Received: 4 August 2020 | Revised: 10 December 2020 | Accepted: 29 January 2021

DOI: 10.1002/nop2.800

RESEARCH ARTICLE

NursingOpen Open Access WILEY

The association between diabetes-related distress and fear of hypoglycaemia in patients with type 2 diabetes mellitus: A cross-sectional descriptive study

Shuang Li[1,2] | Li Fang[3] | Amanda Lee[4] | Mark Hayter[4] | Lu Zhang[2] | Yaxin Bi[2] | Xiaxin Wu[2] | Lin Liu[2] | Hong Zhang[1] | Yuan Yuan[2,5] | Weijuan Gong[2,6] | Yu Zhang[2,6]

[1]Department of Nursing, Taicang First People's Hospital, Suzhou, China

[2]School of Nursing, Yangzhou University, Yangzhou, China

[3]Department of Endocrinology, Affiliated Hospital of Yangzhou University, Yangzhou, China

[4]Faculty of Health Sciences, University of Hull, Hull, UK

[5]Department of Nursing, Affiliated Hospital of Yangzhou University, Yangzhou, China

[6]Jiangsu Co-innovation Center for Prevention and Control of Important Animal Infectious Diseases and Zoonoses, Jiangsu Key Laboratory of Zoonosis, Yangzhou University, Yangzhou, China

Correspondence
Yu Zhang, School of Nursing, Yangzhou University, Jiangyang Road 136, Yangzhou, Jiangsu Province, China and Jiangsu Co-innovation Center for Prevention and Control of Important Animal Infectious Diseases and Zoonoses, Jiangsu Key Laboratory of Zoonosis, Yangzhou, Jiangsu Province, China.
Email: yizhangyu@yzu.edu.cn

Funding information
2019 Yangzhou University "Graduate Cultivation Innovation Project" Project (XKYCX19_165).

Abstract

Aim: The study aimed to explore the association between diabetes-related distress as a dependent variable and fear of hypoglycaemia as a independent variable in Chinese individuals with type 2 diabetes, which can provide a basis for the development of effective nursing interventions.

Design: A cross-sectional descriptive study.

Methods: Pre-piloted scales were used to determine whether they experienced fear of hypoglycaemia and whether this impacted upon their management of the disease. From June–October 2019, participants were asked to complete the "hypoglycaemia fear survey" and "diabetes distress scales" to assess levels of fear and distress. Stepwise multivariate regression analysis was applied to reveal relationship between distress as a dependent variable and fear as a independent variable. Covariates included demographic, clinical or lifestyle factors.

Results: A total of 258 participants were recruited for the survey, and they were characterized by little or no distress (39.53%), moderate distress (45.35%) and high distress (15.12%). The prevalence of moderate to severe distress in patients was 60.47%. Increased diabetes-related distress was strongly correlated with increased fear of hypoglycaemia and closely associated with the scores of the worry and behaviour subscales. These results indicated that 62.3% of diabetes-related distress may be explained by fear of hypoglycaemia.

Conclusion: Increased diabetes-related distress is associated with increased fear of hypoglycaemia in individuals with type 2 diabetes.

KEYWORDS

distress, fear of hypoglycaemia, hypoglycaemia, nursing, type 2 diabetes

Li Fang: Co-first author: Contributed equally to this article.

1 | INTRODUCTION

Approximately 50% of patients with type 2 diabetes mellitus (T2DM) using glucose-lowering medications will experience episodes of hypoglycaemia each month, with 9% experiencing severe hypoglycaemia (Khunti et al., 2017). This is significant, because hypoglycaemia is associated with higher readmission rates and patient distress (Lipska et al., 2014). Hypoglycaemia is a major concern with the management of diabetes. It not only hinders the achievement of optimal glycemic control but also leads to various sequelae, such as diabetes-related distress (DD) (Thanakwang et al., 2014) and impaired quality of life of patients (Janice et al., 2014). Furthermore, it can be life threatening (Hsu et al., 2013; Leiter et al., 2014; Orozco-Beltran et al., 2018; Seaquist et al., 2013).

The potential for sudden, unpredictable and uncomfortable symptoms for those patients with type 2 diabetes can lead to "fear of hypoglycaemia" (FOH) in some (Orozco-Beltran et al., 2018). There is a wide range of literature linking increased FOH with poor self-management behaviours in patients with type 2 diabetes, such as excessive diet control and compulsive monitoring of glucose levels, cause negative impact on disease management (Leiter et al., 2014; Orozco-Beltran et al., 2018; Seaquist et al., 2013). The incidence of DD is 18%–45% and is higher in women than in men (Forsander et al., 2017; Hsu et al., 2013). One study (Martyn-Nemeth et al., 2014) indicated that there was a non-linear relationship between DD and FOH in participants with type 1 diabetes mellitus (T1DM). However, little is known about the correlation between these factors in participants with T2DM. This study investigates FOH and DD to review the relationships between DD and FOH in T2DM.

1.1 | Background

Hypoglycaemia refers to the blood sugar level of <4 mmol/L that is prone to sudden onset and unpleasant or uncomfortable physical and psychological reactions, such as dizziness, fatigue, sweating, mental disorder and irritability (Orozco-Beltran et al., 2018). However, not all hypoglycaemic episodes are detected—as they may be asymptomatic until they reach severe status. This unpredictability increases the difficulty of identifying and treating hypoglycaemia (Leiter et al., 2014; Orozco-Beltran et al., 2018; Seaquist et al., 2013). Mild hypoglycaemia is a symptom that patients can deal with on their own, while severe hypoglycaemia requires assistance from healthcare providers (Ng et al., 2019). Severe hypoglycaemia is common in individuals with diabetes receiving insulin, and this regularly causes distress in patients with type 1 diabetes (Inkster et al., 2012).

DD is the recurring experience of negative emotions in patients with diabetes. It causes adverse emotional reactions in patients and affects disease management, emotional burden and treatment (Thanakwang et al., 2014). In China, the prevalence of moderate or severe DD in patients can be as high as 42.15% (Zhou et al., 2017). These results are similar to the multinational "DAWN" trial results, which identified DD in 45% of participants and concluded that diabetes negatively impacted on their general well-being. (Nicolucci et al., 2013). Other factors such as gender, age, marital status, education level, the course of disease and complications in patients are linked with DD (Fisher et al., 2015; Zhou et al., 2017).

DD not only interferes with patient self-management (Aikens, 2012), but it also negatively impacts treatment compliance (Zhang et al., 2013). This has clinical implications as well, because studies link high levels of DD with higher HbA1c measures (Hessler et al., 2014, 2017; Martyn-Nemeth et al., 2014). High levels of emotional burden and regimen-related distress are also associated with higher HbA1c results (Peyrot et al., 2008). Thus, DD and emotional burden can lead to unstable glycemic control and poor disease management. This is cyclical, because lack of glucose level control is one of the main sources of distress (Tanenbaum et al., 2016), which threatens physical and mental health and well-being. Therefore, the early screening of the psychological state of patients with diabetes is very important.

There are very few studies on FOH and DD in populations with T2DM. Most studies are limited to the analysis of the current situation and influencing factors. One of the sources of distress in patients with diabetes is hypoglycaemia (Fisher et al., 2015; Karter et al., 2010), but studies of the relationship between FOH and DD are scarce. There is a gender difference; one study showed FOH and DD levels in women were twice as high as those in men (Forsander et al., 2017); however, the link between FOH and DD was not explored. One study identified a non-linear relationship between diabetes-related interpersonal distress and the FOH behaviours in participants with T1DM (Martyn-Nemeth et al., 2014). However, these factors have not yet been investigated in populations with T2DM. It is important to identify levels of stress in patients, so that healthcare professionals can provide adequate, evidence-based support and treatment to reduce DD and FOH in populations with all types of diabetes. Improving patients' psychological states can optimize disease management and nurses have a significant role in this.

1.2 | Research questions

1. What is the current status of DD in patients with T2DM?
2. Are there any differences in demographic characteristics, clinical characteristics and FOH among patients with different levels of DD?
3. Do correlations exist between DD and FOH in patients with T2DM?

2 | METHODS

2.1 | Aim

To explore the association between DD and FOH in patients with T2DM.

2.2 | Design

A cross-sectional descriptive study of clinical and survey data from patients with type 2 diabetes who attend healthcare centres and hospitals across the Jiangsu Province of China. The study was conducted using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline for cross-sectional studies (von Elm et al., 2008) (Appendix S1).

2.3 | Study participants

Participants were invited to take the survey and drawn from endocrinology departments across 3 tertiary general hospitals in Yangzhou and Suzhou. The inclusion criteria were as follows: participants with confirmed T2DM (WHO, 2006); participants with a duration of T2DM of at least 1 year who experienced hypoglycaemia in the past half-year; and participants aged 18 years or older. The exclusion criteria included the following: patients diagnosed with T1DM, pregnancy, psychosis or other serious disease (i.e. cancer); serious complications such as myocardial infarction; patients with communication barriers; and patients who were unwilling to participate in this study. All participants agreed to complete our questionnaire, with clinical and demographic data linked through hospital electronic records.

2.4 | Sampling

Cluster random sampling was conducted from June–October in 2019. All participants were invited from three endocrinology departments across three tertiary general hospitals in Yangzhou and Suzhou, Jiangsu Province, China. Sample size was determined by 18% proportion of DD in T2DM (Association Diabetes Association, 2014), with a 95% confidence level and 5% margin of error. We used the formula - $N = Z^2 \times (P \times (1 - P))/E^2$ to calculate it. By adding 10% nonresponse rate, the total sample size was 250. Our sample size had met the requirements (258 > 250).

2.5 | Data collection

After obtaining permission from the relevant departments of the hospital, four researchers conducted investigations in the endocrinology department. The researchers explained the purpose of the study to the inpatients and invited them to complete a survey of general and clinical characteristics, FOH and DD on site after obtaining informed consent and signing. Participants were asked to complete surveys in the clinical institution while in the waiting area. All responses were anonymous and completed surveys kept in individual, sealed envelopes with no identifying features. For illiterates who agreed to participate in the study, they were asked to press their fingerprints at the signature of the informed consent form. The researchers read all the questions to them and recorded the answers. General and clinical characteristics of participants such as age, gender, body mass index (BMI), smoking, alcohol use and HbA1c were obtained from electronic medical records. Diet, exercise and frequency of hypoglycaemia were determined by self-reporting. All participants completed the questionnaires independently under the guidance of the researchers.

2.6 | Ethical considerations

The study was approved by the Ethics Committee of the university and the affiliated hospital (2019-YKL05-30), and informed consent was obtained from all participants.

2.7 | Validity and reliability

2.7.1 | Fear of hypoglycaemia

The Chinese version of the Hypoglycemia Fear Survey II (HFS-II) was developed by Cox (Cox et al., 1987), and the updated version was published in 2011 (Gonder-Frederick et al., 2011). It was translated into Chinese by Mu (Mu, 2015). It is a 5-point Likert scale consisting of an 18-item Chinese version of the Hypoglycemia Fear Survey II-worry scale (CHFSII-WS) and a 15-item behaviour scale (CHFSII-BS). The worry scale reflects fears or worries about hypoglycaemia of patients, and the behaviour subscale contains behaviours that people use to avoid hypoglycaemia. The scores of the HFS-II, CHFSII-WS and CHFSII-BS ranged from 0–132, 0–72 and 0–60, respectively. High scores indicate a high level of fear. Cronbach's alpha values of the HFS-II, CHFSII-WS and CHFSII-BS are 0.94, 0.90 and 0.88, respectively, for Chinese participants.

2.7.2 | Diabetes-related distress

The Chinese version of the Diabetes Distress Scale (DDS) measures emotional burden, physician-related distress, regimen-related distress and diabetes-related interpersonal distress, and it was developed by Polonsky (Polonsky et al., 2005) and translated into Chinese by Yang (Yang & Liu, 2010). It is a 6-point Likert scale with 17 items; Cronbach's alpha value is 0.95 for Chinese participants. The higher the total score, the greater the distress is. According to Fisher's suggestion (Fisher et al., 2012), we divided the DDS into three levels based on the average score (little or no distress, <2.0; moderate distress, 2.0–2.9; high level of distress, ≥3.0). DD was considered clinically significant if the average score was ≥2.0.

2.8 | Data analysis

Data were collated and analysed using SPSS 21.0 (SPSS Inc., Chicago, IL, USA). Categorical variables were summarized using

frequency distributions. Categorical variables between group differences were evaluated by a chi-square test to reveal any associations with levels of DD. The mean and standard deviation (*SD*) were used to describe the continuous variables. Continuous variables that were normally and non-normally distributed were assessed by ANOVA and the Kruskal–Wallis test, respectively. The correlations between the FOH and DD scores were examined using Spearman's correlation coefficients. Stepwise multivariate regression analysis was used to determine correlations between behavioural scores using FOH and DD scales. A statistically significant difference was indicated by $p < .05$.

3 | RESULTS

3.1 | General and clinical characteristics of participants (*N* = 258)

A total of 286 questionnaires were sent out, 258 of which were valid, offering a response rate of 90%. Participants were grouped into (Fisher et al., 2012) levels consisting of "little or no distress" (*N* = 102), "moderate distress" (*N* = 117) and "high level of distress" (*N* = 39). The prevalence of moderate to severe DD in patients was 60.47%. Demographic results are presented across these three groups.

A chi-square test for independence with the Yates continuity correction indicated no significant differences for gender, lifestyle and education levels—Table 1 shows spread in age, gender, BMI and lifestyle between groups was equally dispersed. ANOVA test between groups analysis of variance illustrated no statistically significant differences in mean scores between mean scores for age and BMI across groups. The mean age and BMI for the full group was 61.98 years (*SD* 12.69) and 23.78 kg/m^2 (*SD* 3.39). Less than 15% participants were identified as illiterate. Most participants had completed basic education and very few lived alone.

Table 2 shows clinical characteristics, again, across the three DD groups. More than half the total participants had been diagnosed for over 10 years. Those in moderate or higher levels of distress groups reported insulin use as adjunct to treatment. Most participants had little or no family history of diabetes (*N* = 199/258). In all groups, most had reported complications of their diabetes status (*N* = 163/258). Many participants reported regularly exercising (*N* = 174/258). Only 30% reported smoking and under 30% reported ingesting alcohol on a regular basis. Most participants performed regular blood glucose monitoring (*N* = 237/258).

Participants who had experienced hypoglycaemia episodes more than three times in the past 6 months, and those experiencing hypoglycaemia overnight, were more likely to report higher levels of DD and fall within the "moderate to high distress groups" ($p < .001$). Those who had experience of severe hypoglycaemia also reported higher levels of DD ($p = .001$). In all groups, although the majority of patients with HbA1c more than 7%, there was no statistically significant difference ($p = .495$).

3.2 | Survey and scale characteristics of participants (*N* = 258)

We performed ANOVA and the Kruskal–Wallis test to test for differences among the three groups according to their levels of distress in the HFS-II score. Table 3 presents mean scores from the hypoglycaemia fear, behaviour and worry scales. The S-N-K method was performed following the ANOVA test, and a statistical difference was noted between groups and mean scores suggest those in the

TABLE 1 Demographic characteristics

Demographic characteristics		Diabetes distress group			
Total *N* = 258		Little or no distress (*N* = 102)	Moderate distress (*N* = 117)	High distress (*N* = 39)	*p*
Age (years)	Mean age (61.98 *SD* 12.69)	62.59 (*SD* 10.74)	62.56 (*SD* 13.17)	58.64 (*SD* 15.48)	.205
Gender	Male (*N* = 126)	51 (50.0%)	55 (47.0%)	20 (51.3%)	.859
	Female (*N* = 132)	51 (50.0%)	62 (53.0%)	19 (48.7%)	
BMI (kg/m^2)	Mean BMI (23.78 *SD* 3.39)	23.96 (*SD* 2.81)	23.20 (*SD* 2.70)	23.06 (*SD* 4.15)	.351
Lifestyle and education	Living alone (*N* = 28)	14 (13.7%)	11 (9.4%)	3 (7.7%)	.544
	Illiteracy (*N* = 37)	15 (14.7%)	18 (15.4%)	4 (10.3%)	.621
	Basic education ≤ high school (*N* = 183)	74 (72.6%)	79 (67.5%)	30 (76.9%)	
	Tertiary education > high school (*N* = 38)	13 (12.7%)	20 (17.1%)	5 (12.8%)	

Note: ANOVA and the chi-square test were used to test for differences in the age, BMI, gender, lifestyle and education among the three groups according to their levels of distress.

Abbreviations: BMI, body mass index; *SD*, standard deviation.

moderate and higher distress groups experienced higher levels of DD ($p < .001$)—depicted through behaviour, fear and worry about their diabetes management.

3.3 | Correlation between DD and FOH

To determine the strength and linear relationship between DD and FOH, Spearman's product–moment correlation coefficient was applied (the data of DDS were non-normal.). Table 4 shows a strong, positive correlation between the scores of DDS and HFS-II ($r = .749$, $p < .001$). The CHFSII-BS score also revealed a positive relationship between behaviours and DD ($r = .597$, $p < .001$). Equally, the CHFSII-WS score revealed strong and positive relationship between worry and DD ($r = .750$, $p < .001$). These results indicated that DD is strongly associated with fear, worry and behaviours in T2DM.

3.4 | Association between DD and FOH

Table 5 shows that stepwise multivariate regression analysis was applied to assess correlations between DD as a dependent variable and FOH as a independent variable. Covariates included demographic, clinical or lifestyle factors. The square root of the DDS score was normal, although the initial data were not normally distributed. The HFS-II, CHFSII-WS and CHFSII-BS scores

TABLE 2 Clinical characteristics

Clinical characteristics Total $N = 258$		Diabetes distress group			
		Little or no distress ($N = 102$)	Moderate distress ($N = 117$)	High distress ($N = 39$)	p
Duration type 2 Diabetes diagnosis	<10 years ($N = 111$)	41 (40.2%)	55 (47.0%)	15 (38.5%)	.491
	>10 years ($N = 147$)	61 (59.8%)	62 (53.0%)	24 (61.5%)	
Insulin use	Y ($N = 148$)	49 (48.5%)	70 (59.8%)	29 (74.4%)	.017
	N ($N = 110$)	53 (51.5%)	47 (40.2%)	10 (25.6%)	
Family history (diabetes mellitus)	Y ($N = 59$)	23 (22.5%)	27 (23.1%)	9 (23.1%)	.995
	N ($N = 199$)	79 (77.5%)	90 (84.1%)	30 (76.9%)	
Past history	Y ($N = 179$)	79 (77.5%)	75 (64.1%)	25 (64.1%)	.075
	N ($N = 79$)	23 (22.5%)	42 (35.9%)	14 (35.9%)	
Complications associated with diabetes	Y ($N = 163$)	68 (66.7%)	64 (54.7%)	31 (79.5%)	.014
	N ($N = 95$)	34 (33.3%)	53 (45.3%)	8 (20.5%)	
Lifestyle Diet control	Y ($N = 215$)	94 (92.2%)	85 (72.6%)	36 (92.3%)	<.001
	N ($N = 43$)	8 (7.8%)	32 (27.4%)	3 (7.7%)	
Lifestyle Exercise	Y ($N = 174$)	75 (73.5%)	72 (61.5%)	27 (69.2%)	.162
	N ($N = 84$)	27 (26.5%)	45 (38.5%)	12 (30.8%)	
Lifestyle Smoking	Y ($N = 76$)	32 (31.4%)	30 (25.6%)	14 (35.9%)	.411
	N ($N = 182$)	70 (68.6%)	87 (74.4%)	25 (64.1%)	
Lifestyle Alcohol use	Y ($N = 69$)	28(27.5%)	30 (25.6%)	11 (28.2%)	.932
	N ($N = 263$)	74 (72.5%)	87 (74.4%)	28 (71.8%)	
Self-monitoring of blood glucose	Y ($N = 237$)	96 (94.1%)	103 (88.0%)	38 (97.4%)	.137
	N ($N = 21$)	6 (5.9%)	14 (12.0%)	1 (2.6%)	
Frequency of hypoglycaemia in the past half-year (≥3 times)	Y ($N = 111$)	20 (19.6%)	59 (50.4%)	32 (82.1%)	<.001
	N ($N = 147$)	82 (80.4%)	58 (49.6%)	7 (17.9%)	
Experience of hypoglycaemia at night	Y ($N = 76$)	20 (19.6%)	30 (25.6%)	26 (66.7%)	<.001
	N ($N = 182$)	82 (80.4%)	87 (74.4%)	13 (33.3%)	
Experience of severe hypoglycaemia	Y ($N = 32$)	5 (4.9%)	16 (13.7%)	11 (28.2%)	.001
	N ($N = 226$)	97 (95.1%)	101 (86.3%)	28 (71.8%)	
HbA1c (≥7.0%)	Y ($N = 206$)	78 (76.5%)	95 (81.2%)	33 (84.6%)	.495
	N ($N = 52$)	24 (23.5%)	22 (18.8%)	6 (15.4%)	

Note: The chi-square test was used to test for differences in the variables listed above among the three groups according to their levels of distress.
Abbreviations: N, No; Y, Yes.

TABLE 3 Survey and scale characteristics

	Diabetes distress group			
	Little or no distress (*N* = 102)	Moderate distress (*N* = 117)	High distress (*N* = 39)	*p*
HFS-II (mean [*SD*])	26.67 (6.44)	40.30 (10.76)	57.59 (11.96)	<.001
CHFSII-BS (mean [*SD*])	16.91 (5.85)	23.09 (7.68)	30.21 (6.14)	<.001
CHFSII-WS (mean [*SD*])	10.75 (2.96)	17.33 (5.59)	27.38 (9.14)	<.001

Note: ANOVA and the Kruskal–Wallis test were used to test for differences in the HFS-II, CHFSII-BS and CHFSII-WS scores among the three groups according to their levels of distress.

Abbreviations: CHFSII-BS, behaviour scale; CHFSII-WS, worry scale; HFS-II, Hypoglycaemia Fear Survey II; *SD*, standard deviation.

TABLE 4 The correlation between FOH and DD

	HFS-II		CHFSII-BS		CHFSII-WS	
DDS	*r*	*p*	*r*	*p*	*r*	*p*
Total score	.749	<.001	.597	<.001	.750	<.001
Emotional burden	.743	<.001	.614	<.001	.712	<.001
Physician-related distress	.507	<.001	.404	<.001	.508	<.001
Regimen-related distress	.533	<.001	.395	<.001	.572	<.001
Diabetes-related interpersonal distress	.608	<.001	.508	<.001	.585	<.001

Note: Spearman's correlation coefficients were used to examine the correlations between FOH and DD.

Abbreviations: CHFSII-BS, behaviour scale; CHFSII-WS, worry scale; DD, diabetes-related distress; DDS, the Diabetes Distress Scale; FOH, fear of hypoglycaemia; HFS-II, Hypoglycaemia Fear Survey II.

were analysed in quartiles during the linear regression analyses. Preliminary analyses were undertaken to ensure there were no violations of the assumptions of homoscedasticity, multicollinearity, normality and linearity.

The levels for the HFS-II score were as follows: 1st quartile (≤27), 2nd quartile (28–35), 3rd quartile (36–47) and 4th quartile (≥48). The levels of the CHFSII-WS score were as follows: 1st quartile (≤11), 2nd quartile (12–14), 3rd quartile (15–20) and 4th quartile (≥21). The levels of the CHFSII-BS score were as follows: 1st quartile (≤15), 2nd quartile (16–21), 3rd quartile (22–27) and 4th quartile (≥28). Model 1 showed that the DDS score was associated with the scores of HFS-II ($\beta = 0.825$, $p < .001$), CHFSII-WS ($\beta = 0.794$, $p < .001$) and CHFSII-BS ($\beta = 0.678$, $p < .001$). After adjusting for age, gender, BMI, lifestyle and education, duration, family history, past history, exercise, smoking, alcohol use, self-monitoring of glucose and HbA1c, Model 2 showed that the DDS score was associated with the scores of HFS-II ($\beta = 0.879$, $p < .001$), CHFSII-WS ($\beta = 0.802$, $p < .001$) and CHFSII-BS ($\beta = 0.723$, $p < .001$). Model 3, after adjusting for the 13 independent variables included in Model 2 and the 9 statistically significant independent variables listed in Tables 1-3, showed that patients in the 4th quartile of the scores of HFS-II, CHFSII-WS and CHFSII-BS were more likely to have a higher DDS score (HFS-II: $\beta = 0.753$, $p < .001$; CHFSII-WS: $\beta = 0.675$, $p < .001$; and CHFSII-BS: $\beta = 0.534$, $p < .001$). The adjusted R^2 of three models were 62.3% (HFS-II), 57.2% (CHFSII-WS) and 46.4% (CHFSII-BS), respectively. These results indicated almost that over 50% of DD may be explained by FOH ($p < .01$) and a higher DD score may be associated with higher FOH scores.

4 | DISCUSSION

We explored the relationship between DD and FOH in patients with T2DM. The results indicate that after adjusting for confounding factors, DD expresses a significant association with FOH and the higher the FOH score, the greater the DD score was. Given the few studies on the relationship between FOH and DD, our results may not be representative of the whole world. However, the presence of FOH and DD in patients with T2DM is common in other regions. Therefore, our results have some reference values.

This matters to multidisciplinary care and support networks offered to patients with T2DM. By understanding how and why patients may feel ill at ease, and offering appropriate dietary and lifestyle advice, patients can understand and navigate their own health journeys with diabetes. Our findings offer an intelligence and evidence base for patient support and guidance which focuses on

TABLE 5 Multiple regression analyses of the correlation between FOH and DD

	Model 1			Model 2			Model 3		
	β	95% CI	*p*	*β*	95% CI	*p*	*β*	95% CI	*p*
HFS-II									
1st	1			1			1		
2nd	0.096	−0.009 to 0.407	.061	0.100	0.000–0.413	.050	0.063	−0.072 to 0.334	.205
3rd	0.435	0.696–1.114	<.001	0.469	0.767–1.185	<.001	0.364	0.538–0.975	<.001
4th	0.825	1.525–1.947	<.001	0.879	1.636–2.063	<.001	0.753	1.346–1.818	<.001
$^{Adj}R^2$		0.556			0.588			0.623	
F		108.42	<.001		22.586	<.001		19.378	<.01
WS									
1st	1			1			1		
2nd	0.140	0.093–0.528	.005	0.149	0.108–0.552	.004	0.118	0.047–0.482	.018
3rd	0.519	0.853–1.258	<.001	0.546	0.900–1.319	<.001	0.462	0.715–1.160	<.001
4th	0.794	1.496–1.921	<.001	0.802	1.508–1.943	<.001	0.675	1.208–1.696	<.001
$^{Adj}R^2$		0.532			0.537			0.572	
F		98.568	<.001		18.558	<.001		15.899	<.01
BS									
1st	1			1			1		
2nd	0.117	−0.01 to 0.488	.061	0.112	−0.025 to 0.483	.077	0.037	−0.166 to 0.318	.535
3rd	0.337	0.454–0.964	<.001	0.402	0.579–1.110	<.001	0.265	0.296–0.817	<.001
4th	0.678	1.177–1.689	<.001	0.723	1.261–1.796	<.001	0.534	0.852–1.405	<.001
$^{Adj}R^2$		0.352			0.372			0.464	
F		47.522	<.001		9.945	<.001		10.652	<.01

Note: 1st, 2nd, 3rd and 4th are the quartile scores of the questionnaires. The levels for the HFS-II score were as follows: 1st quartile (≤27), 2nd quartile (28–35), 3rd quartile (36–47) and 4th quartile (≥48). The levels of the WS score were as follows: 1st quartile (≤11), 2nd quartile (12–14), 3rd quartile (15–20) and 4th quartile (≥21). The levels of the BS score were as follows: 1st quartile (≤15), 2nd quartile (16–21), 3rd quartile (22–27) and 4th quartile (≥28). $^{Adj}R^2$ = adjusted R^2. Model 1, unadjusted; Model 2, adjusted for age, gender, BMI, lifestyle and education, duration, family history, past history, exercise, smoking, alcohol use, self-monitoring of glucose levels and HbA1c; Model 3, adjusted for the 13 independent variables included in Model 2 and the 9 statistically significant independent variables listed in Tables 1-3.

Abbreviations: BS, behaviour scale; DD, diabetes-related distress; FOH, fear of hypoglycaemia; HFS-II, Hypoglycaemia Fear Survey II; WS, worry scale.

FOH. To help patients manage their disease, the multidisciplinary team need to identify factors associated with distress and fear in their patients.

DD is not only common in T1DM patients (Hagger et al., 2016) but also common in T2DM patients (Owens-Gary et al., 2019; Snoek et al., 2015). If we consider T1DM, there may be other confounding variables to be considered. For example, some studies have linked female gender, lack of home support, increasingly complex treatment regimes, complications of diabetes and lack of activity as confounding factors in DD (Fonda et al., 2009; Forsander et al., 2017; Ting et al., 2011).

Our findings indicated that nearly 60.47% of participants self-reported moderate to severe distress—a rate far higher than that observed by Zhou et al., (2017). This may be because our study also included data on T2DM who had used insulin or had experienced hypoglycaemia within 6 months of investigation. This is important to note, because fear of hypoglycaemia can lead to DD in patients (Fisher et al., 2015; Karter et al., 2010).

Evidence suggests that patients with a high degree of DD have poor self-management, such as an irregular dietary pattern and monitoring of glucose levels, which leads to more frequent hypoglycaemia (Al Sayah et al., 2019; Kostev et al., 2014). Our study found that patients with hypoglycaemia are more prone to FOH. The higher the FOH score, the greater the DD score. Thus, a vicious circle of fear–worry and exacerbation can seriously damage the physical and mental health status of patients, hindering disease management. This is why the full multidisciplinary team should be included in management strategies.

Patients with frequent hypoglycaemia tend to have FOH, which is not conducive to psychological well-being and stable glycemic control. Poor disease management will also increase the psychological burden of patients. Thus, it is very important to take psychological screening and health education seriously in the early stage of hypoglycaemia. Healthcare providers should encourage patients to express their inner thoughts and assist patients in solving problems related to disease, standardizing their self-care behaviours, and reducing FOH, thus alleviating DD.

A previous study (Martyn-Nemeth et al., 2014) indicated that there was a non-linear relationship between the scores of diabetes-related interpersonal distress and the behaviour subscale for patients with T1DM. However, our study correlated DDS scores with the HFS-II score ($r = .749$, $p < .001$), and the score of diabetes-related interpersonal distress explained over 50% of behaviour and worry in DD ($r = .508$, $p < .001$) ($r = .585$, $p < .001$) Emotional burden also highly correlated with the total FOH score ($r = .743$, $p < .001$), especially with the worry subscale score ($r = .712$, $p < .001$). Emotional burden can limit the self-care behaviours and self-management of patients, which is not conducive to effective disease management (Aikens, 2012). Individuals with diabetes believe that knowledge and support from healthcare providers are important for their self-management and physical and mental health (Balfe et al., 2013). During the investigation, we found that the distress of patients who experienced hypoglycaemia partly came from a misunderstanding of the disease and the heavy burden of treatment regimens. Complex treatment regimens have strict standards for self-management behaviour, which easily leads to patient uncertainty (Gonzalez et al., 2015). Patients often do not understand why patients with diabetes suffer from hypoglycaemia, which easily results in FOH and poor glycemic control. This helps to explain the results of this study, which showed that both the physician-related distress and regimen-related distress scores were moderately correlated with the HFS-II score ($r = .507$, $p < .001$; $r = .533$, $p < .001$). Misunderstanding or uncertainty about the disease, including treatment adherence, and a high FOH score may cause an increased burden in terms of emotion related to both the physician and the regimen. It is clear that increased DD is associated with increased FOH. Clinicians should pay greater attention to early psychological screening and health education, explain the process of treatment to patients and objectively assess whether patients understand the relevant knowledge to ensure that they can prevent, treat and manage their disease correctly to reduce FOH, thus alleviating DD and improving the quality of life in patients.

In summary, we suspected that the most fundamental cause of patient DD may be the misperception of disease-related knowledge among patients we surveyed and we will further confirm it in future research. The lack of knowledge causes self-management and self-care behaviours to become unreasonable, which leads to poor glycemic control and frequent hypoglycaemia. It is easy to cause FOH, which aggravates DD. DD negatively affects physical and mental health, leading to an increased risk of hypoglycaemia (Al Sayah et al., 2019), and this eventually leads to a vicious circle. Therefore, correcting the patient's misperception of the disease is one of the important prerequisites to alleviate FOH and ultimately reduce DD.

The study showed that DD is positively correlated with FOH in T2DM patients and reveals "FOH" as a factor in DD. This result is rarely reported in previous studies. It also highlights the need for nurses to improve education for patients so that they can manage "hypoglycaemia" effectively. Firstly, practitioners need to assess their patients to assess for the presence of FOH and—if present—how debilitating it is for them. If this is a problem, then strategies to address it should be explored—these may simply involve reassurance or moderation of self-management practices—but in severe cases psychological intervention may be required. Close team working with clinical psychology members of the multi-disciplinary team is helpful in this scenario of diabetes care. Strong professional collaboration is one of the foundations for providing good nursing care. Healthcare providers should make serious effort to educate patients about hypoglycaemia and to conduct psychological screening of patients to develop effective nursing interventions to alleviate FOH and DD in individuals with T2DM, which can improve their quality of life.

4.1 | Limitations

The study does have limitations, in that it presents data from just one province of China which has a population of 80 million. Although population levels are high, there may be a cultural element to experiences in diabetes management and self-care. Further studies are therefore recommended to identify any confounding variables which may impact populations in other countries and healthcare systems. In addition, incidents of hypoglycaemia were assessed according to the patient's recollection, which inevitably might lead to recall errors. Therefore, it is necessary to expand the sample size and further explore the mechanism of the interaction between FOH and DD to provide a basis for developing a reasonable intervention strategy in the future.

5 | CONCLUSION

Increased DD is related to increased FOH in Chinese participants with T2DM. Healthcare providers should make serious effort to educate patients about hypoglycaemia and to conduct psychological screening of patients to develop effective intervention measures to alleviate FOH and ultimately reduce DD in patients, which can improve their quality of life.

ACKNOWLEDGEMENTS

The authors sincerely thank Roger Watson, who is from Faculty of Health Sciences, University of Hull, UK, for his suggestions on editing and submitting the manuscript.

CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

AUTHOR CONTRIBUTIONS

Shuang Li, Li Fang, Yu Zhang: Conception and design, analysis and interpretation of data and paper writing. Lu Zhang, Yaxin Bi, Xiaxin Wu, Lin Liu, Hong Zhang: Acquisition of questionnaires. Yuan Yuan, Li Fang: Personnel recruiting. DR Amanda Lee, Professor Mark Hayter, Weijuan Gong, Yu Zhang: Revision of manuscript critically for important intellectual contents.

DATA AVAILABILITY STATEMENT

The data used to support the findings of this study are available from the corresponding author on reasonable request.

ORCID

Amanda Lee https://orcid.org/0000-0003-1378-3123
Mark Hayter https://orcid.org/0000-0002-2537-8355
Yu Zhang https://orcid.org/0000-0002-4976-9158

REFERENCES

Aikens, J. E. (2012). Prospective associations between emotional distress and poor outcomes in type 2 diabetes. *Diabetes Care*, *35*, 2472. https://doi.org/10.2337/dc12-0181

Al Sayah, F., Yeung, R. O., & Johnson, J. A. (2019). Association of depressive symptoms and diabetes distress with severe hypoglycemia in adults with type 2 diabetes. *Canadian Journal of Diabetes*, *43*, 316–321. https://doi.org/10.1016/j.jcjd.2018.11.002

Association Diabetes Association (2014). Standards of medical care in diabetes-2014. *Diabetes Care*, *37*(Suppl1), 14–80.

Balfe, M., Doyle, F., Smith, D., Sreenan, S., Brugha, R., Hevey, D., & Conroy, R. (2013). What's distressing about having type 1 diabetes? A qualitative study of young adults' perspectives. *BMC Endocrine Disorders*, *13*, 25. https://doi.org/10.1186/1472-6823-13-25

Cox, D. J., Irvine, A., Gonder-Frederick, L., Nowacek, G., & Butterfield, J. (1987). Fear of hypoglycemia: Quantification, validation, and utilization. *Diabetes Care*, *10*, 617–621. https://doi.org/10.2337/diacare.10.5.617

Fisher, L., Hessler, D. M., Polonsky, W. H., & Mullan, J. (2012). When is diabetes distress clinically meaningful?: Establishing cut points for the Diabetes Distress Scale. *Diabetes Care*, *35*, 259–264. https://doi.org/10.2337/dc11-1572

Fisher, L., Polonsky, W. H., Hessler, D. M., Masharani, U., Blumer, I., Peters, A. L., Strycker, L. A., & Bowyer, V. (2015). Understanding the sources of diabetes distress in adults with type 1 diabetes. *Journal of Diabetes and Its Complications*, *29*, 572–577. https://doi.org/10.1016/j.jdiacomp.2015.01.012

Fonda, S. J., McMahon, G. T., Gomes, H. E., Hickson, S., & Conlin, P. R. (2009). Changes in diabetes distress related to participation in an internet-based diabetes care management program and glycemic control. *Journal of Diabetes Science and Technology*, *3*, 117–124. https://doi.org/10.1177/193229680900300113

Forsander, G., Bogelund, M., Haas, J., & Samuelsson, U. (2017). Adolescent life with diabetes-Gender matters for level of distress. Experiences from the national TODS study. *Pediatric Diabetes*, *18*, 651–659. https://doi.org/10.1111/pedi.12478

Gonder-Frederick, L. A., Schmidt, K. M., Vajda, K. A., Greear, M. L., Singh, H., Shepard, J. A., & Cox, D. J. (2011). Psychometric properties of the hypoglycemia fear survey-ii for adults with type 1 diabetes. *Diabetes Care*, *34*, 801–806. https://doi.org/10.2337/dc10-1343

Gonzalez, J. S., Shreck, E., Psaros, C., & Safren, S. A. (2015). Distress and type 2 diabetes-treatment adherence: A mediating role for perceived control. *Health Psychology Official Journal of the Division of Health Psychology American Psychological Association*, *34*, 505–513. https://doi.org/10.1037/hea0000131

Hagger, V., Hendrieckx, C., Sturt, J., Skinner, T. C., & Speight, J. (2016). Diabetes distress among adolescents with type 1 diabetes: A systematic review. *Current Diabetes Reports*, *16*, 9. https://doi.org/10.1007/s11892-015-0694-2

Hessler, D., Fisher, L., Glasgow, R. E., Strycker, L. A., Dickinson, L. M., Arean, P. A., & Masharani, U. (2014). Reductions in regimen distress are associated with improved management and glycemic control over time. *Diabetes Care*, *37*, 617–624. https://doi.org/10.2337/dc13-0762

Hessler, D. M., Fisher, L., Polonsky, W. H., Masharani, U., Strycker, L. A., Peters, A. L., Blumer, I., & Bowyer, V. (2017). Diabetes distress is linked with worsening diabetes management over time in adults with Type 1 diabetes. *Diabetic Medicine*, *34*, 1228–1234. https://doi.org/10.1111/dme.13381

Hsu, P.-F., Sung, S.-H., Cheng, H.-M., Yeh, J.-S., Liu, W.-L., Chan, W.-L., Chen, C.-H., Chou, P., & Chuang, S.-Y. (2013). Association of clinical symptomatic hypoglycemia with cardiovascular events and total mortality in type 2 diabetes: A nationwide population-based study. *Diabetes Care*, *36*, 894–900. https://doi.org/10.2337/dc12-0916

Inkster, B., Zammitt, N. N., & Frier, B. M. (2012). Drug-induced hypoglycaemia in type 2 diabetes. *Expert Opinion on Drug Safety*, *11*, 597–614. https://doi.org/10.1517/14740338.2012.694424

Janice, L., Kathy, A., Robert, B., Morisky, D. E., & Marcia, R. (2014). Impact of hypoglycemia on patients with type 2 diabetes mellitus and their quality of life, work productivity, and medication adherence. *Patient Preference & Adherence*, *8*, 683–692.

Karter, A. J., Subramanian, U., Saha, C., Crosson, J. C., Parker, M. M., Swain, B. E., Moffet, H. H., & Marrero, D. G. (2010). Barriers to insulin initiation: The translating research into action for diabetes insulin starts project. *Diabetes Care*, *33*, 733–735. https://doi.org/10.2337/dc09-1184

Khunti, K., Alsifri, S., Aronson, R., Berkovic, M. C., Enters-Weijnen, C., Forsen, T., Galstyan, G., Geelhoed-Duijvestijn, P., Goldfracht, M., Gydesen, H., Kapur, R., Lalic, N., Ludvik, B., Moberg, E., Pedersen-Bjergaard, U., & Ramachandran, A. (2017). Impact of hypoglycaemia on patient-reported outcomes from a global, 24-country study of 27,585 people with type 1 and insulin-treated type 2 diabetes. *Diabetes Research and Clinical Practice*, *130*, 121–129. https://doi.org/10.1016/j.diabres.2017.05.004

Kostev, K., Dippel, F. W., & Rathmann, W. (2014). Predictors of hypoglycaemia in insulin-treated type 2 diabetes patients in primary care: A retrospective database analysis. *Primary Care Diabetes*, *8*, 127–131. https://doi.org/10.1016/j.pcd.2013.10.001

Leiter, L. A., Boras, D., & Woo, V. C. (2014). Dosing irregularities and self-treated hypoglycemia in type 2 diabetes: Results from the Canadian cohort of an international survey of patients and healthcare professionals. *Canadian Journal of Diabetes*, *38*, 38–44. https://doi.org/10.1016/j.jcjd.2013.08.270

Lipska, K. J., Ross, J. S., Wang, Y., Inzucchi, S. E., Minges, K., Karter, A. J., Huang, E. S., Desai, M. M., Gill, T. M., & Krumholz, H. M. (2014). National trends in US hospital admissions for hyperglycemia and hypoglycemia among Medicare beneficiaries, 1999 to 2011. *JAMA Internal Medicine*, *174*, 1116–1124. https://doi.org/10.1001/jamainternmed.2014.1824

Martyn-Nemeth, P., Quinn, L., Hacker, E., Park, H., & Kujath, A. S. (2014). Diabetes distress may adversely affect the eating styles of women with type 1 diabetes. *Acta Diabetologica*, *51*, 683–686. https://doi.org/10.1007/s00592-014-0575-1

Mu, C. (2015). *Revision of Chinese Hypoglycemia Fear Questionnaire and its application in patients with type 2 diabetes mellitus*. Tianjin Medical University.

Ng, S. M., Moore, H. S., Clemente, M. F., Pintus, D., & Soni, A. (2019). Continuous glucose monitoring in children with type 1 diabetes improves well-being, alleviates worry and fear of hypoglycemia. *Diabetes Technology & Therapeutics*, *21*, 133–137. https://doi.org/10.1089/dia.2018.0347

Nicolucci, A., Kovacs Burns, K., Holt, R. I., Comaschi, M., Hermanns, N., Ishii, H., Kokoszka, A., Pouwer, F., Skovlund, S. E., Stuckey, H., Tarkun, I., Vallis, M., Wens, J., & Peyrot, M. (2013). Diabetes Attitudes, Wishes and Needs second study (DAWN2): Cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. *Diabetic Medicine*, *30*, 767–777. https://doi.org/10.1111/dme.12245

Orozco-Beltran, D., Artola, S., Jansa, M., Lopez de la Torre-Casares, M., & Fuster, E. (2018). Impact of hypoglycemic episodes on health-related quality of life of type-2 diabetes mellitus patients: Development and validation of a specific QoLHYPO((c)) questionnaire. *Health and Quality of Life Outcomes*, *16*, 52.

Owens-Gary, M. D., Zhang, X., Jawanda, S., Bullard, K. M., Allweiss, P., & Smith, B. D. (2019). The importance of addressing depression and diabetes distress in adults with type 2 diabetes. *Journal of General Internal Medicine*, *34*, 320–324. https://doi.org/10.1007/s11606-018-4705-2

Peyrot, M., Rubin, R. R., & Polonsky, W. H. (2008). Diabetes distress and its association with clinical outcomes in patients with type 2 diabetes treated with pramlintide as an adjunct to insulin therapy. *Diabetes Technology & Therapeutics*, *10*, 461–466. https://doi.org/10.1089/dia.2008.0031

Polonsky, W. H., Fisher, L., Earles, J., Dudl, R. J., Lees, J., Mullan, J., & Jackson, R. A. (2005). Assessing psychosocial distress in diabetes: Development of the diabetes distress scale. *Diabetes Care*, *28*, 626–631. https://doi.org/10.2337/diacare.28.3.626

Seaquist, E. R., Anderson, J., Childs, B., Cryer, P., Dagogo-Jack, S., Fish, L., Heller, S. R., Rodriguez, H., Rosenzweig, J., & Vigersky, R. (2013). Hypoglycemia and diabetes: A report of a workgroup of the American Diabetes Association and the Endocrine Society. *Diabetes Care*, *36*, 1384–1395. https://doi.org/10.2337/dc12-2480

Snoek, F. J., Bremmer, M. A., & Hermanns, N. (2015). Constructs of depression and distress in diabetes: Time for an appraisal. *The Lancet Diabetes & Endocrinology*, *3*, 450–460. https://doi.org/10.1016/S2213-8587(15)00135-7

Tanenbaum, M. L., Kane, N. S., Kenowitz, J., & Gonzalez, J. S. (2016). Diabetes distress from the patient's perspective: Qualitative themes and treatment regimen differences among adults with type 2 diabetes. *Journal of Diabetes and Its Complications*, *30*, 1060–1068. https://doi.org/10.1016/j.jdiacomp.2016.04.023

Thanakwang, K., Thinganjana, W., & Konggumnerd, R. (2014). Psychometric properties of the Thai version of the Diabetes Distress Scale in diabetic seniors. *Clinical Interventions in Aging*, *9*, 1353–1361. https://doi.org/10.2147/CIA.S67200

Ting, R. Z., Nan, H., Yu, M. W., Kong, A. P., Ma, R. C., Wong, R. Y., Loo, K., So, W. Y., Chow, C. C., Ko, G. T., Wing, Y. K., & Chan, J. C. (2011). Diabetes-related distress and physical and psychological health in Chinese type 2 diabetic patients. *Diabetes Care*, *34*, 1094–1096. https://doi.org/10.2337/dc10-1612

von Elm, E., Altman, D. G., Egger, M., Pocock, S. J., Gøtzsche, P. C., Vandenbroucke, J. P., & Initiative, S. (2008). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies. *Journal of Clinical Epidemiology*, *61*, 344–349. https://doi.org/10.1016/j.jclinepi.2007.11.008

WHO (2006). *Definition and diagnosis of diabetes mellitus and intermediate hyperglycemia*. Report of a WHO/IDF consultation (pp. 1–30). WHO.

Yang, Q., & Liu, L. (2010). Reliability and validity of the Chinese version of diabetes distress scale. *Journal of Nursing*, *17*, 8–10.

Zhang, J., Xu, C. P., Wu, H. X., Xue, X. J., Xu, Z. J., Li, Y., Gao, Q., & Liu, Q. Z. (2013). Comparative study of the influence of diabetes distress and depression on treatment adherence in Chinese patients with type 2 diabetes: A cross-sectional survey in the People's Republic of China. *Neuropsychiatric Disease and Treatment*, *9*, 1289–1294.

Zhou, H., Zhu, J., Liu, L., Li, F., Fish, A. F., Chen, T., & Lou, Q. (2017). Diabetes-related distress and its associated factors among patients with type 2 diabetes mellitus in China. *Psychiatry Research*, *252*, 45–50. https://doi.org/10.1016/j.psychres.2017.02.049

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Li S, Fang L, Lee A, et al. The association between diabetes-related distress and fear of hypoglycaemia in patients with type 2 diabetes mellitus: A cross-sectional descriptive study. *Nurs Open*. 2021;00:1–10. https://doi.org/10.1002/nop2.800