## Comparing the quality of life in insulin recipient and refusal patients with type 2 diabetes

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### **A**BSTRACT

**Background:** Better control of blood sugar and reduction of diabetes complications through insulin therapy could convince people to choose this method. However, patients might refuse insulin therapy due to its painful injection, limitations in daily activities, and hypoglycemia. Thus, insulin therapy could have both positive and negative effects on patients' quality of life (QOL). Therefore, the aim of this study was to compare the QOL of insulin recipient and insulin refusal patients with type 2 diabetes.

**Materials and Methods:** This study was a descriptive and comparative research conducted on 126 patients; 63 were insulin recipients and 63 had refused insulin therapy. Participants were under the care of the Endocrine and Metabolism Research Center of Isfahan, Iran. Data were gathered using the Diabetes Quality of Life (DQOL) questionnaire. In this tool, higher scores indicated lower QOL in patients. Data were analyzed using independent *t*-test, analysis of covariance, Mann–Whitney, Chi-square, and Pearson and Spearman's correlation.

**Results:** There was a significant difference (P < 0.001) between insulin recipient patients (mean = 2.02, SD = 0.31) and insulin refusal patients (mean = 1.74, SD = 0.41) in terms of mean QOL score. In addition, men and participants with higher educational levels reported a better QOL (P < 0.001).

**Conclusions:** Results showed that insulin refusal patients had a better QOL. It seems that QOL is associated with the acceptance or refusal of insulin therapy. Therefore, enhancement of QOL could be related to all aspects of the disease, especially its treatment method and solving the therapeutic problems.

Key words: Insulin therapy, Iran, quality of life, quality of life in type 2 diabetes, type 2 diabetes mellitus

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### **INTRODUCTION**

iabetes mellitus is a chronic disease characterized by disturbances in carbohydrate, fat, and protein metabolism. <sup>[1]</sup> Diabetes is attracting more attention each day due to its delayed and dangerous complications. <sup>[2]</sup> The short-term and long-term complications of diabetes could be prevented through controlling the metabolic condition. <sup>[3]</sup> For some patients, insulin therapy is one of the most important parts of diabetes care. However, some other patients are not willing to use insulin, which in turn causes more severe and dangerous complications. <sup>[4]</sup> These complications could have negative effects on patients'

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well-being, health condition, and the physical, mental, and social aspects of quality of life (QOL). [5] QOL is an intellectual concept that incorporates individuals' physical, mental, and social situations and is affected by beliefs, culture, economy, and spirituality. [6] QOL is of great importance because when ignored, it can lead to desperation, lack of motivation, and reduced social activity. [7]

QOL in diabetic patients is an important factor in analyzing the effectiveness of their treatments and other received cares. [8] In most cases, therapeutic interventions have been evaluated through studying the results of HbA1C test, and QOL has been considered and studied less frequently; [9] however, a comprehensive approach is necessary during treatment.[8] As therapeutic factors, insulin and oral anti-diabetic drugs, each with their barriers and limitations, affect QOL. Diabetic patients must cope with different types of consultations, recommendations, and drugs, and this could be unpleasant for them. Even if these factors could improve the blood sugar level, the medication might disturb diabetic-related health condition and QOL.[5] Oral anti-diabetic drugs, like any other drugs, have side effects and complications. Their side effects include hypoglycemia, bloating, diarrhea, stomach ache, nausea, and so on.[10] Intolerance to oral medication or experiencing any side effect renders the consumption of insulin necessary.[11] However, Chen et al. reported in their study that patients who consume oral drugs are less inclined to use insulin than the patients who have only recently started to use insulin. [12] Therefore, with the reduction in complications of the disease, satisfaction with treatment will indirectly affect QOL.[13] A study has shown that diabetic patients who were not able to control their disease through consuming oral drugs reported more satisfaction with their treatment after starting insulin therapy.<sup>[14]</sup> In patients who are prescribed insulin by a physician, if the injection dose is appropriate and the injection effective, the blood sugar level will be controlled. However, if for any reason, the patient does not tolerate daily insulin injection, blood sugar level will not be controlled and its complications will reduce QOL.[15] Therefore, the side effects and obstacles of insulin therapy must be discussed. Some of the side effects of insulin therapy are morning hyperglycemia and insulin resistance. [10]

Alizad Jahani *et al.* have categorized in their study the factors responsible for reluctance to insulin therapy into five groups of fear of injecting insulin, restrictions, negative beliefs, lack of education, and inability. <sup>[15]</sup> Moreover, some patients believe that insulin might have a negative effect on their QOL and that insulin therapy represents their failure in managing their disease. <sup>[16]</sup> Although some studies have compared the QOL of diabetic patients with that of normal people, there are few evidences about the relation between insulin therapy and QOL of diabetic patients. <sup>[13]</sup> On the other hand, there

are controversial studies about the effect of insulin therapy and consuming oral drugs on the QOL of patients with type 2 diabetes. For example, Podbielska et al. reported in their study that patients with type 2 diabetes who were consuming oral drugs experienced a better QOL in comparison to those who only used insulin.[17] In addition, the study by Fal et al. revealed that patients who consumed oral drugs had a higher score in the physical aspect of QOL and those who used insulin scored higher in the mental aspect of QOL.[8] On the other hand, we did not find any studies on the QOL of patients who refused to take insulin. Therefore, there are no conclusive evidences about the relation between insulin therapy and QOL. Furthermore, any effort toward accepting insulin therapy must be focused on recognition and reduction of barriers in accessing it. Thus, the present study evaluated the QOL of two groups of diabetic patients: Insulin recipient and insulin refusal groups.

### **MATERIALS AND METHODS**

The present study was a comparative descriptive research approved by the Ethics Committee of Isfahan University of Medical Sciences, Isfahan, Iran. The study population consisted of all patients with type 2 diabetes who referred to the Endocrinology and Metabolism Research Center of Isfahan. The calculated sample size for each group was 63 subjects. The inclusion criteria consisted of being a patient with type 2 diabetes and referred to the above-mentioned center with an active profile and having made at least one visit to the center during the past year, being able to read and write, being recommended by a specialized physician to use insulin during the past 3 months, having an HbA1C level of higher than 7%, and not having any mental disorder or retardation based on the patient's profile. The exclusion criteria included amputation, physical disability, unwillingness to participate in the study, and not completing the questionnaire. The insulin recipient group comprised those patients who had been taking insulin at least for the past 3 months. Those who refused insulin therapy and were still consuming oral drugs formed the insulin refusal group. The target level of HbA1C is lower than 7%<sup>[18]</sup> and its increase is a criterion for recommending insulin therapy. Therefore, to eliminate the effect of the controlled factor of HbA1C, the insulin recipients also had an HbA1C level higher than 7%. The researcher studied the files of patients with type 2 diabetes in the study environment and sampling took place from September to December 2014 (for about 3 months). To begin with, a list of 140 patients who met the inclusion criteria was prepared. After confirming the cooperation of the participants, 126 patients were enrolled in the study and they completed the questionnaire. Written consent forms were obtained from the participants and they were ensured that their answers would remain confidential. Demographic data (including age, gender, marital status, educational level, and duration of disease) were gathered from the questionnaires and the files. After reaching the calculated number of samples, gathered data were statistically analyzed and homogeneity of age, gender, educational level, marital status, and occupation of participants in both groups was evaluated. Both groups had a similar percentage in the above-mentioned factors and statistical analysis also showed no significant difference between the two groups, except in the age factor. However, by controlling the variable of age, the results of QOL and its indexes did not change. Therefore, sampling was completed with these results. The Diabetes Quality of Life (DQOL) questionnaire was completed by the participants. This questionnaire was created by Jacobson in English and translated to Farsi by Masaeli et al., and its reliability was confirmed with Cronbach's  $\alpha$  of 0.89.[19] This questionnaire includes 46 questions in four domains (satisfaction with diabetes, effects of diabetes, concerns about diabetes, and social-occupational concerns). Each question was answered based on a 5-point Likert scale and the total score of the questionnaire ranged between 1 and 5, which was obtained by dividing the total score by 46 (the number of the questions). Scores closer to 1 represented better QOL. The score of each domain is also calculated by dividing the obtained score by the number of questions of that domain. The time needed to complete this questionnaire is about 20 min. Moreover, questions about demographic characteristics of diabetics were also added to the questionnaire. To compare the QOL of patients with type 2 diabetes who received and refused insulin, data were analyzed using independent t-test, analysis of covariance (ANCOVA), Mann-Whitney test, Chi-square, and Pearson and Spearman's correlation through SPSS software (version 16; SPSS Inc., Chicago, IL, USA). In total, data gathering lasted from September to December 2014 (for about 3 months).

### RESULTS

A total of 126 subjects were studied, 75% of whom were women. The mean age of the refusal group was 52 years (SD = 6.9) and the mean age of the recipient group was 54 years (SD = 7.2). The mean duration of the disease in the refusal group was 9 years and in the recipient group was 12 years. The marital status, educational level, and occupation of participants are presented in Table 1.

The mean QOL score in the recipient group was higher than in the refusal group (P < 0.05) and significant differences were also observed between their domains [Table 2]. By controlling the variables of age and duration of the disease (P2), ANCOVA showed a significant difference between the mean QOL score of the recipient and the refusal groups

[Table 2]. However, no significant difference was observed between the groups in the domain of concerns about diabetes (P > 0.05).

There was no significant statistical correlation between QOL and age (P=0.25, r=-0.06), duration of the disease (P=0.23, r=-0.06), and occupation (P=0.44, r=-0.76). Independent t-test showed a significant relation between the mean QOL scores of women (1.97, SD = 0.36) and men (1.62, SD = 0.33). Spearman's correlation coefficient showed a significant relation between QOL score and educational level (P<0.001, r=-0.31).

### **DISCUSSION**

Insulin therapy is one of the most important options in diabetes treatment. Nevertheless, some of the patients are

Table 1: Demographic data of the participants

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Variable	Number	Percentage					
Gender							
Women	95	75					
Men	31	25					
Marital status							
Married	114	90.50					
Single	2	1.60					
Divorced	1	0.80					
Widowed	9	7.10					
Educational level							
Lower than high school	ol 92	73.02					
High school	25	19.84					
University degree	9	7.14					
Occupation							
Employed	22	17.50					
Unemployed	104	82.50					

Table 2: Comparison of QOL between the two groups

Score of QOL and its domains	Insulin refusal group		Insulin recipient group		Statistical test		
	Mean	SD	Mean	SD	t-test	<i>P</i> 1	P2
Satisfaction with diabetes	1.94	0.40	2.27	0.50	4.08	<0.001	<0.001
Effects of diabetes	1.84	0.40	2.16	0.55	3.73	<0.001	<0.001
Concerns about diabetes	1.06	0.13	1.12	0.21	2.05	0.040	0.080
Social- occupational concerns	1.68	0.46	1.94	0.57	2.80	0.006	0.005
QOL	1.74	0.31	2.02	0.41	4.33	<0.001	<0.001

QOL: Quality of life, SD: Standard deviation

not willing to use insulin, even though they need it. QOL could be one of the reasons for this issue. Therefore, the present study was conducted to evaluate QOL of insulin recipient and refusal patients with diabetes.

The results of this study showed that QOL score was better in the insulin refusal group. The study by Podbielska et al. in 2014 also showed that patients with type 2 diabetes who received oral anti-diabetic drugs had a better QOL in comparison to those who only used insulin.[17] In addition, regarding the significant relation between QOL and the treatment method, the study of Shim et al. was in line with the present study and revealed that insulin therapy correlated with a lower QOL.[20] Nevertheless, the study by Sadeghi Ahari et al.[21] and some other studies found no significant relation between QOL and the treatment method.[22-24] It seems that these differences were caused due to homogeneity of some demographic factors in the present study. However, in the above-mentioned study, homogeneity was not created, which can be seen as their weakness. In the present study, the number of participants in the two groups was equal, but this was not the case in other studies. Moreover, in the mentioned studies, diabetes-specific tools were not used. However, a health-related QOL tool directly evaluates the effect of disease or its treatment, and in cases where the complications of diseases are being studied, it is better to use tools that are more sensitive to health changes.<sup>[25]</sup>

In all the domains (satisfaction with diabetes, effects of diabetes, concerns about diabetes, and social-occupational concerns) the QOL of insulin refusal patients was better. Fal et al. showed in their study that the two groups had no statistical differences regarding QOL score, but the physical domain was better in those who consumed oral anti-diabetic drugs and the mental domain was better among those who used insulin.[8] The difference in results could be due to the different characteristics of samples, the used questionnaire, or cultural differences. In the present study, sampling was performed in an outpatient clinic, but in the study by Fal et al., samples were selected from among the patients who were hospitalized in a Hungarian hospital due to diabetes complications. [8] It seems that dealing with complications that could lead to hospitalization could have caused the difference in the results of the two studies. Furthermore, these two studies were conducted in two different cultures (Iranian and Hungarian), and thus, the difference could also be due to cultural differences. In each culture, QOL, in addition to objective criteria, is based on each individual's perception of financial and communication resources.[19] It seems that the reason for higher emotional QOL among insulin users is their belief in the negative effect of insulin on their QOL.[15] In addition, the relation of spiritual-mental factors with diabetes management<sup>[26]</sup> and patients' failure to manage their disease when starting insulin injection could be other causes of this issue. This is due to the patients' belief that their lifestyle will be limited by insulin injection. Therefore, limitations caused by insulin therapy have led to emotional difficulties for patients. These problems are recognized as important factors and can affect patients' commitment to self-care and blood sugar control and the risk of complications. [27] On the other hand, low blood sugar after repeated injections of insulin during the day causes the patient to feel tired and lose the feeling of exhilaration and usefulness. Therefore, the fear of death due to low blood sugar after insulin injection always accompanies the patients. Moreover, they feel dependent because of their need to inject during the day. It is even possible that because of the limitations caused in society due to patients' dependence on injection, they will not inject insulin on time. Therefore, controlling their blood sugar level will be compromised. All of these cases could be reasons that have negative effects on accepting insulin therapy. On the other hand, the study by Braun et al. in 2008 showed that patients with type 2 diabetes, who started insulin therapy along with educational programs, reported a better QOL after 6 months in comparison to those who only used insulin. [26] The reason for low QOL in the present study may be the lack of educational and follow-up programs. However, this variable was not evaluated in the present study.

In the present study, most of the subjects were women, which is similar to many other studies. [2,7,8,28] The majority of study participants had an educational level of elementary or lower and were unemployed. These results were similar to the results of previous studies. [2,7] Regarding the low educational level of subjects, it could be assumed that patients with lower educational levels refer to public clinics and those with higher educational levels usually attend private clinics. [2]

In this study, no significant relation was found between occupation and QOL. The studies by Peymani *et al.*<sup>[29]</sup> and Sadeghi Ahari *et al.*<sup>[21]</sup> also confirmed this finding. Nevertheless, in the studies by Yaghoobi *et al.*<sup>[30]</sup> and Baghiani Moghadam *et al.*<sup>[24]</sup> a significant relation was found between occupation and QOL; patients with higher occupational status and income reported better QOL. The reason for this finding in the present study may be the low frequency of employed patients. For example, in the study by Yaghoobi *et al.*, 26.9% of participants were employed, but in the present study, this rate was only 17.5%.<sup>[30]</sup>

Age and duration of the disease had no significant relation with QOL. Alavi *et al.* also reported no relation between age and duration of the disease, and QOL. [23] Yaghoobi *et al.* 

also found no relation between age and QOL. [30] However, in this study, older patients reported lower QOL. Tang *et al.* also reported that older patients had a lower QOL in comparison to younger patients. [31] In the study by Khaledi *et al.* [7] and some other studies, [27,28] the relation between age and QOL was significant. Furthermore, in the study by Baghiani Moghadam *et al.*, [24] a significant relation was found between duration of the disease and QOL.

Gender and educational level had a significant relation with the score of QOL, but the domain of concerns about diabetes had no significant relation with QOL; men had a better QOL than women and as the educational level increased, their QOL was improved (lower score in the questionnaire indicated better QOL). Regarding gender, the results of this study are in line with the results of many other studies. [2,7,22,28-30] Although no significant relation was reported between gender and QOL in the study by Baghiani Moghadam et al., mean QOL score was higher in men than women.<sup>[24]</sup> However, in the studies by Peymani et al.[29] and Monjamed et al.,[2] women reported a better QOL than men. Regarding the significant relation between educational level and QOL, this study is in line with some previous studies. [2,29,30] Nevertheless, in the study by Baghiani Moghadam et al., no significant relation was found between educational level and QOL. [24] It seems that self-care has a direct relation with increased educational level and individual's knowledge about the importance of controlling diabetes through diet, exercise, and monitoring of metabolic condition, and it results in a better QOL.

### **CONCLUSION**

Results showed that the refusal of insulin therapy by some patients with type 2 diabetes who had been prescribed insulin by a physician had physical, emotional, and social reasons. Their decision had led to reporting a better QOL. Moreover, the effect of insulin therapy on QOL and its reduction could be another reason that has negative effects on its acceptance. Therefore, it could be assumed that enhancement of QOL is related to all aspects of the disease, especially its treatment method and solving therapeutic problems. Therefore, it is necessary to evaluate patients' QOL and their needs before taking any clinical measures.

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### **Conflicts of interest**

There are no conflicts of interest.

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