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Fear of hypoglycemia and its predictive factors among diabetic pregnant women

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ABSTRACT

Objective: The purpose of the present study was to investigate the fear of hypoglycemia (FoH) and its predictors among diabetic pregnant women.
Study design: Cross-sectional conducted between January to August 2022.
Methods: In the present study, 250 diabetic pregnant women from Qazvin province participated. Demographic and fertility characteristics, FoH, adherence to treatment, self-efficacy, anxiety and depression were assessed. Data were analyzed using univariable and multivariable linear regression models.
Results: The participants' mean age was 31.02 years (SD=4.72). The FoH mean score was 32.88 (out of 72). Based on the multivariable linear regression model, having a history of hypoglycemia ($\beta = 0.44$, $p < 0.001$), lower education ($\beta = 0.17$, $p = 0.001$), being treated with insulin ($\beta = 0.22$, $p < 0.001$), being treated with both insulin and diet ($\beta = 0.16$ $p = 0.003$), being of younger age ($\beta = -0.13$, $p = 0.008$), and depression ($\beta = 0.16$, $p = 0.002$) were independent predictors of FoH among pregnant women.
Conclusion: Diabetic pregnant women experience FoH, particularly those with a history of hypoglycemia. Therefore, providing education and counseling concerning hypoglycemia, complications, and necessary measures for this group of diabetic pregnant women are needed along with those who are younger, less educated, and have comorbid mental health conditions.

1. Introduction

Diabetes Mellitus (DM) is among common metabolic diseases experienced during pregnancy [1]. DM is classified into one of three categories (type 1, type 2 and gestational diabetes [GDM]) by the World Health Organization (WHO) [2]. GDM and DM type 2 are manifestations of the same disease at different times during a women's lifespan [2]. GDM is defined as form of carbohydrate intolerance that leads to hyperglycemia and seen for the first time during pregnancy [3]. The prevalence of gestational and preexisting diabetes vary in different populations [5]. Worldwide, hyperglycemia is diagnosed among 16.9% of pregnancies based on WHO criteria [10]. Based on a recent systematic review, the pooled prevalence rates of pre-existing type 1 and type 2 diabetes in pregnancy were low (0.3% and 0.2% respectively) but the rates had doubled between 1990 and 2020 [11]. Also, the pooled global prevalence of GDM was estimated in another recent systematic review as 14% but World Bank country income groups had different prevalence rates of GDM: 14.2% in high-income countries, 9.2% in middle-income countries and 12.7% in low-income countries [12].

Pregnancy with diabetes (regardless of being pre-existing type 1 or type 2 diabetes DM or GDM) can endanger maternal health and fetal development [4, 5]. The maternal health risks in contribution of uncontrolled diabetes during pregnancy include increased chance of gestational hypertension and pre-eclampsia, increased rate of caesarean section, and increased rate of postpartum hemorrhage [6, 7]. The neonatal health risk of pre-existing and gestational diabetes during pregnancy include fetal abnormalities, spontaneous abortion, fetal loss, macrosomia, neonatal hypoglycemia, and hyperbilirubinemia and increased future risk of obesity and type 2 diabetes among their offspring [6, 7]. The condition is also related to the development of psychological problems such as anxiety and depression among pregnant women [8, 9].

The main objective of diabetes management is control of blood sugar. The initial treatment of gestational diabetes includes lifestyle changes such as diet and daily exercise. Patients control their blood sugar at home, and where there is a lack of optimal glycemic control, medical interventions are initiated [8]. Fear and worry related to the health and growth of the fetus, use of insulin, blindness, and amputation are major concerns among diabetic pregnant women [13]. Therefore, the available evidence shows the importance of managing psychological problems among diabetic pregnant women. Fear of hypoglycemia is a psychological concerns of diabetic patients, and is defined as a degree of fear related to the occurrence of hypoglycemia and its consequences [14]. Ineffective hypoglycemia preventive behaviors including limitation of physical activities, self-reduction of consumed dose of administered insulin, and increasing carbohydrate consumption and increased blood sugar are some consequences of FoH [15]. According to the available empirical evidence, few studies have investigated the FoH among diabetic women, and since the existence of this fear can affect the control of diabetes (and consequently the rate of pregnancy complications among diabetic pregnant women), the present study assessed the FoH and its predictors among diabetic pregnant women in Qazvin province, Iran.

2. Methods

2.1. Study design

This cross-sectional telephone interview study was conducted between January to August 2022 in Qazvin province (Iran).

2.2. Participants and eligibility criteria

The participants in the present study were pregnant women with any type of diabetes (type 1, type 2 or GDM). Other inclusion criteria were (i) being at least 18 years old, (ii) being treated with insulin, diet only or simultaneous treatment with both insulin and diet, and (iii) confirmation of type 1 or 2 diabetes or gestational diabetes by a specialist. Exclusion criteria included not providing informed consent to participate in the study.

2.3. Sampling method and procedure

Census sampling method was used due to limited number of potentially eligible individuals. Qazvin Province has six counties. Each county has several urban/rural comprehensive health centers under supervision of County Main Health Center. Pregnant women are provided with free prenatal services in urban/rural comprehensive health centers. With higher than 80% coverage of prenatal care in this province, comprehensive health centers were selected as the study settings. All pregnant women with any prenatal complication including diabetes are listed in comprehensive health centers. This list is accessible at County Main Health Center. At the beginning of the study, a list of all pregnant women with diabetes (with their name and phone contact details) was prepared with the help of the provincial Health Deputy and Counties' Main Health Center. A total of 250 pregnant mothers with diabetes in the province were identified at the time of the study. A trained interviewer (SJ) called all individuals, explained the study aims and asked them to participate. Then individuals arranged an appropriate time for a telephone interview. At the appointed time, they were telephoned by trained interviewer and survey questions were responded to.

2.4. Power analysis

Due to the expected low number of pregnant women with diabetes, all of them in the province were contacted and invited to participate in the study. After completing the study, the power of the study was checked to check the adequacy of the sample number. Considering 0.05 as the first type error and the sample size of 250 individuals, the power of the regression test was calculated. Based on this power calculation, the power of present study to determine the predictors of FoH among diabetic pregnant women was more than 80% (type II error = 0.2).

2.5. Measures

In the present study, demographic and fertility variables, FoH, adherence to treatment, general self-efficacy, anxiety, and depression were assessed.

Demographic, diabetes, and fertility information: A short checklist was used to collect demographic, diabetes, and fertility information concerning age, gestational age, education level, economic status, spousal support, job, history of hypoglycemia, history of infertility, and type of diabetes and treatment method.

Fear of hypoglycemia: The Hypoglycemia Fear Survey-II Scale (HFSS-II) [16] was used to assess fear of hypoglycemia. The HFSS-II includes two subscales comprising worry and behavior. In the present study, only the worry subscale was used. The subscale contains 18 items assessing FoH in the past 6 months, and items (e.g., *"For the past 6 months, I have been worried about not being able to detect hypoglycemia because of the possibility of hypoglycemia"*) are rated on a four-point scale from 0 (*never*) to 4 (*always*). The total scores range from 0 to 72, with higher scores indicating greater FoH [16]. The validity and reliability of the Persian HFSS-II has been shown to be very good [17]. In the present study, the Cronbach's alpha coefficient was excellent (0.96).

Self-efficacy: The General Self-Efficacy Questionnaire (GSEQ) [18] was used to assess self-efficacy. The GSEQ comprises 10 items (e.g., *"I can always manage to solve difficult problems if I try hard enough"*) which are rated on a four-point scale from 1 (*not at all*) to 4 (*always*). The total scores range from 10-40 and higher score indicates greater self-efficacy. The psychometrics properties of Persian version have been shown to be good [19]. In the present study, the Cronbach's alpha coefficient was excellent (0.96).

Adherence to treatment: The Medication Adherence Rating Scale (MARS) [20] was used to assess treatment adherence. The MARS assesses treatment adherence over a one-week period based on individuals' thoughts and behaviors. This scale comprises ten items (e.g., *"Have you ever forgotten to take your medication?"*) answered yes or no. Total scores range from 0 to 10 and higher scores indicate greater treatment adherence. The MARS has good validity and reliability in English version [16] and the Persian version [21]. In the present study, the Cronbach's alpha coefficient was very good (0.89).

Anxiety and depression: The Hospital Anxiety and Depression Scale (HADS) was used to assess anxiety and depression [22]. This scale comprises 14 items with two subscales (i.e, anxiety and depression). Each item (e.g., *"I still enjoy the things I used to enjoy"*) is rated on a four-point scale from 0 (*Definitely as much*) to 3 (*Hardly at all*). Total scores on each subscale range from 0 to 21. Scores above 11 on each of the subscales are considered to indicate significant anxiety or depression, whereas scores from 8 to 10 indicate borderline cases, and scores from 0 to 7 are

considered normal [22]. The HADS has very good psychometric properties [23] including the Persian version [24]. In the present study, the Cronbach's alpha coefficient was very good (0.82).

Partner social support: Partner social support during pregnancy was assessed using a self-devised one-item question rated on a 10 point scale. The item was: *"How much support do you have from your spouse in different life situations especially during your pregnancy (for example, in situations where you feel the need for empathy, like-mindedness, participation in doing things, etc.)?"*

2.6. Ethical considerations

The study was approved by the ethics committee of Qazvin University of Medical Sciences (IR.QUMS.REC.1400.321). After obtaining required permissions, all pregnant mothers with diabetes who met the inclusion criteria and give consent to participate, were recruited. Written informed consent (with information regarding the research objectives, autonomy to participate, confidentiality and anonymity of collected data) was acquired prior to the telephone interview by midwife working in the comprehensive health center during their prenatal visits.

2.7. Data analysis

After collecting and coding the data, they were analyzed using SPSS version 24 software. Frequencies and percentages were used to describe categorical variables, and means and standard deviations were used to describe ordinal variables. The level of significance in the present study was $p<0.05$. In order to investigate the relationship between the FoH and the independent variables of the study, linear and multivariate linear regression models were used. In the first stage, univariate linear regression model was used to investigate the relationship between FoH as a dependent variable and independent variables of the study, including demographic and fertility characteristics, self-efficacy, anxiety, and depression. Considering the aforementioned significance level, the variables that had a significant relationship with the FoH were included in the multivariate linear regression model. Following this, a multivariate linear regression model was built considering the total score of FoH as the dependent variable and selected variables from the univariate model as independent variables. The multivariate regression model was performed based on the step-by-step method. The assumptions of using the linear regression method, including the normal distribution of FoH scores and the absence of outlier data, were checked and confirmed. After running the VIF model, all the independent variables of the model were below 1 and the tolerance was less than 1.5, confirming the absence of a linear relationship between the independent variables.

3. Results

In the present study, 250 pregnant women with diabetes participated with the average age of 31.02 years (SD=4.72) and the average gestational age was 30.30 weeks (SD=4.78). The mean score of FoH in the present study was 32.88 (SD=14.68). A total of 120 individuals participating in the research were women with gestational diabetes whose diabetes was diagnosed before the 24th week (48%). In terms of type of treatment, half of the individuals (n=126) were treated with insulin (50.4%). The distribution of the participants' demographic, diabetes, and fertility characteristics and their relationship with the FoH based on the univariable linear regression model is presented in Table 1.

Table 1. distribution of demographic, diabetes, and reproductive characteristics, and their association with FoH (N=250)

Variable	Range	Mean (SD) or No (%)	Results of univariable linear regression analysis		
			B	SE	*p*
Age (year)	20-44	31.02 (4.72)	-0.47	0.20	0.02
Education	Illiterate	11 (4.4)	11.38	4.81	0.02
	Primary	40 (16.0)	8.77	3.10	0.01
	Guidance	50 (20.0)	5.99	2.93	0.04
	High school	103 (41.2)	0.86	2.54	0.74
Job	Housewife	218 (87.2)	-6.47	2.76	0.02
	Employed	32 (12.8)			
Economic status	Poor	66 (26.4)	6.57	3.18	0.04
	Fair	153 (61.2)	2.41	2.87	0.40
	Good	31 (12.4)		RG	
Diabetes type	Pre-pregnancy diabetes	68 (27.2)	8.45	2.51	0.001
	Pregnancy diabetes diagnosed before 24 weeks	120 (48.0)	0.37	2.23	0.87
	Pregnancy diabetes diagnosed after 24 weeks	62 (24.8)		RG	
Hypoglycemic history	No	152 (60.8)	RG		
	Yes	98 (39.2)	16.92	1.57	<0.001
Diabetes treatment	Diet	95 (38.0)	RG		
	Insulin	126 (50.4)	12.37	1.82	<0.001
	Diet and insulin	29 (11.6)	13.89	2.84	0.001
Partner social support	0-10	7.58 (2.48)	-1.39	0.37	<0.001

Medication adherence	0-100	38.15 (11.38)	0.13	0.08	0.12
Self-efficacy	10-40	25.75 (8.37)	- 0.49	0.11	<0.001
Anxiety	0-21	8.48 (4.20)	0.87	0.22	<0.001
Depression	0-21	8.66 (4.19)	1.17	0.21	<0.001
FoH	0-72	32.88 (14.68)			
Gestational age (week)	16-50	30.30 (4.78)	-0.45	0.19	0.02
Gravid	0-6	1.85 (1.05)	-1.38	0.88	0.12
Infertility history	Yes	37 (14.8)	1.37	2.62	0.60
	No	213 (85.2)		RG	

Reference group: RG

In the univariable linear regression model, age, gestational age, spousal support, self-efficacy, anxiety and depression, education level, economic status, occupation, type of diabetes and treatment method, having a history of hypoglycemia had a significant relationship with the FoH and entered the multivariable model.

Based on the multivariable linear regression model (Table 2), a positive history of hypoglycemia (β=0.44, p<0.001) was determined as the strongest predictor of FoH among diabetic pregnant women. The mean score of FoH in individuals who had a history of hypoglycemia was 13 higher than individuals without a history of hypoglycemia (scale range = 0-72). The mean score of FoH among participants with primary education was 6.72 points higher than those with university education (β=0.17, p=0.001). With each unit increase in depression score, there was a 0.57 increase in FoH score (β=0.16, p=0.002). The type of diabetic treatment was another predictive variable of FoH. The average FoH score was highest among individuals with a combination of diet and insulin (7.33 higher score on FoH) and insulin (6.42 higher score on FoH) compared to individuals being treated by diet only (standardized beta coefficients equal to 0.22, 0.16 and p<0.05). Age was also a predictive variable with a negative significant relationship with FoH, and every year the individual's age increased, the average FoH score decreased by 0.4 (β=-0.13, p=0.01). In total, these variables explained 42% of the variance of FoH among diabetic pregnant mothers.

Table 2. Predictors of FoH among pregnant women with diabetes based on results of multivariable linear regression

	Unstandardized Coefficients	Standardized Coefficients	Sig.	Collinearity Statistics

		B (95% CI)	S.E.	Beta		Tolerance	VIF
Hypoglycemic history		13.12 (9.92; 16.32)	1.63	0.44	<0.001	0.79	1.27
Depression		0.57 (0.22; 0.92)	0.18	0.16	0.002	0.89	1.12
Education status (primary vs. academic)		6.67 (2.74; 10.59)	2.00	0.17	0.001	0.93	1.08
Diabetes treatment (Reference group of diet)	Diet and insulin	7.33 (2.51; 12.16)	2.45	0.16	0.003	0.80	1.24
	Insulin	6.42 (3.20; 9.64)	1.63	0.22	<0.001	0.74	1.35
Age		-0.41 (-0.71; -0.11)	0.15	-0.13	0.008	0.97	1.03

Model summary: R= 0.66; Adjusted R^2= 0.43; Durbin- Watson= 0.60

4. Discussion

The present study investigated FoH and its predictors among diabetic pregnant women. Based on the findings of the study, the average FoH score in the present study was 32.88 (out of 72). Different estimations of FoH have been reported among different populations of diabetic patients in other studies. For instance, in the study conducted by Bahrami et al., the of fear of hypoglycemia was compared between two groups (those with an awareness of hypoglycemia and those without), and the level of fear of hypoglycemia was higher among those who were not aware of hypoglycemia [25]. Sheikhi et al. [26] reported the average fear score of 32.15 (SD=10.54) among patients with type 2 diabetes. Also, in a study by Yeke Fallah et al. [27], the average FoH score among type 2 diabetics was 22.07 (SD=8.06). the difference in type of diabetes, and differences in the average time since diabetic diagnosis are possible sources of the different estimations of FoH. The majority of participants in the present study were mothers with gestational diabetes who did not have a history of diabetes.

Based on the multivariable linear regression model, having a history of hypoglycemia, lower education, type of treatment (those being treated with a combination of insulin and diet), being of younger age, and depression were independent predictors of FoH. Among these, (and arguably unsurprisingly), having a history of hypoglycemia was the strongest predictor of FoH. According to previous studies, the frequency of occurrence of hypoglycemia and especially severe

hypoglycemia and the number of symptoms that occur during mild hypoglycemia are related to the level of FoH [28, 29]. It has also been shown that the frequency of occurrence of hypoglycemia in the past 12 months is also related to FoH, and the occurrence of severe hypoglycemia in the past six months is associated with a decrease in self-efficacy and diabetes stress [28]. The results of these studies are consistent with that of the present study.

According to the study's findings, individuals who had higher education had less FoH, which is in line with Bohm et al.'s study [14]. However, the studies by Yeke Fallah et al [27] and Momeni et al. [17] reported no association between education level and FoH. However, in both of these studies, FoH among individuals with higher education was lower than those with lower education level. Yeke Fallah et al. [27] posited that the reason for lower FoH among educated individuals can be due to the fact that participants with higher education had tried to learn more about diabetes, its treatment methods, side effects of drugs and how to overcome the side effects including hypoglycemia.

In the present study, the type of diabetes treatment was related to FoH, which was also found in the study of Yeke Fallah et al. [27]. In the present study, the mean score of FoH among participants treated with both insulin and diet was higher than among those undergoing insulin treatment or diet alone, but the same as previous studies [27, 30]. In these studies, hypoglycemic fear was more associated with the frequency of hypoglycemia and the presence of severe hypoglycemia among patients treated with insulin.

Little information is available regarding the relationship between age and FoH. In the study by Yeke Fallah et al. [27], there was no association between age and FoH. This is despite the fact that some studies have reported it to be more prevalent among those who are elderly [31], whereas other studies have reported the prevalence of FoH to be more prevalent in older ages [32]. In the present study, older diabetic pregnant women had less FoH, therefore further studies are needed to investigate the effect of age on FoH.

In the present study, there was a relationship between FoH and the level of depression among diabetic pregnant mothers, but the direction of the relationship could not be determined in the present study due to its cross-sectional nature (see limitations). Beléndez [33] reported that FoH was associated with anxiety and depression. Also, according to McConville et al. [34], parents of children with type 1 diabetes who had a higher average depression score also had a higher FoH.

Krawczyk et al. [35] also reported that fear of high hypoglycemia is associated with anxiety and depression.

4.1. Limitations

The limitations of the present study include the cross-sectional nature of the study (which means that causality between the variables could not be determined), the self-reported data by participants (which is subject to various methods biases), and the small sample of Iranian women from one province (which means the findings cannot be generalized to other Iranian women from other areas or to non-Iranian women). Therefore, further studies are needed with larger and more representative samples, and with longitudinal and/or experimental designs both inside and outside of Iran.

5. Conclusion

Based on the findings of the present study, fear of hypoglycemia (FoH) appears to be common among diabetic pregnant women living in Iran and is associated with being younger in age, lower education level, type of treatment (being insulin-dependent), having a history of hypoglycemia, and depression. Diabetic pregnant women experience FoH particularly those with a history of hypoglycemia. Therefore, providing education and counseling concerning hypoglycemia, complications, and necessary measures for this group of diabetic pregnant women are needed along with those who are younger, less educated and have comorbid mental health conditions.

Conflict of interest: There is no conflict of interest among the authors of the present study.

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