Research Paper

Association Between Fear of Hypoglycemia and Treatment Satisfaction Among Patients With Diabetes Mellitus

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ABSTRACT

Background: Treatment satisfaction is one of the main factors of assessing care quality in patients with chronic diseases. Some factors may influence treatment satisfaction and improve or impair clinical outcomes. This study aimed to determine the relationship between fear of hypoglycemia and satisfaction with treatment in patients with type 2 diabetes treated with oral antidiabetic drugs.

Methods: This cross-sectional study was carried out in one of the hospitals of Qazvin Province, Iran, in 2021. The research sample was 390 patients with type 2 diabetes who used oral antidiabetic drugs, selected through convenience sampling. The data were collected using the hypoglycemic fear survey (HFS) and the diabetes medication satisfaction (DiabMedSat) questionnaire. Then, the obtained data were analyzed using the independent t-test, one-way analysis of variance, and multiple linear regression in SPSS software, version 26. Statistical significance was set at $P<0.05$.

Results: Patients' Mean±SD age was 53.4±11.49 years, and most (57.4%) were female. Treatment satisfaction score was lower in females ($\beta=-0.12$, $P<0.007$) and patients with diabetes complications ($\beta=-0.138$, $P<0.005$). Patients with college education had higher treatment satisfaction ($\beta=0.173$, $P<0.001$). Patients with very severe ($\beta=-0.29$, $P<0.001$) or severe hypoglycemia ($\beta=-0.157$, $P<0.034$) experienced lower treatment satisfaction than those with mild hypoglycemia. Low treatment satisfaction scores were associated with fear of hypoglycemia ($\beta=-0.39$, $P<0.001$).

Conclusion: In this study, fear of hypoglycemia was associated with a decreased level of satisfaction with treatment. As a consequence, patients with type 2 diabetes must be assessed for hypoglycemia fears and their adverse effects. Also, to prevent complications caused by not taking antihyperglycemic drugs, nursing managers and clinical nurses are recommended to prepare appropriate programs to implement psychological interventions to reduce the fear of hypoglycemia.

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Highlights

- Treatment satisfaction is one of the critical factors of care quality in patients with diabetes mellitus.
- One of the main side effects of treatment with antidiabetic drugs in patients with type 2 diabetes is hypoglycemia, which may cause fear of hypoglycemia in these patients.
- Treatment satisfaction was significantly associated with fear of hypoglycemia in this study.
- Being female, diabetes complications, low education level, and severe or very severe hypoglycemia were associated with lower satisfaction with treatment in patients with type 2 diabetes taking oral antidiabetic drugs.

Plain Language Summary

Treatment of diabetes mellitus is a complex process. One of the most important concerns in the treatment of diabetes is maintaining an appropriate level of blood sugar along with preventing hypoglycemic episodes. Following the experience of hypoglycemia, patients may develop a fear of hypoglycemia and, thus, non-adherence to treatment. The findings of the present study indicated that the fear of hypoglycemia is related to a decrease in patients' satisfaction with treatment. Therefore, the determination of patients at risk of fear of hypoglycemia by health care workers can be effective in improving treatment satisfaction and quality of life of these patients.

Introduction

Diabetes mellitus is one of the prevalent non-communicable and metabolic diseases with debilitating effects. Meanwhile, rapid economic growth and urbanization have increased its prevalence worldwide (Onyango & Onyango, 2018). It is estimated that the number of diabetes will increase to 600 million people by 2035, more than 80% of whom live in developing countries (Bakker et al., 2016). It was reported that 85.5% of Iranians suffer from type 2 diabetes mellitus (T2DM) (Esteghamati et al., 2017).

Treating T2DM involves a complex and multidisciplinary process (Williams et al., 2012). Glycemic control without hypoglycemia is one of the main challenges in diabetes treatment (Stargardt et al., 2009). Despite various antidiabetic treatments, most T2DM patients do not achieve optimal glycemic control (Avramopoulos et al., 2015). Severe and recurrent hypoglycemia may lead to fear of hypoglycemia in patients with T2DM (Sheu et al., 2012) and adverse effects on diabetes management (Erol & Enc, 2011). Fear of hypoglycemia is associated with negative feelings such as psychological distress and anxiety in patients with diabetes. It is also considered a barrier to glycemic control, which negatively affects the self-management, quality of life, and mental health of patients with diabetes (Hapunda et al., 2020; Huang et al., 2022).

Treatment satisfaction is an essential indicator of the quality of care (Othman et al., 2015). It is defined as the "confirmation of expectations" for a patient, that is, the agreement between the patient's expectations from the treatment and the results obtained (Alcubierre et al., 2014). To achieve treatment satisfaction, it is essential to understand the patient's perspective on the current medication (Khdour et al., 2020). The patient's negative attitude toward the effectiveness of the treatment is an important obstacle to adherence to treatment (Farhat et al., 2019). Many antidiabetic treatments lead to hypoglycemia and are therefore perceived by the patient as unpleasant and life-threatening, which may affect treatment adherence (Walz et al., 2014). Fear of hypoglycemia can lead to inadequate blood sugar control and blood sugar-increasing behaviors such as high carbohydrate intake, avoiding exercise, and reducing the dose of antihyperglycemic medications (Mitchell et al., 2013).

Considering that treatment satisfaction can increase the effectiveness of treatment and adherence to it, as well as blood sugar control (Chang et al., 2023), it seems necessary to investigate treatment satisfaction in patients with T2DM and its related factors. According to our search, no study has specifically focused on the relationship between fear of hypoglycemia and satisfaction with treatment in these patients. Therefore, the present study was carried out to assess the relationship between fear of hypoglycemia and satisfaction with treatment in Iranian patients with T2DM.

Materials and Methods

This cross-sectional study was conducted in the outpatient clinic of Velayat Hospital in Qazvin Province, Iran, in 2021. A total of 390 patients with T2DM treated with oral antidiabetic drugs were recruited by convenience sampling. The inclusion criteria were as follows: Being 18 years old or older, suffering from T2DM as diagnosed by the hospital doctor, and taking antihyperglycemic medication for at least 6 months. Patients with type 1 diabetes, pregnant women, and those treated with insulin were excluded from the study.

Considering a type I error of 0.05, a standard deviation of the fear of hypoglycemia in patients with T2DM as 8.6 (Yeke Fallah, 2019), a precision of 0.9, and a probability of 10 % missing data, the sample size was estimated to be 390 based on the Equation 1:

$$1.\ n = \frac{(Z_{1-\alpha/2})^2 \sigma^2}{d^2}$$

The data were collected using demographic and clinical characteristics questionnaires, diabetes medication satisfaction (DiabMedSat), and hypoglycemia fear survey-II (HFS).

The first part of the questionnaire included demographics (age, gender, education level, employment, marital status) and clinical characteristics (family history of diabetes, name and number of oral antihyperglycemic drugs, diabetes complications, hypoglycemia experience, and severity of hypoglycemia) of the patients. Complications of diabetes were assessed by asking patients and referring to their medical records. Answers to the question, "Have you ever felt symptoms of hypoglycemia?" (such as sweating, confusion/feeling disoriented, shakiness, clumsy or jerky movements, dizziness, sudden moodiness or behavior changes, hunger, tingling sensations around the mouth, difficulty concentrating, headache, and pale skin color) were used to evaluate patients' reports of hypoglycemia symptoms in the past 6 months. According to recommendations of the American Diabetes Association Hypoglycemia Workgroup, the patients with hypoglycemia rated their hypoglycemia severity by selecting one of the following choices: 1) Mild (little or no interruption of activities and no assistance needed to manage symptoms), 2) Moderate (some interruption of activities and no assistance needed to manage symptoms), 3) Severe (needed the assistance of others to manage symptoms e.g. to bring food or drink, and 4) Very severe (requires medical attention including calling an ambulance, going to the emergency room or hospital, or seeing a doctor or nurse) (Marrett et al., 2011).

DiabMedSat contains 21 items divided into three domains: The burden domain (11 items) measures any bothersome aspect of treatment, the efficacy domain (5 items) measures satisfaction with any physical or emotional effects of treatment, and the symptoms domain (5 items) evaluates symptoms that may have occurred as a result of the treatment. Each item is rated on a 7-point Likert scale ranging from 1 (never/not at all/not at all bothered/extremely dissatisfied) to 7 (all the time/extremely/extremely bothered/extremely satisfied) by the subjects. The range of raw scores of the subscales and the whole questionnaire is as follows: Burden, 11-57; efficacy, 5-33; symptom, 5-30; total (DiabMedSat), 120. The scores are then transformed from 0 to 100. The total score of each domain will be the result of the mean score of the items in that domain. The mean of the three domain scores determines the total score. Total and domain scores range from 0 to 100. A higher score indicates greater levels of treatment satisfaction. Items 1 (a-d), 2 (a-e), 5 (a-d), and 6 (a-c) are scored reversely. The DiabMedSat has acceptable internal consistency with an alpha coefficient=0.9 (Brod et al., 2006).

There are two subscales in the HFS-II: Behavioral and worry (Gonder-Frederick et al., 2011). Both subscales of the survey can be analyzed separately (Przezak, Bielka, & Molęda, 2022). This study evaluated patients' concerns about hypoglycemia episodes using the HFS-worry subscale (HFS-W) alone (Atallah et al., 2020; Marrett et al., 2011; Sheu et al., 2012; Wild et al., 2007; Yeke Fallah et al., 2019). The HFS-W is composed of 18 items rated on a 5-point Likert scale ranging from 0 (never) to 4 (always) and is scored from 0 to 72 (most worry) (Gonder-Frederick et al., 2011). The HFS-W has high internal consistency (α=0.94) (Gonder-Frederick et al., 2013).

The above instruments were translated into Persian by a PhD candidate in translation studies who then back-translated them into English. The content validity of the instruments was confirmed by 10 faculty members of the Nursing Department of Qazvin University of Medical Sciences. Content validity index (CVI) and content validity ratio (CVR) were calculated for the Persian version of the HFS-W subscale and the Persian version of DiabMedSat, and the results were (CVR=0.74, CVI=0.86) and (CVR=0.78, CVI=0.89), respectively. The reliability of the questionnaires was tested on 20 patients with T2DM before the final versions of the instruments were considered ready to use. The internal consistency reliability (α) for the Persian version of HFS-W was 0.96 and for the Persian version of DiabMedSat was 0.81. All the questionnaires were completed through face-to-face interviews with the subjects by the second author.

Data analysis

Continuous variables were presented by Mean±SD, whereas categorical variables as frequency and percentage. Univariate analysis (using the independent t-test, one-way analysis of variance, and Pearson correlations) was initially conducted to assess relationships between the independent variables and treatment satisfaction. A multiple linear regression with a backward elimination method was performed to determine potential factors that might affect the treatment satisfaction of patients with T2DM so that the dependent variable was treatment satisfaction, and the factors with P<0.05 in the univariate analysis were considered the independent variables. P<0.05 was considered statistically significant. The SPSS software, version 26 statistical software was used for data analysis.

Results

Demographic and clinical characteristics are summarized in Table 1. The Mean±SD age of the subjects was 53.49±11.49 years. Most patients were female (57.4%) (Table 1). The mean scores of treatment satisfaction and fear of hypoglycemia are presented in Table 2.

Univariate analysis using the Pearson correlation test indicated that fear of hypoglycemia is negatively correlated with treatment satisfaction (r=-0.504, P<0.001). Treatment satisfaction is negatively associated with age (r=-0.248, P<0.001) and diabetes duration (r=-0.343, P<0.001). The univariate relationships of diabetes treatment satisfaction and categorical variables are shown in Table 3.

In multivariate linear regression analysis, treatment satisfaction scores were lower in females (β=-0.12, P<0.007) and patients with diabetes complications (β=-0.138, P<0.005). Patients with college (β=0.173, P<0.001) or secondary education (β=0.115, P<0.023) experienced higher treatment satisfaction than those with primary education. Patients with very severe (β=-0.29, P<0.001) or severe hypoglycemia (β=-0.157, P<0.034) experienced lower treatment satisfaction than those with mild hypoglycemia. Fear of hypoglycemia was associated with lower treatment satisfaction scores (β=-0.39, P<0.001). The regression model explained (27.7%) of the variance of treatment satisfaction (Table 4).

Table 1. Demographics and clinical characteristics of the subjects

Variables	Category	Mean±SD/No. (%)
Age (y)		53.49±11.49
Diabetes duration (y)		8.44±6.66
Gender	Male	166(42.6)
	Female	224(57.4)
Marital status	Married	281(72.1)
	Single/widowed/divorced	109(27.9)
Education	Primary	122(31.3)
	Secondary	197(50.5)
	College education	71(18.2)
Employment	Employed	119(30.5)
	Housewife/Unemployed	200(51.3)
	Retired	71(18.2)
Diabetes complications	Yes	161(41.3)
	No	229(58.7)
Family history of diabetes	Yes	179(45.9)
	No	211(54.1)

Variables	Category	Mean±SD/No. (%)
Taking sulfonylurea	Yes	316(81)
	No	74(19)
Taking biguanide	Yes	93(23.8)
	No	297(76.2)
Taking thiazolidinediones	Yes	23(5.9)
	No	367(94.1)
Taking dipeptidyl peptidase inhibitors	Yes	25(6.4)
	No	365(93.6)
Number of oral antihyperglycemic drugs	1	83(21.3)
	2	286(73.3)
	≥3	21(5.4)
Hypoglycemia	Yes	297(76.2)
	No	93(23.8)
Severity of hypoglycemic symptoms	Very severe	64(16.4)
	Severe	63(16.2)
	Moderate	79(20.3)
	Mild	91(23.3)

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Discussion

The purpose of this study was to assess patients' concerns about hypoglycemia episodes using the HFS-W.

In the current study, fear of hypoglycemia was significantly associated with lower treatment satisfaction. To the best of our knowledge, this study is one of the first of its kind to address the relationship between fear of hypoglycemia and treatment satisfaction in Iranian diabetic patients. It has been shown that the fear of hypoglycemia is related to the anxiety domain of the quality of life. At the same time, anxiety itself has been associated with lower satisfaction with treatment (Khdour et al., 2020). The fear of hypoglycemia is common among patients with diabetes. Anxiety, emotional stress, and insecurity associated with excessive fear can reduce one's quality of life (Przezak et al., 2022).

Hypoglycemic events in patients with T2DM treated with antihyperglycemic drugs subject them to fear of hypoglycemia (Bradley et al., 2018; Sheu et al., 2012; Simon et al., 2015; Vexiau et al., 2008). The current study demonstrated that severity of hypoglycemic episodes is

Table 2. Mean scores of treatment satisfaction and its subscales and fear of hypoglycemia

Scales	Subscales	Mean±SD
Treatment satisfaction	Burden	59.48±16.56
	Efficacy	43.20±16.65
	Symptoms	47.20±16.11
	DiabMedSat: Total score	49.96±12.42
Fear of hypoglycemia	HFS score	18.86±14.98

HFS: Hypoglycemic fear survey.

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Table 3. Univariate analysis of relationship between demographic and clinical characteristics and treatment satisfaction

Variables		Mean±SD	t/F	95% CI		P
				Lower	Upper	
Gender	Male Female	51.81±13.56 48.59±11.34	-2.55	-5.7	-0.74	0.011[a]
Marital status	Married Single/widowed/ divorced	51.26±11.82 46.61±13.33	-3.35	-7.36	-1.92	0.001[a]
Education	Primary Secondary College education	45.76±11.8 50.63±12.3 55.31±11.47	14.84	43.64 48.9 52.6	47.87 52.36 58.03	0.001[b]
Employment	Employed Housewife/unemployed retired	53.66±11.52 48.16±11.99 48.78±13.79	8.02	51.59 46.49 45.51	55.77 49.84 52.04	0.001[b]
Diabetes complications	Yes No	44.43±13.07 53.85±10.32	-7.94	-11.75	-7.08	0.001[a]
Family history of diabetes	Yes No	49.64±12.91 50.23±12.01	-0.46	-3.07	1.89	0.641[a]
Taking sulfonylurea	Yes No	48.98±12.74 54.14 ±10.0	-3.25	-8.27	-2.04	0.001[a]
Taking biguanide	Yes No	49.01±12.77 52.99±10.72	2.72	1.1	6.86	0.007[a]
Taking thiazolidinediones	Yes No	51.56±9.07 49.86±12.74	0.63	-3.55	6.95	0.526[a]
Taking dipeptidyl peptidase inhibitors	Yes No	41.5±14.48 50.54±12.07	-3.57	-14.01	-4.06	0.001[a]
Number of oral antihyperglycemic drugs	1 2 ≥3	54.36±10.17 49.36±12.42 40.7±14.16	12.02	52.14 47.91 34.25	56.58 50.81 47.14	0.001[b]
Hypoglycemia	Yes No	47.63±12.3 57.38±9.5	-7.001	-12.49	-7.01	0.001[a]
Severity of hypoglycemic symptoms	Very severe Severe Moderate Mild	41.44±14.93 40.84±10.89 50.52±8.19 54.18±9.58	27.76	37.71 38.1 48.69 52.19	45.17 43.59 52.36 56.18	0.001[b]

[a]Independent samples test, [b]One-way analysis of variance.

Table 4. Multivariate linear regression analysis of relationship between demographic and clinical characteristics, fear of hypoglycemia, and treatment satisfaction

Variables		Unstandardized Coefficients		Standardized Coefficients	95% CI		t	P
		B	SE	β	Lower	Upper		
Gender	Female	-3.044	1.119	-0.12	-5.243	-0.844	-2.721	0.007
	Male*	0						
Education level	Secondary	2.873	1.262	0.115	0.392	5.354	2.277	0.023
	College education	5.615	1.678	0.173	2.315	8.915	3.345	0.001
	Primary*	0						
Severity of hypoglycemic symptoms	Very severe	-8.79	1.87	-0.29	-12.48	-5.09	-4.67	0.001
	Severe	-4.7	2.2	-0.157	-9.04	-0.358	-2.13	0.034
	Moderate	-2.09	1.61	-0.075	-5.28	1.08	-1.29	0.196
	Mild*	0						
Diabetes complications	Yes	-3.526	1.244	-0.138	-5.971	-1.081	-2.836	0.005
	No*	0						
Fear of hypoglycemia (HFS-II score)		-0.327	0.040	-0.39	-0.405	-0.248	-8.185	0.001
R^2					0.286			
Adjusted R^2					0.277			

*Reference group.

Statistical test: Multiple linear regression; HFS: Hypoglycemic fear survey.

significantly associated with treatment satisfaction so that patients with severe hypoglycemia reported lower treatment satisfaction. This finding is consistent with previous studies showing that patients with hypoglycemic symptoms experienced non-adherence to medications and were less satisfied with treatment (Guisasola et al., 2008; Simon et al., 2015; Walz et al., 2014).

Hypoglycemia and fear of hypoglycemia may have detrimental effects on treatment satisfaction and glycemic control (Simon et al., 2015; Wang et al., 2020). To prevent hypoglycemia, patients who fear hypoglycemia tend to maintain high glucose levels. Hence, assessing patients' fear of hypoglycemia in clinical practice and participation in individual and group psychotherapy sessions can promote the quality of diabetes care (Przezak et al., 2022). As well, patients' satisfaction with treatment can be improved by teaching them the symptoms of hypoglycemia and how to prevent it. In line with previous studies, our study also showed that female gender is associated with lower treatment satisfaction (Nicolucci et al., 2009; Suzuki et al., 2021). According to Przezak et al. (2022), women with diabetes experience a greater fear of hypoglycemia, which can have adverse effects on their beliefs about the effectiveness of treatment. According to the findings of the present study, several studies showed that treatment satisfaction has an inverse relationship with diabetes complications in addition to being inversely related to the female gender (Atallah et al., 2020; Nicolucci et al., 2009; Zhou et al., 2019). Having complications of diabetes increases comorbidities and lowers quality of life, which can reduce satisfaction with treatment.

In contrast to the results of the current study, another study showed that patients with macrovascular complications had higher treatment satisfaction. They explained that healthcare providers probably pay more attention to patients with diabetes complications, which leads to higher treatment satisfaction. Also, they attributed the discrepancy in results to the different definitions and classifications of diabetes complications in various studies (Boels et al., 2017). In the present study, patients with higher education levels had higher treatment satis-

faction. This finding was similar to other studies (Farhat et al., 2019; Zhou et al., 2019). Another study found that treatment satisfaction was positively associated with receiving diabetes education and medication counseling (Suzuki et al., 2021). Our study emphasizes the necessity of increasing patients' awareness of diabetes and its potential complications and the importance of screening for diabetes complications.

Conclusion

Most patients with T2DM treated with oral antihyperglycemic drugs experience hypoglycemia, and the exposure of patients to hypoglycemic symptoms increases their fear of hypoglycemia. The present study showed that fear of hypoglycemia is associated with decreased satisfaction with treatment. Considering the importance of treatment satisfaction in blood sugar control and patients' quality of life, screening patients for fear of hypoglycemia is recommended. In addition, it seems necessary to plan psychological interventions to reduce the fear of hypoglycemia in patients with T2DM.

This study has some limitations. First, the study's cross-sectional nature allowed us to describe treatment satisfaction and fear of hypoglycemia at only one point in time. It is suggested that future studies design and implement interventions to increase treatment satisfaction with an emphasis on reducing the fear of hypoglycemia in patients with T2DM. The samples of this study were recruited from one hospital in Qazvin City, which can reduce the generalizability of the findings. Therefore, it is suggested that multicenter studies be conducted in the future to obtain more reliable evidence.

Ethical Considerations

Compliance with ethical guidelines

The study was approved by the Ethics Committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1399.101). The study objectives were explained to the patients, and they were assured of the confidentiality of their information. Written informed consent was obtained from all subjects.

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Authors' contributions

Conceptualization, methodology, statistical analysis, supervision, writing the original draft: Maryam Momeni and Hamideh Hakimi; Data collection: Pegah Afsaneh Abadi; Final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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