a partial direct relation between economic-social low level and environment quality with high incidence of diabetic.

Winder & his colleagues (2013) also considered the lack of access to fresh fruits, vegetables and nutrients of low-income class as a one of diabetes's reasons, and simulated the result of health policies on these foods availability based on a basic factor. For example, they could locate required centers for suitable foods in Buffalo city through GIS and designated population to them [5].

Grabsic & his colleagues (2014), in their research, prepared population distribution maps of diabetes in USA. One of the

applied major source in their statistic data, is the controlled system of behavioral risk-taking standards. This system contacted randomly with individuals of different resident regions and asked them, whether up to now, has said by a doctor which you have diabetes? Then, they used spatial analysis methods in GIS in order to determine different risk, sensitive or low-risk regions [6].

Davidson (2004), reviewed incidence diabetes through GIS in Ohio province. The results showed increased incidence of diabetes in given province. Also, incidence distribution of diabetes correlated high with economical and social factors such as poverty [7].

Dena Garsia (2011) in a research under subject of "applied programs of GIS in analysis, control and prevention of diabetes", reviewed the incidence of diabetes in different provinces of America. The results showed that GIS could help significantly to health and hygiene experts in determination of regions exposed to diabetes and also determine the health, prevention, evaluation plans policy [8].

Omi and his colleagues (2013), following related data to diabetics in 83 sections of Michigan province, reviewed spatial trend of diabetes in this province. The results showed that incidence of diabetes increased from 7.7 percent in 2004 to 9.2 percent in 2009 [9].

Vahidnia & his colleagues (2015) (1394), prepared consistent GIS map of disease distribution in research under subject of "the role of the GIS system in analysis of diabetes based on available data about diabetes state in the country" and GIS analysis and determined sensitive provinces to disease incidence. Also, the main other analysis included interpolation analysis, point patterns clustering, ecological analysis and regional patterns analysis and sensitive regional clustering [10].

Monitoring and evaluation are of key elements of health plans and GIS could facilitate monitoring and evaluation of plans effects through showing diseases distribution situation and health problems, services provision method and available resources situation in fixed temporal and spatial conditions. Diabetes is the most common endocrine disorders condition and also one of common non-communicable in the worldly society health [9]. And also it is one of the most common metabolic glands disorders of childhood [12]. In field of type 1 diabetes also, the low incidence age and incidence rate in the world is warning.

In general, every year, one percent is added to statistics of diabetics in the country and because of being young population and occurrence of disease, in particular, type 2 diabetes in old ages [13] and while about 4 million persons (5-7 percent) suffering from diabetes in

country which it's side effects involve total of body organs, thus Iran and developing countries face with diabetes epidemy, that includes one of the major treatment health problems of the world [14]. Therefore, incidence of diabetes and its complications, are along with plenty economical-social consequences and its acute and chronic complications demand for significant charges by patients and treatment-health system of the society [15]. Thus, the first step in resolving problems is to record accurately the situation of diabetics.

Methodology

Hashtrood County is a large county in East Azerbaijan Province in Iran. The capital of the county is Hashtrood. At the 2006 census, the county's population was 64,611 which about 60% of them live in rural areas. The present paper is of descriptive and analytical type. The research population, based on inclusion criteria, consists of individuals suffering from types 1 & 2 diabetes, diabetics during 2010-2015 and diabetics in area of Hashtrood. Total of diabetics, were located based on defined criteria through GPS system by spatial accuracy 6-16m. Also, the length and width data in GIS were calibrated on UTM page and bias became less and less. The other issue is the diabetics immigration which based on care of patients forms, the partial situation of them extracted and following designation of coordinate location through GPS registered in GIS system.

Based on fixed objects, the style, objective variables, statistic method suitable with object were explained briefly. The spatial distribution of diabetics was completed based on geographic coordinates through GPS and demodulating it on spatial database GIS. Then, the incidence of diabetics was determined in Hashtrood based on spatial statistic methods in GIS. For this reason, hotspot analysis statistic along with directional distribution functions have been used.

Moran's index & Getis

In general, there are different indices in order to measure spatial correlation. In the present research, Moran's index was used to review the spatial distribution of location quality values. Moran's statistic is one of the best indices to design clustering. This statistic determines whether adjacent regions have similar or unsimilar values. Also, Getis index was used to determine significance of cumulative pattern of diabetes condition in Hashtrood. This index designates whether desired area is located near areas with higher (G_i^* for positive values) or lower values (G_i^* for negative values) than general mean or not [16].

Findings

The review of diabetics' frequency in Hashtrood shows 79.04 percent among the women in study years and 21.70 percent among the males. Figure (1) shows the location of diabetics in Hashtrood based on extracted spatial data through GPS in GIS system.

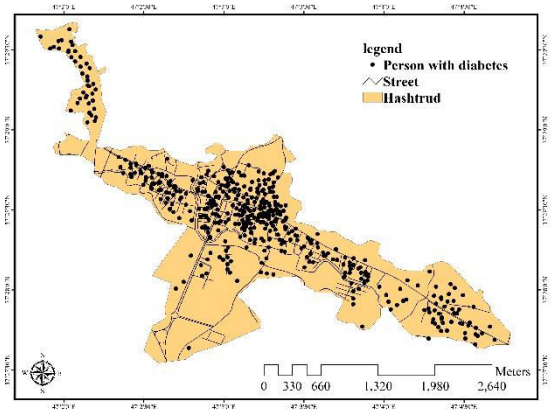

Fig (1): location of diabetics in Hashtrood

Also results of Moran's index in related with spatial distribution of diabetics in Hashtrood was shown in Fig (2). In particular, positive Moran is observed among the diabetics in fig (2) which indicate non-branching of Moran's index. The negative Moran's Index shows random pattern which spatial distribution pattern of diabetics follows it (Moran's I=-2.636). In other words, couldn't approve the cumulativeness of diabetics in both sexs.

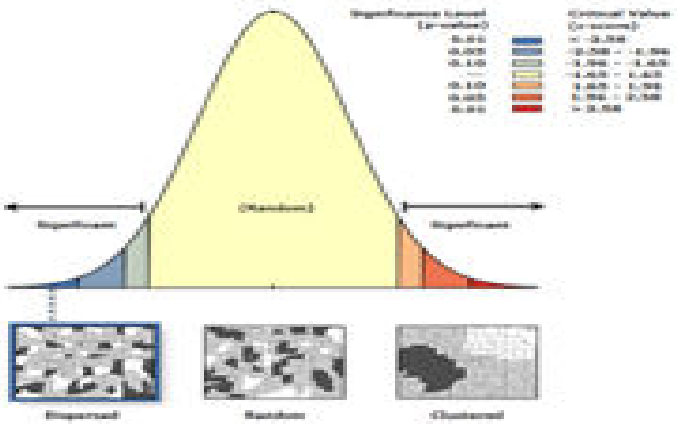

Figure (2): Moran's spatial statistic in order to determine location pattern of diabetics in Hashtrood

Then, following displaying location of diabetics in Hashtrood through Hotspot analysis, is determined that twenty percent of Hashtrood regions have higher cumulative pattern and also to the same extent some of regions of Hashtrood show lowest statistic. The high cumulative pattern means that A high percentage of

patients with diabetes are within a limited area (limited area). Figure (3) shows the Hotspot spatial location statistic of diabetes in Hashtrood.

It is notable to say that, in order to test obtained results of Hotspot statistic analysis in location data, there is capability to display significance level on same data field of diabetes layer. Based on results of figure (4), with regard to obtained results of north and east regions of health and treatment network of Hashtrood (P Value = < 0.05), have dense and weak diabetics distribution patterns respectively. Also other regions of Hashtrood which have maximum area (65 percent), distribution of diabetics is in significant

.

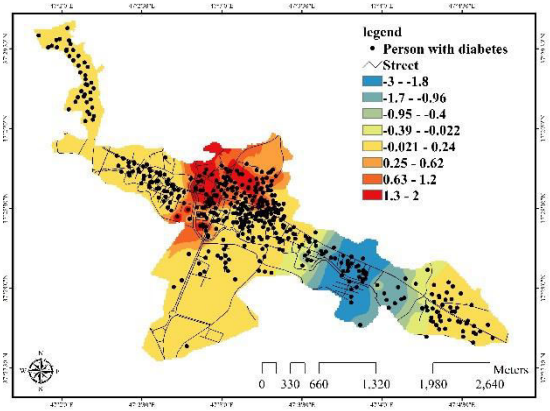

Figure (3): Hotspot location-spatial statistic of diabetes in Hashtrood

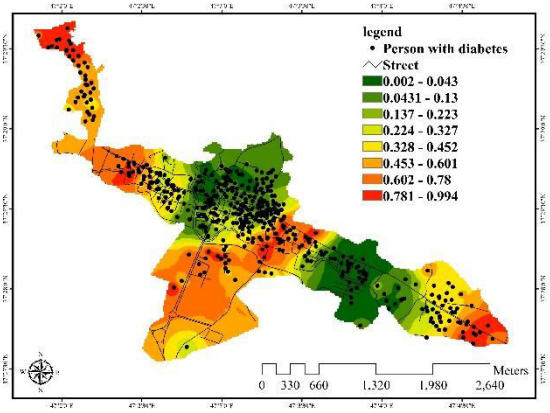

Figure (4): Significantness level test of accumulative pattern of diabetes in Hashtrood

The designated diabetics showed significant trend in different years, so that from 1976 until 2016, there was significant increase in percent of diabetics. The highest percent of patients was reported on 85-95 and lowest one on early years of research. This trend appears in both sexes and accession is sensible.

Nevertheless, accession trend is more sensible among women.

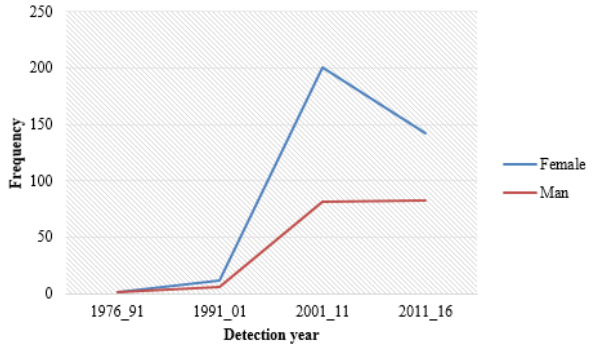

Diagram 1: frequency of diabetics in Hashtrood during 1979-2016

Discussion and Conclusion

In the present research, the role of GIS in location analysis of diabetes and how to consider geographic and environmental factors in modeling based on GIS were reviewed. The most important capability in first stage, is to display conditions map and categorizing patient's data but other main analysis include interpolation, point patterns clustering, regional patterns analysis, sensitive regions branching.

In the present research, location of diabetics in Hashtrood was determined through Hotspot analysis test which twenty percent of Hashtrood have higher cumulative pattern. Also, results of Moran's Index in relation with spatial distribution of diabetics in Hashtrood shows that couldn't approve the cumulativeness of diabetics in both sexs to the same extent some of regions of Hashtrood also show so lower statistics analysis in spatial data system, the capability for display of significance level shows that northern and eastern regions of treatment and health system have dense and weak diabetics distribution patterns respectively. Also, in other regions of Hashtrood which have maximum area (65 percent), diabetics' distribution is insignificant.

The percentage of peoples with diabetes in urban and rural areas were equal to 2.51 and 0/58, respectively. In overall, the percentage of people with diabetes in urban areas is about 5 times greater than in rural areas. Perhaps the most important cause is lifestyle, sedentary and overweight, and so on. Most studies were conducted on diabetes by GIS system in America (6, 7, 8, 9). The most important results show that distribution maps of diabetics could have determinant role in field of management and control, and also

effectively determines health prevention and evaluation plans policy.

In the present research, spatial database GIS was created with regard to available data and prepared analytical maps such as consistent map of disease distribution based on interpolation and sensitive and insensitive regions map. By integration of geographic data could complement and improve analysis process of diabetes in future research. Also it is proposed a consistent and classifiable map of diabetes is prepared in interpolation analysis by using of available data of patients location in different geographic points. By such map, could designate which regions have more or less patients. In clustering of point patterns, the location of patients was used and analyzed whether there is geographic pattern in patients' distribution or it is randomly and not recognized any relation.

In general, the superiority of the GIS system to manual and other methods is to display the disease map and the large number of patient information categorization, interpolation analysis, spatial pattern clustering, ecological analysis, Analysis of regional patterns and clustering of sensitive areas and placement of the exact position of individuals on the geographical plates.

The analysis of regional patterns is same as point patterns one but is possible by different methods. For example, one of effective criteria in regional geographic relation is the issue of adjacency which isn't definable for points. Finally, in branching of sensitive regions, the regions which could be referred as high-risk one in terms of diabetes incidence, are explored.

References

1. Masoumi Z, Saadi M. Fitting a model in place-for statistics on skin cancer decision support, Geomatics 85 National Cartographic Center. Tehran, Iran, 2006; 4: 25-41.

2. Rezaeian M. An introduction to the practical methods for mapping the geographical morbidity and mortality rates. Tollo-e-Behdasht, 2004; 2: 41-51.

3. Snow J. On the Adulteration of Bread as a Cause of Rickets". The Lancet 1857; 70 (1766): 4.

4. Green C, Hoppa R.D, Young T.K, Blanchard J.F. "Geographic Analysis of Diabetes Prevalence in an Urban Area", Social Science & Medicine, 2003; 3: 551–560.

5. Widener M.J. Metcalf S, Bar-Yam Y. "Agent-Based Modeling of Policies to Improve Urban Food Access for Low-

Income Populations", Applied Geography, 2013; 1: 1–10.

6. Grubesic T.H, Miller J.A, Murray A.T. "Geospatial and Geodemographic Insights for Diabetes in the United States", Applied Geography, 2014; 1: 117-126.

7. Davidson, M. Establishing prevention, education and community awareness through a comprehensive diabetes, hypertension and hypercholesterolemia screening program: the Smith Island, Maryland, USA experience. International Journal of Nursing Practice, 2004; 2: 242 - 246.

8. Dena G. The Applications of Geographic Information System (GIS) in the analysis of Diabetes Control and Prevention Program, 2011; 317-320.

9. Amy B, Curtis C, Kothari R. Using GIS and Secondary Data to Target Diabetes-Related Public Health Efforts 2013; 212-220.

10. Mohammad H. V. M., Alavi refuge. “The role of geographic information systems to analyze diabetes”, Journal of Transplantation Science, second, fifth year, 2015; 64-58.

11. Qiao Q, Hu G, Tuomilehto J, Nakagami T, Balkau B, Borch-Johnsen K, et al. Age- and sex-specific prevalence of diabetes and impaired glucose regulation in 11 Asian cohorts. Diabetes Care, 2003; 26(6): 1770- 1780.

12. Nematpoor S, Shahbazian H. B. Contact stressful factors caused by diabetes in parents of children with diabetes type one with their general health. Medical Journal 2005; 5(2 Issue 49): 530-537.

13. Karimi F, Nabi Pur I, Efri M, Gholam Zadeh F. Farkhondeh. Selective Screening For Gestational Diabetes Mellitus In Bushehr, Based On A 50-Gram Glucose Challenge Test. Iranian Journal of Diabetes and Lipid Disorders 2004; 2(1): 51-45.

14. Liesenfeld B, Heekeren H, Schade G, Hepp K. Quality of documentation in medical reports of diabetic patients. International J Qual Health C 1996; 8(6): 537.

15. Bhopal RS, Fallon RJ. (.Variation in time and space of nonoutbreak egionnaires’ disease in Scotland. Epidemiology and Infection 1991; 106: 45-61.

16. Hosseini A. The role of communication networks distribution to local user with passive defense approach (Case Study of Tehran Tuesday, University of Zanjan. 2012; 183.

17. Breen TJ, Keck B, Hosenpud JD, White R, Daily OP. Thoracic organ transplants in the United States from October 1987 through December 1992: a report from the UNOS Scientific Registry for Organ Transplants, Clinic Transplant, 1993; 7:37-45.

Comparing the knowledge and performance of prenatal care among pregnant women referred to health centers in urban and rural areas of Babol

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Abstract

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Background: The health care of pregnant women is one of the major problems in many communities; despite the fact that different forms of health care are offering by the health center, most of pregnant women do not receive the necessary care during pregnancy. This study aimed to determine the level of knowledge and performance of prenatal care among pregnant women referred to health centers in urban and rural areas of Babol.

Methods: This descriptive-comparative study was conducted on 200 pregnant women between 18-35 years who were eligible based on inclusion criteria. Participants were selected using multistage random method and divided into two groups of 100 samples included urban and rural areas. Research tool for data collection was a questionnaire in three parts (demographic characteristics of the subjects, specified questions foe knowledge and performance) which was designed by the researcher.Scientific validity of the questionnaire and content validity were assessed by Pearson coefficient statistical method which was 82% and its reliability was evaluated by test-retest. Data were analyzed using the spss-20 software and Chi-square, Fisher exact test and McNemar test.

Results: 43% rural women had poor knowledge, while 39% of urban women had moderate knowledge. Also, 40% of rural women and 38%of urban women had poor performance.McNemar test showed the relationship between knowledge and performance, so that 55%of rural women with poor knowledge also had poor performance (p=0.41). Chi-square test showed significant relationship only between some characteristics such as education level, women's employment status, monthly income and their knowledge. This means that there wasno significant relationship in rural group, but significant relationship was observed in urban group. In terms of other features, both groups showed no statistically significant relationship. The chi-square test only showed significant relationship between performance and some features such as employment and sources of information in the urban group, while these relationship were not significant in rural groups. Other features showed no statistically significant relationship in both groups.

Conclusion: According to our findings, knowledge level of urban and rural women were respectively medium and poor, but the performance was poor in both groups. Therefore, it seems necessary to improve the knowledge and performance of pregnant women by health workers, midwives and other health workers.

Keywords: pregnant women, prenatal care, knowledge, performance, urban, rural.

Introduction

Pregnancy and the childbirth are the most important events in every woman's life. Although pregnancy is not a disease and it is a biological and natural process, it is likely to be associated with some complications, which can be prevented by prenatal care (1,2).The main goal of prenatal care is to ensure the birth of a healthy baby with a minimum risk for the mother and is one of the medical standards for measuring the quality of women's health care (3-5).Prenatal care is a comprehensive health care program including a coherent approach to medical care and psychosocial support; this program normally starts before pregnancy and continues throughout the pre-natal period. This comprehensive program includes: pre-pregnancy care, early diagnosis of pregnancy, first visit and follow-up visits for prenatal care (4-6). The American Center for Disease Control has reported that mortality rate among women who have not received pregnancy care is 6.5 times higher than women who received adequate care(3). In Iran, a study conducted by Zarei et al. in Kurdistan concluded that the probability of maternal mortality who did not receive necessary care was 22 times higher than those who received care (7).According to the World Health Organization, the death rate of pregnant women in Iran was 37.4 in 2006 and 20.3 in 2013 per 100,000 live births (8-10). Increasing awareness and preparation during pregnancy can lead to changes in health behaviors and allow the mother to pass this stage of her life with fewer complications and more satisfaction (11-13).

Researches have also shown that increasing maternal awareness about the process of pregnancy and childbirth

leads to their greater participation and reduces the complications of this period (14, 15). So, this study aimed to determine and compare the knowledge and performance of pregnant women of prenatal care.

Methods

This descriptive-comparative study was examined and compared the level of knowledge and performance of 200 primiparous women in urban and rural areas who were at their 36th week of pregnancy or higher with the age range of 18-35 years.This study was conducted in 13 urban and 26 rural health centers that were located in north, east, and west of Babol, according to the distribution of population. Some of the health centers were selected through multi-stage random sampling method; so that, a list of urban and rural health centers in Babol was prepared.Then, according to the number and geographical location, some of these centers were selected by simple random method and at the next stage, the samples were selected from the pregnant mothers referred to these centers.Research tool for data collection was a questionnaire in three parts (demographic characteristics of the subjects, specified questions foe knowledge and performance) which was designed by the researcher. The number of questions in each section was 20, 25 and 20 questions, respectively.Scientific validity of the questionnaire and content validity were assessed by Pearson coefficient statistical method which was 82% and its reliability was evaluated by test-retest. Data were analyzed using the spss-20 software and Chi-square, Fisher exact test and McNemar test.

Findings

According to the findings, the study subjects were homogeneous in terms of some characteristics such as their age and their husbands' age, their employment status, insurance coverage, the type of referral to the doctor or

midwife, the information resources and the satisfaction level of the accountability of health personnel there was no significant difference between them.But,there was a significant difference between the two groups in terms of factors such as the level of education of pregnant women, the level of education and employment status of their husbands, the amount of monthly income, how to visit health centers, the frequency of visits to urban and rural public or private health centers, the waiting time for receiving care and their participation in prenatal health care classes (P<0.05).43% rural women had poor knowledge, while 39% of urban women had moderate knowledge. Chi-square test showed no significant difference between the knowledge of urban and rural women. (figure 1)

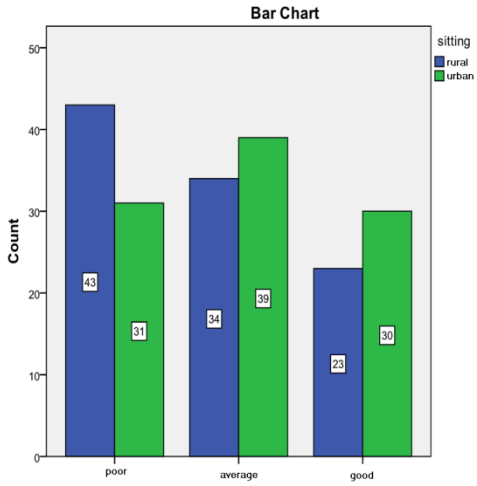

Figure 1. Distribution of Absolute and Relative Frequency of Knowledge Levels among study subjects about the prenatal care

Based on the results, 40% of rural women and 38%of urban women had poor performance and Chi-square test showed no significant difference between urban and rural groups (Figure 2).

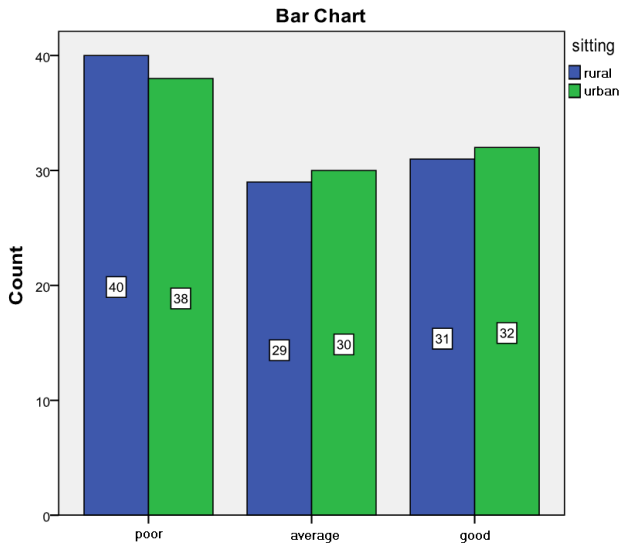

Figure 2. Distribution of Absolute and Relative Frequency of performance Levels among study subjects about the prenatal care

55%of rural women with poor knowledge also had poor performance, also 46.2% of urban women with moderate knowledge had poor performance. According to McNemar test, the lack of correlation between the two variables was rejected. Therefore, there was a significant relationship between the two variables.

Chi-square test showed significant relationship only between some characteristics such as education level, women's employment status, monthly income and their knowledge, so that there was no significant relationship in rural group, but significant relationship was observed in urban group, which means the factor of the living environment can be an influencing factor in this regard.

In terms of other features, both groups showed no statistically significant relationship. The chi-square test only showed significant relationship between performance and some features such as employment and sources of information in the urban group, while these relationship were not significant in rural groups.Other features showed no statistically significant relationship in both groups.

The results showed that 49% of rural pregnant women and 53% of urban pregnant women received information about prenatal care from their relatives

and friends. Chi-square test showed no significant difference between the two groups, which indicates that both groups are identical in terms of the sources of information.

Discussion

The findings showed that rural pregnant women had poor knowledge and urban pregnant women had a moderate knowledge. Chi-square test did not show a significant difference between urban and rural women's knowledge level.In study conducted by Zhao et al. in 2007, 64% of rural women had good knowledge (16); the reason for this difference can be the difference in the factors such as the level of education, monthly income and insurance coverage, and better access to health care.

The results also showed that rural and urban pregnant women had poor performance and Chi-square test showed no significant difference between urban and rural groups. Bener et al. found that only 12.4% of pregnant women had a good performance in the first trimester of gestation(17); while the results of Mirmolaee et al. showed that 49.3% of pregnant women had a relatively good performance and 50.7% had a good performance(7).

Based on the results of present study, more than half of the rural women, who had poor knowledge, had also poor performance; while the performance of urban women with moderate knowledge was also poor. According to the McNemar test, the relationship between the two variables was acceptable. Therefore, there is a significant relationship between the two variables and the level of performance was decreased by poor knowledge.

Chi-square test showed significant relationship only between some characteristics such as education level, women's employment status, monthly income and their knowledge, which is consistent with the results of Ziaee et al. study; they found that there was a significant relationship between the occupation of pregnant women and their level of knowledge, so the employed women had higher awareness than housewives (18).Also, the results of Mazloomi et al. showed that the employed women had more knowledge

than housewives (p<0.001) (19).Also, Zhao et al. found that the higher the annual income offamily, the better the knowledge of women (16).

Besides, the results of the study showed that there was a significant relationship between performance and characteristics such as job and information resources in urban group, while the same was not significant in the rural group. Kazemi et al. in their research found that the performance of employed women was better than the housewives, and this difference was statistically significant (p = 0.02), which is consistent with the findings of the present study. The results of Safdari et al. showed no statistically significant relationship between women's performance and their information resources. In their study, the largest source of information included midwives and doctors (20).

The results showed that 49% of rural pregnant women and 53% of urban pregnant women received information from relatives and friends about prenatal care. Chi-square test did not show any significant difference between the two groups, which indicates that both groups are identical in terms of the sources of information.Safdari quoted from Levin et al.that: Health care providers can be the best source of information for pregnant women, so that they prefer to hear the most information from health care providers. According to a study conducted in North Carolina, the majority of women (70.8%) received their information from health center staff . While the results of Ziaee et al. in 2008 were consistent with the results of present study, they found that the most likely source of information for pregnant women included their mothers, relatives and friends (18).

Conclusion

Based on the results of this research, women's access to all health services along with their increased knowledge through prenatal education and counseling sessions about the pregnancy, childbirth and postpartum are effective factors in preventing mortality and complications. Today, the education needed for prenatal care is not quite favorable in Iran based on related standards.Findings of this study were proved that 43% of rural women

had poor knowledge. This level was not better among urban pregnant women, and only 39% of them had moderate knowledge.Midwives can be good instructors for pregnant womento provide the necessary information and to make important changes in their lifestyle. Prenatal care educations and classes can have a positive impact on women's behavior and improve care behaviors. Therefore, the knowledge of society on the desirable care behaviors within special occasions such as pregnancy should be revised and also undesirable behaviors should be reduced.

Acknowledgement

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References

1) Epstein B, Grant T. Does Rural Residence Affect Access to Prenatal Care in Orego- n.Journal of Rural Health 2009; Vol 7 (4): page150.
2) Danesh KM, Karimi S, Shekarabi R, Hossinei F. A study of satisfaction with prenatal care servisec in the women attending to the health centers of the Shirvan Chardavel (Iran), in 2005. Iran J Nurs 2005; 18(43):61-9
3) Lockwood C, Magriples U. The initial prenatal assessment and routine prenatal care 2010; Official reprint from UpToDate®www.uptodate.com © UpToDate®.
4) Lowdermilk D,Perry Sh. Maternity&Women s healthcare,9th ed 2008. evolve, Mosby elsevire.
5)Gregoryk, Johnson T. Gabbe:Obstetrics:Normal and Problem Pregnancies,5th ed 2007; section 2, chapter 5, page 114.
6) Zeidan ZA. Satisfaction among pregnant women towards antenatal care in public and private care clinics in Khartoum. Khartoum Med J 2012; 4(2):590-5.
7) Mirmolaei S, Khakbazan Z, Kazemnejad A, Azari M. Prenatal Care Utilization Rate and Patients Satisfaction. Hayat. 2007; 13 (2) :31-40. (Persian).

8)Emami Moghadam Z, Ajami BM, Behnam Vashani HR, Sardar Abadi F. Perceived benefits based on the health belief model in oral health related behaviors in pregnant women, Mashhad, 2012. Iran J Obstet Gynecol Infertil 2013; 16(44):21-7. (Persian).

9) Sehati Shasaei F, Sheibaei F. Lifestyle and its relation with pregnancy outcomes in pregnant women referred to Tabriz

teaching hospitals. Iran J Obstet Gynecol Infertil 2015; 16(131):13-9. (Persian).
10) Maureen H, Wendy S, Lawrence E, Michael M, Michael E H, Heather M, etal.Perceptions of barriers, facilitators andmotivators related to use of prenatal care:A qualitative descriptive study of inner-citywomen in Winnipeg, Canada. SAGE Open Medicine3: 2050312115621314© The Author(s) 2015 Reprints and permissions:sagepub.co.uk/journalsPermissions.nav .DOI: 10.1177/2050312115621314.
11) Feijen-De Jong EI, Jansen DEMC, Baarveld F, et al.Determinants of late and/or inadequate use of prenatal healthcare in high-income countries: a systematic review. Eur JPublic Health 2012; 22: 904–913.
12) Phillippi JC. Women's perceptions of access to prenatal carein the United States: a literatur review. J Midwifery WomensHealth 2009; 54: 219–225.
13)Lathrop B. A systematic review comparing group prenatalcare to traditional prenatal care. Nurs Womens Health 2013;17: 118–130
14) WorldHealth Organization. World health statistics 2010. Geneva: World Health Organization; 2010. P. 61-83.
15) Ruiz-Mirazo E, Lopez-Yarto M, McDonald SD. Groupprenatal care versus individual prenatal care: a systematicreview and meta-analyses. J Obstet Gynaecol Can 2012; 34:223–229.
16) Zhao Qi&Kulane A.etal. Knowledge and attitude on maternal health care among rural-to-urban migrant women in Shanghai, China. BMC Women's Health 2009, 9:5.
17) Bener A&Maadid M,etal(2006).Maternal Knowledge,attitude and prac- tice on folic acid intake among Arabian Qatari Women. Reproductive Toxicology 21: 21-25.
18) Ziaee T, Azgoli G,et al. Survey of Knowledge, Attitude and Practice of Pregnant Women towards Arbitrary use of Drugs in Pregnancy 2008; 18(62):35-39. (Persian)
19) Mazloomy S,Shahidi F,Abbasi M,SHahrizadeh F. Survey of Knowledge, Attitude and behavior of Pregnant Women Towards pregnancy health .JOURNAL OF REPRODUCTION AND INFERTILITY 2006; 7(4):391-400. (Persian).
20) Safdari Z, Ghods F. The effect of education on level of knowledge towards the role and consumption of folic acid supplement in pregnancy. JQUMS 2008; 12(3): 32-37. (Persian).

The impact of daisies capsule on hot flashes in postmenopausal women

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Abstract:

Introduction and purpose: Menopause is an important issue in women's life that brings about a transition to a new biological status and the gradual loss of fertility. Menopause is the transition from fertility to infertility, and it is regarded as an indication of old age and a predictor for diseases and health problems, and women's only experience is that their menstrual periods stop.Women experience numerous problems including hot flashes in menopausal period. Given the midwife's duties for promoting the health status of menopausal women, the present research aims at studying the effect of oral chamomile capsule on hot flashes in menopausal women.

Method: The present study is a triple blind clinical trial conducted on 82 menopausal and premenopausal women experiencing hot flashes. The samples were randomly dividedinto two 41-participant groups. One of the intervention groups received two capsules a day, each of which contains 250 milligrams of chamomile extract. The other group received two capsules containing starch for 8 weeks. After the intervention, the hot flashes mean scores were determined using the intensity recording form and the duration and number of hot flashes. Data analyses were conducted using a variety of tests including ANOVA, Kruskal–Wallis, Chi-square, MannWhitney, Wilcoxon, andFriedman.

Findings: The findings obtained in the present study indicated that the hot flashes mean scores of the placebo group were 4.42±1.93, 4.4±3.026, and 0.62±3.06, and the mean scores of the chamomile group were 3.63±3.96, 2.25±2.65, and 4.02±4.22; the difference of the scores was significant in the chamomile group. In the end, 74 individuals participated in the intervention.

After 4 and 8 weeks of intervention, improvement was observed in the number, intensity, and duration of hot flashes in both groups that is statistically significant. However, the effect was more observable in the intervention group than the placebo group ($p<0.0001$).

Conclusion: The findings of the present study indicate that taking at least one capsule of chamomile a month can be effective in treating the hot flashes of menopausal women. Thus, taking chamomile capsule, as a herbal supplement, is recommended for these women.

Key words: Menopause, Chamomile, Hot flashes

Introduction:

Menopause is an important issue in women's life that brings about the transition to new biological status and the gradual loss of fertility. Menopause is the transition from fertility to infertility, and it is considered as an indication of old age as well as a predictor of diseases and health problems. Women's only experience is that their *menstrual periods stop (1). The increasing menopausal age in different countries is associated with reasons beyond the increasing life expectancy; it has to do with nutrition and public health status (2).*

The menopausal age ranges from 46.01 to 52.4 in different cities of Iran; the mean is 48.18 (Rajaei Fard, Beigi, and Salehi, 2011). Hot flashes account for the main symptom of menopause and it is behind most of the complaints made by women (3).

Hot flashes are sudden feelings of feverish heat that starts from the back of the head or neck. It is then spread all over the body and it is accompanied by intense heat. Hot flashes are preceded by the feeling of heartbeat or pressure inside the head. Hot flashes are likely to be accompanied by perspiration, anxiety, inflammability, and panic. Hot flashes are followed by cold and shivering. The duration of hot flashes ranges from some seconds to some minutes. In average, hot flashes last for 4 minutes. However, they are likely to last for 10 minutes; each time, five or ten times, and 30 times a day. This status is even more intense at night, or it occurs more frequently waking the person up (4). Menopause is accompanied by nightly perspiration, sleeping disorder, inflammability, and disorders in memory and concentration.

The prevalence of hot flashes in menopausal women has been reported up to 70 percent. It has been reported that hot flashes are more intense and more frequent during the night. The prevalence of hot flashes has been reported to be70-85 percent in Europe and49-56 percent in Iran. However, in countries rich in vegetarian foods, such as China and Japan, it has been reported to be 8-17 percent (5). For most women, hot flashes stop automatically without receiving any treatment within a few years. In one-third of the women, the symptoms of hot

flashes can last more than 5 years. In 20 percent of the women, the symptoms can be constantly seen for up to 15 years (6). Europe, and 49-56 percent in Iran. However, in countries rich in vegetarian foods, such as China and Japan, it has been reported to be 8-17 percent. For most women, hot flashes stop automatically without receiving any treatment within a few years. In one-third of the women, the symptoms of hot flashes can last more than 5 years. In 20 percent of the women, the symptoms can be constantly seen for up to 15 years (7). The prevalence of hot flashes has been reported to be70-85 percent in. The prevalence of hot flashes in menopausal women has been reported to be up to 70 percent. They have been reported to be more intense and even more frequent at night bringing about sleeping disorders accompanied by intense perspiration and shivering (8). Thus, findings solutions to treat hot flashes, being one of the most common problems of menopause, can play an important role in maintaining the menopausal women's mental and physical health and perpetuating a peaceful life for them (9).

Plants such asvalerian, Black Cohosh, Chamomile, h*yper cum* perforatum, Liquorice, Fennel, soybean, red clover with phytoestrogen quality have been recommended for treating menopause (10). Chamomile is of the chicory family that is one of the oldest plants used in medicine, and it is known as Matricaria Chamomillaall over the world. Its medical usage is internationally known and it is one of the most commonly used medicinal plants (11). In most of the Iranian cities, it is planted largely. It has benefits such as reduced fever and perspiration, reducing headaches and migraine pains, arthritis, relieving menstrual pains, relieving menopausal complications, lowering blood pressure, relieving vertebral column pains, disinfectant uses, gastric anti-inflammatory effect, anti-itch effects, appetizing and carminative effects, antiemetic effects, restiveness, and herpes, preventing osteoporosis, and reducing rheumatism pains. Chamomile is also used locally for treating mastitis and hemorrhoid. In Europe and western Asia, chamomile tea has been used for feeling relief and improving one's sleep for than one hundred years. Chamomile has been often used as a mild sedative and sleep inductor, Chamomile helps nerve relaxation. It can also lead to reduced anxiety, nightmare, insomnia, and other sleeping disorders (12). In Britain, chamomile is used as an aspirin (13).Given

article 2 of the national law for midwife's job description, one of the most important duties of the midwives is promoting women's health in menopausal period. According to article 6 of the aforementioned law, timely introduction and prescription of herbal supplements is one of duties of the midwives. Given the dangerous complications and side effects arising from the hormone replacement therapy, adopting natural, complication-free, and cheap therapies such as medicinal plants have been widely welcomed by the public. Thus, given the cost-effectiveness and availability of chamomile, the present study aims at studying its effect on the hot flashes of menopausal women, so that a step is taken towards the goals of developing and promoting women's health in both family and society.

Materials and methods:

The present study is a random triple blind clinical trial conducted on two groups. The statistical population of the present study includes 82 45-to-60-year-old menopausal women referring to the menopausal clinic of the comprehensive women's health care hospital; they were reported to complain about hot flashes. The inclusion criteria of the present study include :being 45 to 60 years old; suffering from hot flashes for at least 3 months; complaining about hot flashes for at least 3 times a day; not receiving hormone therapy in the last 3 months; not receiving therapy through taking drugs for sedating the menopausal symptoms; not receiving therapy through taking phyto estrogens such as soybeans and, not suffering from heart diseases, blood pressure, diabetes, mental disorders, thyroid disorders, liver diseases, cancer, abnormal uterine bleeding; not taking anxiolytics ; not taking any medicinal plants; not taking anticoagulants; not taking any soporific drugs; and not smoking.The exclusion criteria are as follows: taking anxiolytics, soporific drugs, anticoagulants such as aspirin, warfarin, and heparin; taking phytoestrogens and non-hormonal drugs such as clonidine for sedating menopausal symptoms; receiving hormone-therapy during the study; having allergy to chamomile during the study; suffering from abnormal uterine bleeding or any other systemic diseases during the study; and lack of willingness to proceed the study. The data tool of the present study include a demographic form including the

participant's age, l*ast-menstrual-period age, level of education, employment status, marital status, number of deliveries, and number of children, and a questionnaire for studyingthe daily hot flashes recording form over the last month. The method for recording the hot flashes is that a symbol is recorded each time for the hot flashes whenthey happen (morning, noon, night). For determining the intensity of hot flashes, according to the recommendation made by* Food and Drug Administration of the Islamic Republic of Iran, the hot flashes intensity was classified as free of symptoms, minor (feeling of heat without perspiration), average (feeling of heat and perspiration, without disturbing the daily activities), and intense (feeling of feverish heat and perspiration disturbing the daily activities); the scores given were 0, 1, 2, and 3 respectively. The number of hot flashes was recorded on a daily schedule and the mean will be obtained.

The hot flashes duration is more than 5 minutes, 3-5 minutes, 1-3 minutes, 30-60 seconds, and less than 30 seconds; the average is obtained though. The weekly average of each variable is measured separately through dividing its total (over a week) to the number of days of the same week in which the form is filled out. The findings are evaluatedbased on the average changes of the mean of each variable during the intervention in comparison with those obtained at the outset of the study (Baghdari et al, 2009). The less the mean score, the less the duration, intensity, and number of hot flashes will be.

The hot flashes recording form has been previously used by the researchers outside the country. The academic credit of the form has been measuredthrough evaluatingit content validity. Having been translated, the form's face validity as well as content validitywereconfirmed by 12 faculty members of Mashhad University of Medical Sciences (Baghdari et al, 2009).Moreover, the validity of the tool has been measured by evaluating its content validity in a study conducted by Sadeghi et al (2012) at the Nursing and Midwifery School of Tehran University of Medical Sciences as well as another study conducted by Nahidi et al (2008) at ShahidBeheshti University of Medical Sciences.

The reliability of this form was confirmed at Mashhad University of Medical Sciences in a pilot study applying test-retest method by obtaining r=0.87 and r=0.9 respectively (Baghdari et al, 2009). Moreover, at ShahidBeheshti University of

Medical Sciences, for measuring the validity and reliability of the tool, content validity and retest were used with the correlation coefficient of r=0.96 (14, 15, 16).

Having delivered the letter of consent, the qualified women were randomly placed in one of either of two groups. The drugs were classified by a pharmacist into two groups; A and B. The route of administration was taught for both groups. The chamomile user group took chamomile capsule (250 milligram a day, in two divided dose), and the control group took two capsules containing 250 milligram of starch twice a day for 8 weeks. The capsules have been produced by the researchers at TarbiatModares University Research Center of Medicinal Plants. Both the researcher, the participants of the present study, and the data analysts were unaware of the kind of capsules used. Both capsules were the same shape produced with A and B codes by the consultant pharmacist and were given to the research participants. For conducting the supervision need on the route of administrating the capsules, the researcher controlled the route of administration by calling the participants; in case of taking the wrong route in administrating the capsules or having any other exclusion criteria, the participant was then excluded from the study. The data was analyzed using SPSS 22.b as well as other tests such as independent t-test, *chi-square,* Mann*Whitney, and*Wilcoxon.

Findings

Of the 82 participants, 41 received chamomile capsules, and 41 received placebo capsules (containing starch). During the administration of the drugs, 4 women from the chamomile group (2 owing to diarrhea and 2 owing to gastrointestinal complications), and 4 women from the placebo group (2 owing to irregular taking of the drugs and 2owing to diarrhea) were excluded from the study. In the end, the analysis was conducted on 74 women. Table 1 indicates that both groups were similar with respect to age, l*ast-menstrual-period age, average number of deliveries, and number of children, and number of abortions. With respect to their employment status, most of the*

participants were housewives (%83.8 in the test group, and %75.7 in the control group). 94.5 percent of the test group and 70.3 percent of the control group enjoyed average economic status. 100 percent of the test group and 91.9 percent of the control group were married. With respect to the educational level, most of the participants had finished middle school or secondary school (%35 in the test group). Wilcoxon test in tables 2 and 3 indicates that the intensity, duration, and number of hot flashes in the two groups differ significantly before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention (p≤0.0001).
By comparing the mean difference and standard deviation of the two groups, Mann*Whitney test seems to be effective in reducing the intensity, duration, and numberof hot flashes before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention (p=0.0001).*

Discussion

One of the most important reasons behind hot flashes in the menopausal period is the reduced sexual hormones. Physical as well as mental changes related to the hormones bring about hot flashes in these ages. The study conducted byYazdani et al (2004) aiming at studying the effect of chamomile on dysmenorrhea and premenstrual syndrome indicated that chamomile turned out to be effective for relieving abdominal and pelvic pain, fatigue and lethargy, and anger; it can help reduce these symptoms significantly (17). In the study conducted by Kupfer et al (2003) aiming at studying the effect of chamomile and dong quai combination on the menopausal symptoms for 12 weeks, the findings indicated that there was a remarkable reaction in the intervention group in the first month of therapy for improving sleeping disorder and fatigue. Moreover, the placebo had no effect on the improvement of sleep. This is consistent with the findings of the present study about the effect of chamomile and the ineffectiveness of placebo (18). The study conducted by Vahidi et al (2007) aiming to compare the chamomile extract and morphine showed that the analgesic effect of chamomile is similar to that of morphine. Flavonoid combinations are responsible for the *spasmolytic effects. They are analgesic, and the essences, especially bisabolol*and*chamazulene, are responsible for the anti-inflammatory effects (19).*

The study conducted by Jenabi et al (2009) aiming to study the effect of chamomile tea on primary dysmenorrhea indicated that chamomile tea brings about an improvement of the menstrual pain. The mechanism of chamomile has been proved to be effective for improving dysmenorrhea and premenstrual syndrome. It is owing to the extract and ethanol taken from the flowers of this plant; they have anti-inflammatory, *anti-spasmolytic, sedative and anti-restive effects (20).*

Concerning the effect of placebo, there are contradictory findings. In the study conducted by Kazemian (2006) aiming to study the effect of valerian on menopausal women's hot flashes, the placebo brought about a reduction of hot flashes from %36.8 to %15 ($p<0.05$). Thus far, no other studies have been conducted to study the effect of chamomile on the hot flashes. However, other medicinal plants (havingphytoestrogenic effects) have been used to treat hot flashes (20). Kazemian's study (2006) aimed to study the effect of valerian on menopausal women's hot flashes. It was conducted on 48 women for 2 months. Valerian turned out to be effectivein reducing the duration of hot flashes 2 months after the treatment ($p<0.05$). Moreover, it turned out to be effective in reducing the number of hot flashes 1 month after the treatment ($p<0.05$) (21).

The study conducted by Kazemian (2006) aimed to study the effect of passion flower on menopausal women's hot flashes; it was conducted on 54 menopausal women for 30 days and indicated a significant reduction in the intensity of hot flashes ($p<0.05$) (22).

The study conducted by Taghizadeh et al (2005) aimed to study the effect of *Vitagnus on the early menopausal complications; it was conducted on 50 menopausal women for 3 months and indicated a significant reduction in the amount of menopausal complications and showed great improvement of hot flashes (%52.2). The findings of all these studies are consistent with those of the present study; chamomile has been proved to be effective on the number, duration, and intensity of the hot flashes (23).*

Table 3 shows the comparison of intensity, duration, and number of hot flashes before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention in both groups. The findings of *Kruskal–Wallis* statistical test indicates that the duration, intensity, and number of hot flashes in the two groups did not show a significant difference before the

intervention, and the groups are similar in this regard (p=0.6). However, the groups showed a significant difference 4 weeks and 8 weeks after the intervention (p≤0.001).

Given the contradictory findings on taking this herbal supplement, more studies need to be conducted in this regard. The intervention with a larger sample size and a longer follow-up was not possible. Thus limited sample size and short follow-up are the limitations of the present study.

Conclusion:

The findings of the present study indicated that chamomile capsules are effective in improving the menopausal women's hot flashes. Thus, the midwives and *gynecologists*are recommended using chamomile plant as a safe, cheap, and harmless remedy in treating menopausal women's hot flashes.

Acknowledgments:

The present study is the outcome of a *thesis submitted in partial fulfillment* of the*requirements* for the degree of Master of Science in midwifery. It was conductedwith the approval of Tehran University of Medical Sciences Ethics Committee with the registration number of 9201282144190058. The findings of the present study have been registered at the Iranian Registry of Clinical Trials with the registration number of N 201307302751 9. Hereby, the researchers appreciate the Vice-chancellor of Research of Tehran University of Medical Sciences. The researcher appreciates the comprehensive women's health care hospitalfor their cooperation on finding the samples of the study. The participants of the present study are appreciated as well.

Table 1. The Comparison of demographic information mean and standard deviation in chamomile group and placebo group

Group	Placebo standard deviation ±mean	chamomile standard deviation ±mean	P-value
Age	52.24±4.41	52.73±4.26	p=0/082
l*ast-menstrual-period age*	47.7±47.38	47.38±3.174	p=0/062
Number of deliveries	0.065±10.60	0.059±0.0865	p=0.062
Number of children	3.024±1.83	3.27±1.194	p=0/77
Number of abortion	0.065±1.06	0.059±0.0865	p=0/09

Table 2. The frequency distribution of intensity, duration, and number of hot flashes in three phases: before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention

	Groups	Mean±SD	Mean±SD	Mean±SD
Chamomile	Before	4.022±4.22	6.30±6.37	2.17±0.038
	4 weeks after the intervention	3.36±3.96	8.27±5.28	1.37±0.075
	8 weeksafter the intervention	25.2±2.65	6.730±5	1.039±0.0174
Placebo	Before	0.622±3.06	7.84±6.25	2.039±0.0389
	4 weeks after the intervention	4.4±3.026	4.76±6.05	1.4±0.055
	8 weeksafter the intervention	4.42±1.93	12.76±5.26	1.1±0.484
Pvalue	Before	0.08	0.06	0.012
	4 weeks after the intervention	0.003	≤0.001	≤0.0001
	8 weeksafter the intervention	0.0001	≤0.0001	≤0.0001

The findings of *Kruskal–Wallis* statistical test indicates that the duration, intensity, and number of hot flashes in the two groups did not show a significant difference before the intervention, and the groups are similar in this regard. However, the groups showed a significant difference 4 weeks and 8 weeks after the intervention.

Table 3. The comparison of weekly mean and standard deviation of the duration, intensity, and number of hot flashes before the intervention, 4 weeks after the intervention, and 8 weeks after the intervention in chamomile group and placebo group

Groups		Mean±SD	Mean±SD	Mean±SD	Friedman
Chamomile		2.17±0.038	2.2±0.0625	5.22±4.02	p≤0.001
		371±0.0756	811±0.815	3.36±3.96	p≤0.001
		170 1.039±0.704	10 0. 961±0.85	2.25±2.65	p≤0.001
Placebo		2.393±0.319	324±0.717	622±3.06	1.0041
		2.012±0.055	1.25±0.086	40	1.37

		1.822±0.484	0.96±0/08	3.1±3.026	1.17

The findings obtained from Friedman test and its post-hoc Wilcoxon test:

The chamomile and placebo group did not show a significant difference with respect to the duration, intensity, and number of hot flashes before the intervention. However, the duration, intensity, and number of hot flashes showed a significant difference 4 weeks and 8 weeks after the intervention ($p<0.0001$).

References

1. Perez JA, Garcia FC, Palacios S, Perez M.2009 .Epidemiology of risk factors and symptoms associated with menopause in Spanish women. Maturitas; 62: 30-36.

2-Noble JH Jr.Meta-analysis: Methods, strengths, weaknesses, and political uses. J Lab Clin Med 2006: 147: 7-20

3. Steams V, Ullmer L, López, Smith Y, Isaacs C, Hayes DF. Hot Flushes.Lancet 2002; 360:1851–61.

4. VanderA, Westhuizen. 2009. BPharm Department Pharmacology, University of Pretoria. HOT FLUSHES. SA Pharmaceutical Journal.342-356.

5. Zick S, Benjamin D, Ananda S.**2011.**Preliminary examination of the efficacy and safety of a standardized chamomile extract for chronic primary insomnia: A randomized placebo-controlled pilot study. 8411, 11-32.

6. Bruce D, Rymer J 2009. Symptoms of the menopause. Best Practice & Research Clinical Obstetrics and Gynaecology; 23:25–32.

7. Ryan K, Ber cowits R, Bar bieri R. In: Ryan K, Bercowits R, Barbieri R.2003.Menopuase kist ners gynecology & women health. 8thed: 504-40.

8. Speroff L, Marc A, Fritz MA.2005. Post-menopausal hormone therapy. In: Speroff L, Marc A, Fritz MA. Clinical gynecologic andinfertility.Philadelphia: Lippincot Williams & Wilkins; 7thed.p: 689-777.

9. Vikas Gupta, Payal Mittal, ParveenBansal. 2010. Pharmacological Potential OfMatricariaRecutita-A Review.

10. Janmejai K.2011. Srivastava-Chamomile: A herbal medicine of the past with bright future.

11. Baghdari, N. Akbari, A. Ayati, S. (2010), The study of the effect of flax seed on *perimenopausal women's hot flashes, thesis submitted in partial fulfillment* of the*requirements* for the degree of Master of Science in midwifery, Mashhad University of Medical Sciences.

12. Bakhshi, M. Sadeghi, H. (2012), The study of the effect of common sage on menopausal women's hot flashes, *thesis submitted in partial fulfillment* of the*requirements* for the degree of Master

of Science in nursing, Tehran University of Medical Sciences.

13.Nahidi, F. Taherpoor, M. (2008), The study of the effect of Anise extract on the menopausal hot flashes, *thesis submitted in partial fulfillment* of the*requirements* for the degree of Master of Science in nursing, ShahidBeheshti University of Medical Sciences.

13. Nahidi, Fatemeh et al (2009), The study of the effect of Liquorice extract on the menopausal hot flashes, *thesis submitted in partial fulfillment* of the*requirements* for the degree of Master of Science in nursing, ShahidBeheshti University of Medical Sciences.

14. Yazdani, Maryam et al (2004), The comparison of fennel drop and chamomile against the free-drug control in treating dysmenorrhea and premenstrual syndrome, Medical Journal of Hormozgan, volume 8, issue 1, 2004, pp. 57-61.

15. Kupfersztain, Rotem C, Fagot R, Kaplan B; 2003. The immediate effect of natural plant extract, Angelica Sinensis and MatricariaChamomilla (Climex) for the treatment of hot flushes during menopause. Apreliminary report. vol. 30, n°4, pp. 203-206.

16.Vahidi, A, Dashti, M. (2007), The comparison of the analgesic effect of chamomile extract with morphine in mice, Ardabil University of Medical Sciences Scientific Journal, volume 7, issue 4, 2007, pp. 409-417.

17. Jenabi, A. Ebrahimzadeh, S. (2009), the effect of chamomile tea on the improvement of primary dysmenorrhea.

18. Kazemian, A. et al (2006), the study of the effect ofpassion flower on menopausal hot flashes, Medical University of Ilam Scientific Journal, volume 14, issue 2.

19. Kazemian, A. et al (2006), the study of the effect of valerian on menopausal hot flashes, Shahrekord University of Medical Sciences, volume 8, issue 2, pp. 35-40.

20. Taghizadeh et al (2006), the study of the effect of *Vitagnus on the early complications of menopause, journal of the School of Nursing and Midwifery, Tehran University of Medical Sciences, volume 12, issue 1, pp. 66-67.*

A Study of the Effectiveness of Group Play Therapy upon the Theory of Mind in Preschool Children

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Abstract

Background

Theory of mind is a one of the most important issues of social cognition topics and whereas it is a prerequisite for understanding the social environment and involvement in social behavior competitive, it has been considered during the last decades in the field of psychology. In this regard, the purpose of this study was to evaluate the effectiveness of group play therapy on levels of childrenin preschool's theory of mind.

Materials and Methods
The present study, was a Quasi-experimental study design with pre-test and post-test and control groups which for this purpose 30 students selected by cluster random sampling and random assignment to experimental and control groups, respectively.
38-item test of theory of mind was used as a tool to obtain data.Package of six sessions of play therapy was administered to the experimental group. Data were analyzed using descriptive and inferential statistics covariance.

Results
The results showed that there was a significant difference between the experimental and control groups in terms of levels of theory of mind test.Follow up test after one month, showed the stability of results.

Conclusions
According to data obtained from this study can be concluded that the play therapy promotes children's theory of mind levels and since training activities were based on cognitive-behavioral and there is a close relationship between social cognition and doing group play, visible impact on the promotion of children's theory of mind test levels can be explained.

Key words: Play therapy, Theory of Mind, childrenin preschool

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1- INTRODUCTION

Theory of mind is regarded as one of the newest topics in social cognition, which has attracted the attention of many developmental psychologists. The basic framework of this theory is social cognition (1). Social cognition is one's critical ability to succeed in social relations in everyday life(2, 3). One of the aspects of social cognition that has received more attention is the theoryofmind development for children (4). Theory of mind means understanding the fact that anybody has thoughts, wishes and opinions, and their behaviors are controlled by their mental conditions. In fact, it is a fundamental ability in understanding human behavior, which plays a major role in everyday life (5). The term 'theory of mind' was applied by Premack &Woodruf (1987) to explain a child's ability to interpret behavior with the help of one's mental states or other's (6).
Studying the skills of theory of mind development dates back to the early work

of Piaget about children's thinking and autonomy (7). Flavell et al. (1993) believes that this theory develops in children at five levels. At the first level, the concept of mind is exploited by children to show needs, emotions and other states. At the second level, children perceive that mind is associated with the physical world. At the third level, children understand that mind is apart from the physical world and they are different. At the fourth level, children learn to recognize mind, objects and events as true or false, and finally, at the fifth level, children learn to understand that events are actively interpreted by the mind (8). Further, children acquire the concept of desire at the age of two, they start talking about beliefs, thoughts and desires at age three, and at the age of four, they believe the thoughts of others and understand their wishes. The theory of mind enables children to recognize emotions, understand beliefs and desires and predict and explain the behavior of others(9, 10).

The 'theory of mind' was defined by Premack & Woodruff (1987) as one's ability to invoke one's mental states and others'. A system of these references can be considered a theory, first because these states are not directly visible, and secondly because the behavior of other organisms can be especially predicted using this system (11). As a result of previous studies, at least three different theoretical approaches emerged: 1) theory-theory, 2) simulation, and 3) modularity. From the viewpoint of the advocates of theory-theory approach, children's understanding of the mind or the theory of mind has witnessed different developments and qualities in various stages. To further explicate this approach, it can be expressed that children use their overall intelligence capacity to develop a theory about their mental states. Popar (2008) believes that children acquire a visual understanding of the mind at the age of four and regard the mental states as propositional attitudes. Before the age of four, it cannot be claimed that children have theory of mind, but the existence of a type of behavior theory may be accepted in them (12).

Game is one of the most important components of a child's life. Children can learn the basic and extensive skills through playing games, which are associated with physical, emotional and social health (13). Play therapy is a unique method to help children communicate through creating balance in emotional behaviors (Richards et al., 2012). Game is a structured approach based on the theory of therapy on which the children's learning process and natural and normal relationships are established (14). Play therapy affects the various skills of students with intellectual disabilities, such as academic achievement (15), and social skills and adaptive behaviors (16). In a study conducted by Vahedi (17), the normal and aggressive students weretrained in social skills through puppetry. The results indicated that puppetry was efficacious in lessening the aggressive children's aggressiveness and boosting the social skills of normal and aggressive children. Puppets are very useful for playing roles and exploring thoughts and feelings. Using puppets also provides opportunities for expressing feelings, concerns and innovative ideas that are inhibited under normal circumstances for any reason.

Playing games enables children' inner thoughts to communicate with the outside world, thereby controlling the external objects. In addition, playing games allows children to display their experiences, feelings and tendencies that are threatening to them. Furthermore, games enable children to express their feelings and outer relationships. They also develop attitudes and communication skills and increase children's happiness and harmony with the environment (18). The results of some cross-cultural studies (19, 20)and observational studies (21)showed that the diversity of social experiences help individual differences in the theory of mind. In two separate studies, Ornaghi et

al. (2014) reported that children with the chance to participate in discussions about their mental states had a better performance in terms of the theory of mind (22).

The group play therapy is a psychological and social process in which children learn about themselves through communicating with each other in the game rooms. Given that games for children are like speech for adults and they are the means to express emotions, communicate, describe experiences, and reveal wishes and self-actualization, the present study aimed to find out if play therapy is efficacious in enhancing the levels of the theory of mind or not.

2- Materials and Methods

2-1. Study Design and Statistical Population

The present study was a quasi-experimental one with a pre-test-post-test control group design, which aimed to determine the effectiveness of group play therapy on preschool children's theory of mind.

2-2. Methods

The statistical population consisted of all female students aged 6-7 years old who were studying in Bistoon-based primary schools, Kermanshah, Iran, in the academic year 2014-2015. Using the cluster sampling, a school was selected from the primary schools based in this township and 30 students were chosen (15 students in each experimental and control groups) and were given pre-tests.

2-3. Measuring Tools: Validity and Reliability

2-3-1.Theory of Mind Test (TOM Test)

This 38-item test was developed by Steerneman (1999) to assess the theory of mind in normal children and those with pervasive developmental disorders aged 5-12 years old. This test provides information about social perception, children's sensitivity and insights and how much they are able to accept other people's feelings and thoughts. Some alterationswere made to this test by Ghomrani et al. (2006), and the number of questions was reduced from 72 to 38. Then the validity and reliability of the test were assessed on a number of educable mentally retarded and normal students residing in Shiraz, Iran(23). To examine the validity of the test, the content validity and concurrent validity were utilized. Moreover, the concurrent validity of the test measured 0.89 ($p<0.01$). In addition, the correlation coefficients of subtests with the total scores were significant in all cases (0.82-0.96). Furthermore, the reliability of the test was examined using test-retest, Cronbach's alpha, and coefficients of credit scoring. Not to mention, the test-retest measured between 0.70 and 0.94 ($\alpha=0.1$). Additionally, the internal consistency of the test was calculated using the Cronbach's alpha for the whole test and each of the subscales (0.86, 0.72, 0.80, and 0.81, respectively), and the coefficients of credit scoring measured 0.98 (Ghomrani et al., 2006). Moreover, the Cronbach's alpha measured 0.83 in the present study.

2-4. Intervention

Group Play Therapy: This therapy included six 60-minute sessions, once per week, which was based on cognitive behavioral principles as follows:

First Session: The members were introduced to each other. In this session, children's compatibility with the environment and each other was intended,

and any game suggested by children was played with the aim of building friendship and a sense of security.

The Second and Third sessions: In these two sessions, puppets and soft toys were used to teach prosocial behaviors to children.

The Fourth Session: Toy animals were used to detect children's fear of relationships with others and to find their concerns about establishing relationships through role playing as animals.

The Fifth Session: Imaginative games were played to help children express fears, wishes and ideas verbally and nonverbally. In addition, playing with patterns was performed at the request of children.

The Sixth Session: Playdough was used by children to express their feelings and concerns through sculptures. While playing with playdough, members of the group proposed solutions whereby they could solve their problems and strengthen their interrelationships. In this session, they were helped to leave their therapeutic sessions and generalize their learning to the outside world. After selecting the groups, the 38-item theory of mind tests were distributed among the respondents in both groups individually. Then, six weekly 60-minute programs were conducted by a researcher for the experimental group. During the intervention, no one left the study, and both groups were given post-tests.

2.5-Ethical Consideration

To consider the ethical principles, informed consent was taken from the parents before completing the questionnaires.

2-6. Inclusion and Exclusion Criteria

The inclusion criteria were 1) having normal IQ, being in the 6-7 age range, the consent of the principal allowing the child to participate in the study, the right to freely accept or reject participation in the research, and assuring them of the confidentiality of the collected information. Moreover, mentally or physically sick subjects and more than two absences in the intervention sessions were excluded from the study.

2-7. Data Analyses

For data analysis, the descriptive statistics (mean and standard deviation) and inferential statistics (ANCOVA) were used. All tests were analyzed using the SPSS Statistics Software Version 23.0.

3- RESULTS

The results of Table 1 show the descriptive findings, including mean and standard deviation for the dimensions and total score of theory of mind.

Table 1. The Mean and Standard Deviation of the Levels of Theory of Mind in the Experimental and Control Groups

Test	The Levels of the Theory of Mind	Mean	Test	Group	Control
			STDEV	Mean	STDEV

Pre-test	1st	16.20	1.81	16.33	**1.53**
	2nd	7.30	2.12	7	**1.51**
	3rd	0.38	0.45	0.37	**0.45**
	Total	24.25	2.46	23.41	**2.23**
Post-test	1st	19.85	1.18	16.80	**1.45**
	2nd	11/27	1/43	7/23	**2/16**
	3rd	4/13	1/03	0/53	**0/64**
	Total	34/63	1/86	24/47	**3/1**

Table 2. The Results of Levene's Test for Examining the Equality of Variances of Scores at Different Levels of the Theory of Mind

Variable	F	Df1	Df2	Sig.
1st level	3.76	1	28	**0.06**
2nd level	1.60	1	28	**0.21**
3rd level	0.13	1	28	**0.71**
Total	0.24	1	28	**0.62**

To examine the assumptions of analysis of covariance (ANCOVA), the homogeneity of the slopes of post-tests and pre-tests were calculated. Moreover, to compare the experimental and control groups in terms of the theory of mind, the multivariate analysis of covariance was used. The results revealed that the tests were significant at $p<0.01$, an indication that the control and experimental groups were significantly different at least in one of the levels (see Table 3).

Table 3. The Results of Multivariate Analysis of Covariance on the Mean Scores of Post-tests of Variables in Both Groups

Test	Value	F	Df of Assumption	Df of Error	Sig.	Eta Squared
Pillai Trace	0.67	65.49	3	23	0.001	0.84
Wilks Lambada	0.11	65.49	3	23	0.001	0.84
Hotelings Trace	6.78	65.49	3	23	0.001	0.84
Roys Largest Rot	6.87	65.49	3	23	0.001	0.84

Table 3 merely states that there are significant differences between the experimental and control groups in one of the domains. So, to identify the domain, the multivariate analysis of covariance (MANCOVA) was used (see Table 4).

Table 4. The Results of Multivariate Analysis of Covariance on the Mean Scores of Post-tests of Variable Levels in the Experimental and Control Groups

Sources of Change	Mean Square	Degree of freedom	F	Sig.	eta squared
1st level	63.16	1	42.76	0.001	0.64
2nd level	127.34	1	45.83	0.001	0.64
3rd level	87.27	1	131.64	0.001	0.85

4- DISCUSSION

The present study aimed to investigate the effectiveness of group play therapy on boosting the levels of preschool children's theory of mind. As the results revealed, the group play therapy was efficacious in enhancing the levels of preschool children's theory of mind, so that the mean score of theory of mind in all three levels as well as the mean score of total theory of mind increased after the therapeutic interventions based on the assessments of theory of mind test. This result was consistent with the results of studies conducted by Dehghan et al. (24), Ansarinejad et al. (25), Kakajoybari et al. (26), Ghafari et al. (27), Adib Sereshki et al. (28), Resches & Perez – Pereira (29), Lecce et al. (19), Ryan et al. (30)and Rus-Calafell et al. (31). It should be noted that this method was effective in the case of the third level of the theory of mind (understanding the secondary false belief), and it seems that the effectiveness of this method to achieve high levels of theory of mindrequires more cognitive and mental processes and interventions. This finding was inconsistent with the results of studies done by Fombonne(32), Adib Sereshki (28), Moghtari (33) and Naderi et al. (34). No change was observed in the third level of the theory of mind in the said studies, which might be due to the chosen statistical populations. In other words, in the said studies, the statistical populations included children with autism and mental retardation, while the present work studied the normal and ordinary children.

The abovementioned studies were among those which dealt with the effectiveness of teaching the theory of mind in improving the levels of the theory of mind. However, no study was found to deal with the effectiveness of play therapy in enhancing the levels of the theory of mind. The results of previous studies (28) suggest that experience can be effective in developing the theory of mind, and it is required for the development of theory of mindbecause experience provides more opportunities for learning about other people's thinking, and communication and social learning can act as major sources for the development of children's understanding of the mind. People can express their emotions to family members, friends and relatives through building intimate relationships, thereby strengthening their emotional connection with them and coping with problems with the best way possible through asking for timely assistance from others.

5-CONCLUSION

Based on the findings of the present study and abovementioned material, it can be concluded that weakness in the theory of mind can be regarded as a major sign of one's psychological problems and especially social interactions in the future. Therefore, to enhance the ability of theory of mind in children, more efforts and training should be done. Moreover, one of these approaches is playing games whose effects on the theory of mind of children were confirmed in the present study. Games are useful for children because they are provided with suitable opportunities for diagnosis and treatment. Playing games come from intrinsic motivation and reflect the inner feelings of children. Playing games helps children to express their feelings and external communications, thereby developing orientations, communication skills and increasing children's happiness and harmony with the environment (18).

The present study was conducted on preschool children whose genders were not matched. In this regard, it is suggested that matching be done for both genders in the future.

6- CONFLICT OF INTEREST: None.

7- REFERENCES

1. Khanjani Z, Hodavandkhani F. Theory of Mind: Evolution and approach. Quarterly of Psychology, University of Tabriz. 2009;4(16):85-115.
2. Newen A, Vogeley K, Zinck A. Social cognition, emotion and self-consciousness: A preface. Academic Press; 2008.
3. Nazari B, Bakhshi S, Kaboudi M, Dehghan F, Ziapour A, Montazeri N. A Comparison of Quality of Life, Anxiety and Depression in Children with Cancer and Healthy Children, Kermanshah-Iran. International Journal of Pediatrics. 2017;5(7):5305-14.
4. Razza RA, Blair C. Associations among false-belief understanding, executive function, and social competence: A longitudinal analysis. Journal of Applied Developmental Psychology. 2009;30(3):332-43.
5. Ferguson FJ, Austin EJ. Associations of trait and ability emotional intelligence with performance on Theory of Mind tasks in an adult sample. Personality and Individual Differences. 2010;49(5):414-8.
6. Kalbe E, Schlegel M, Sack AT, Nowak DA, Dafotakis M, Bangard C, et al. Dissociating cognitive from affective theory of mind: a TMS study. cortex. 2010;46(6):769-80.
7. Aminyazdi A. Social Cognition: the Developments of Theory of Mind in Children. Quarterly of Education and Psychology Studies. 2012;5:43-66.
8. Flavell JH. Cognitive development: Past, present, and future. Developmental psychology. 1992;28(6):998.
9. Bodden ME, Dodel R, Kalbe E. Theory of mind in Parkinson's disease and related basal ganglia disorders: a systematic review. Movement Disorders. 2010;25(1):13-27.
10. Bakhshi S, Montazeri N, Nazari B, Ziapour A, Barahooyi H, Dehghan F. Comparing the Self-Esteem and Resiliency between Blind and Sighted Children and Adolescents in Kermanshah City. World Family Medicine. 2017;15(7):46-51.
11. Premack D, Woodruff G. Does the chimpanzee have a theory of mind? Behavioral and brain sciences. 1978;1(04):515-26.
12. Kazdin A. Encyclopedia of Psychology Washington. American Psychological Association. 2000;3:1-8.
13. Ginsburg KR. The importance of play in promoting healthy child development and maintaining strong parent-child bonds. Pediatrics. 2007;119(1):182-91.
14. Azarnioshan B, BehPajooh A, Ghobary-Bonab B. The effectiveness of cognitive behavior based play therapy on the behavioral problems among primary students with intellectual disabilities. Iranian Journal of Exceptional Children. 2012;5(2):5-17.
15. Mehrdad H. A Study of the Effects of Play Therapy on the Progression of Mentally Retarded Primary School Students Residing in Khorramabad, Iran, in the Academic Year 2009-2010. Journal of Intellectual Disability. 2011;1(2):119-44.
16. Sartin M. Book review: Social skills games for children Plummer, DM: London: Jessica Kingsley.(2008) 176pp. Pbk£ 15.99; ISBN 978 1 8431 0617 3. Child Language Teaching and Therapy. 2009;25(2):274-6.
17. Vahedi S. The effect of Nmaysharvsky in social skills training on reducing aggression and social skills. Second National Congress on Iranian art therapy. Family Research Institute Shahid Beheshti University, Tehran. 2009.

18. Landreth G. Play therapy: The art of the relationship. New York, N.Y:BrunnerRuttledge. Gallagher. 2011.
19. Lecce S, Bianco F, Devine RT, Hughes C, Banerjee R. Promoting theory of mind during middle childhood: A training program. Journal of experimental child psychology. 2014;126:52-67.
20. Lecce S, Hughes C. The Italian job?: Comparing theory of mind performance in British and Italian children. British Journal of Developmental Psychology. 2010;28(4):747-66.
21. Hughes C. Social understanding and social lives: From toddlerhood through to the transition to school. London: Psychology Press. 2011:356-70.
22. Ornaghi V, Brockmeier J, Grazzani I. Enhancing social cognition by training children in emotion understanding: A primary school study. Journal of Experimental Child Psychology. 2014;119:26-39.
23. Ghamarani O, Alborz E. The validity and reliability test" theory of mind in a group of students with mental

retardation and normal cityJournal of Psychology. Journal of Psychology. 2006;10:181-99.
24. Dehghan F, Yazdanbash K, Momany K. The impact of Communicational Skills Training on Improving Children's Theory of Mind. Social Cognition. 2015;Special Edition:83-96.
25. Ansarinejad S, Moleli G, Adib Sereshki N. A Study of the Effectiveness of Teaching the Theory of Mind on the Improvement of the levels of Theory of Mind in Mentally Retarded Students. Quarterly of Clinical Psychology Research and Counseling. 2011;1(2):105-20.
26. Kakajoybari A, Shaghaghi F, Baradaran M. Development of Social Cognition in theory of mind in childrenSocial Cognition. Social Cognition. 2011;1(2):32-9.
27. Ghafari U, Karaskian A, Biglari S. A Comparative Study of Theory of Mind in People with Schizophrenia, Bipolar Affective Disorder and Normal Individuals. Quarterly of Modern Psychological Research. 2013;8(31):77-97.
28. Adib Sereshki N, Nesaian A, Asadi Gandomani R, Karimloo M. A Study of the Effectiveness of Teaching the Theory of Mind on the Improvement of Cooperation, Self-control and Determination of Autistic Boys Aged 7-12 from the Perspective of Mothers. Quarterly of Intellectual Disability. 2013;3(11):127-45.
29. Resches M, Pereira MP. Referential communication abilities and theory of mind development in preschool children. Journal of Child Language. 2007;34(01):21-52.
30. Ryan NP, Anderson V, Godfrey C, Eren S, Rosema S, Taylor K, et al. Social communication mediates the relationship between emotion perception and externalizing behaviors in young adult survivors of pediatric traumatic brain injury (TBI). International Journal of Developmental Neuroscience. 2013;31(8):811-9.
31. Rus-Calafell M, Gutiérrez-Maldonado J, Ortega-Bravo M, Ribas-Sabaté J, Caqueo-Urízar A. A brief cognitive–behavioural social skills training for stabilised outpatients with schizophrenia: A preliminary study. Schizophrenia research. 2013;143(2):327-36.
32. Fombonne E. Epidemiological surveys of autism and other pervasive developmental disorders: an update. Journal of autism and developmental disorders. 2003;33(4):365-82.
33. Moghtari I. A Study of the Effectiveness of Theory of Mind on Asperger Children's Social Skills. A thesis submitted to Allameh Tabatabaei University for the partial fulfilments of master's degree. 2010.
34. Naderi S, Dadkhah A, Borjali A, Hashemi Azar Z, Panaghi L. Dohsa Training and Theory of Mind in High Functioning Autistic Children. Iranian Rehabilitation Journal. 2014;12(2):34-8.

Prevalence of Molar Incisor Hypomineralisation (MIH) in 7-10 year old school children in southern Saudi Arabia: A cross-sectional study.

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ABSTRACT

Aim: The purpose of this study was to determine the prevalence of Molar Incisor Hypomineralisation (MIH) in 7-10 years old school children in Southern Saudi Arabia. **Materials & Method:** A Total of 596 school children of age group 7-10 years were screened for MIH. Clinical examination were done inside the respective schools. Dental examination were carried out by using a standard mouth mirror and dental probe. After thorough brushing, the four Permanent First Molars (PFM) and eight erupted permanent incisors were examined on wet for demarcated opacities and enamel breakdown under portable light source. The results were recorded and analyzed for statistical significance using the Chi-square test and t-test with a P value of <0.05 considered significant. **Results:** The prevalence of MIH in a group of Saudi school children was 21.3%. Permanent first molar was most affected individual teeth in this study as compared to incisors. MIH cases were found to be more affected in maxillary arch as compared to mandibular arch. Permanent lower laterals were the least affected teeth compared to centrals and first molar. **Conclusions:** MIH is a clinically and epidemiologically relevant problem in Saudi school children. The high rate of severe forms is of clinical concern. The findings of the present study stress the need for educating present and future dentists and pediatric specialists in MIH, as well as for developing public health policies for the prevention and adequate treatment of MIH.

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Keywords: MIH, FPM, Enamel defect, Prevalence, Children, Saudi Arabia.

Introduction

Developmental defects in enamel (DDE) like Molar Incisor Hypomineralization (MIH) may predispose for plaque accumulation and dental caries, leading to pain and discomfort for the child. This, in turn, may result in dental behavior management problems (BMPs) and dental fear and anxiety, and it may also cause aesthetic problems.[1,2] Clinical studies have revealed a higher prevalence of enamel hypomineralization in both primary[3,4] and permanent dentitions[5] in children born preterm. Due to profound sensitivity of affected teeth, children are reluctant to carry out effective oral hygiene (OH) and to accept dental treatment, being at risk of developing dental phobias and presenting behaviour management problems.

Molar-incisor-hypomineralisation (MIH) is defined as the developmentally derived dental defect that involves hypomineralisation of 1 to 4 first permanent molars (FPM) that is frequently associated with similarly affected permanent incisors. The condition has been referred to as 'hypomineralized permanent first molars', 'idiopathic enamel hypomineralization', 'non-fluoride hypomineralization', and 'cheese molars' by different authors.[6,7] The defect is clinically presented as demarcated enamel opacities of different colour in the affected teeth, occasionally undergoing post-eruptive breakdown due to soft and porous enamel. This may result in atypical cavities or even complete coronal distortion, requiring extensive restorative treatment. Most prevalence studies of MIH have been carried out in European countries, and rates between 3.6% and 19.3% were reported.[8] At the time of this study, there has been no

published prevalence study on MIH in southern part of Saudi Arabia. The aim of this study was to investigate retrospectively the prevalence of MIH in a group of Saudi Arabian children.

Subjects and Methods

A total number of 596 male school children were participated in the study with mean age of 8.5 years and age ranges from 7-10 years were screened for MIH in southern Saudi Arabia. The clinical examinations were performed by experienced clinicians in those children who fulfilled the required inclusion criteria. The examiners received training and were calibrated against each other prior to this study. The study participants were given clear explanation about the objective of the study. Voluntary informed consent were obtained from the parents before examination of child. Dental examination were carried out by using a standard mouth mirror and dental probe. The location of demarcated opacities and enamel breakdown were recorded on a specially designed patient research data sheet. All the participating children were instructed to brush their teeth in their classroom before examination. After thorough brushing, the four FPM's and eight erupted permanent incisors were examined on wet for demarcated opacities and atypical restorations under portable light source.

Inclusive criteria:

(i) 7- to 10-year-old children

(ii) No systemic disease history

(iii) Life-long residents in the selected regions (children born and living in the study area).

(iv) Well-demarcated opacities when examined under wet condition

(v) Children's mothers and fathers should have permanently lived in the respective area for at least 5 years before the child's birth, while breastfeeding was also practiced in the same region.

(vi) Four PFMs and eight permanent incisors erupted.

(vii) Dentitions with generalized opacities present on all teeth (such as in several forms of amelogenesis imperfecta), rather than limited to the PFMs and permanent incisors, are not considered to have MIH.

(viii) The defects in the permanent incisors were not associated with history of trauma or infection in the primary dentition.

The diagnostic criteria used in this study, however, were basically the same as those adopted in epidemiologic studies, [9.10] and the three examiners were calibrated and well familiar with diagnosis of MIH, which would help to reduce the magnitude of error caused by study design. Ethical clearance was obtained from ethical approval committee of the King Khalid University, Abha, Saudi Arabia. The criteria used for the diagnosis of MIH were those developed by Weerheijm et al [11] and described at the European meeting held in Athens in 2003. The results were recorded and analyzed for statistical significance using the Chi-square test and t-test with a P value of <0.05 considered significant.

Results

A total number of 596 male school children were participated in the study with mean age of 8.5 years and age range from 7-10 years. Of the children examined, 127 were affected by MIH, with prevalence rate of 21.3%.

Table 1 shows the prevalence of MIH among the different ages. Prevalence of

MIH according to age was, 17% at 7 years, 14% at 8 years, 30% at 9 years and 39% at 10 years of age. The majority of children diagnosed with MIH were 10 years old (39 %), while those aged 8 years had the lowest MIH prevalence (14 %). Pearson Chi-Square showed statistically significance between the age and the prevalence of MIH.

633 teeth were affected by MIH, of which 225 (36%) were central incisors, 94(15%) were lateral incisors and 314(49%) were FPM [Table. 2], showed statistically significance. Prevalence of MIH occurrence is more in maxillary arch 96(69%) as compared to mandibular arch 43 (31%) [Figure 1].

Discussion

A wide range of prevalence (4 to 25%) was reported for MIH by various investigators in different countries. However, most of these studies were conducted in European countries.[2,8,12,13] To our knowledge, at the time of this study only two studies were reported in Jeddah and Riyadh, Saudi Arabia.[14,15] Prevalence of MIH in southern part of Saudi Arabia were not published in literature.

The prevalence of MIH in a group of Saudi children was found to be 21.3%, presently there are very few studies on prevalence of MIH from Saudi Arabia generally. The prevalence of MIH in present study as compared to other Arabian countries, were similar to that reported in Iraq (21.5%),[16] is much higher to that reported in Jeddah, Saudi Arabia(8.6%),[14] Turkey (7.7%),[17] Jordan (17.6%),[18] Libya (9%),[19] and Iran (18.4),[20] but lesser than reported in Riyadh, Saudi Arabia (40.6%).[15] The high variation in the prevalence of MIH could be due to differences in methods, sample sizes, criteria

used to diagnose MIH, different age cohorts, or real differences between regions and countries (Jalevik, 2010; Tadikonda et al., 2015).[21,22] Another drawback of this study was that the severity of the hypomineralization was not recorded in the clinical notes. In the present study, only boys were included as boys and girls have separate schools in Saudi Arabia. More local studies are required to evaluate gender predilection regarding MIH through combined studies in girls and boys schools.

The age range of this study with 7- 10-years of age is ideal, as the FPM and incisors have just erupted. Later, caries and extractions of severely affected molars mask the detection of MIH (Balmer et al., 2012).[23] Most studies did not find a significant association between MIH and age (Preuisser et al. 2007),[24] in our study showed a higher prevalence of MIH among children 10 years old as compared to younger age groups. Similar finding observed by Costa-Silva et al (2010),[25] this is due to hypomineralization lesions may be dynamic defects, which changes in the oral environment as the child grows older.

According to the definition of MIH, only if at least one FPM was presented with MIH, the case was diagnosed as MIH. Children with enamel defects only in incisors or other non-index teeth were not included in the MIH group, which could lead to an underestimation of MIH. In our study, FPM (49%) were affected as compared to permanent central incisors (36%) and permanent lateral incisors (15%). Maxillary molars were affected more compared to mandibular molars (Martinez Gomez et al., 2012; Parikh et al., 2012; Preusser et al., 2007). [26,27,24] On the other hand, there are also studies indicating the opposite (Jälevik et al., 2001)[9] or even no difference between the jaws (Chawla et al., 2008a).[28] Togoo RA (2011),[29] conducted a study to determine prevalence of FPM caries among

7-10 years old school going boys in Abha, Saudi Arabia. Concluded that point prevalence of dental caries in FPM was recorded to be 66.4%. Teeth affected by MIH exhibits enamel defected and rapid progression of caries; therefore, in many cases, affected teeth require restorative treatment right after eruption. If the defect is deep and widespread, it can lead to severe loss of tooth material and early loss of permanent teeth because of caries progression. The age-dependent severity of MIH had been reported in previous studies as well, suggesting that over a period of time MIH, a pre-existing congenital defect of enamel, results in post enamel breakdown of FPM due to heavy masticatory forces (Leppaniemi et al. 2001; Jasulaityte et al. 2007).[30,31] Petrou et al (2015) [32] found that almost one-fifth of the teeth diagnosed with MIH exhibited severe defects. Trauma to primary teeth has been attributed to cause MIH in the corresponding permanent incisors (Balmer et al. 2015).[33] In addition, in adolescents with active social lives and a developing interest in appearance and slight defects can have a serious impact on self-esteem.[34]

Although the etiology of MIH is not fully known, it is likely to be complex and multifactorial, with some degree of genetic or epigenetic involvement (Silva et al., 2017).[35] Recently, Kotsanos et al.,[36] stated that children exhibiting MIH have 11 times greater probability of undergoing restorative treatment in their FPM's compared with children of a control group. Moreover, fillings and sealants in MIH-affected children have over three times a greater probability of needing re-treatment than interventions on children of the control group.[36] Despite the higher treatment demands, restorative treatments for these teeth are challenging for both patient and dentist.[37] Clinically, treating MIH in

children has serious drawbacks. The problems in treating child patient having MIH are related to unexpectedly rapid caries development in the erupting FPM, pain and sensitivity, oral hygiene and diet habits, difficulty to anesthetize the MIH molars (Jalevik & Klingberg, 2002).[37] It has been shown that children with MIH receive much more dental treatment that unaffected children. (Jalevik & Klingberg, 2002, Kotsanos et al., 2005).[37,36] Thus, treatment planning should also consider the long-term prognosis of teeth suffering from this condition. Allazzam et al (2014)[14] conducted study in Jeddah, observed that lack of exposure to MIH in undergraduate training, future dentists will face similar challenges in terms of managing patients with MIH.

Since MIH is not a classical disease, parents may not pay attention to the discolorations or even the enamel breakdown of their children's teeth before the child itself starts to complain of pain or discomfort during daily activities (e.g. eating). Hence, information regarding MIH should be made available to the public and parents in particular should be made aware of the features of MIH, the high necessity of tooth brushing and of regular visits at the dental practice for early preventive and therapeutic steps.

The present study shows that MIH is an existing problem in southern part of Saudi Arabia. However, findings are not representative of the Saudi community as a whole. Despite these limitations, the findings of the study contributes to better understanding of MIH as it provides data on MIH from a country where there have very few studies in the literature.

Conclusions

1- The prevalence of MIH in a group of Saudi school children was 21.3%.

2- Permanent first molar was most affected individual teeth in this study as compared to incisors.

3- MIH cases were found to be more in maxillary arch as compared to mandibular arch.

4- Permanent lower laterals were the least affected teeth compared to centrals and first molar.

In conclusion, MIH is a clinically and epidemiologically relevant problem in Saudi school children. The high rate of severe forms is of clinical concern. Therefore, diagnosing and treating MIH should be part of the basic undergraduate education in Saudi universities. As the interest in MIH is very recent, continuing education should also address this topic to bring it to the attention of all dental practitioners. The findings of the present study stress the need for educating present and future dentists and pediatric specialists in MIH, as well as for developing public health policies for the prevention and adequate treatment of MIH.

What this paper adds

- There is clearly a lack of data on the prevalence of Molar Incisor Hypomineralization (MIH) from this region of the world. At the time of the write up of this manuscript, there had been only two published studies from Saudi Arabia (Jeddah and Riyadh region). However, there were no data available in the southern part of Saudi Arabia in the literature. This study found that the prevalence of MIH in 7 to 10 year old Saudi Arabian boys children was 21.3% which is comparable to other studies that have examined children of the similar ages (between 7 and 8 years) using the EAPD criteria.

- This study provides baseline data on prevalence of MIH in Saudi Arabian population

Why this paper is important to pediatric dentists

- Pediatric dentists would have high chances to encounter children with MIH.
- Pediatric dentists who treat Saudi children should be aware that this population group can also be affected with MIH.
- This is important as this knowledge may provide clinicians direction on treatment planning for patients afflicted by MIH.
- The findings from this study suggest the association between MIH occurrence and the Arabic ethnicity.

References

1. Willmott NS, Bryan RA, Duggal MS. Molar-incisor hypomineralisation: a literature review. Eur Arch Paediatr Dent 2008; 9:172–9.
2. Ja¨levik B, Klingberg G, Barregard L, Nore´n JG. The prevalence of demarcated opacities in permanent first molars in a group of Swedish children. Acta Odontol Scand 2001; 59:255-60.
3. Grahne´n H, Sjo¨ lin S, Stenstro¨m A. Mineralization defects of primary teeth in children born pre-term. Scand J Dent Res 1974; 82:396–400.
4. Aine L, Backstrom MC, Maki R, Kuusela AL, Koivisto AM, Ikonen RS, Maki M. Enamel defects in primary and permanent teeth of children born prematurely. J Oral Pathol Med 2000; 29:403–9.
5. Seow WK. A study of the development of the permanent dentition in very low birth weight children. Pediatr Dent 1996; 18:379–84.
6. Wilson-Costello D. Is there evidence that long-term outcomes have improved with intensive care. Semin Fetal Neonatal Med 2007; 12:344–54.

7. Allen MC. Neurodevelopmental outcomes of preterm infants. Curr Opin Neurol 2008; 21:123-8.
8. Cho SY, Ki Y, Chu V. Molar incisor hypomineralization in Hong Kong Chinese children. Int J Paediatr Dent 2008; 18(5):348-52.
9. Jälevik B, Klingberg G, Barregard L, Norén JG. The prevalence of demarcated opacities in permanent first molars in a group of Swedish children. Acta Odontol Scand 2001; 59:255-60.
10. Calderara PC, Gerthous PM, Mocarelli P, Lukinmaa PL, Tramacere PL, Alaluusua S. The prevalence of molar incisor hypomineralisation (MIH) in a group of Italian school children. Eur J Paediatr Dent 2005; 6:79-83.
11. Weerheijm KL, Duggal M, Mejàre I, Papagiannoulis L, Koch G, Martens LC, *et al*. Judgement criteria for molar incisor hypomineralisation (MIH) in epidemiologic studies: a summary of the European meeting on MIH held in Athens, 2003. Eur J Paediatr Dent 2003; 4:110-3.
12. Koch G, Hallonsten AL, Ludvigsson N, Hansson BO, Holst A, Ullbro C. Epidemiologic study of idiopathic enamel hypomineralization in permanent teeth of Swedish children. Community Dent Oral Epidemiol 1987; 15(5):279-85.
13. Weerheijm KL, Groen HJ, Beentjes VE, Poorterman JH. Prevalence of cheeses molars in eleven year old Dutch children. ASDC J Dent Child 2001; 68(4):259-62.
14. Allazzam, SM., Alaki, SM. and El Meligy, OA. (2014): Molar Incisor Hypo-mineralization, Prevalence, and Etiology. Int J Dent., 1-8.
15. Hammad N. Molar incisor hypomineralization in a group of female children in Riyadh: prevalence and

clinical characteristics. Int J Adv Res 2017; 5(11):614-22.

16. Ghanim A, Morgan M, Mariño R, Bailey D, Manton D. Molar-incisor hypomineralisation: prevalence and defect characteristics in Iraqi children. Int J Paediatr Dent 2011; 21(6):413-21.
17. Sonmez H, Yildirim G, Bezgin T. Putative factors associated with molar incisor hypomineralisation: an epidemiological study. Eur Arch Paediatr Dent 2013; 14(6):375–80.
18. Zawaideh FI, Al-Jundi SH, Al-Jaljoli MH. Molar incisor hypomineralisation: prevalence in Jordanian children and clinical characteristics. Eur Arch Paediatr Dent 2011;12(1):31–6.
19. Fteita D, Ali A, Alaluusua S. Molar-incisor hypomineralization (MIH) in a group of school-aged children in Benghazi, Libya. Eur Arch Paediatr Dent 2006; 1(2):92-5.
20. Salem K, Aziz D, Asadi M. Prevalence and Predictors of Molar Incisor Hypomineralization (MIH) among Rural Children in Northern Iran. Iran J Public Health Nov 2016; 45(11):1528-30.
21. Jalevik, B. Prevalence and diagnosis of Molar-Incisor Hypo-mineralization (MIH): A systematic review. Eur Arch Paediatr Dent 2010; 11:59-64.
22. Tadikonda AN, Acharya S, Pentapati, K.C. Prevalence of Molar Incisor Hypomineralization and its Relation with Dental Caries in School Children of Udupi District, South India. World J Dent 2015; 6(3):143-6.
23. Balmer R, Toumba J, Godson J, Duggal M. The prevalence of molar incisor hypomineralisation in Northern England and its relationship to socioeconomic status and water fluoridation. Int J Paediatr Dent 2012 Jul; 22:250-7.
24. Preuisser SE, Ferring V, Wleklinski C, Wetzel WE. Prevalence and severity of

MIH in a region of Germany: a brief communication. J Public Health Dent 2007; 67:148–50.

25. da Costa-Silva CM, Jeremias F, de Souza JF, Cordeiro Rde C, Santos-Pinto L, Zuanon AC. Molar incisor hypomineralisation: prevalence, severity and clinical consequences in Brazilian children. Int J Paediatr Dent 2010 Nov; 20:426–34.
26. Martinez Gomez TP, Guinot Jimeno F, Bellet Dalmau LJ, Giner Tarrida L. Prevalence of molar incisor hypomineralisation observed using transillumination in a group of children from Barcelona (Spain). Int J Paediatr Dent 2012 Mar; 22(2):100-9.
27. Parikh DR, Ganesh M, Bhaskar V. Prevalence and characteristics of Molar Incisor Hypomineralisation (MIH) in the child population residing in Gandhinagar, Gujarat, India. Eur Arch Paediatr Dent 2012 Feb; 13(1):21-6.
28. Chawla N, Messer LB, Silva M. Clinical studies on molar incisor hypomineralisation. Part 1: distribution and putative associations. Eur Arch Paediatr Dent 2008; 9(4):180-90.
29. Togoo RA, Yaseen SM, Zakirulla M, Al Garni F, Khoraj AL, Allahbaksh M. Prevalance of first permanent molar caries among 7-10 years old school going boys in Abha city, Saudi Arabia. J Int Oral Health 2011 Oct; 3(5):29-34.
30. Leppaniemi A, Lukinmaa PL, Alaluusua S. Nonfluoride hypomineralizations in the permanent first molars and their impact on the treatment need. Caries Res 2001; 35:36-40.
31. Jasulaityte L, Veerkamp KL, Weerheijm KL. Molar incisor hypomineralization: review and prevalence data from study of primary school children in Kaumas (Lithiania). Eur Arch Paediatr Dent 2007; 8:87-94.

32. Petrou MA, Giraki M, Bissar AR, Wempe C, Schafer M, Schiffner U, *et al.* Severity of MIH findings at tooth surface level among German school children. Eur Arch Paediatr Dent 2015 Jun; 16(3):271-6.
33. Balmer R, Toumba KJ, Munyombwe T, Godson J, Duggal MS. The prevalence of incisor hypomineralisation and its relationship with the prevalence of molar incisor hypomineralisation. Eur Arch Paediatr Dent 2015 Jun; 16(3):265-9.
34. Cortes MIS, Marcenes W, Sheiham A. Impact of traumatic injuries to the permanent teeth on the oral health-related qualithy of life in 12-14-year old children. Community Dent Oral Epidemiol 2002; 30:193-8.
35. Silva MJ, Kilpatrick N, Crombie F, Ghanim A, Manton D. What's New in Molar Incisor Hypo-mineralization? Dent Update 2017; 44:100-6.
36. Kotsanos N, Kaklamanos EG, Arapostathis K. Treatment management of first permanent molarsin children with molar–incisor hypomineralisation. Eur J Paediatr Dent 2005; 6:179-84.
37. Jälevik B, Klingberg GA. Dental treatment, dental fear and behaviour management problems inchildren with severe enamel hypomineralization of their permanent first molars. Int J Paediatr Dent 2002; 12(1):24-32.

Table 1: Distribution of MIH (n, %) among children in different age groups (in years)

AGE	MIH CASES	No MIH	Total Number
7	21 (17%)	73 (83%)	94
8	18 (14%)	110 (86%)	128
9	38 (30%)	126 (70%)	164
10	50 (39%)	160 (61 %)	210

TOTAL	127(21.3%)	469 (79%)	596
Chi-square	21.315		
df	3		
P-value	**0.000***		

**Statistically Significant at 5% level of Significance*

Table 2: Distribution of permanent teeth affected by MIH.

	MAXILLARY ARCH	MANDIBULAR ARCH	Total n (%)
Central incisor	162	63	225 (36%)
Lateral Incisor	56	38	94 (15%)
FPM	163	151	314 (49%)
TOTAL	381	252	633 (100%)
Chi-Square	111.52	83.88	116.08
df	2	2	2
P-Value	**0.000***	**0.000***	**0.000***

**Statistically Significant at 5% level of Significance*

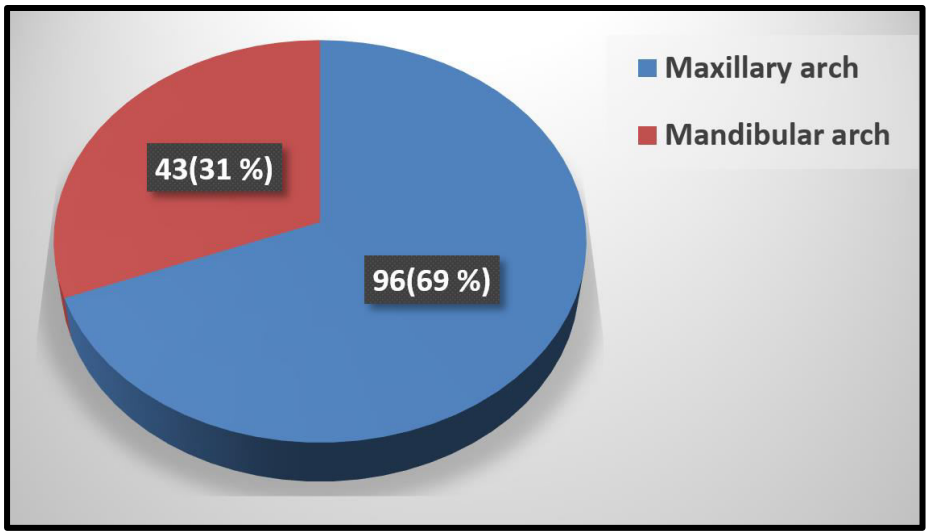

Figure 1: Distribution of MIH according to dental arch - n (%)

ON SECURING THE FINANCIAL STABILITY OF THE HEALTH SYSTEM UNDER IMPLEMENTATION OF COMPULSORY SOCIAL HEALTH INSURANCE

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Abstract

Healthcare in Kazakhstan will be gradually transferred to the system of compulsory social health insurance, based on the joint responsibility of the population, the state and employers. The need for a scientific justification for the financial sustainability of the system determines the relevance of this study.

The majority of respondents (55%) believe that at the moment the implementation of SHI in Kazakhstan is relevant. The distribution of respondents by types of economic activity and the amount of insurance contributions, in the case of financing compulsory health insurance from their income, showed that in general, the population engaged in various fields of activity is willing to pay, only, from 1 to 3 thousand. In the opinion of the majority of the professional medical team (77.8%), under compulsory social health insurance (CSHI), only one single insurance fund should be submitted, which should be managed by the state.

Keywords: compulsory health insurance, financing the health care, private insurance, budget financing, medical services.

Objective

In the message of the Head of Republic N.Nazarbayev to the people of Kazakhstan dated January 10, 2018, in the item "First-class health care and a healthy nation", it was stated that health care will be gradually transferred to the system of compulsory social health insurance (CSHI), based on the joint responsibility of the population, the state and employers.

However, more preparatory work is required and the boundaries of the state's obligations are clearly defined. The population will be able to receive services that are not guaranteed by the state, by becoming a member of the CSHI or through voluntary medical insurance, as well as co-payment.
Preparatory work for the implementation of CSHI continued from 2014 according to the instructions of the Head of State. The Law of the Republic of Kazakhstan "On compulsory social health insurance" was putoperation, the Medical Insurance Fund was established.
Noting the progressiveness of the health insurance system for the development of the country's healthcare, at a joint session of the Chambers of Parliament on September 4, 2017, the Government was instructed to ensure equal participation of all categories of citizens in the CSHI system. First of all, he focused on issues of access to health care and conditions of participation in CSHI system of over 2.7 million Kazakhstanis related to "self-employed" category.
The essence of financial stability is manifested in the ability to provide supplies and costs as sources of financing. The need for a scientific justification for the financial stability of the system determines the relevance of this study.
The range of healthcare financing models used in the world can be classified according to various parameters: sources of funds, the number and type of payers, the degree of coverage, and others. In the framework of this study, first of all, we draw attention to the classification by sources of funds:

1. Budgetmodel
2. The model of compulsory social health insurance
3. The model of voluntary medical insurance
4. Medical savings accounts

Budget model

The budget model is characterized by the payment of medical care by state bodies at the expense of the state budget (Beveridge principle).
Within the framework of the budget model, the budgetary rules - the requirements for development, the rigid framework of targeted budget programs, multistage formal procedures, etc. - are distributed to health care funds. Minimal incentives for efficiency are both on the side of taxpayers who are obliged to maintain the functioning of the network of medical institutions and the suppliers side.
Among the developed countries, the budget model is used by the United Kingdom, Australia, Canada, the countries of Northern Europe.

The model of compulsory health insurance

The essence of the model is to pay mandatory targeted contributions to health care, and the amount of the contribution does not depend on the individual risk of getting sick. The funds can be consolidated both in a single state fund and in a variety of private funds (the Bismarck model).
The principle of solidarity in CHI is expressed in an explicit form; the principle of social justice is also well respected due to the proportionality of contributions to incomes.
The model assumes a higher level of competition at the supplier level for the distribution of funds, makes bankruptcy of suppliers possible if necessary.
Today SHI functions in many countries, including Germany, France, Japan, Korea, Russia, etc.

Private Health Insurance Model

Classic examples of private health insurance as a major health care financing model of

the system are the United States and Switzerland.
The model is characterized by compulsory contributions, but the size of the contribution depends on the likelihood of getting sick. Thus, the pooling of risks occurs in a weakened form, and a negative selection of risks leads to a reduction in the overall coverage and financial security of the population. That is why this system with variable success functions in countries with high incomes.

Medical savings accounts

The model of medical savings accounts, which also combines the functions of social security, operates in Singapore. The economically active population makes contributions commensurate with income to personal savings accounts. Thus, the principles of solidarity and sociality are completely excluded.
However, none of the models, with the exception of the budget, in practice, does not apply to international practice in its purest form. The most common combination is compulsory health insurance and budget financing.
Budgetary and budget-insurance forms of financing are the most acceptable in the context of today's healthcare system in Kazakhstan. The price for superiority is increased administrative costs. It is also characteristic that this fact is the most critical in the information space of the opponents of the SHI.
Prior to implementation UNHS, as the second half of the 2000s (2005-2009), funding for health care in the Republic of Kazakhstan, remaining completely budget after unsuccessful attempts to introduce compulsory medical insurance in 1996-1998, continued to gravitate toward the passive form. The system was characterized by outdated methods of financing and the almost complete absence of competition between health care providers.
These factors continued to be supported exclusively by bilateral relations "Administrator of budgetary programs - recipient of budget funds", in which the main focus of health care providers was not on improving the quality and availability of services, but on establishing formal and informal links with budget allocators and the full development of allocated funds.
In general, the system was characterized by high stability in that it was guaranteed to maintain the functioning of the existing network of health organizations.
Further in the work, the evaluation of the sustainability and effectiveness of the budget form of funding under UNHS was analyzed. In the period from 2009 to 2014, a number of significant reforms were carried out that solved the key problems of the budgetary system of financing, shifting the focus within the budget model to a more active form of interaction between administrators of budget programs and providers of medical care.
Active modernization of the system began in 2009 with the creation of a single payer at the national level.
An indirect positive impact on the sustainability of the budget financing system was the introduction of results-based budgeting in the Ministry of Health.
In general, all these measures led to increase competition by medical organizations, and also changed the nature of the relationship between the Payer and the providers of bilateral assistance to "one-to-many." This played a role in enhancing the system's sustainability in terms of the emergence of alternatives in the choice of provider of health services.
Particular attention should be paid to the "partial fund-holding" mechanism, which supplemented the per capita financing system for outpatient care in 2014. This

mechanism implies the allocation of funds for outpatient care between PHC organizations, in accordance with the amount of the attached population.
Another system-level tool that has made a significant contribution to financial sustainability is the policy on the volume of cases treated. Starting from 2012, the total number of hospital cases was recorded, including cases treated in a day hospital (including outpatient surgery), in a 24-hour in-patient clinic and high-tech medical services. This allowed us to contain the volumes in the conditions of the unprecedentedly active development of the day hospital and high-tech medical care.
The above policy allowed to shift the focus of health care consumption in the outpatient unit, and in a short time to introduce modern methods of treatment, while maintaining the financial sustainability of the system.

However, the form of budgetary financing is conditioned by the limitations and drawbacks of the scheme, such as the absence of an explicit financial participation of employees and employers; lack of diversification of financial sources of filling the health system; imbalance of state guarantees and financial resources.
Thus, the degree of system availability, namely, high efficiency and the level of sustainability acceptable for this form of financing, as well as the presence of the listed deficiencies of the budget model, were arguments for the introduction of the OSMS.
In order to obtain a complete picture of the public's attitude towards the introduction of compulsory social health insurance, a survey of opinions was conducted: a survey of the population and a survey of medical personnel.

Methods of research

A sociological survey of urban and rural population, as well as medical workers, was conducted in 3 cities of the Republic of Kazakhstan: Astana, Almaty, Atyrau.
The study surveyed adult population of the Republic of Kazakhstan at the age of 18 years and older.

Quantitative methods of collecting information and a survey were used.

The survey was conducted in the technique of personal formalized interviews in public places when the interviewer filled in or self-filled questionnaires on paper questionnaires. The estimated duration of the interview is 25-35 minutes. The questionnaire included the following blocks of questions: personal data; information on the socio-economic situation; questions on the introduction of CSHI in the Republic of Kazakhstan.

The total population is the inhabitants of the surveyed cities and corresponding areas in the return range from 18 years and older. The sample size - 200 respondents in each city, as well as 150 doctors and 300 nurses - employees of medical organizations of both public and private forms of ownership.

The survey involved interviewers who had received general training in conducting interviews and had experience in conducting consumer surveys.

Information processing and analysis. The data entry was carried out using specialized software SPSS. The evaluation of the actual correspondence of the data file to real questionnaires, data cleaning and logical data control are implemented. Using the package of applied statistical programs SPSS, verification of the data entered in Excel was carried out.

Poll Results

One third (32.5%) of respondents have one of the following types of insurance: life

insurance, health insurance, civil liability of vehicle owners, etc. Thus, it can be assumed that the population of Kazakhstan has an understanding of insurance in whole.

In a number of changes required in the health care system of Kazakhstan to meet the needs of the population, 68.6% of respondents think that the most necessary is to improve the quality of medical care, 52.4% to shorten waiting time and turn. More than 43% of respondents believe that it is necessary to improve the availability of medical services and the freedom to choose a medical organization.

The majority of respondents (55%) believe that at the moment the implementation of CSHI in Kazakhstan is relevant.

The distribution of respondents' answers to this question in terms of their incomes showed that the population with income from 100 thousand to 200 thousandtengeconsider the introduction of CSHI relevant. A group of individuals with a monthly income of more than 200 thousandtenge less agree with this opinion (50.8%).

According to the data shown in the table below, less than half of the respondents are willing to pay the premiums. So, just 43,1-65,1% of the respondents, in terms of their monthly income, responded positively to the question of willingness to pay, if it will give access to expensive medical procedures and medications.

Different sample of respondents with an income of 150 thousand. 200th.tg. willing to pay fees in order to have access to expensive medical procedures and medicines (65.1%), did not have to pay informal payments from the pocket (59.5%), live longer and have good health (59%).

Only in the position "The waiting time in the medical organization was reduced", the share of respondents with incomes over 200 thousand tenge prevailed. (54.8%), which indirectly explains the inexpediency for these persons to spend a lot of time in queues.

Table. Distribution of respondents' answers to the question "How relevant is the introduction of CSHI in Kazakhstan?" Intermsofrevenues.

Revenuesofrespondents	Up to 50 th.tenge	50 - 100 th.tenge	100 – 150 th.tenge	150 - 200 th.tenge	over 200 th.tenge	overall
To have access to expensive medical procedures and medicines						
Agree	43,1	54,7	57,1	65,1	56,5	1168
Do not agree	56,9	45,3	42,9	34,9	43,5	1151
No need to pay informal payments out of your pocket while receiving medical care						
Agree	38,1	47,0	51,9	59,5	52,4	1027
Do not agree	61,9	53,0	48,1	40,5	47,6	1294
The waiting time in the medical organization was reduced						
Agree	35,7	42,9	46,4	47,0	54,8	931
Do not agree	64,3	57,1	53,6	53,0	45,2	1362
Live longer and have good health						
Agree	40,1	48,8	55,2	59,0	55,7	1062
Do not agree	59,9	51,2	44,8	41,0	44,3	1236

This indicator in the context of respondents' incomes showed that people with different income levels equally do not support the principle of solidarity in financing health care. However, there are some differences among respondents with lower and higher incomes - respondents with the indicated income levels least of all support the principle of solidarity in financing.
Thus, from all respondents, only less than half support solidarity principle (46.4%). The majority of respondents (73.5%), in case the CSHI will be financed from the salary / income of citizens, have shown willingness to pay monthly from 1 to 3 thousand. 15.3% of respondents - from 4 to 6 thousand. 5.6% - from 7 to 9 thousand tenge; 6.6% - 10 thousand tons and more.

Respondents' answers in terms of their income showed that the lower the income of respondents, the lower the amount of anticipated insurance premiums.

The distribution of respondents by types of economic activity and the amount of insurance contributions, in the case of financing compulsory health insurance from their income, showed that in general, the population engaged in various spheres of economic activity is willing to pay, only, from 1 to 3 thousand. The share of the population engaged in the sphere of extractive industry, wholesale and retail trade, manufacturing industry, public administration, real estate transactions, allowed themselves to distinguish themselves by the fact that they are ready to pay from 7 thousand tenge. and higher.

Regarding the payment of insurance premiums for the following categories of citizens, the majority of respondents were unanimous in the view that the fees they must pay the state. This category consists of conscripts, the participants of the Second World War and the soldiers-internationalists, pregnant women, people with disabilities, seniors, children and the unemployed. Although, a few (15.4%) said that the unemployed and informally employed population themselves must pay insurance premiums.

Further, in the analyzed results of the survey of health workers in some aspects of health care financing and implementation mechanism with compulsory health insurance.

As shown in the figure, according to the opinion of the majority of the professional medical team (77.8%), with OSMS, only one single insurance fund should act. Of these, 57.3% believe that a single OSMS fund should be managed by the state. On the contrary, the other 19% of respondents believe that the MHIF should be managed by joint efforts of the state, employee and employer.

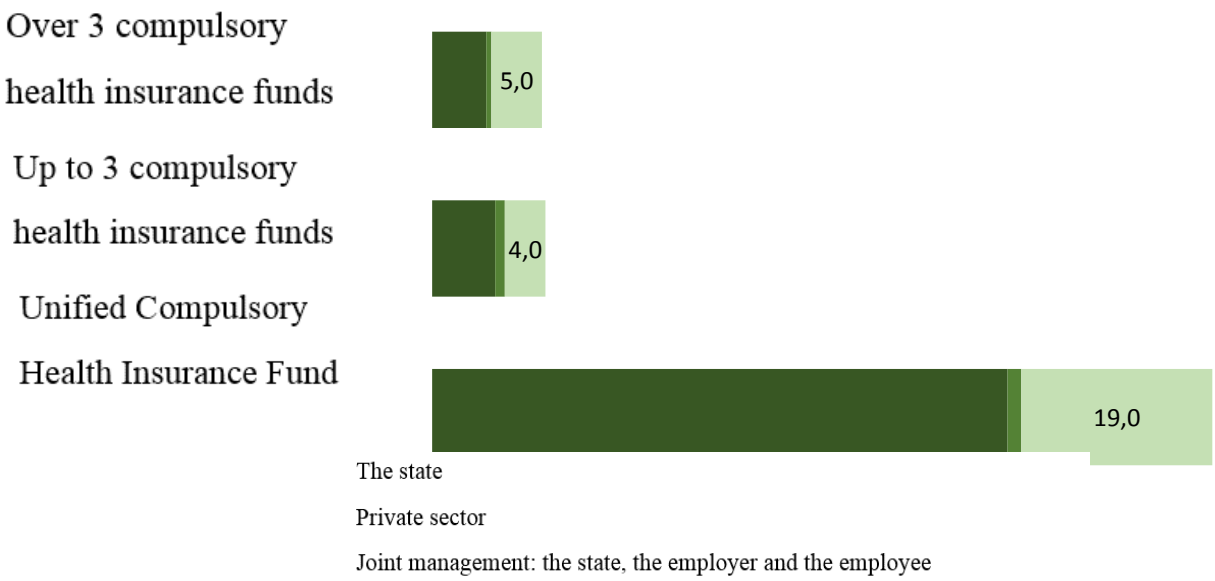

Figure. Distribution of respondents' answers to questions about the number of insurance funds and fund management.

According to respondents, the most reliable way of allocating funds to the OSMS is the Ministry of Finance of the Republic of Kazakhstan (47.6%). Insurance premiums can also be placed in the National Bank of the Republic of Kazakhstan (44.6%). At the same time, the majority of respondents believe that the OSMS funds should be accountable to the Ministry of Health of the Republic of Kazakhstan.

83% of respondents, medical respondents agreed that the following types of services should be covered under the insurance scheme: medical supplies, specialized medical care, consultations in polyclinics and a doctor's examination, laboratory tests. 73% believe that this list can include emergency first aid, rehabilitation treatment, medical care for pregnant women, routine dental care, transportation of patients for medical care and vaccination. 62% of respondents believe that psychiatric care should also be covered by CSHI.

According to the majority of respondents, additional funding from the state budget (85.8%), free choice of the medical organization (80.9%) and competition among medical organizations for patients (70.7%) contribute to the improvement of the healthcare system in Kazakhstan. Half of the surveyed physicians (50%) are confident that improvements in the health system can be achieved by increasing the autonomy of medical organizations.

According to the results of the survey, more than 70% of respondents expect that with the introduction of CSHI, the quality of medical services will improve, there will be real opportunities to choose medical organizations, and the lists of provided medical services will expand. 68.9% and 68.3% of respondents, respectively, believe

that the incomes of health workers will increase and citizens will better take their health. Thus, about 52% believe that positive changes are unlikely.

Thus, the opinions of the general public and providers of health services on the introduction of CSHI and the positive changes needed by the health care system to meet the needs of the people it will contribute are shared.

Conclusion

However, at the present circumstances, based on the results of studying international experience and domestic practices, the implication of the introduction of CSHI, where the financial sustainability of the system, is guaranteed by the joint responsibility of the population, the state and employers, which will improve the health of Kazakhstanis and increase the availability of quality medical care, and together in order to reduce the level of informal payments in the industry.

References

1. Khominich I.P., Finogenova Y.Y., Chelukhina N.F., Savvina O.V. Insurance mechanisms of reforming the social sphere. – M: Dashkov and Co., 2014. Internet resources.
2. Dudnik V.Y. Models of development of the health system: world experience (literature review) // International Journal of Applied and Fundamental Research. – 2016. – No. 3-1. – P. 60– 64.
3. Musinov S. There is no alternative to modernization. // Kazakhstan's truth. 2012, December 25th.
4. Evseeva T. Health of the nation - the basis of a successful future // Kazakhstan's truth, 2012, December 29.
5. Golovnina, N.V. Ekonomicheskie modeli nacional'nyh sistem zdravoohranenija [Economic models of national health care systems]. Municipal'naja ekonomika [Municipal economy]. 2010. №3.
6. Kolosnicina, M.G. Shejman, I.M., Shishkin, E.V. Ekonomika zdravoohranenija [Economy of Public Health Care]. Moscow: izd. dom GU VShJe, 2009. 479 p.
7. Mahnova, N.A. Osnovnye tendencii razvitija zdravoohranenija Rossii [Major trends in the Russian health care]. Sovremennye problemy nauki i obrazovanija [Modern problems of Science and Education]. 2014. №3. URL: www.science-education.ru/117-13304 (Accessed on March 12, 2015).
8. Minjaeva, V.A, Vishnjakov, N.I. Obshhestvennoe zdorov'e i zdravoohranenie [The public health and health care]. Moscow: MEDpress-inform, 2009. P. 508.
9. The official website for WCIOM. URL: www.wciom.ru (Accessed on March 12, 2015).
10. Ploticyna, L.A. Social'naja politika - ob'ektivnaja neobhodimost' i uslovie dal'nejshego razvitija [Social policy - the objective need and a condition for further development]. Finansy i kredit [Finance and Credit]. 2003. №11. P. 32-34.
11. Solov'eva, V.Ju. Razvitie finansovogo obespechenija sistemy

zdravoohranenija [Development of financial support of the health care system]. Molodoj uchenyj [Young Scientist]. 2011. T.1. №5. P. 224-226.