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Surgical approach of bronchogenic cancer in correlation with tumor type and risk factors

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Original Article

Abstract

BACKGROUND: This study is conducted with the aim to analyse the epidemiological pattern of bronchogenic carcinoma in Erbil City, Iraq, with identification of any underlying causative factor, gender variations, as well as surgical approach.

METHODS: Patients with bronchogenic carcinoma who underwent an operatio were from Shar and PAR hospitals (n = 30) and their individual characteristics, such as age, gender male-to-female (M:F) ratios, weight loss, smoking status, histological types, and operative procedure in relation to the tumor subtype were obtained for each patient.

RESULTS: The incidence of bronchogenic carcinoma increased with age proportionally. The male patients with an operation for bronchogenic carcinoma were more than females. 25 out of 30 patients experienced weight loss and 5 patients had no weight loss at the time of operation. Among all patients undergoing the operation, 96.67% were smokers and only 3.33% were non-smokers, in addition, the majority of the smoker patients were active smokers. Adenocarcinoma was commonest among operable adenocarcinoma with different histological subtypes in bronchogenic carcinoma, moreover, large cell carcinoma had the lowest rate. The dominant procedure performed for bronchogenic carcinoma was lobectomy, which was used more frequently than pneumonectomy.

CONCLUSION: An apparent increase in bronchogenic carcinoma incidence was observed in Erbil that might indicate some local environmental risk factors, in addition to changing smoking habits. The study findings do not support the hypothesis that females in general are at higher risk for bronchogenic carcinoma development, but tobacco and histologic-specific susceptibility cannot be ruled out.

KEYWORDS: Bronchogenic Carcinoma; Weight Loss; Lobectomy; Pneumonectomy; Risk Factors; Lung

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Introduction

Bronchogenic carcinoma has a great morbidity, poor prognosis, and high mortality rate.[1,2] It is considered as the most common cause of cancer-related death in both genders in the United States.[3] The incidence of bronchogenic carcinoma is increasing over time.[4] Bronchogenic carcinoma is responsible for more deaths than the combined 5 largest causes of cancer mortality including breast, prostate, colon, ovarian, and pancreatic cancer,[1] because it is usually diagnosed in the advanced stage and is usually surgically unresectable.[5,6] Bronchogenic carcinoma has a dismal prognosis with a five-year survival rate of only 5%.[7]

The exact pathology of this complication is unknown, however, previous studies reported that smoking (both active and passive smoking), alcohol consumption, dietary, life style, family history, air pollution, occupation,

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and asbestos exposure have been proposed as possible causative factors.[8]

Some of the risk factors are preventable such as smoking and this results in a significant decrease in cancer development. A meta-analysis of cohort studies reported that individuals who started smoking in an early age had greater risk of malignancy in both males and females,[9] thus awareness or cessation of smoking could be a protective factor against bronchogenic carcinoma development. Lung carcinomas are classified according to the microscopic cell size into non-small-cell lung carcinoma (NSCLC) and small-cell lung carcinoma (SCLC) as well as mixed adenosquamous and carcinoid tumors, bronchial gland carcinomas, and sarcomatoid carcinomas.[10-13] Furthermore, NSCLCs are divided into adenocarcinoma, squamous cell carcinomas (SCCs), and large-cell carcinoma. It is of therapeutic value to recognize the histopathological sub-types of bronchogenic carcinoma because the management strategy will change based on each sub-type. The bronchogenic carcinoma is managed as surgery, if the mass is surgically operable, as chemotherapy, and/or as radiotherapy.[14,15] Sometimes surgical resection is preceded by radiotherapy to optimize the resection.[16] The surgical resection of bronchogenic carcinoma is greatly related to the stage of the tumor, tumor size, location of the tumor, mediastinal lymph node involvement, and adhesion to the surrounding tissues.[17] The procedures performed to remove the tumor surgically could be either wedge resection, segmentectomy, lobectomy, or pneumonectomy.[18] The aim in this study is to investigate the specific surgical approach applicable for each patient and its relation to causative factors of bronchogenic carcinoma, in addition to establishing a relationship between risk factors and the development of bronchogenic carcinoma in order to establish a specific criteria and guidelines to minimize the prevalence of bronchogenic carcinoma.

Materials and Methods

The samples were collected from outpatient department of thoracic surgery and patients visiting fibro-optic bronchoscopy unit, as well as from patients undergoing an operation at Shar and PAR private hospitals located in Erbil.

The patients who were undiagnosed were thoroughly examined and sent for chest x-ray, and in case of any suspicion, the patient was sent for computed tomography (CT) scanning of the chest. The patients who were already diagnosed were included in the study.

The questionnaire form designed was filled in by each patient in a way that all the risk factors were included. The questionnaire form included the name, sex, smoking habit, weight loss up to the onset of symptoms, and occupational exposures. The surgical approach was left for later filling after the surgery was performed. The comparison was carried out in a random manner and included sex, age, smoking, weight loss up to the onset of symptoms and occupational exposures, concomitant medical condition, and length of history.

Bronchoscopy findings were collected, as well as the histopathology results obtained from biopsy samples obtained after operation (excisional biopsy) if the patient was operable upon the diagnosis.

A comparison and statistical analysis were performed among the types of bronchogenic carcinoma with a specific focus on SCC and adenocarcinomas. Subtypes of tumor were compared for each causative factor. The surgical procedure performed for each patient correlated to the sub-types of bronchogenic carcinoma as well as the risk factors.

The patients who were operable at the time of diagnosis were included in the study and patients with bronchogenic carcinoma who were beyond the operative stage were excluded from the study.

Data were presented as mean ± standard

errors of the means (SEM). Statistical evaluations were performed using non-parametrical tests (Mann-Whitney) or parametric tests (t-test). P < 0.05 was considered significant and *n* represented the number of patients.

Results

Age in bronchogenic carcinoma

The patients operated on were divided into five age groups (< 40, 40-50, 50-60, 60-70, and > 70). The patients operated on for bronchogenic carcinoma were predominantly among 50-70 years old. The least age-group operated was younger age group (< 40) as shown in figure 1, however, the second least group was > 70 years. The latest rate does not indicate that bronchogenic carcinoma will decrease after the seventh decade of life, rather it could be due to the fact that the patients with such age are associated with other comorbidities that do not allow for operation (Figure 1).

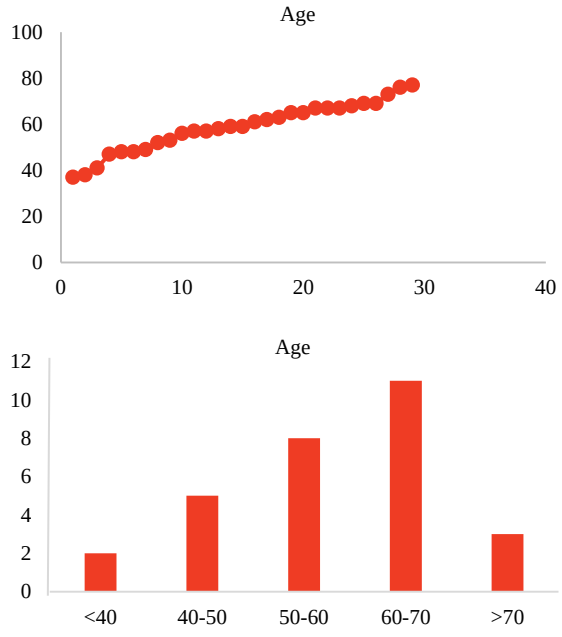

Figure 1. Age distribution in patients operated on for bronchogenic carcinoma. The peak age was between 60-70 years old. The lowest age group was the group younger than 40 years. A total of 30 patients were included in the study

Sex distribution in bronchogenic carcinoma

Among 30 patients who were operated on for bronchogenic carcinoma, 21 and 9 were males and females, respectively. There was a statistical difference (P < 0.50) between these two groups, implying that patients affected by bronchogenic carcinoma are predominantly males in Erbil city. This could be due to the fact that males are more active smokers than females in this area (Figure 2).

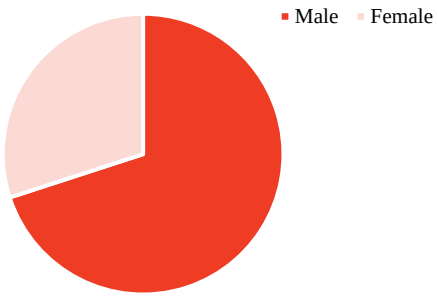

Figure 2. Male to female ratio in patients operated on for bronchogenic carcinoma. Among patients operated on for bronchogenic carcinoma, 21 were males and 9 were females. There was statistical difference between these two groups (P < 0.05) (n = 30)

Weight loss at the time of operation

Among the total of 30 patients who were operated on for bronchogenic carcinoma, 25 suffered from weight loss, and there was a statistical difference between the two groups (P < 0.05) (Figure 3).

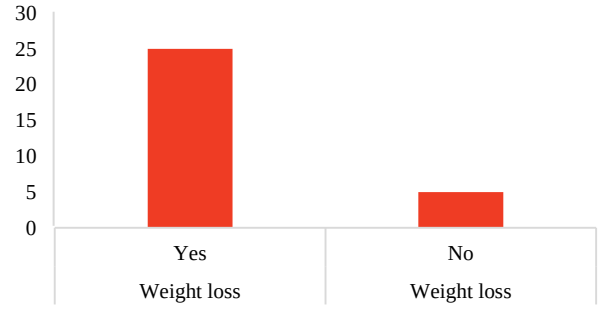

Figure 3. Weight loss in patients operated on for bronchogenic carcinoma. Out of 30 patients operated on for bronchogenic carcinoma, 5 experienced weight loss (*P < 0.05), (n = 30)

Smoking and bronchogenic carcinoma

Smoking plays a great role in the development of bronchogenic carcinoma. Among total 30 patients operated on for bronchogenic carcinoma, 96.67% were smokers and only 3.33% were non-smokers. Among those who were smokers, 96% were at least passive smokers, however, 90% were active smokers and 10% had a history of occupational carcinogen exposure (Figure 4).

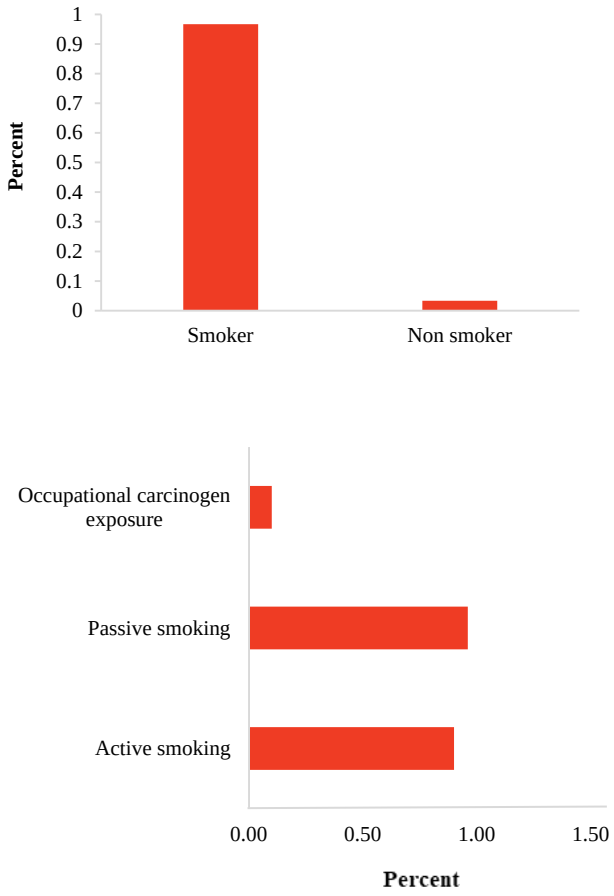

Figure 4. Smoking in bronchogenic carcinoma. The rate of patients operated on for bronchogenic carcinoma was significantly higher considering smoking. The patients operated on for bronchogenic carcinoma had at least passive exposure to smoking. 10% of patients operated on for bronchogenic carcinoma had a history of exposure to occupational bronchogenic carcinoma carcinogens

Histological types of operated patients

In the present study, of the histological results of all 30 patients who were operated on, 38.8%, 29.5%, 1.6%, and 10.6% were adenocarcinoma, SCC, large cell carcinoma, and mixed adenosquamous carcinoma, respectively, in addition to lymphoma accounting for 19.7% of the cases among the patients operated on for bronchogenic carcinoma (Figure 5).

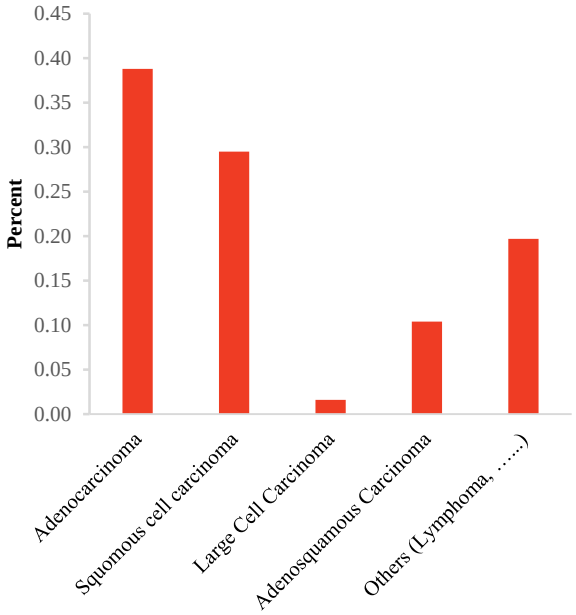

Figure 5. Histological types in patients operated on for bronchogenic carcinoma. The largest proportion of patients operated on for bronchogenic carcinoma were adenocarcinoma, followed by squamous cell carcinomas (SCCs). The lowest one was large cell carcinoma

Side and approach of operation

Unexplainably, the tumors of operated patients were more affecting the right side of lung, 19 were from right side and 11 patients from left side. The surgical approach was done by posterolateral thoracotomy, 21 patients were operated with lobectomy and 9 patients were treated with pneumonectomy (Figure 6).

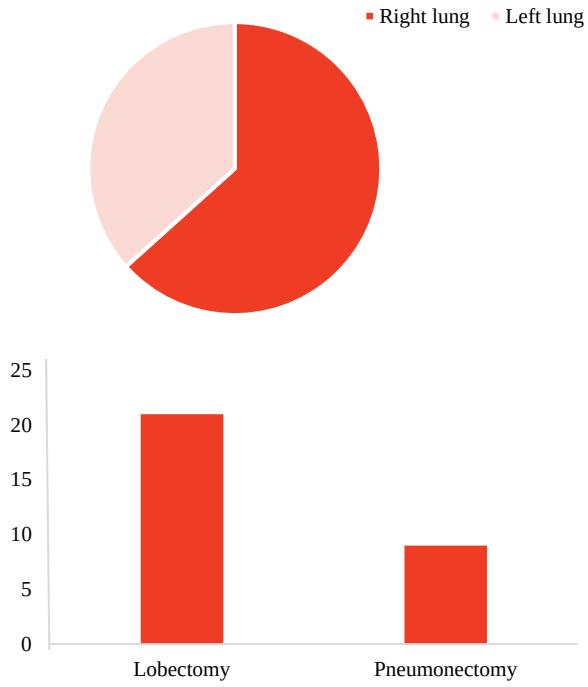

Figure 6. Surgical approach of operation in patients with bronchogenic carcinoma. The tumors operated on were mainly on the right side (21 operations on the right side vs 9 operations on the left side). The procedures performed were lobectomy and pneumonectomy in 21 and 9 patients, respectively

Discussion

The findings of this study demonstrate that bronchogenic carcinoma is proportionally increasing with increasing age and smoking plays a significant role in the pathogenesis of bronchogenic carcinoma. Moreover, the results show that in Erbil City, male patients are more affected with bronchogenic carcinoma compared to females. Furthermore, the findings reveal that most patients with bronchogenic carcinoma suffered from weight loss during the time of operation. Additionally, adenocarcinoma was commonest among histological subtypes and lobectomy was the more frequent procedure used in the present study. Bronchogenic carcinoma is the leading cause of cancer-related death all over the world. Since smoking habit has increased during the last few decades, there is an expected peak rise in the number of people affected with bronchogenic carcinoma.[19] In some countries such as China, smoking habit increased during the last 2 decades, so a peak in bronchogenic carcinoma incidence is expected.[20,21]

Age is considered as one of the major determinants of cancer risk. In the present investigation, the peak age of incidence was between 60-70 years; this is in line with a study performed in Poland.[22] In the current study, there was a decrease in the number of patients operated on for bronchogenic carcinoma after the age of 70 years, which could be due to the fact that older patients usually have other comorbidities which do not fit them for such major operation. In the global scale, females are more affected to bronchogenic carcinoma than males.[23-25] However, the proportion is reverse in the present study, i.e. male patients were more operated on for bronchogenic carcinoma in comparison to females. This could be due to the fact that smoking was more prevalent among males in the past decades, in contrast in the past few decades, smoking was scant among females. Even though, smoking increased among females in the recent years, which could result in the rise in the proportion of females affected with bronchogenic carcinoma in the next few decades. Smoking is associated with all types of bronchogenic carcinoma; the majority of patients in this study had a history of smoking, at least a history of passive smoking exposure which is adequate to stimulate the development of bronchogenic carcinoma if persistent for a long period.[26,27]

In the present study, weight loss was a profound feature in patients operated on for bronchogenic carcinoma, this is in line with previous studies describing weight loss as a feature in patients with bronchogenic carcinoma.[28-30] Weight loss in bronchogenic carcinoma is related to systemic inflammatory response to the disease.[31]

In most studies, SCC is more related to smoking, however, the relation of different tumor types with smoking was not examined in this study, but histopathology reports revealed that adenocarcinoma was commonest among operated patients followed by SCC. This is in line with some other studies which showed the histopathological distribution of bronchogenic carcinoma among population.[32,33]

The surgical approaches for bronchogenic carcinoma are wedge resection, segmentectomy, lobectomy, and pneumonectomy.[34,35] The selection of each approach is largely dependent on the tumor staging. In the current investigation, the patients were classified only for lobectomy and pneumonectomy because wedge resection and segmentectomy are merely used due to late presentation at the time of operation. Lobectomy was more used than pneumonectomy in the present study.

Conclusion

To conclude, the present novel findings demonstrate that patients operated on for bronchogenic carcinoma are mainly between 6th and 7th decade of life. Males are more operated for bronchogenic carcinoma compared to females. Smoking plays a crucial role in the development of bronchogenic carcinoma. Weight loss is a profound sign in patients operated on for bronchogenic carcinoma. Adenocarcinoma is the commonest among operated patients and lobectomy is more widely used surgical approach. This study was carried out among patients operated on in Erbil City.

Conflict of Interests

Authors have no conflict of interests.

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The prevalence of diabetes mellitus among the patients with tuberculosis in Qom, Iran, during 2004-2016

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Original Article

Abstract

BACKGROUND: Several studies have indicated the increasing risk of active tuberculosis (TB) due to diabetes mellitus (DM). The increasing prevalence of DM in areas with endemic TB may adversely influence spreading of TB. The current study is undertaken aiming to assess the prevalence of DM in patients with pulmonary TB.

METHODS: This case control study was conducted on 522 participants during a period of 12 years from 2004-2016 in Qom city, central Iran. The control group was symptomatic respiratory patients without preceding history of active pulmonary TB in the same clinic (n = 261). The case and control groups were compared using the Chi-square test. In addition, adjusted odds ratios (OR) and 95% confidence interval for comparison of the DM prevalence among patients with TB across different groups were calculated by multivariate logistic regression.

RESULTS: Mean age of the case and control patients were 51.0 ± 20.5 and 54.0 ± 14.9 years, respectively and 40.4% of all participants were males. The prevalence of DM was higher in patients with TB compared to the control patients and the rate was found to be 26.5% with adjusted OR of 3.54. The DM prevalence was significantly associated with TB in patients with older age (P < 0.001).

CONCLUSION: The prevalence of DM is significantly higher among patients with TB compared to the general population. Moreover, the mean age of patients with TB with DM is significantly higher than expected in patients with TB without DM.

KEYWORDS: Tuberculosis; Risk Factors; Diabetes Mellitus

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Introduction

Tuberculosis (TB), an air born infection caused by Mycobacterium Tuberculosis, is a major global health concern. It infects millions of people each year and is the second deadly infectious disease worldwide, after the human immunodeficiency virus (HIV).[1] It has been estimated that in 2017, 10 million new cases were diagnosed worldwide, the majority (95%) of whom living in the low and middle income regions. However, the number of TB deaths and incidence rate continuously fall globally.[1] The incidence rate of TB in Iran is 16 cases per 100000 population and at present, 16,000 people suffer from the disease. Moreover, the annual death rate due to TB is 2000 among Iranians.[2]

Diabetes mellitus (DM) describes a group of metabolic disorders characterized by increased blood glucose concentration. DM is a mainly asymptomatic disease, as a result it is diagnosed in late stages. The global prevalence of DM in adults has been increased over the recent decades following population aging, urbanization, alteration of diet, and reduction of physical activity patterns leading to increasing obesity.

The main portion (≃ 80%) of the 415 million estimated DM cases globally are from low and

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middle income countries. It has been proposed that the DM prevalence will be exponentially increased in regions with high TB incidence over the next 30 years.[3] In 2011, impaired fasting glucose and total DM prevalence rates were 14.60% and 11.37% among Iranian adults, respectively. Moreover, in 2005-2011, trend analysis revealed a 35.1% increase in DM prevalence in Iran.[4]

Several risk factors are involved in prevalence and incidence of TB, including age, gender, asthma, smoking habits, and family history of contact with patients with TB. People with suppressed immune system are susceptible to developing the latent to active TB. Factors such as poverty, homelessness, wars, immigration, malnutrition, renal insufficiency, alcoholism, social disorders, HIV infection, and especially DM play significant roles in growth of TB rates.

The risk of progression of latent to active TB in patients with DM is 2-3 times higher than in subjects without DM.[5] A study using dynamic TB transmission models to analyze the potential effects of DM on TB epidemiology in 13 countries with high burden of TB determined that stopping the growth of DM would decrease almost six million incidence of TB and more than one million TB deaths in 20 years.[6] Therefore, it is of crucial importance to evaluate the prevalence of DM and its contribution to TB. Furthermore, DM may negatively influence TB treatment outcomes in patients with active TB, by delaying the time for microbiological response, decreasing the chance of favorable consequences, growing the risk of relapse, deaths, and drug resistance.[7]

The prevalence of DM has been elevated in developing countries where TB is highly endemic. As a result, the co-incidence of DM and TB has been increased, warning about emerging concern in this field.[8] Therefore, the current study was designed to assess the prevalence rate of DM in patients with pulmonary TB.

Materials and Methods

This case control study was carried out in Qom City located in central Iran (34°38′24″N 50°52′35″E). Medical records of 1500 patients suffering from pulmonary TB during a period of 12 years (April 2004 to March 2016) referred to Tuberculosis and Leprosy Control Office of Communicable Disease Management Center were analyzed. Pulmonary TB cases were defined based on the World Health Organization (WHO) and Iranian national TB guidelines. According to the guidelines, at least three sputum samples should be taken from the suspected cases of pulmonary TB in the early morning and sent for TB microscopy and culture before starting possible treatments. Spontaneously produced sputum is preferred, if it is not possible, induction of sputum or bronchoalveolar lavage (BAL) should be used. A case of pulmonary TB is considered to be smear-positive if 1-9 bacilli are observed in each microscopic field and graded as 1+, 2+, and 3+. In smear negative pulmonary TB, no bacilli can be seen in microscopic field, but growth is positive in cultures or radiological findings are consistent with active pulmonary TB.[9]

DM was defined based on the diagnostic criteria described by the American Diabetes Association (ADA) as follows:

A fasting plasma glucose (FPG) level of 126 mg/dl or higher, a two-hour plasma glucose level of 200 mg/dl or higher during a 75-g oral glucose tolerance test (OGTT), or a random plasma glucose of 200 mg/dl or higher in a patients with classic symptoms of hyperglycemia or hyperglycemic crisis.[10]

The study inclusion criteria included pulmonary TB and age above 15 years old. The exclusion criteria included HIV positive patients, intravenous (IV) drug abuser, previous history of gastric bypass surgery, end stage renal disease (ESRD), cancer, leukemia and lymphoma, immunocompromised patients, and patients on oral corticosteroid or immunosuppressant drugs. The control group were symptomatic respiratory patients from the same health units without prior history of

active pulmonary TB who matched to the same age and gender subcategory in the case group. Considering the inclusion and exclusion criteria, finally 261 patients with TB as the case subjects and 261 symptomatic respiratory patients as the control subjects were selected for the study. The sociodemographic parameters were monthly family income (minimum, medium, and high wage), marital status (single, married), age, gender, nationality, residency (urban, rural), education (undergraduate, graduate), and body mass index (BMI).

All the information obtained was kept confidential. The study was initiated after the approval from the Ethics Review and Research Committee, Islamic Azad University. Permission from the health authorities was also taken prior to the study.

Descriptive statistics including mean and standard deviation (mean ± SD) were used to present data. Comparisons between groups were made using the Chi-square test or Fisher's exact test as appropriate for qualitative/categorical variables. Multivariate logistic regression was used to calculate adjusted odds ratios (OR) and 95% confidence intervals for comparison of DM prevalence among patients with TB across different subgroups. A two-way analysis of variance (ANOVA-2) was performed for assessing the effects of demographic parameters and grouping (case and control) on the level of fasting blood sugar (FBS). Data analyses were performed using Statistical Package for Social Science (SPSS) (version 20, IBM Corporation, Armonk, NY, USA) and P values less than 0.050 was considered significant.

Results

Table 1 represents the demographic data and characteristics of the participants. As can be seen, mean age of the case and control patients were 51.0 ± 20.5 and 54.0 ± 14.9 years old, respectively (P < 0.180). Moreover, 44.1% of the patients with TB and 41% of the patients in the control group had age less than 50 years old. Furthermore, 37.5% of the case group and 43.3% of the control group were comprised of men. The proportion of the patients with TB with BMI < 25 was 18.3%, and more than 80% of the participants were Iranians the majority (90.4%) of who were urban residents.

Table 1. Demographic data and characteristics of the participants

Variable	Group	Case (%)	Control (%)	Total (%)	P
Gender	Male	98 (37.5)	113 (43.3)	211(40.4)	0.180
	Female	163 (62.5)	148 (56.7)	311 (59.6)	
Nationality	Domestic	165 (63.2)	256 (98.5)	422 (80.8)	< 0.001
	Foreigner	96(36.8)	5(1.5)	100(19.2)	
Residency	Urban	233 (89.3)	239 (91.6)	472 (90.4)	0.370
	Rural	28 (12.3)	22 (8.4)	50 (10.1)	
Marriage	Single	54 (20.7)	39 (14.9)	93 (17.8)	0.086
	Married	207 (79.3)	222 (85.1)	429 (82.2)	
Education	Undergraduate	226 (86.6)	194 (74.3)	420 (80.5)	< 0.001
	Graduated	35 (13.4)	67 (25.7)	102(19.5)	
Income	Low	181 (69.3)	139 (53.3)	320(61.3)	< 0.001
	Medium	70 (26.8)	63 (24.1)	133(25.5)	
	High	10 (3.8)	59 (22.6)	69(13.2)	
Age (years)	Below 50	115 (44.1)	107 (41.0)	222 (42.5)	0.470
	Above 50	146 (55.9)	154 (59.0)	300 (57.5)	
BMI	Below 25	48 (18.3)	42 (16.0)	90 (17.2)	0.480
	Above 25	213 (81.7)	219 (84.0)	432 (82.8)	
FBS (mg/dl)	Below 100	117 (44.8)	202 (77.3)	319 (61.1)	< 0.001
	Between 100-126	75 (28.7)	27 (10.3)	102 (19.6)	
	Above 126	69 (26.5)	32 (12.4)	101 (19.3)	

BMI: Body mass index; FBS: Fasting blood sugar

Table 2. Comparison of diabetes mellitus (DM) prevalence among patients with tuberculosis (TB) across different groups

Variable	Categories	TB (%)	TB + DM	Prevalence (%)	OR	95% CI	P
Age (years)	< 50	115 (44.1)	10	8.7	7.14	3.43-14.70	< 0.001
	> 50	146 (55.9)	59	40.4			
Gender	Male	98 (37.5)	22	22.4	1.40	0.78-2.50	0.250
	Female	163 (62.5)	47	28.8			
Nationality	Iranian	165 (63.2)	54	32.7	2.62	1.38-4.98	0.003
	Foreigner	96 (36.8)	15	15.6			
BMI	< 25	48 (18.4)	12	25.0	1.09	0.53-2.25	0.800
	> 25	213 (81.6)	57	26.8			
Marital status	Single	54 (20.7)	10	18.5	1.75	0.82-3.71	0.130
	Married	207 (79.3)	59	28.5			
Residency	Urban	233 (89.3)	64	27.5	0.57	0.20-1.57	0.270
	Rural	28 (10.7)	5	17.9			
Education	Undergraduate	226 (86.6)	60	26.5	0.95	0.42-2.16	0.910
	Graduated	35 (13.4)	9	25.7			
Income	Low	181 (69.3)	49	27.1	1.01	0.61-1.66	0.480
	Medium	70 (26.8)	16	22.9			
	High	10 (3.8)	4	40.0			

TB: Tuberculosis; DM: Diabetes mellitus; OR: Odd ratio; CI: Confident interval; BMI: Body mass index

The frequency of DM was higher in patients with TB compared to those in the control group. 69 of the patients with TB and 32 of the control ones had DM and the prevalence of DM in the case and control groups were found to be 26.5% and 12.4%, respectively [P < 0.001, crude OR = 2.57 (1.62-4.07), adjusted OR = 3.54 (2.13-5.88)]. Consistently, mean of FBS in the patients with TB and the control individuals was 125.2 ± 57.5 and 99.8 ± 33.6 mg/dl (P < 0.001), respectively.

Comparing the DM prevalence among various subcategories of patients with TB described in table 2 revealed that significant differences were present among only the two demographic variable of age [crude OR = 7.14, (3.43-14.7) with adjusted OR = 6.77 (3.25-14.1) and nationality [crude OR = 2.62, (1.38-4.98) with adjusted OR = 2.36 (1.20-4.63)].

ANOVA-2 was conducted to examine the effects of demographic parameters and grouping (case and control) on the level of FBS and statistically significant interaction was noticed only between the age and grouping (F = 16.20, P < 0.001). This means that FBS was significantly higher in patients with TB with the age of more than 50 years old (Table 3).

Discussion

In the current study, the prevalence of DM in patients with TB was found to be 26.5% which was higher than that in the control group (12.4%) with OR more than 3. Similar findings have been reported by other researchers.[11,12] The association between TB and DM has previously been confirmed and several epidemiologic studies have reported a significant correlation in this regard,[13,14] Patients with DM are at 2-3 folds higher risk of developing active TB compared to the general population.[15] A systematic review of 13 observational studies demonstrated that DM was associated with an increased risk of TB [relative risk = 3.11, 95% confidence interval (CI) 2.27-4.26] and case-control studies were heterogeneous with ORs of 1.16 to 7.83.[16] Additionally, systematic review of the literature determined that in the top 10 countries with the highest prevalence of TB, 12.6% (95% CI 9.2-17.3) of the new cases had to be attributed to DM in 2030.[17]

Table 3. Comparison of fasting blood sugar (FBS) level among the case and control subjects in different groups

Variable	Categories	TB	Control	P
		FBS (mean ± SD)	FBS (mean ±SD)	
Age (years)	< 50	105.4 ± 47.6	98.0 ± 32.0	< 0.001
	> 50	140.8 ± 59.8	101.0 ± 34.0	
Gender	Male	119.3 ± 48.7	99.6 ± 35.4	0.270
	Female	128.8 ± 62	99.9 ± 32.3	
Nationality	Iranian	131.2 ± 60.4	100.0 ± 33.8	0.860
	Foreigner	114.9 ± 50.6	87.7 ± 14.2	
BMI	< 25	121.3 ± 49.5	96.0 ± 23.6	0.980
	> 25	126.1 ± 59.2	100.5 ± 35.2	
Marriage	Single	116.2 ± 58.9	98.3 ± 25.4	0.380
	Married	127.5 ± 57	100.1 ± 34.9	
Residency	Urban	127.1 ± 59.4	99.1 ± 32.4	0.059
	Rural	109.2 ± 34.2	107.7 ± 44.8	
Education	Undergraduate	125.1 ± 56.4	99.3 ± 34.8	0.930
	Graduated	126.1 ± 64.6	101.3 ± 30.3	
Income	Low	125.7 ± 56.8	99.0 ± 32.8	0.700
	Medium	122.4 ± 59.6	101.5 ± 41.2	
	High	135.9 ± 53.7	100.4 ± 27.8	

TB: Tuberculosis; FBS: Fasting blood sugar; SD: Standard deviation; BMI: Body mass index

The present study findings showed a significantly higher prevalence of DM in older patients with TB with an OR of more than 7 for the age of above 50 years old. In support of this finding, it has been claimed that type 2 DM appears to be a critical risk for the onset of TB, particularly for adults in their 40s and early 50s, the period which coincides with the onset of type 2 DM in the general population.[18,19] Despite the improvement of health care services, better living conditions, and changing life styles, the prevalence of DM is rising. Continuous screening and distinguishing of pre-diabetic stage play an important role in the reduction of TB incidence.

Contrary to other studies, higher BMI was not observed in patients with TB and DM compared patients without DM with TB in this study.[18] However, few other studies have shown a lower BMI in patients with DM.[20] The current findings suggest that screening for DM is necessary in patients with TB even in case of the lack of a high BMI among them.

Several studies have offered convincing biological evidence in support of the causal association between DM and impaired host immunity for TB activation.[21,22] It has been demonstrated that the expression of adaptive immunity is delayed in chronic diabetic mice compared to euglycemic mice. This is evidenced by declined early production of gamma interferon (IFN-γ) and interleukin-12 (IL-12) in the lung and the presence of fewer *M. tuberculosis* antigen early secreted antigen 6 kilodaltons (ESAT-6)-responsive T cells within the first month of infection, marking a diminished T helper 1 (Th1) adaptive immunity; this plays a crucial role in controlling TB infection.[23] In another study, to investigate the immune cell profile alterations in patients with TB with type 2 DM, it was noticed that patients with TB with coincident type 2 DM had higher percentages of Th2 and Th17 cells after stimulation with TB antigens, while they had unchanged Th1 cells and decreased $CD8^+$ cytotoxic T cells compared to patients with TB without type 2 DM.[24]

This study was constructed on the data obtained from observational studies which could be confounded by variables associated with both DM and TB. To decrease the interference, it was tried to match important

parameters of sociodemographic status with the application of adjustment. However, the samples were representative of the population with definite TB, because all the patients were registered at one of the reference TB centers in Qom.

Conclusion

In summary, the current findings indicate that the prevalence of DM is significantly higher in patients with TB. DM can activate latent TB by suppressing immune system, therefore, people with DM, especially the elderly, may be important targets for assessment for active case finding and management of latent TB and efforts to diagnose, detect, and treat DM may have a beneficial impact on the control of TB.

Conflict of Interests

Authors have no conflict of interests.

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A qualitative investigation into lived experiences of patients with hypertension in Soran District, Iraqi Kurdistan

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Original Article

Abstract

BACKGROUND: Hypertension (HTN) which is highly prevalent is called a silent killer because it is asymptomatic at its early stages. Moreover, personal and social factors have been reported as effective causes of HTN. In this regard, the present study was aimed at investigating the lived experiences of patients with HTN living in Soran District, the Kurdistan Region of Iraq, in 2018.

METHODS: The current study was conducted by a qualitative method. In so doing, in-depth semi-structured interviews were conducted with 12 patients with HTN who referred to Ashti Hospital in Soran District in 2018. To analyze the recorded and transcribed interviews, Van Manen's (1990) hermeneutic phenomenological method was employed, and finally the themes were obtained.

RESULTS: Data analysis led to appearance of four main themes which were: denial and ignorance of the disease, disturbance in social and familial life, interference with physical and mental health, and treatment difficulty.

CONCLUSION: Given the themes obtained from analyzing the interviews, medical teams are recommended to convince patients with HTN about seriousness of their disease and help them with their physical and mental health. Also, families of such patients are advised to learn how to deal with them while their blood pressure (BP) is high. And finally, governmental authorities are suggested to provide such patients with insurance services so they can afford the treatment costs.

KEYWORDS: Hypertension; Lived Experiences; Hermeneutic Phenomenological Method

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Introduction

Patients with hypertension (HTN) do not have any symptoms and they perform well during the early stages of their disease;[1,2] therefore, most studies have referred to it as a silent killer.[3-6] When the patients undergo vascular changes, clinical symptoms emerge and their lives will be affected greatly.[5-7] Different physical damages and problems have been reported to be associated with HTN including vascular disease, coronary disease, cerebrovascular disease, chronic renal failure, heart failure (HF), and eye problems.[8-10] In addition to the negative effects of HTN on the patients' physical health, this disease can also threaten their mental health, such that some studies have reported a positive association of this disease with psychological problems such as anxiety and depression which can in turn have negative effects on their daily lives and activities.[11-14]

HTN is a chronic disease which can be with the patient for the whole life; therefore, its development can be controlled through lifelong

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treatment.[15] Moreover, studies have indicated that HTN development and its subsequent complications can be controlled by recognizing and controlling its causes.[16,17] Patients with HTN are normally prescribed to utilize different medications at the same time, which may lead to the risk of drug interaction and development of side effects.[18] It is also stated that beside medication, patients need to comply with treatment method in order to achieve favorable results regarding their blood pressure (BP) control.[19,20] Furthermore, changing lifestyle and engaging in regular physical exercise have been introduced as important factors in controlling BP and enhancing the quality of life among patients with HTN.[21]

Research has indicated that HTN can develop as a result of different causes which vary in different communities and countries. It has also been pointed out that even the individual lifestyle and experiences of patient with HTN can have an effect on initiation and development of HTN.[22] Moreover, different factors have been reported to be associated with HTN development including sociocultural, economic, and environmental situations, attitudes, beliefs, nationality, generation status, race, and genetics.[23,24] Therefore, it seems necessary to study such factors in different communities through the lived experiences of patients with HTN by a phenomenological method. Information about the individuals' lived experience is typically gathered through in-depth interviews which are analyzed by qualitative methods; therefore, in the present study, the required data on the patients' lived experiences were collected through in-depth semi-structured interview by a qualitative method. Since lived experiences of individuals is shaped by their culture, system of value, standards, expectations, and goals, a phenomenological method was utilized in the present study.[25] The ultimate goal in phenomenology is clarifying the meaning, nature, quality, and context of the participants' experiences of a unique issue.[26]

According to the global statistics, an approximate number of 1.39 billion adults are suffering from HTN,[27] which is predicted to reach 1.56 billion by 2025.[26] Based on the statistics published by the World Health Organization (WHO), 40% of Iraq population are over 25 years of age, and more than 4 million adults of that age group suffer from high BP.[27] Therefore, it threatens the lives of a large number of people, which is worth paying lots of attention and conducting qualitative studies. To the best of the author's knowledge, no qualitative study has been conducted to deal with this significant issue in Kurdistan Region of Iraq. Therefore, the current qualitative study was carried out to investigate the lived experiences of patients with HTN who were living in Soran District, the Kurdistan Region of Iraq.

Materials and Methods

The present investigation was a qualitative study, which was carried out by Van Manen's hermeneutic phenomenological method. This method consists of 6 methodological steps which are "Turning to the nature of lived experience", "Investigating experience as we live it", "Reflecting on the essential themes which characterize the phenomenon", "Describing the phenomenon in the art of writing and rewriting", "Maintaining a strong and orientated relation to the phenomenon", and "Balancing the research context by considering the parts and the whole".[28-30]

In order to carry out the study, 12 patients with HTN who had referred to Ashti Hospital in Soran District, in 2018, were selected as the study sample. A convenience sampling method was utilized as the sampling approach. The inclusion criteria included lack of other chronic diseases, decisive diagnosis of HTN, and participation willingness, and the exclusion criteria were lack of willingness to participate in the study and presence of other chronic diseases. The study sample consisted

of 7 men and 5 women with an age range of 28 to 53 years. They were all from Soran District.

The required data were collected through in-depth semi-structured interviews with the participants from October 2018 to December 2018. A relaxing small room at Ashti Hospital was used to conduct the studies, a friendly relationship with them was created, and confidentiality of their information was ensured in order to elicit as much information as possible from the participants. In addition, sufficient time was given to them so they could answer the questions during the interviews. In order to create a comfortable environment for the participants and elicit as much detailed information as possible, a female interviewer interviewed the females and a male interviewer carried out the interviews with the male participants. Predetermined questions were used to conduct the interviews and decide their direction. The interviews began with general questions such as "What is it like to suffer from hypertension (HTN)?", "When were you diagnosed with HTN?", or "How was your feeling when you noticed you had HTN?" followed by more specific questions such as "How has your life changed by HTN?", "What are the effects of HTN on your daily social life?", or "How do you deal with the problems that HTN has caused?". Each interview lasted about 50 to 70 minutes. All interviews were recorded, and then transcribed and translated for further analysis, for which the participants' permission was obtained in advance.

The transcripts of the interviews were analyzed through the six methodological activities proposed by Van Manen (1990)[30] (Table 1).

In addition, the translated transcripts were compared to the recorded interviews several times in order to make sure about the accuracy. Moreover, to obtain a deep understanding of the patients' lived experiences, the transcripts were reread and scrutinized several times.

Trustworthiness: Trustworthiness in qualitative studies refers to the level of adequacy or soundness.[26] Describing the data analysis procedure and justifying the reliability of the results are necessary to make sure about trustworthiness of a qualitative study.[31] Furthermore, the trustworthiness in the present investigation was ensured by benefiting from the comments made by the field experts, obtaining the patients' trust through establishing a good relationship with them, conducting the interviews at suitable time and place, and rereading the transcripts for several times. In addition, the researchers' reliability was ensured because they have been working as nurses.

Table 1. Six methodological activities in Van Manen's method

	Van Manen's methodical activities	The researchers' activities
1	Turning to the nature of lived experience	Because a large number of people refer to clinics and hospitals in the region because of their HTN and the problems it causes, and given the need for developing effective methods to help hyperactive patients and improve the quality of their daily lives, the researchers decided to conduct a qualitative investigation into the lived experiences of patients with HTN.
2	Investigating experience as we live it	Some patients with HTN were selected.
3	Reflecting on the essential themes which characterize the phenomenon	For this purpose, thematic analysis was used.
4	Describing the phenomenon through the art of writing and re-writing	A phenomenological text was created by writing and rewriting.
5	Maintaining a strong and oriented relation to phenomenon	The themes were discussed in relation to the phenomenon.
6	Balancing the research context by considering parts and whole	The researcher moved between transcripts and themes several times.

HTN: Hypertension

Ethical considerations: By obtaining necessary approval from the Ethics Committee of Erbil Polytechnic University, Kurdistan Region, Erbil, Iraq (No. 810 on January 29, 2019), observation of the ethical considerations was ensured. Furthermore, the participants were provided with sufficient explanations about the study's objectives, the data collection method, and confidentiality of the collected data. In addition, the participants were informed that they had the right to quit the study whenever they intended to. Moreover, informed written consent was retrieved from the patients. In order to maintain the anonymity of the collected data, each participant was given a unique code (participant 1, participant 2, etc.), and the confidentiality of the collected information was ensured by keeping the transcripts and recorded audios in a safe place.

Results

Analyzing the transcripts of the recorded in-depth interviews with the participants led to appearance of four main themes: "denial and ignorance of the disease", "disturbance in social and familial life", "interference with physical and mental health", and "treatment difficulty".

Denial and ignorance of the disease: The first and most frequent theme that emerged from the participants' talks was the fact that they had tried to deny their disease during the first days after they were diagnosed with it and ignored it after they were convinced to have it. In this regard, participant 3 referred to his problem with accepting his disease in the beginning until he developed serious symptoms. He continued:

"I was always fine and energetic. I could sleep well, perform well at work, and live a quite normal life, so when I was diagnosed with high blood pressure (BP), I could not believe, because I didn't feel anything wrong inside my body. As a result, I simply ignored that diagnosis, but one day I started to have very bad headaches, and my doctor told me they were because of my high BP, so I had to take it seriously and do something about it."

Participant 7 also underwent a similar experience and stated:

"When I was diagnosed with high BP, denial was my first reaction because I had no health problem. So, I went back home that day without taking the diagnosis seriously, but after a while, I referred to my doctor for some eye problem and after some examinations, I was told that my eye problem is related to my hypertension (HTN). After that day, I started to feel nervous about my health."

Having lived with HTN for more than 20 years, participant 10 stated:

"I was diagnosed with high BP about 20 years ago, so my memories of that time are not that clear, but I remember that my first reaction after I was told I had the disease was laughter in disbelief, because I was alright before some symptoms I got at the age of 32."

Disturbance in social and familial life: The second theme obtained from analyzing the interviews was the fact that the participants stated that their social and familial life had been negatively affected by their high BP. In this regard, participant 2 revealed:

"One of the worst effects of high BP on me is that I get angry and restless quickly which in turn affects my relationship with my husband and children. I'm really worried about it, and I wish I could do something about it, but it's quite out of my control."

Referring to the bad effects of HTN on his relationship with his colleagues, participant 4 said:

"I always feel tired, so my co-workers think that I'm lazy and want to evade responsibilities, but that's not true or fair at all, I really enjoy my job and want to get things done well, but my disease takes all my energy and makes me tired."

In the same regard, participant 9 referred to

the negative effect of HTN on her sexual relationship with her husband and revealed:

"My disease has a negative effect on my relationship with my family members especially my husband; we're not as intimate as before, and it's all because I'm hardly ever in the mood for sex, which is all because of my high BP, anxiety, and stress."

Interference with physical and mental health: The third theme obtained from data analysis was the interference of HTN with the patients' physical and mental health. Almost all of the patients referred to the fact that after that the serious symptoms of HTN developed, they had serious problems with their physical and mental health. In this regard, participant 1 said:

"Since my disease got worse and serious, I have been experiencing headaches. Sometimes they are really excruciating and I cannot stand them. Because of my high BP, as my doctor told me, I even had some kidney problems last year."

Regarding the complications caused by HTN, participant 8 revealed:

"My disease has actually affected all aspects of my life especially my mental health. Because of my high BP, my mental health is not at a good status because I feel anxious and stressed most of the time."

Participant 12 referred to the effect of HTN on both his mental and physical health and said:

"You may be able to control your physical problems with some medicine, but mental problems are so bad. My high BP has negatively influenced my physical health, causing headaches and dizziness, and mental health, causing anxiety and impatience."

Treatment difficulty: The last theme that was obtained from analyzing the interviews was treatment difficulty. In this regard, some patients referred to the financial side of treatment difficulty. For example, participant 5 said:

"I've been suffering this disease for years and I have to spend lots of money on medication. Sometimes, I just feel that it's all in vain and I will never get quite fine."

Participant 6 also referred to the same problem and said:

"So far, I have experienced several complications of high BP including headache, kidney problem, and eye problem which have made this disease so costly to treat."

In the same regard, participant 11 revealed:

"To control and treat this disease, in addition to taking different medicines, I have had to change my lifestyle completely, which all makes treating the disease difficult."

Discussion

The results of the present qualitative investigation into the lived experiences of patients with HTN in Soran District led to appearance of 4 main themes namely "denial and ignorance of the disease", "disturbance in social and familial life", "interference with physical and mental health", and "treatment difficulty".

Most of the patients in the present study revealed that their first reaction to diagnosis of their HTN was denial and ignorance. While relating their first experience of the disease, they stated that since they had felt well before, they could not believe that they were really ill; however, after that they underwent serious symptoms, they had to accept their disease and do something about it.[26,31-33] Similarly, in their qualitative study on elderly patients with HTN, Udompittayason et al. reported that patients with HTN did not take their disease seriously and they somewhat ignored their high BP.[32] These researchers pointed out that the patients with HTN in their study were affected by their traditional assumptions and beliefs which caused them not to accept their disease or change their inappropriate behaviors. Similar findings were reported by other researchers such as Shamsi et al.[6] and Akter et al.[19] The patients in the present study stated that they had started to take their disease seriously and think of some solutions only when they had developed some serious complications caused by their HTN. This finding is in line with the one reported by Samranbua.[33]

The patients with HTN in the present study pointed out that their disease had negatively affected their social and familial lives. They stated that high BP had some serious complications such as tiredness, anxiety, anger, and restlessness which in turn had negative effects on their relationship with their close family members such as spouse and children and also their colleagues. In their study on the quality of life among patients with high BP, Xu et al. reported that patients with HTN had poor relationships with their family members and friends,[34] which is similar with the finding of the present study. This finding is also in line with that of the study carried out by Shamsi et al. in Iran.[6]

The third theme that was obtained from the interviews with the patients with HTN in the present study was the interference of HTN with the patients' physical and mental health. In relating their experiences regarding their physical and mental health, the patients stated that their high BP had negative effects on both their mental and physical health. They stated that HTN was associated with different complications such as headache, dizziness, renal failure, anxiety, and stress which in turn disturbed their physical and mental health. Similarly, McCartney Feild carried out a thesis in University of Tennessee, Knoxville, Tennessee, United States (US), and reported that the patients with HTN were concerned and stressed out about their disease complications.[35] This finding was also in agreement with that of the study carried out by Shamsi et al. who reported that the patients with HTN in their study suffered from stress and anxiety.[6] The patients in the present study also complained about the negative effect of HTN on their physical health. In this regard, they stated that they had headaches, dizziness, and kidney problems. This finding is in line with the results of other previously conducted studies.[6,36,37] The patients in the present study also talked about the difficulty of treating their high BP. In this regard, they referred to the financial side of the treatment and stated that it was costly to treat the numerous complications of the disease. Similar findings were reported by Lewis et al.[38] and Arredondo and Zuniga.[39] This problem can be tackled by providing patients with medical insurance, as mentioned in the study conducted by Shamsi et al.[6] Another side of treatment difficulty, as stated by the participants, was related to changing their lifestyle. Similarly, the patients in the studies carried out by Shamsi et al.,[6] Whitt-Glover et al.,[40] and Oliveria et al.[41] had a difficult time changing their lifestyles, which was reported to be quite effective in controlling and reducing high BP. Like any other qualitative study, the present study included some limitations. The first limitation was related to the study setting which was a public hospital in Soran District, which might have affected the results and they cannot be generalized to other settings especially to private hospitals in which patients may undergo different experiences, leading to different findings. The second limitation was related to the participants' ethnicity and culture. All of the participants were Kurds sharing the same culture.

Conclusion

Following the results of the present study, the lived experiences of patients with HTN were interpreted as the four themes: "denial and ignorance of the disease", "disturbance in social and familial life", "interference with physical and mental health", and "treatment difficulty". These themes indicate that medical practitioners need to pay more attention to patients with HTN in terms of convincing them that their disease can be seriously debilitating if they neglect it. Moreover, their families should be trained on how to deal with them while their BP is high. Medical practitioners are also recommended to pay attention to both physical and mental conditions of such patients while treating them or prescribing medications. Finally, the

governmental authorities are recommended to provide such patients with insurance, so they can afford their long-term treatment.

Conflict of Interests

Authors have no conflict of interests.

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A qualitative investigation into the lived experiences of patients with type 2 diabetes mellitus

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Original Article

Abstract

BACKGROUND: Type 2 diabetes mellitus (T2DM) is a chronic disease which afflicts a large number of people all over the world and causes numerous complications to the patients and decreases the quality of their lives. The present study was carried out in order to investigate the lived experiences of patients with T2DM.

METHODS: The present study was carried out by a qualitative method. To collect the required data, in-depth semi-structured interviews were carried out with 10 patients with T2DM who referred to Bli Hospital in Mergasour District, the Kurdistan Region of Iraq, in 2018. The interviews were transcribed and analyzed using Van Manen's (1990) hermeneutic phenomenological method, and the themes were retrieved.

RESULTS: Based on the results of analyzing the interviews, it was seen that the patients referred to DM as a disease that cannot be treated, which was labelled as "incurable disease". They also referred to the fact that DM had made their life very hard, which was labelled as "difficult life". Moreover, they stated that DM was a silent killer, which was labelled as "silent disease". Finally, they referred to taking insulin shot as addictive, which was referred to as "problem with taking insulin".

CONCLUSION: According to the results, the patients' lived experiences were interpreted as incurable disease, difficult life, and silent disease, which requires social and individual support to be tackled. Moreover, alternative medicines should be figured out because insulin injection was referred to as addictive. The results of the present study can be utilized by clinical trials focusing on treating and helping patients with T2DM and enhancing the quality of their lives.

KEYWORDS: Type 2 Diabetes Mellitus; Qualitative Evaluation; Lived Experience; Van Manen's Hermeneutic Phenomenological Method

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Introduction

As a chronic complex condition, diabetes mellitus (DM) has been reported to afflict almost all populations all over the world.[1] It is characterized by high levels of blood sugar resulting from the body's failure to produce or use insulin effectively.[2] This disease can be associated with numerous complications including gangrenous feet, cerebrovascular disease, coronary heart disease (CHD), retinopathy, and nephropathy.[3]

According to International Diabetes Federation (IDF) (2013), there are three types of DM namely type 1 DM (T1DM), type 2 DM (T2DM), and gestational DM (GDM). In T1DM, the pancreas cannot produce insulin. In T2DM, the pancreas cannot produce sufficient insulin

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or the produced insulin cannot be processed. In GDM, the insulin produced during pregnancy is not effective enough.[4] As reported by World Health Organization (WHO) (2013), T2DM is the most common type of DM and accounts for 90% of DM cases worldwide.[1] For the purpose of the present study, T2DM is focused on.

T2DM is associated with various symptoms including skin infections, genital itchiness, stomach pains and constipation, polydipsia (excessive thirst), fatigue, polyuria (frequent urination), and blurred vision due to dry lens of the eye.[5] However, these symptoms are almost unrecognizable; therefore, this type of DM is called silent killer.[6]

Research has indicated that there are more than 500 million cases of T2DM worldwide and it is estimated that its prevalence will increase over the next 10 years.[7] According to the reports published by IDF (2017), prevalence of DM in Iraqi adults was 7.5% with 1411500 cases in 2017.[8] The increasing prevalence of DM has been attributed to prevalence of obesity and low socio-economic status.[9]

T2DM can have various negative effects on the patients' lives. For example, life expectancy among patients with T2DM is reported to be 15 years shorter than others.[10] Patients with DM have been reported to suffer from various psychological complications including anxiety, depression, sexual dysfunction, or eating disorders.[11-13] In addition to the mentioned psychological complications, DM can lead to numerous physiological problems including pain in the legs, toes, feet, arms, hands or fingers, numbness, indigestion, wasting of the feet or hand muscles, urination problems, nausea or vomiting, constipation, diarrhea, and dizziness.[14]

Given the abovementioned complications and problems caused by T2DM, quality of life among patients with the disease can be negatively affected.[15,16] In this regard, research has suggested that a range of factors such as attitudes, available healthcare, biology, and behavior can be effective in controlling DM and its associated complications.[17] Most studies dealing with T2DM have focused on the causes and therapy methods;[16,18,19] however, effectiveness of the proposed therapies depends on the patients' personal characteristics, experiences, life conditions, and requirements.[20,21] Therefore, it is highly significant to achieve deep understanding of the lived experiences of patients with T2DM in order to provide them with better healthcare services and improve the quality of their lives.

In this regard, the present qualitative study was aimed at investigating into the lived experiences of patients with T2DM who referred to Bli Hospital in Mergasour District, the Kurdistan Region of Iraq, in 2018.

Materials and Methods

Study design: In order to carry out the present study, a qualitative method using Van Manen's hermeneutic phenomenological method was employed.[22]

Participants: The study sample consisted of 10 patients with T2DM who had referred to Bli Hospital in Mergasour District in 2018. They were selected by a convenience sampling method. The patients were chosen based on some inclusion criteria such as being officially diagnosed with T2DM, lack of other chronic diseases, and willingness to participate in the study. Some of the patients who referred to the hospital were not included in the study based on the exclusion criteria such as having other chronic diseases and lack of willingness to participate in the investigation. The participants were 6 men and 4 women with an age range of 38 to 56 years. They were all from Mergasour District. Table 1 presents the patients' socio-demographic and clinical data.

Data collection: In order to collect the required data, in-depth semi-structured interviews were carried out with the participants from November 2018 to December 2018.

Table 1. Socio-demographic and clinical data of patients

Socio-demographic and clinical variables		n (%)
Sex	Female	4 (40)
	Male	6 (60)
Age (year)	30-40	4 (40)
	41-50	4 (40)
	51-60	2 (20)
Place of residence	Urban	7 (70)
	Rural	3 (30)
Education level	Illiterate	3 (30)
	Primary	2 (20)
	High school	3 (30)
	University	2 (20)
Religion	Islam	10 (100)
Ethnicity	Kurdish	10 (100)
Employment	Employed	6 (60)
	Unemployed	4 (40)
Disease duration (year)	< 5	6 (60)
	> 5	4 (40)
Current treatment	Insulin injection	8 (80)
	Metformin	2 (20)

All of the interviews were conducted in a relaxing small room at Bli Hospital. In order to elicit as much information as possible from the participants, friendly relationship was established with them, and they were ensured that their information would be confidential. Moreover, they were given sufficient time to consider and answer the questions raised by the interviewers. Also, the women were interviewed by a female interviewer and the men by a male interviewer in order for the patients to feel more comfortable and relate their lived experiences with more details. The interviews were led by asking predetermined questions beginning with general questions such as "How is it like to suffer from type 2 diabetes (T2DM)?", "When did you notice you had T2DM? How did it feel?", or "What is it like to have T2DM?" followed by more specific questions such as "How has T2DM changed your life?" or "What have been the effects of T2DM on your daily life?". Each interview lasted for about 55-70 minutes. Following the participants' permission, all interviews were recorded and then transcribed and translated for further analysis.

Data analysis: In order to analyze the transcript of the interviews, the six methodological activities proposed by Van Manen (1990)[22] were employed (Table 2).

In order to make sure about the accuracy of the translated transcripts, they were compared to the recorded interviews several times. Afterwards, the themes depicting the patients' lived experiences were extracted by breaking down the interviews into words, phrases, and sentences by utilizing holistic, detailed, and selective approaches. The transcripts were reread and scrutinized several times in order to thoroughly understand the experiences of patients with T2DM.

Table 2. Six methodological activities in Van Manen's method

#	Van Manen's methodical activities	The researchers' activities
1	Turning to the nature of lived experience	Given the high prevalence of T2DM in the region and its negative effects on the patients' quality of life and finally the need for developing effective approaches to improve the patients' daily lives, the researchers decided to carry out an investigation into the lived experience of the patients with T2DM.
2	Investigating experience as we live it	Selecting the patients with T2DM
3	Reflecting on the essential themes which characterize the phenomenon	Using thematic analysis
4	Describing the phenomenon through the art of writing and rewriting	Writing and rewriting to create a phenomenological text
5	Maintaining a strong and oriented relation to phenomenon	Discussing the themes in relation to the phenomena
6	Balancing the research context by considering parts and whole	Moving between transcripts and themes

T2DM: Type 2 diabetes mellitus

Trustworthiness: In qualitative studies, the level of adequacy or soundness is referred to as trustworthiness.[23] To ensure trustworthiness of a qualitative study, it is necessary to describe the data analysis procedure and justify the reliability of the results.[24] The trustworthiness in the present investigation was ensured by establishing a good relationship with the patients and obtaining their trust, benefiting from the comments made by the field experts, conducting the interviews at suitable time and place, and going over the transcripts for several times. In addition, the researchers have been active nurses in the field for years; therefore, their reliability can be ensured.

Ethical considerations: In order to make sure about the observation of the ethical considerations, necessary approval was obtained from the Ethics Committee of College of Medicine, Hawler Medical University, Erbil, Iraq (No. 4 on 12-11-2018). Furthermore, the study's objectives, data collection method, and confidentiality of the collected information were explained to the participants. Moreover, the participants were given the right to quit the study whenever they wanted to. In addition, informed written consent was obtained from the patients. In order to keep the collected data anonymous, each patient was given a unique code (patient 1, patient 2, etc.), and the confidentiality of the data was ensured by keeping the files containing the collected data in a safe place.

Results

Analyzing the patients' lived experiences led to elicitation of 4 main themes namely "incurable disease", "difficult life", "silent disease", and "problem with taking insulin".

Incurable disease

Most of the participants were fed up with their frequent referral to physicians and hospitals and referred to the fact that their disease was untreatable. In this regard, patient 2 stated: "*Since I was diagnosed with diabetes, I have been always in hospitals and clinics. I have taken so many medicines, and I'm really tired of taking medicine. I want to get rid of this disease, but I know that there is no final cure for it, and it's so sad to have an incurable disease.*"

Referring to having taken various medicines to control his blood glucose, patient 6 said: "*My blood sugar cannot be controlled by any means. I don't eat much, and I take all medicine prescribed by my doctor, but my blood sugar is still very high. My disease cannot be cured. It's so frustrating and worrying.*"

Being completely frustrated and tired of taking medication and losing hope, patient 8 revealed: "*I've been on medication for more than 5 years, but there has been no sign of being cured forever. I'm sure there is no final treatment. I know this disease will be with me until I die. Death is the only cure for it.*"

Difficult life

The second theme that emerged from the patients' lived experiences was their difficult life conditions. In this regard, patient 3 said: "*I haven't enjoyed my life at all since I was diagnosed with this disease. My life is full of worry and concern about my future. It's so difficult to live with such a disease.*"

Regarding difficult life conditions, participant 7 stated: "*Living with diabetes is the most difficult thing ever. It has affected all aspects of my personal, social, and familial life. When you're suffering from diabetes, you no more enjoy your life like ordinary people, you always need to be careful about what you do and what you eat, and it's really saddening.*"

Also, patient 10 said: "*Diabetes has made my life so difficult. Apart from all worry and concern it has given me, I can't live like a normal person anymore. Since I was diagnosed with it, everything in my life has changed, my eating and my sleeping habits, my free time activities, and so forth.*"

Silent disease

The third theme that the patients referred to was the fact that T2DM is labeled as a silent killer because the patient does not feel the disease in

the early stages until serious complications start to appear. In this regard, patient 1 said: "*Few years ago, everything was ok with me, I didn't feel any pain, but for a while I started to feel so tired and restless, my body was so itchy, I had constipation almost all the time, so I went to the doctor, and I was diagnosed with diabetes. I was told that I had the disease many years ago, and I was so shocked*."

In the same regard, patient 5 said: "*It's so difficult to be told that you have had a disease for many years, but you haven't noticed. It's really unbelievable. I wish I had never known I had the disease*."

Also, patient 4 said: "*Seemingly, I had no problem and I was quite well until that really sad thing happened. I lost two of my sons. I underwent a mental trauma, and right after that, I was diagnosed with type 2 diabetes. I don't know how I have developed that nasty disease*."

Problem with taking insulin

The last theme that was obtained from analyzing the patients' lived experiences was the fact that they had problem with taking insulin as a medicine. In this regard, patient 9 said: "*I think that I'm addicted to insulin. Every time I inject insulin, I feel that my body needs more, and when I intentionally postpone my injection, my body starts wanting it. I prefer to take some oral medication*."

Discussion

As a result of analyzing the transcripts of the interviews carried out with the participating patients with T2DM, four main themes namely "incurable disease", "difficult life", "silent disease", and "problem with taking insulin" emerged.

During the interviews, some of the patients revealed their worries about incurability of their disease and uncontrollable level of blood glucose. In their qualitative study focusing on the diabetic patients' ideas of illness course, Lai et al. reported that the participating patients considered DM as a chronic incurable disease which led to serious complications including renal injury, leg amputation, blindness, and poor peripheral circulation.[25] Similarly, in relating their experiences with DM, the patients participating in the study carried out by Natarajan referred to DM as an incurable disease.[26] Moreover, the patients with DM in the study carried out by Selman et al. referred to DM as an incurable progressive disease.[27] The same theme has been reported by the study carried out by Abazari et al.[28]

The second theme that emerged from analyzing the patients' lived experiences was difficult life. By referring to the limitations caused by DM, the patients stated that they had not enjoyed their lives since their diagnosis with T2DM. In their study of lifestyle changes as a result of T2DM among women from western Sweden, Ahlin and Billhult observed that the lifestyle of women with DM became more difficult and overwhelming,[29] which is in line with the second theme of the present study. The patients participating in the investigation carried out by Svedbo Engstrom et al. also referred to their hard time dealing with the complications and limitations resulting from their DM. These patients stated that support from others could help them overcome the difficulty of dealing with the disease.[30]

The third theme that emerged from the patients' lived experiences was silent disease. DM has been referred to as a silent disease or killer in different studies including those carried out by Carolan et al.,[31] Abdoli et al.,[32] and DiZazzo-Miller et al.[33] Since the symptoms of T2DM are not apparent in the early stages of the disease until serious complications develop, this disease is called a silent killer.[6]

The final theme emerging from the patients' lived experiences was labeled as problem with taking insulin. In this regard, one of the patients stated that insulin taking was addictive and she preferred to take oral medicines. Participants of some previously studies stated that insulin injection was

addictive.[34-36] Moreover, in their study of exploring Brazilian and Canadian patients' perceptions for insulin therapy in T2DM, Guimaraes et al. reported that the patients with DM in their study referred to insulin injection as drug addiction.[37]

There were two limitations in the present study. The study setting was the first limitation because all of the participants were selected from a public hospital in Mergasour District, which can have an influence on the results and their generalizability to other settings particularly to private hospitals where patients might have different experiences, resulting in different outcomes. Also, the participants' ethnicity and culture made another limitation. All of the participants were Muslim Kurds with the same culture and religion. As a result, the findings may not be quite generalizable to other cities and towns in the Kurdistan Region and Iraq where Kurds, Arabs, and other ethnicities live.

Conclusion

The results of the present study indicated that while relating their lived experiences, the patients with T2DM referred to their experience with the disease as "incurable disease", "difficult life", "silent disease", and "problem with taking insulin". According to the results, future treatments should be based on the patients' lived experiences. In this regard, they need to be socially and individually supported in order to help them overcome their belief about the incurability of their disease, the difficulty of their lives, and the silence of the disease and its complications. Patients with T2DM should also be provided with alternative medicines instead of insulin injection.

Conflict of Interests

Authors have no conflict of interests.

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Comparison of the effectiveness of two mindfulness and logotherapy methods on anxiety index in chronic daily headache of women with marital conflict: A clinical trial study

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Original Article

Abstract

BACKGROUND: Anxiety is considered as the most common psychiatric disorder and the most common response to stress stimuli. Women with marital conflict experience a significant level of anxiety, which can have an adverse effect on other psychological and, in general, quality of life. This study was conducted to compare the effectiveness of two mindfulness and logotherapy methods on anxiety in women with chronic daily headache (CDH) with marital conflict.

METHODS: In a randomized clinical trial (RCT), during April 2015 to July 2015, 45 female patients with marital conflict were selected from among the referrers to the psychiatric centers of Hamadan City, Iran, using a purposive sampling method and were assigned into two treatment and control groups through block randomization method. Two mindfulness and logotherapy methods were presented in the form of 8 weekly sessions to the participants of the experimental group and the control group merely received the routine treatments of the center. Evaluation of two anxiety and marital conflict indices was performed at two points before and after treatment. The data were analyzed using analysis of covariance (ANCOVA) and Shefeh test in the software environment of SPSS.

RESULTS: The primary outcomes of the study showed that both mindfulness therapy and logotherapy were associated with a decrease in total anxiety scores ($P < 0.0010$). Secondary outcomes also showed that logotherapy had a significant effect in reducing apparent anxiety ($P < 0.0010$) and hidden anxiety ($P < 0.0040$) compared to mindfulness therapy.

CONCLUSION: The results of this study, consistent with the research background, suggest that both mindfulness therapy and logotherapy are effective in reducing anxiety syndrome in women. However, the logotherapy was associated with more favorable therapeutic outcomes. These findings can have clinical applications in the context of family interventions.

KEYWORDS: Mindfulness; Logotherapy; Anxiety

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Introduction

Nowadays and along with human development, there has been a growing awareness of life stressors, so that it is necessary to pay attention to the response that individuals are taking in the face of anxiety and to design appropriate interventions.[1]

Restlessness, sadness, grief, anorexia, increased blood pressure, increased respiratory distress, cardiac palpitations, and disorders in the daily activities are considered as signs and symptoms of these anxious elements. As a result of these factors, women are greatly affected and can seriously endanger

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their health dimensions. On the one hand, social life is the basis of growth and, on the other hand, it can be a platform for creating psychological and interpersonal problems. One of the manifestations of human social life is the existence of a healthy and constructive interaction.[2]

Researchers have suggested that a common predisposition to anxiety disorders, depression, and migraine may exist. Migraine and chronic daily headaches (CDHs) are common in people who suffer from anxiety disorders.

One of the important problems of marital life is couples' marital conflict, in which personality traits and psychiatric disorders are among the most important causes of conflicts in couples. Interpersonal problems in couples cause feelings of anger, frustration, or dissatisfaction that is called marital conflict. In today's societies, due to the complexity of dimensions of life, marital conflicts, divorce, and re-marriage are grown significantly. Some personality traits and psychiatric disorders increase tensions and conflicts among couples and threaten the continuity of marital life.[3] One of the most perceptible syndromes in marital conflict is anxiety. In this regard, studies have shown that anxiety in men is lower than that of women and women are twice as likely to experience this disorder. About 3% of the general population experience anxiety. Paying attention to the mental health of women and their impact on maintaining the family center and having a healthy society is one of the goals of the World Health Organization (WHO).[4]

In all years of psychological treatment, various methods have been used to treat and reduce anxiety. However, in the last decade, a generation of cognitive therapies has been formed, the so-called third-wave therapy treatments. In the third wave of psychotherapy, it is believed that knowledge and emotions should be considered in the conceptual context of phenomena. For this reason, instead of approaches, such as cognitive behavioral therapy (CBT), which correct inadequate cognitive beliefs and knowledge to correct emotions and behaviors, here, the patient is trained to take his emotions in the first step and in living here and now take more psychological flexibility.[5,6]

In this regard, mindfulness therapy has formed the core of many of the third-wave therapies. This therapeutic approach is one of the techniques that go into mind-body therapy. This method refers to an acceptable, instantaneous, and non-judgmental knowledge, and its underlying assumption refers to the fact that increased awareness leads to increased perceived self-awareness and, as a result, increased coping potency. In mindfulness, the mental representation of objects in life is taught through breathing and thinking.[7] Anxiety-based mindfulness is a structured group program that aims to reduce anxiety in order to promote mental health and reduce marital conflicts. The results of the studies show that meditation improves mood awareness and its short-term education reduces fatigue and anxiety. Also, the education of mindfulness is effective on psychological indices of depression, anxiety, and psychological compatibility.[1,8]

On the other hand, logotherapy is a paradigm that is a result of an existential approach that provides a philosophical and theoretical basis for group work. Logotherapy can provide a conceptual structure to help individuals find challenges in their lives. Logotherapy emphasizes on four notions of interest that are rooted in human existence, that is, death, freedom, loneliness, and meaninglessness. One of the factors reducing self-esteem and creating anxiety problems is the lack of meaning in life.

Despite the research background on the effectiveness of mindfulness therapy and logotherapy, the effectiveness of these two approaches on the anxiety index in women has not been studied yet. Considering the importance of anxiety in causing systemic

damages to the family system and considering the lack of research in scientific literature, this study was conducted to compare the effectiveness of mindfulness therapy and logotherapy on anxiety index in women with CDH with marital conflict.

Materials and Methods

In a randomized clinical trial (RCT) with pre-test and post-test, during April 2015 to July 2015, 45 women with CDH with marital conflict who referred to counseling centers of Hamadan City, Iran, were selected through purposive sampling method and were equally assigned into two treatment and control groups (15 patients in each group) through block randomization method.

The inclusion criteria were: 1) age range of 18-40 years, 2) minimum education level of diploma, and 3) CDHs occurring 15 days or more a month for longer than three months. Exclusion criteria were: 1) diagnosis of acute psychiatric disorders, 2) more than two absentee sessions in the treatment process, and 3) lack of informed consent.

Two methods of mindfulness therapy and logotherapy were presented to the participants of the experimental group in the form of 8 weekly sessions (twice a week and each session for 90 minutes) and the control group merely received the routine treatments of the center. Two indices of anxiety and marital conflict were evaluated at two intervals of before and after treatment.

Data were collected using demographic checklist, semi-structured clinical interview, the State-Trait Anxiety Inventory (STAI), and Marital Conflict Questionnaire (MCQ).

Demographic checklist: This questionnaire was prepared and used by the researcher to collect demographic information.

Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (DSM) (SCID): It is a clinical interview which is used for diagnosis of Axis I Disorders based on DSM, fourth edition (DSM-IV). Inter-rater reliability coefficient for SCID has been reported equal to 0.6.[9] The diagnostic agreement of this tool in Persian was favorable for most general and specific diagnoses with reliability greater than 0 60. The Kappa coefficient for all of the current diagnoses and longevity diagnosis was obtained equal to 0.52 and 0.55, respectively.[10]

STAI: This tool consists of 19 items that are designed in the form of a 4-point Likert scale. Spilberger's apparent and hidden anxiety questionnaire includes separate scales of self-esteem in order to evaluate apparent and hidden anxiety. The apparent anxiety scale of y-1 form consists of 20 items that assess the individual's emotions at this moment and at the time of response. The hidden anxiety scale of y-2 form consists of 20 items that measure the general and ordinary feelings of individuals. The scores of each of the two apparent and hidden anxiety scales can range from 20 to 80. The test reliability and the criterion validity of the mentioned test were reported as desirable in two apparent and hidden anxiety indices.

Revised MCQ (MCQ-R): The MCQ is a 54-item questionnaire designed to evaluate couples' marital conflicts based on clinical experiences. This tool is designed in the form of 5-point Likert scale. The maximum score is 270 and at least is 54. In this tool, a higher score means more conflict and fewer score means better relationships and less conflict. The reliability and validity of this tool have been reported well.

Data were analyzed by analysis of covariance (ANCOVA) test in SPSS software (version 22, IBM Corporation, Armonk, NY, USA) and the significance level was considered as 0.05.

To analyze the data, ANCOVA test was used and the effect of pre-test was deleted. Before applying the parametric test of ANCOVA, its assumptions were examined. The assumption of normal distribution of the

data was verified by Kolmogorov–Smirnov test (K-S test) (P > 0.0500). Moreover, the results of Levene's test showed the equalization of variances (P > 0.0500). The assumption of the linearity of the variables was also established.

All stages of the study were performed after obtaining written consent from patients and based on the latest version of the Declaration of Helsinki. In order to observe ethical principles, after the end of the treatment process, the control group received 6 sessions of mindfulness therapy and logotherapy.

Results

In table 1, the distribution of participants' scores in the research is presented in two pre- and post-test stages.

Table 1. The scores of apparent, hidden, and general anxiety of women in two pre-test and post-test stages (N each group = 15)

Stages	Variables	Groups	Mean ± SD
Pre-test	Apparent anxiety	Control	53.87 ± 7.44
		Logotherapy	57.73 ± 6.45
		Mindfulness	58.93 ± 7.87
	Hidden anxiety	Control	55.40 ± 10.19
		Logotherapy	59.33 ± 8.76
		Mindfulness	61.00 ± 8.15
	General anxiety	Control	109.27 ± 16.70
		Logotherapy	117.07 ± 14.28
		Mindfulness	119.93 ± 15.56
Post-test	Apparent anxiety	Control	55.13 ± 7.96
		Logotherapy	34.27 ± 7.19
		Mindfulness	47.27 ± 7.57
	Hidden anxiety	Control	55.40 ± 10.71
		Logotherapy	38.27 ± 9.02
		Mindfulness	50.40 ± 7.97
	General anxiety	Control	110.53 ± 16.94
		Logotherapy	72.53 ± 14.44
		Mindfulness	97.67 ± 14.86

SD: Standard deviation

The ANCOVA was used to compare the effectiveness of the two therapies. The results of the test are presented in table 2.

As can be seen in the results of table 2, the significance level shows that there is a significant difference between the three groups.

In order to evaluate the difference in the effectiveness of the therapies, Shefeh post-hoc test was used. The results are presented in table 3. According to the results of table 3, F statistics in comparing the effectiveness of meaningfulness therapy and logotherapy on the general anxiety of women with marital conflicts (i-j = 25.13, P = 0.0001) indicated that there was a significant difference between the effect of logotherapy and mindfulness therapy on the general anxiety of women with marital conflicts.

Therefore, the effect of logotherapy method on reducing the general anxiety of women with marital conflicts was more than that of mindfulness therapy.

In order to investigate the inter-group effects, the ANCOVA test was used. The results are presented in table 4.

Discussion

This study was conducted to compare the effectiveness of mindfulness therapy and logotherapy on anxiety in women with CDH with marital conflict.

The primary outcomes showed that both mindfulness therapy and logotherapy were associated with decreasing in total anxiety scores. Secondary outcomes also showed that logotherapy had a more significant effect in decreasing the apparent and hidden anxiety scores than mindfulness therapy.

Table 2. Results of the analysis of covariance (ANCOVA) test in comparing three groups of the research

Test name	Magnitude	F	Assumption DF	Error DF	P
Pillai's trace	0.59	8.79	4	84	0.0001
Wilk's lambda	0.42	11.29	4	82	0.0001
Hotelling's trace	1.39	13.89	4	80	0.0001
Roy's largest root	1.38	28.97	2	42	0.0001

DF: Degree of freedom

Table 3. Shefe test in comparing the effectiveness of two therapies of mindfulness therapy and logotherapy on total anxiety

Group i		Group j		
		Control	Logotherapy	Mindfulness
Control	i-j difference	-	38.00	12.87
	P	-	0.0001	0.0860
Logotherapy	i-j difference	38.00	-	-25.13
	P	0.0001	-	0.0001
Mindfulness	i-j difference	-12.87	25.13	-
	P	0.0860	0.0001	-

In a review of existing literature, a similar study was not found in comparing the effectiveness of two methods of mindfulness therapy and logotherapy on reducing anxiety in women with marital conflict and the effectiveness of these interventions has often been studied separately. Therefore, considering the exploratory nature of the present study, we reviewed the literature on the effectiveness of each of the two treatments studied. The primary outcomes of the present study reflect the effectiveness of logotherapy on the reduction of anxiety syndrome. In this regard and in line with our results, the results of the study by Robatmili et al. showed that the use of logotherapy was associated with the reduction of depression syndromes.[11] In the study by Rasoli and Borjali about the effectiveness of group logotherapy on the reduction of anxiety in patients with multiple sclerosis (MS), the results showed that the logotherapy decreased anxiety and increased self-confidence in patients.[12] In addition, the results of the study by Cheavens et al. showed that logotherapy was associated with reduction of anxiety syndrome.[13]

A part of the results of this study showed that mindfulness intervention was associated with reduction of anxiety syndrome. In this regard, in line with the results of the present study, the results of the study by Pirnia and Pirnia showed that the mindfulness therapy could reduce the negative mood syndrome in women with cancer.[1] In this regard, the results of the study by Akbari Daghi showed the effectiveness of the stress-reducing mindfulness in reducing anxiety, stress, and depression in cardiac patients.[14] In this regard, the results of the study by Walsh et al. showed that training of mindfulness played a significant role in anxiety and anxiety dependency.[15]

Table 4. Results of the analysis of covariance (ANCOVA) in the study of intergroup effects

Source of changes	Dependent variable	Sum of squares	DF	Mean of squares	F	P
Group's effect	Apparent anxiety	3331.51	2	1665.76	28.96	0.0001
	Hidden anxiety	2328.84	2	1164.42	13.45	0.0001
	General anxiety	11206.18	2	5603.08	23.48	0.0001
Error	Apparent anxiety	2415.60	42	57.51	-	-
	Hidden anxiety	3636.13	42	86.28	-	-
	General anxiety	10024.80	42	238.68	-	-
Total	Apparent anxiety	99136.00	45	-	-	-
	Hidden anxiety	109741.00	45	-	-	-
	General anxiety	415287.00	45	-	-	-
Modified total	Apparent anxiety	5747.11	44	-	-	-
	Hidden anxiety	5964.97	44	-	-	-
	General anxiety	21230.98	44	-	-	-

DF: Degree of freedom

In explaining the effectiveness of mindfulness intervention, it can be acknowledged that if the root of anxiety problems in patients is considered as a process of rumination, the teaching of mindfulness through purposeful life, understanding now, and the belief that "I can" without judgment or bias can reduce the level of mood syndrome.[16] The study of the effect of logotherapy and mindfulness therapy on reducing the anxiety of women with marital conflict can be the starting point for designing psychological interventions in order to adapt, reduce syndrome, and empower women.

This study had some limitations in the implementation process. Due to the sample constraint, the generalization of the results to other groups is not possible; also the lack of follow-up of therapeutic changes due to time constraints can be cited as the limitation of this study. It is suggested that future studies along with the paper and pen tools should use biological evaluations to evaluate the efficacy of the therapy. Also, a clinical trial in men with marital conflict can be a good route for future studies.

Conclusion

In The results of this study suggest that both mindfulness therapy and logotherapy are effective in reducing anxiety syndrome in women. However, the logotherapy was associated with more favorable therapeutic outcomes.

Conflict of Interests

Authors have no conflict of interests.

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The prevalence of allergic reaction in acute complications of injection of packed red blood cell in patients hospitalized in Sina Hospital, Kamyaran City, Iran, during the years 2014-2018

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Short Communication

Abstract

BACKGROUND: Acute complications are among the most common complications in blood transfusion reactions and one of the leading causes of death. The reduction in acute complications as well as blood safety and health of patients should be considered. The aim of this short report study is to determine the prevalence of allergic reactions in acute complications of packed red blood cell (RBC) injections in patients hospitalized in Sina Hospital, Kamyaran City, Iran, from 2014 to 2018.

METHODS: This was a retrospective cross-sectional study with the statistical population including all patients who required blood transfusion in Sina hospital in Kamyaran City since 2014 to 2018. The standard checklist called "A form of reporting unwanted complications after blood transfusions and its related products" was used in this study. Data were entered into the SPSS statistical software. Descriptive statistics were analyzed as mean and standard deviation (SD) and analytical results were analyzed using Fisher's exact test.

RESULTS: In this study, the prevalence of transfusion complications during this period was 0.016. 5 (29%) and 12 (71%) of the patients were men and women, respectively. The most common sign of blood transfusion included restlessness and tachycardia. The most common acute complication of blood transfusions was allergic reaction (47%). Based on the Fisher's exact test, a statistically significant relationship was found between the blood group, sex, and history of injection with the diagnosis of transfusion ($P < 0.001$).

CONCLUSION: Registering the complications of blood transfusion is always a concern and important for the blood transfusion organization. In this study, it was found that the most common acute complication of blood transfusions was allergic reactions (8 out of 17).

KEYWORDS: Allergy Reaction; Blood Transfusions; Transfusion Reaction; Blood Safety; Iran

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Introduction

Blood transfusion is a process in which the whole blood or blood products such as packed red blood cells (RBCs) (also known as packed cells) are transferred from the donor to another person's circulatory system in order to increase tissue oxygenation and prevent bleeding and ultimately improve the prognosis of the disease.[1] Blood transfusion is one of the most common processes for hospitalized patients which can dramatically help revive life of the patients.[2]

Blood transfusion reactions may be acute or delayed, with the acute reaction occurring during or within the first 24 hours of injection, but the delayed reaction may occur days, weeks, or years later.[3]

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In the past 15 years, the prevention of complications due to the transfer of blood products has gained higher importance than before.[4] According to the Iranian Blood Transfusion Organization, 3708 cases of blood transfusions across the country were reported to the Blood Transfusion and Hemovigilance Unit during 2009- 2013.[5] The types of acute complications include febrile non-hemolytic transfusion reactions (FNHTR), allergic reaction, acute hemolytic disorder, septicemia, transfusion-related acute lung injury (TRALI), anaphylaxis shock, and acute pulmonary edema.[6]

Nowadays, patient safety is affected by various factors, so studies show that nurses have a significant impact on patients' outcomes; they play an important role in identifying life-threatening complications.[7] Registration of blood transfusion complications have always been a concern of blood transfusion organizations, hence it is important to take preventive measures as a first step.

The aim of this short report study is to determine the prevalence of allergic reaction in acute complications of packed RBC injection in patients hospitalized in Sina Hospital in Kamyaran, Iran, since 2014 to 2018.

Materials and Methods

This was a cross-sectional study with the statistical population including all patients requiring blood transfusion (emergency and non-emergency) hospitalized in Sina hospital of Kamyaran City in Kurdistan Province. The city is located in 65 km south of Sanandaj, Iran. The city of Kamyaran has only one treatment center and all patients from the surrounding villages are referred to this center, so it covers a high number of patients. The convenience sampling method was used in this study and included all cases of blood transfusion error in Sina Hospital since 2014 to 2018.

The tool applied in this study was the national standard checklist "Report Form of Possible Side Effects after Transfusion of Blood and its Products" which includes demographic characteristics, clinical status, history of transfusion, patient blood group, blood product characteristics, clinical symptoms, cause of blood administration, and treatment. The study inclusion criteria included all cases of blood transfusion complications over a period of time and the exclusion criteria were unregistered or altered data. Throughout the project, the patient information was emphasized to be protected.

Data were entered into SPSS software (version 16.0, SPSS Inc., Chicago, IL, USA). The descriptive data were analyzed using descriptive statistics [mean and standard deviation (SD)] and analytical results using the Fisher's exact test.

Results

In this study, of about 1200 cases of blood transfusions performed at the center over the period, about 20 cases of undesirable complications were recorded, of which 3 had confidential information and were excluded from the study. The frequency of inpatient variables is shown in table 1.

The prevalence of blood transfusion complications during this period was 0.016. The mean and SD of age of the patients were 45.00 and 20.07, respectively (the age range of 2-76 years old). The most common symptoms after transfusion were restlessness, tachycardia, and chills. The most common side effects diagnosed by the physician were allergic reaction, dyspnea, and FNHTR, respectively.

Moreover, the frequency of clinical symptoms caused by packed cell injections was reported by bar graph in Figure 1.

Based on the Fisher's exact test, there was a significant statistical relationship between blood group and diagnosis of blood transfusion complications ($P < 0.001$).

Table 1. Frequency of variables in patients hospitalized in Sina Hospital in Kamyaran City, Iran, from 2014 to 2018

Variable		Frequency	Rate (%)
Sex	Male	5	29.4
	Female	12	70.6
Etiology	Chronic anemia	8	47.0
	Acute anemia	1	5.8
	Hemorrhage	6	35.3
	Surgery	2	11.7
ABO type	A	4	23.5
	B	4	23.5
	O	9	53.0
	AB	0	0.0
Transfusion History	Less than 3 months	5	29.4
	More than 3 months	3	17.6
	No history	9	53.0
Severity	Mild	11	64.7
	Severe	6	35.3
Diagnosis	FNHTR	3	17.6
	Allergic reaction	8	47.0
	TAD	6	35.3
History of disease	Abortion	3	17.6
	Reaction history	1	5.8
	Cardiac disease	2	11.7
	Pulmonary disease	1	5.8
	Immune deficiency	1	5.8
	Renal disease	5	29.4
	None	4	

FNHTR: Febrile non-hemolytic transfusion reactions; TAD: Transfusion-associated dyspnea

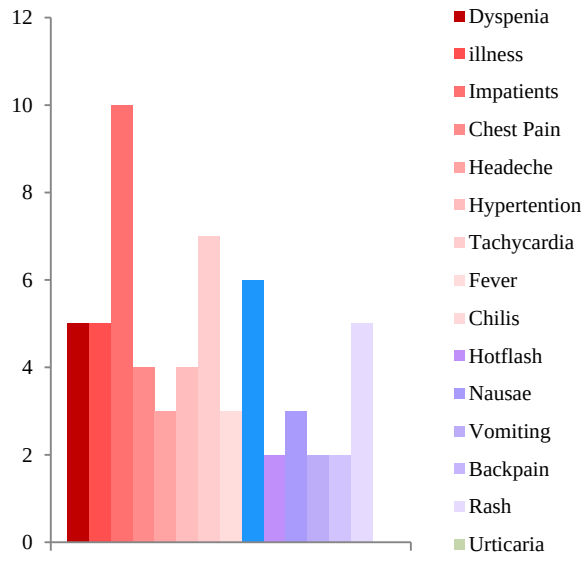

Figure 1. Bar graph of frequency of clinical symptoms caused by packed red blood cell (RBC) injections in patients hospitalized in Sina Hospital, Kamyaran City, Iran, from 2014 to 2018

The frequency of different blood group types according to the acute complication of blood transfusion in patients hospitalized in Sina Hospital is shown in table 2.

Additionally, given table 3, there was a significant relationship between gender and diagnosis of blood transfusion complication ($P < 0.001$). Besides, as table 4, there was a significant relationship between blood transfusion history and diagnosis of blood transfusion complications ($P = 0.020$).

Furthermore, in accordance with table 5, there was a significant relationship between the history of blood transfusion and the cause of blood transfusion ($P = 0.004$).

In the case of treatment of adverse events, all transfusions were stopped immediately and appropriate supportive treatments were given to relieve the complication.

Table 2. Frequency of different blood group types according to the acute complication of blood transfusion in patients hospitalized in Sina Hospital, Kamyaran City, Iran, from 2014 to 2018

Blood group / Diagnosis	ABO-type [n (%)] A^+	B^+	O^+	Total [n (%)]
FNHTR	0 (0)	1 (25)	2 (22)	3 (17.0)
Allergic reaction	2 (50)	2 (50)	4 (44)	8 (47.1)
TAD	2 (50)	1 (25)	3 (33)	6 (35.0)
Total	4 (100)	4 (100)	9 (100)	17 (100)

FNHTR: Febrile non-hemolytic transfusion reactions; TAD: Transfusion-associated dyspnea

Table 3. Frequency of gender based on type of acute complications of blood transfusion in patients hospitalized in Sina Hospital, Kamyaran City, Iran, from 2014 to 2018

Sex / Diagnosis	Male [n (%)]	Female [n (%)]	Total [n (%)]
FNHTR	1 (20)	2 (16)	3 (17)
Allergic reaction	1 (20)	7 (58)	8 (47)
TAD	3 (60)	3 (26)	6 (35)
Total	4 (100)	5 (100)	12 (100)

FNHTR: Febrile non-hemolytic transfusion reactions; TAD: Transfusion-associated dyspnea

Discussion

In this study, which was carried out for the first time at Sina Hospital of Kamyaran City, about 1200 patients underwent blood transfusion, among whom 20 acute post-injection complications were observed. The percentage of acute complications after transfusion was 1.66%, which is comparable to the statistics reported in the studies by Aminiahidashti et al.[8] as 1.24% and Teimuri et al;[6] acute complications following blood transfusion were high in both studies.[6] The high rate of the complications in the present study may be attributed to the location of Kamyaran City and the high rate of accidents resulting in high emergency blood consumption. The most common clinical symptoms were restlessness, tachycardia, and chills as 10 (58.8%), 7 (41.0%), 6 (35.2%), respectively. The complication diagnosed by the physician was also an allergic reaction as 8 (47.0%). Allergic reaction is seen in the injection of cellular products. The results of the study showed that dense RBC injection is responsible for the allergic reaction.[9]

Transfusion-associated dyspnea (TAD) and FNHTR as respectively 6 (35.3%) and 3 (17.6%) patients accounted for the highest rate of acute post-injection complications. It should be noted that in all patients, there was no shock and severe decrease in consciousness. In a study by Tajali et al., the incidence of apnea occurred in 19.82% of patients with high prevalence. This finding is in line with the present study.[10]

However, in other studies such as the study by Bodaghkhan et al.[3] conducted in Namazi Hospital of Shiraz, Iran, the rate of allergic reaction was 28.8% (15 out of 52 cases). Besides, in the study by Teimuri et al.[6] performed in Tehran and Mazandaran hospitals, 45% allergic reaction (9 out of 20 complicating patients) was reported; in our study, it was higher than both studies.[3,6]

Table 4. Frequency of blood transfusion history by type of acute complication of blood transfusion in patients hospitalized in Sina Hospital, Kamyaran City, Iran, from 2014 to 2018

Transfusion history / Diagnosis	Less than 3 months [n (%)]	More than 3 months [n (%)]	None [n (%)]	Total [n (%)]
FNHTR	1 (20)	1 (33)	1 (11)	3 (17.0)
Allergic reaction	1 (20)	1 (33)	6 (66)	8 (47.1)
TAD	3 (60)	1 (33)	2 (22)	6 (3.1)
Total	5 (100)	3 (100)	9 (100)	17 (100)

FNHTR: Febrile non-hemolytic transfusion reactions; TAD: Transfusion-associated dyspnea

Table 5. Frequency of blood product injection based on blood transfusion in patients hospitalized in Sina Hospital, Kamyaran City, Iran, from 2014 to 2018

Transfusion history / Diagnosis		Less than 3 months [n (%)]	More than 3 months [n (%)]	None [n (%)]	Total [n (%)]
Etiology	chronic Anemia	4 (80)	1 (33)	3 (33)	8 (47.1)
	Acute Anemia	0 (0)	1 (33)	0 (0)	1 (5.0)
	Hemorrhage	1 (20)	0 (0)	5 (55)	6 (35.0)
	Surgery	0 (0)	1 (33)	1 (11)	2 (11.0)
Total		5 (100)	5 (100)	3 (100)	9 (100)

In other countries, the most common type of allergic reaction with a prevalence of 2.51% was reported in the study by Kato et al. in Japan, which is consistent with the present study, in addition, FNHTR had a prevalence of 0.43%.[11] Studies have shown that the most common complication of this study has been fever, chills, and allergies.[8,12]

There was a significant relationship between the blood type of the patient and the type of complication diagnosed by the physician. So O^+ blood type had the most prevalence [9 (53%) out of 17]. This result was consistent with the results of other studies.[13]

On the other hand, there was a significant relationship between gender and diagnosis of blood transfusion complication ($P < 0.001$).[12] out of 17 (70.5%) blood transfusion responders were female; this was consistent with other studies.[14] Of these, 7 (58%) developed an acute allergic reaction, which it is a high rate.

According to table 4, the subjects who did not have a previous blood transfusion was more likely to have an acute complication of blood transfusion that was in contradiction with previous studies.[6]

Conclusion

One of the most important goals of blood transfusion centers is to consume blood and its products properly. Another important goal of blood transfusion is to establish a consistent system between hospitals and the Blood Transfusion Organization to evaluate and analyze the various side effects of all injectable products. On the other hand, training and updating physicians and developing their information will be of great efficiency to the accuracy of blood transfusion registration.

Conflict of Interests

Authors have no conflict of interests.

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The relationship between quality of life with metacognitive belief and cognitive fusion in couples

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Short Communication

Abstract

BACKGROUND: Quality of life (QOL) is one of the most important factors of family stability. The objective in this study is to investigate the relationship between metacognitive belief and cognitive fusion with QOL among couples in Ardabil City, Iran.

METHODS: This was a descriptive-correlational study in which the statistical population included all couples in Ardabil in 2016 who were selected by the convenience sampling method (54 couples). Data were collected using questionnaires and were analysed using Pearson correlation coefficient.

RESULTS: The results showed that there was a significant relationship between metacognitive belief and fusion cognitive with QOL of the couples ($P < 0.05$).

CONCLUSION: It can be concluded from this study that couples with higher levels of metacognitive beliefs and cognitive fusion have a lower QOL compared to their peers.

KEYWORDS: Quality of Life; Cognition; Metacognitive Knowledge; Cognitive Function

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Introduction

Quality of life (QOL) is defined as the individuals' personal perceptions of their place of living according to the culture and value system in which they live, which is influenced by their goals, expectations, and standards.[1] Metacognitive beliefs and cognitive fusion are among the factors that can influence the QOL of couples. Metacognitive beliefs refer to the beliefs and theories that individuals have about their thinking.[2] Meta-cognitive experiences include evaluations and feelings that individuals have in various situations about their mental state, and metacognitive strategies are responses used for controlling and modifying thinking as well as for emotional self-regulation.[3] Studies on metacognitive beliefs have shown that metacognitive beliefs are influential factors in mental disorders, anxiety, marital satisfaction, and life expectancy of couples.[4-7] In cognitive fusion, individuals are overly influenced by their thoughts. These thoughts cause behavior and experience to dominate other sources of behavioral regulation and make one less susceptible to indirect consequences.[8] Findings in various investigations have shown that cognitive fusion is one of the factors affecting QOL[8] and mental disorders.[9] In general, it can be concluded that meta-cognitive beliefs and cognitive fusion are among the influential factors in mental disorders. Due to the importance of the subject, the present study aimed to investigate the relationship between

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QOL and morphological and cognitive fusion between couples.

Materials and Methods

This was a descriptive-correlational study in which the statistical population included all couples in Ardabil in 2016 (probable estimate as 30,000). Due to the limitations of the researcher in the sample selection, 54 couples were randomly selected by referring to the key locations of the city.

Wells' Meta-Cognitive Beliefs Questionnaire (MCBQ): This scale was developed by Wells and Cartwright-Hatton[2] to measure individuals' beliefs, and consists of 30 items. The scale is rated on a four-point scale from *disagree* to strongly *agree*. In Iran, the validity of the scale has been reported favorably. The reliability coefficient of the scale was 0.93 and the test reliability was 0.75 within four weeks.[7]

Cognitive Fusion Questionnaire (CFQ): This scale was developed by Gillanders et al. to measure cognitive fusion and includes 7 items on a 7-point Likert scale. The validity of the scale has been confirmed in Iran. The Cronbach's alpha coefficient of the instrument was also reported above 0.70.[9]

World Health Organization Quality of Life (WHOQOL) Assessment: This scale was developed in 1996 by a team of WHO experts. The scale is comprised of 26 items and is rated on a 5-point Likert scale. A desirable validity has been reported for this instrument in Iran. Additionally, the reliability of the instrument was above 0.70.[1]

After confirming homogeneity of variances using Levene's test results, the study data were analyzed using Pearson correlation coefficient.

Results

The results showed that there was a negative significant relationship between metacognitive beliefs (-0.55) and cognitive fusion (-0.39) with QOL ($P < 0.05$) (Table 1).

Table 1. Correlation of study variables

Variables	Metacognitive Belief	Cognitive fusion	QOL
Metacognitive Belief	-	-	-
Cognitive fusion	0.42	-	-
QOL	-0.55	-0.39	-

QOL: Quality of life

Discussion

The findings indicated a significant negative relationship between metacognitive beliefs and QOL in couples. This result was consistent with the findings of other studies.[2-7] Cognitive beliefs play an important role in the selection and persistence of dysfunctional coping strategies, and in fact, the use of dysfunctional coping strategies leads to the formation and continuity of psychological problems. The activation of metacognitive belief components leads to the individual's emotional state. Experience of emotional stress results in a high score in metacognitive beliefs. The subjects with such a high score become involved in maladaptive coping strategies, and the use of these strategies makes the threat concepts more accessible to process and reduce QOL.[3-4] The other part of the results showed that there is a negative significant relationship between cognitive fusion and QOL among couples. This result is consistent with the findings of other studies[7-9] in which cognitive fusion is the strongest predictor of anxiety syndrome in individuals.[8]

The other part of the results showed that there is a negative significant relationship between cognitive fusion and QOL among couples. This result is consistent with the findings of other studies in which cohesion is the strongest predictor of anxiety syndrome in individuals.[7-9] Couples need to be able to interpret, analyze, and evaluate various issues in order to play social, psychological, and physical roles, and overall QOL, and this would not be possible without cognitive skills. Using the convenience sampling method and limiting the sample to couples in Ardabil were

among the limitations of the present study. Therefore, it is suggested that other studies be carried out using a random method and on more samples and other sections of the population to make the results more reliable. It is also recommended that counseling centers and pre- and post-marriage workshops be employed to help couples with poor QOL to improve it by training them to overcome inappropriate cognitive strategies.

Conclusion

Finally, it can be concluded that couples with higher levels of metacognitive beliefs and cognitive fusion have lower QOL in comparison to other couples.

Conflict of Interests

Authors have no conflict of interests.

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