RESEARCH PAPER

Beliefs about insulin as a predictor of fear of hypoglycaemia

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The present study extends previous research by exploring the predictive value of beliefs about insulin therapy in fear of hypoglycaemia (FoH). Data were collected on 81 Spanish adults (aged 18–58 years) with type 1 diabetes. Participants completed a survey questionnaire containing the following measures: state-trait anxiety inventory (STAI), beliefs about medicines questionnaire (specific scale), a modified version of the FoH Survey (worry scale) and different questions about demographic and clinical information (duration of diabetes, daily shots of insulin, severe hypoglycaemic episodes, metabolic control). Regression analyses showed that history of severe hypoglycaemic episodes and concerns about insulin therapy had the most predictive influence on FoH. Treatment perceptions, particularly concerns about insulin, were related to reported FoH. However, FoH is a complex phenomenon and more research is needed in order to gain a better understanding of its predictors and correlates.

Keywords: Beliefs about medicines, Diabetes, Fear of hypoglycaemia, Treatment perceptions, Worry

INTRODUCTION

Hypoglycaemia or insulin reaction (low blood glucose) is the most significant acute complication of type 1 diabetes, particularly during intensive insulin treatments.¹ Symptoms of hypoglycaemia include weakness, hunger, dizziness, mental confusion, pounding heart, irritability, trembling and sweating. Severe hypoglycaemia can lead to loss of consciousness, coma and potential death. Consequently, insulin reaction represents one of the patient's greatest fears.

Two key components or dimensions of fear of hypoglycaemia (FoH) have been identified: specific worries associated with insulin reaction and the different behaviours to avoid hypoglycaemia. The Hypoglycaemic Fear Survey (HFS)² is the most widely used

instrument for examining FoH in adults and includes two subscales assessing *Worry* and *Behaviour*. Previous studies have found that factors such as *trait anxiety* and past *hypoglycaemic episodes* are significant predictors of FoH.^{3,4} At the same time, some research has suggested that FoH might promote non-adherence behaviours in order to avoid hypoglycaemia, which in turn would affect metabolic control.² However, other studies have found that individuals with well-controlled diabetes had the highest levels of FoH.⁴

Apart from personality factors, such as trait anxiety, it would be interesting to identify other more specific and proximal psychological factors as predictors of FoH. Research has found that patients' beliefs about treatment, and associated emotional responses, can have an important influence on their decisions about treatment and

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illness outcomes. In this way, people's views about treatment (perceived necessity and concerns) have been identified as strong predictors of treatment adherence.⁵ Although the majority of people with diabetes, particularly those with type 1 diabetes, agree that insulin therapy is essential for their health, a percentage of them express concerns about potential adverse effects associated with taking insulin.⁶ However, little is known about the potential links between treatment beliefs, especially concerns about insulin therapy, and FoH.

The present study extends previous research by exploring the predictive value of concerns about insulin taking on FoH. The primary purpose of this study is to evaluate the specific influence of concerns about insulin on FoH after controlling the contribution of personality, such as trait anxiety, and situational factors, such as past negative experience with hypoglycaemia. It is predicted that higher levels of concerns about insulin therapy will be related to higher level of FoH. In addition, a further aim is to explore the relationships between FoH, treatment adherence and metabolic control.

METHOD

Sample and Measures

Data were collected on 81 adults, 56% females, (aged 18–58 years, $M=30.2$ years) with type 1 diabetes recruited from one hospital and several patients associations located in Spain. Participants completed a survey questionnaire containing the following measures:

The *State-Trait Anxiety Inventory (STAI), Trait Subscale*,⁷ a measure of anxiety assessing the trait of anxiety proneness which is made up of 20 items asking participants to indicate how they usually feel on a 4-point Likert scale (0 = never to 3 = always). The internal consistency (Cronbach's alpha) for the subscale in the present study was 0.88.

The *Beliefs about Medicines Questionnaire (BMQ)-Specific*,⁸ which comprises two scales assessing beliefs about the 'necessity' of the insulin (e.g. 'My health at present depends on my medicines') and the 'concerns' about taking it (e.g. 'Having to take my medicines worries me'). Participants are required to indicate the extent they agree or disagree with each statement, using a 5-point Likert-type scale (where 1 = strongly disagree; 5 = strongly agree). The internal consistency (Cronbach's alpha) for the BMQ-scales in the present study were 0.74 (concerns) and 0.65 (necessity).

The *Fear of Hypoglycaemia Survey (Worry Scale)*² (adapted from Cox *et al.*²). Eight items that assess the degree of worry (0 = never; 4 = many times) about hypoglycaemic episodes (e.g. 'I worry about having a hypoglycaemia while sleeping', 'I worry about having a hypoglycaemia when responsible for others'). The current research found a high internal consistency (Cronbach's alpha): 0.88.

Frequency of hypoglycaemic episodes experienced in the previous 12 months (never = 0 to daily = 5).

Severe hypoglycaemic episodes in the previous 12 months (requiring external assistance): yes/no.

Treatment adherence: Four items to assess the frequency of performing diabetes self-care tasks adapted from previous studies:⁹ diet (two items: 'Some people don't follow their dietary recommendations – e.g., eat high fat foods, skip meals, how often does this happen to you?', 'Some people eat sweets and desserts. How often does this happen to you?'; never = 4 to very often = 0), insulin taking (one item: 'Some people don't take their insulin injections that they are supposed to. How often does this happen to you?'; never = 4 to very often = 0) and glucose monitoring (one item: How often do you test your glucose levels? 0 = never to 4 = three or more times a day), with higher scores indicating higher adherence. The internal consistency (Cronbach's alpha) for this scale was 0.65.

Metabolic control was calculated using levels of glycosylated haemoglobin (HbA1c), a retrospective measure of average blood glucose during the previous 2–3 months, with higher levels reflecting poorer control (good metabolic control: <7%). HbA1c values were obtained from medical records.

RESULTS

Intercorrelations and scales descriptives of the research variables are presented in Table 1. The mean score of FoH (worry scale) illustrates that participants in this study reported levels of fear close to the midpoint of the scale ($M = 1.86$, $SD = 0.9$). About one-third of the sample reported being worried about developing hypoglycaemia. The percentage of participants endorsing (often or many times) some of the items representing FoH was as follows: 53.3% of participants were worried about having a hypoglycaemia when responsible for others, 48.1% about having a hypoglycaemia while sleeping, 33.8% were worried about suffering a hypoglycaemia in public, 32.5% were worried about having a hypoglycaemia while alone or 31.2% were worried about not recognizing hypoglycaemia symptoms.

Hypoglycaemic episodes were frequent. More than a half of participants reported to experience hypoglycaemia, at least, once a week. Also, as expected, participants with a more intensive treatment (more injections and more frequency of glucose monitoring) reported more frequency of hypoglycaemic episodes. However, only a total of 13 participants (16% of the study population) reported a severe hypoglycaemic episode (requiring external assistance) during the last year. The mean scores for the BMQ scales illustrated that, as expected, 'necessity' scores were higher than 'concerns' about insulin. However, about 25% had higher than mid-point scores on the 'concerns' scale.

FoH: Predictors

As can be seen in Table 1, there were significant positive relationships between FoH, concerns about insulin ($r = 0.38$, $p < 0.01$), trait anxiety ($r = 0.33$, $p < 0.01$) and experience of severe hypoglycaemic events ($r = 0.27$, $p < 0.05$). In this respect, those participants who reported severe hypoglycaemia expressed higher levels of FoH ($M = 2.41$, $SD = 0.81$) when compared with individuals who did not report episodes of severe hypoglycaemia ($M = 1.74$, $SD = 0.92$; $p = 0.018$). However, FoH and frequency of hypoglycaemic episodes in the previous year were not correlated.

A two-step hierarchical multiple regression analysis was used to assess the amount of variance in FoH that could be explained by concerns about taking insulin, once the effect situational variables (past experience of severe hypoglycaemic events) and personality factors (trait anxiety) were accounted for (Table 2). Analysis showed that past experience of severe hypoglycaemic episodes ($\beta = 0.25$, $p < 0.05$) and trait anxiety ($\beta = 0.32$, $p < 0.01$) in the first step accounted for 17% of the variance. In the second step, the entry of concerns about insulin explained an additional 9% of the variance in FoH with past experience of severe hypoglycaemic events ($\beta = 0.29$, $p < 0.01$) and concerns about insulin ($\beta = 0.33$, $p < 0.01$) accounting for unique variance in FoH. Thus, trait anxiety, although correlating with FoH, was not found to be a significant predictor when entered together with the rest of variables. This is suggestive that concerns about insulin might be a mediating variable between trait anxiety and FoH.

Following Baron and Kenny¹⁰ four conditions are necessary in order to establish mediation: (a) a significant association between predictor (trait anxiety) and outcome variable (FoH), (b) a significant relationship between predictor (trait anxiety) and presumed mediator (concerns about insulin), (c) a significant association between presumed mediator (concerns about insulin)

TABLE 1. *Bivariate correlations among study variables*

Variables	M (SD)	1	2	3	4	5	6	7	8	9	10	11
1. Duration of diabetes	11.9(9.5)											
2. Number injections ^a	2.9(0.7)	0.04										
3. STAI	1.1(0.5)	-0.09	-0.05									
4. Severe hypo episodes ^b	-	0.37**	0.17	0.06								
5. Frequent hypo episodes	2.6(1.3)	0.16	0.25*	0.16	0.00							
6. Adherence-Diet ^c	2.6(0.7)	0.11	0.05	-0.16	-0.08	0.03						
7. Adherence-Insulin ^c	3.5(0.7)	0.05	0.10	0.01	-0.09	0.13	-0.29**					
8. Glucose monitoring ^c	2.6(1.5)	0.00	0.27*	0.22	0.15	0.32**	-0.12	0.21				
9. Fear of hypoglycaemia	1.86(0.9)	-0.09	0.18	0.33**	0.27*	-0.03	-0.05	0.23	0.14			
10. BMQ-Concerns	2.5(0.8)	-0.36**	-0.13	0.39**	-0.09	-0.24*	-0.02	0.03	-0.17	0.38**		
11. BMQ-Necessity	4.3(0.6)	0.15	0.20	0.13	0.13	0.24*	0.22*	0.28*	0.35**	-0.00	0.11	
12. Control (HbA _{1c})	8.0(1.6)	-0.10	-0.05	0.05	-0.07	-0.36**	-0.35**	-0.32*	-0.21	-0.20	0.07	-0.12

* $p < 0.05$, ** $p < 0.01$; ^aInsulin injections per day; ^bSevere hypoglycaemic episodes last year (no: 83.5%, yes: 16.5%); ^cFrequency diabetes self-care tasks: theoretical range: 0 (low) to 4 (high frequency); STAI-T, State-Trait Anxiety Inventory, Trait version: theoretical range: 0 (low) to 3 (high anxiety); FoH, Fear of hypoglycaemia: theoretical range: 0 (low) to 4 (high fear); HbA_{1c} (Glycosylated haemoglobin, higher levels: poorer metabolic control; <7%: good metabolic control); BMQ, Beliefs about Medication Questionnaire: theoretical range: 1-5 (high necessity/concerns).

and outcome variable (FoH) and (d) the previously significant relation between predictor (trait anxiety) and outcome variable (FoH) is no longer significant (full mediation) or diminishes (partial mediation) when the presumed mediator (concerns about insulin) is controlled. On this basis, four separate regression analyses were conducted. First, a simple regression analysis with trait anxiety predicting FoH ($\beta = 0.33$, $p < 0.01$), second, with trait anxiety predicting concerns about insulin ($\beta = 0.39$, $p < 0.001$), third, with concerns about insulin predicting FoH ($\beta = 0.38$, $p < 0.01$), and finally, a multiple regression analysis with trait anxiety predicting FoH and controlling the influence of concerns about insulin. In this final step the effect of concerns about insulin remained significant ($\beta^* = 0.30$, $p < 0.01$) and the regression weight for trait anxiety diminished ($\beta^* = 0.22$, $p = 0.052$). Therefore, the conditions were met and concerns about insulin partially mediated the relationship between trait anxiety and FoH.

TABLE 2. Summary of hierarchical regression analysis for variables predicting FoH

	ΔR^2	B	SE B	β
Step 2	0.17			
Severe hypoglycaemic episodes		0.61	0.26	0.25*
Trait anxiety		0.59	0.20	0.32**
Step 2	0.09			
Severe hypoglycaemic episodes		0.71	0.25	0.29**
Trait anxiety		0.34	0.21	0.18
BMQ-Concerns		0.36	0.12	0.33**

Total $R^2 = 0.27$. $F(3, 72) = 8.71$, $p < 0.001$. * $p < 0.05$, ** $p < 0.01$.

The regression analyses performed are depicted in the Fig.

Relationships between FoH, Adherence and Metabolic Control

Most of participants reported a high level of adherence to insulin and medium levels of frequency of performing diabetes care tasks such as blood glucose testing or avoidance of inappropriate foods. There were not significant correlations between FoH and diabetes self-care tasks (adherence). However, as expected, beliefs about the necessity of insulin (very high in this population) were associated to diabetes self-care tasks which, in turn, were associated to better metabolic control. Also, there was no relationship between FoH and metabolic control (HbA1c values). In addition, better metabolic control (lowest HbA1c values) was associated with frequency of hypoglycaemic episodes.

DISCUSSION

Although participants as a group reported moderated levels of FoH more than half of participants were worried about having hypoglycaemia when responsible for others and nearly half of them were worried about having an insulin reaction while sleeping. These findings reveal that FoH deserves special consideration for researchers and practitioners.

The primary purpose of this study was to evaluate the specific influence of concerns about insulin on FoH. The regression model revealed the association between concerns about insulin and FoH after controlling for past history of severe hypoglycaemic

FIG. 1. Concerns about insulin partly mediated the influence of trait anxiety on FoH.

episodes and trait anxiety. These findings suggest that concerns about insulin therapy accounted for unique variance in FoH, supporting our central hypothesis. Also, consistent with previous research, our results supported the hypothesis about the role of past history of severe hypoglycaemic episodes as a significant predictor of FoH.¹¹ Personality variables, such as trait anxiety, have also been proposed in previous studies as determinants in the development of FoH.⁴ In the present study trait anxiety, although correlating with FoH, was not found to be a significant predictor when entered together with the rest of variables. In order to clarify the role of trait anxiety in FoH we tested whether the effect of trait anxiety on FoH was mediated by concerns about insulin. Mediation analysis revealed that anxiety might be associated to FoH via its effects on concerns about insulin.

We did not find a relationship between frequency of hypoglycaemia and FoH. When analysing the role of experience of hypoglycaemia in explaining FoH it is the severity of insulin reactions instead of its frequency the main determinant on FoH. At the same time, we found logical and interesting correlations among our study variables. For example, those people with more intensive treatments (more daily injections and more frequency of glucose testing) reported a higher number of hypoglycaemic episodes and also had a better metabolic control. This pattern of interrelations supports the evidence in medical research that intensifying treatment to lower HbA1c values results in an increase in the frequency of hypoglycaemia. Similarly, we found that those participants who had diabetes longer reported lower levels of insulin-related concerns. Perhaps more experience with insulin therapy may be associated with a higher level of knowledge about its effects and lower level of concerns.

Regarding our secondary research question we did not find a significant relationship between FoH and adherence; also, there was no relationship between FoH and metabolic control. Although some previous research

has reported a negative impact of FoH on diabetes control,¹² other studies have failed to find a relationship³ or have suggested that the tighter the metabolic control (lower HbA1c values) the greater the worry.¹³

Finally, this study also had several limitations that should be considered. On one hand, the sample size might limit the generalization of the results. On the other potential limitation of the study refers to the instruments to assess adherence or self-care tasks. The use of self-report measures might have overreported the levels of performance of self-care tasks; however, about 30% of the participants reported that they performed less than one glucose test a day, which indicates reliable and honest answers.

CONCLUSIONS

This exploratory study has shown that treatment perceptions, particularly concerns about insulin, and past history of severe hypoglycaemic episodes were related to reported FoH. Some practical implications may be proposed. First, given the role of past history of severe hypoglycaemia in FoH, it would be appropriate to prevent these events in special subgroups of patients who have problems to detect early signs of insulin reactions. Also, given the role of concerns about insulin in FoH, it would be interesting to assess patients' beliefs about treatment among specific groups, for example, patients with type 2 who are candidates to change to insulin therapy because their therapy with oral agents has failed to control diabetes. Likewise, as we found that participants with a shorter duration of diabetes reported higher level of concerns about insulin, it would be especially recommended the assessment of their treatment beliefs early after the diagnosis.

In summary, FoH is a complex phenomenon and more research is needed to understand the interactions between its biological and psychological determinants and its impact on treatment adherence and metabolic control.

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