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Symptoms of depression and diabetes-specific emotional distress are associated with a negative appraisal of insulin therapy in insulin-naïve patients with Type 2 diabetes mellitus. A study from the European Depression in Diabetes [EDID] Research Consortium

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Abstract

Aims A meta-analysis concluded that depression is associated with poor glycaemic control in Type 2 diabetes (DM2). In DM2 patients with deteriorating glycaemic control, the initiation of insulin therapy is often postponed. The aim of the present study was to determine whether symptoms of depression and diabetes-specific emotional distress are associated with a more negative appraisal of insulin therapy.

Methods We collected cross-sectional data in two outpatient university clinics in Istanbul, Turkey. The study sample consisted of 154 insulin-naïve patients with DM2. A self-report questionnaire was used to obtain demographic and clinical data. Main instruments were the Centre for Epidemiologic Studies Depression Scale, (CES-D), the Problem Areas In Diabetes scale (PAID) and the Insulin Treatment Appraisal Scale (ITAS).

Results Analysis of variance revealed that patients with a higher depression score rated insulin therapy significantly more negative then patients with lower depression scores. Moreover, 47% of patients with a high depression score had a negative appraisal of insulin therapy on 7 or more of the 20 ITAS-items, compared to 25 to 29% of those with low-moderate depression scores. Multiple regression analyses showed that a negative appraisal of insulin therapy was significantly associated with higher depression and diabetes-distress scores and low education, but not with sex, age or duration of diabetes.

Conclusions Our results suggest that in insulin-naïve Type 2 diabetes patients, higher levels of depression and diabetes-distress tend to be associated with more negative beliefs about insulin. Whether these negative attitudes translate into postponing initiation of insulin therapy needs to be tested in longitudinal research.

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Keywords diabetes mellitus, depression, insulin

Abbreviations CES-D, Center for Epidemiologic Studies Depression Scale; ITAS, Insulin Treatment Appraisal Scale

Introduction

Depression can be regarded as a serious and common complication of diabetes, as a recent meta-analysis concluded that depression is 2–3 times more prevalent in people with diabetes than in the general population, affecting 10–15% of the diabetes patients [1]. Moreover, depression in diabetes is associated

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with impaired glycaemic control, and as a consequence depressed diabetes patients are at a higher risk for long-term complications of the disease [2,3]

Although results of the United Kingdom Prospective Diabetes Study (UKPDS) have shown convincingly that good glycaemic control can prevent or delay the onset of diabetes complications in Type 2 diabetes patients, a reluctance to start insulin therapy has been observed in many patients with Type 2 diabetes [4–7].

Only a few studies have reported results regarding the prevalence of negative appraisals of insulin, or 'psychological insulin resistance'. For example, in the UKPDS, 27% of the patients randomized to insulin therapy initially refused insulin, compared to 7% in the Glibenclamide group and 13% in the Chlorpropamide group [4]. A study by Polonsky *et al.* had comparable results, showing that about 28% of insulin naive diabetes patients reported to be unwilling to begin insulin if prescribed [6]. Hence, these results suggest that considerably strong, negative appraisals regarding insulin therapy exist in about one third of the insulin-naïve patients. However, the determinants of a negative appraisal of insulin therapy are still unclear. A negative appraisal of insulin therapy was found to be more common in women compared to men (31% versus 21%) and in ethnic minorities versus whites (35% versus 22%) [6].

Besides low mood, depressed patients often complain about reduced energy and low self-efficacy, resulting in difficulty finishing tasks and a decreased motivation in undertaking new projects [8]. We can therefore hypothesize that higher levels of depressive symptoms are associated with a more negative appraisal of insulin therapy, that could result in postponing initiation of insulin treatment. In this cross-sectional study we aimed to test whether depression and diabetes distress are associated with a more negative attitude towards insulin in a group patients with Type 2 diabetes treated with diet and/or oral agents.

Research design and methods

This study was conducted in two outpatient clinics in Istanbul, Turkey: the Istanbul Medical Faculty Hospital and the Cerrahpaşa Medical Faculty Hospital. The Cerrahpaşa Medical Faculty Hospital is a tertiary clinic serving approximately 10 000 patients with diabetes annually.

We aimed to include a sample of at least 150 insulin-naïve patients with Type 2 diabetes. Therefore, we invited consecutive patients with Type 2 diabetes mellitus who were treated with a diet and/or oral agents. Exclusion criteria for this study were being illiterate or not being able to read due to vision problems. All subjects gave written informed consent and the Ethical Review Committee of the Istanbul University Medical Faculty and Cerrahpaşa Medical Faculty approved the study.

Measures

Demographic data and information regarding medical treatments for diabetes and depression were obtained from self-report and HbA_{1c} values were collected using the medical charts of participants.

Appraisal of Insulin Therapy Scale

The Insulin Treatment Appraisal Scale [ITAS] has been developed to assess attitudes towards insulin treatment and contains 20 items (16 negative, 4 positive statements) that are scored on a 5 point Likert scale, ranging from strongly disagree to strongly agree. The topics covered in ITAS include for example that insulin signifies: feeling sicker, being more dependent, having a higher risk of hypoglycemia, painful injections, being restricted in daily life, being protected from complications or feeling more energetic. The ITAS appeared to have satisfactory psychometric qualities for diagnostic and research purposes in relation to perceptual barriers to insulin therapy [9]. To date, Cronbach's alpha was 0.88 and item-total correlations were all larger than 0.25. The total ITAS score is calculated as the sum of the 20 items, where a higher score indicates a more negative perception of insulin therapy. In the present samples, Cronbach's alpha was 0.82 and 0.87 for the in the Istanbul University Clinic and Cerrahpaşa University Clinic respectively.

Depression

Depression was assessed using the Turkish version of the Centre for Epidemiologic Studies Depression Scale (CES-D). This is a 20-item, self-report scale that asks respondents to indicate the frequency of occurrence of 20 depression symptoms during the last week. The instrument uses a four-point response set, ranging from 'rarely or none of the time' to 'most or all of the time'. Higher scores indicate more depressive symptoms and a cut-off point of 16 or more is generally accepted as indicative of a clinically significant level of depression symptoms [10–12].

Diabetes-specific emotional distress

The Problem Areas in Diabetes (PAID) scale is a 20 item, self-report scale that asks individuals to rate how much of a problem, on a five-point scale ('not a problem' to 'serious problem') they find each of the 20 issues raised [13]. The items consist of 20 statements that Polonsky and colleagues identified as common negative emotions related to living with diabetes, for example 'feeling alone with diabetes', 'worrying about the future and the possibility of serious complications'. The PAID scores are summed and transformed to a 0–100 scale, with higher scores indicating higher emotional problems. The ITAS and the PAID were translated from English to Turkish by two authors (CM and ÇK), who are both fluent in English and Turkish. Back translations by another translator who was not familiar with the scales indicated no substantive differences with the originals.

Statistical analysis

SPSS version 12 for Windows was used to carry out statistical analyses. In case of missing values on the CESD and the ITAS, a maximum number of 3 items were estimated using the mean of the other completed items of that particular questionnaire. Firstly, demographic, clinical and depression data of two

clinics were compared, using the Chi-square tests for dichotomous variables and t-tests and analysis of variance for variables with a continuous distribution. These analyses were performed separately for men and women. For all statistical testing, we used two-sided hypothesis testing with an alpha level of 0.05. To explore whether demographic variables (gender, age, low education and duration of diabetes) and depression scores were associated with appraisal of insulin therapy, stepwise multiple linear regression analyses were performed. Total ITAS score was entered as the dependent variable in all regression analyses. Variance inflation factor (VIF) and tolerance values were used to indicate multicollinearity. We used the rule of thumb that tolerance should be > 0.20 and VIF < 4 to suggest no multicollinearity. We used combined data of both clinics to determine the percentages of subjects who responded to individual ITAS items with: 'somewhat agree' or 'strongly agree'. These percentages are described for each of the 20 ITAS items, in three subgroups of patients with different CES-D depression scores: 0–15 (low/moderate), 16–23 (elevated depressive symptoms), 24 or more (high level of depressive symptoms).

Results

Demographic indices

The total study sample comprised of 154 subjects, of whom 84 were women (55%). A total number of 220 patients were invited, and 154 patients (70%) agreed to participate and met the inclusion criteria. A total 30% of the invited patients did not want to participate or could not participate because being illiterate or not able to read without an optical device. The mean age for women was 56 ± 9 years and for men 57 ± 11 years (total ranging from 28 to 81 years). There were no significant differences between the two clinics regarding gender, age or duration of diabetes. A considerable percentage of the sample appeared to be highly educated (41%). Compared to the male participants, women had a significantly lower level of education. The majority of the individuals were married (84%). The mean HbA1c of the total sample was 6.7 ± 1.0 (4.8–10.0), 63% responded not to have a complication of diabetes. The percentage of missing values was for the CES-D was 1.2% and for the ITAS 2.4%. Compared to the patients from the Istanbul University Clinic, high levels of depression scores (CES-D ≥ 16) were significantly more common in the Cerrahpaşa University Hospital: 19% (18/95) versus 32% (18/56, $P < 0.05$). As to be expected, women had higher mean depression scores compared to male participants (Table 1).

Associations between depression and the appraisal of insulin therapy

The total mean ITAS-score was 54 ± 10. There was no significant difference between male and female participants regarding the appraisal of insulin therapy. The total ITAS score, was significantly higher for depressed patients (mean 56.5, SD 11.1) than for non-depressed patients (mean 52.8, SD 9.5).

Next, in Table 2 it is shown that patients with a high depression score rated insulin therapy more negatively on more than half of the items, compared to patients with lower depression scores. Moreover, 47% of patients with a high depression score had a negative appraisal of insulin therapy on 7 or more ITAS-items, compared to 25 to 29% of those with low-moderate and elevated depression groups (Chi-square, $P = 0.086$).

Table 3 shows the results of stepwise, multiple regression analyses that were conducted to evaluate whether demographic data, symptoms of depression and diabetes-specific emotional distress were associated with a negative appraisal of insulin therapy (ITAS). Values for VIF and tolerance did not indicate multicollinearity problems. The first regression model included four demographic variables: being female, low level of education, age and duration of diabetes. In this model, patients with a low education tended to have a more negative appraisal of insulin therapy (Beta 0.15, $P = 0.08$), while the other variables were not significantly associated with appraisal of insulin. In the second model, depression was significantly associated with a more negative appraisal of insulin therapy (Beta: 0.20, $P = 0.02$). In the third model, diabetes-specific emotional distress was added to the analysis: this resulted in a large drop of the Beta between depression and negative insulin-appraisal from 0.20 to 0.02.

Discussion

The aim of our research was to study whether higher levels of depression symptoms and diabetes-specific distress are associated with a more negative appraisal of insulin therapy, underlying a reluctance to start insulin. Indeed we found that patients with Type 2 diabetes who reported increased levels of depressive symptoms had significantly more negative beliefs about insulin therapy, as measured with the ITAS, compared to non depressed patients. In the linear regression analyses, depression symptomatology was found to be positively associated with a more negative appraisal of insulin therapy. Adjustment for diabetes-specific emotional problems lowered this to almost zero. Moreover, the positive association between diabetes-distress and a negative insulin appraisal was considerably stronger than the association with depression. This suggests that in insulin-naïve Type 2 diabetes patients, higher levels of diabetes-distress directly contribute to more negative expectations of insulin therapy.

It is important to note that both outpatient samples in our studywere in rather good control, with no apparent need to start insulin therapy. Nevertheless, like in the United Kingdom [4] and in the U.S.A. [6,7], a considerable number of the Turkish diabetes patients in our study had negative appraisals of insulin therapy. The patients' reasons for disliking insulin therapy clearly extend beyond fear of injections alone. Other factors, such as worries about the impact of insulin therapy on the social environment and feelings that insulin therapy signifies that one has failed to manage diabetes with diet/tablets also appear to play a role.

Table 1 Demographic, clinical and psychological characteristics of male and female participants with type 2 diabetes, who were treated in the outpatient clinic of the Istanbul University Hospital or the Cerrahpaşa University Hospital

	Istanbul University Hospital		Cerrahpaşa University Hospital	
	Male	Female	Male	Female
% (*n*)	48% (47)	52% (51)	41% (23)	59% (33)
Age (years)	56 ± 10	55 ± 9	60 ± 13	56 ± 9
BMI	27 ± 3	30 ± 5	29 ± 4	31 ± 6
HbA_{1c}	6.8 ± 1.2	6.6 ± 0.9	6.3 ± 0.9	6.6 ± 0.9
Duration of diabetes (years)				
< 1	9% (4/47)	2% (1/51)	26% (6/23)	15% (5/33)
1–2	15% (7/47)	16% (8/51)	9% (2/23)	15% (5/33)
3–4	15% (7/47)	20% (10/51)	13% (3/23)	15% (5/33)
5–10	38% (18/47)	41% (21/51)	35% (8/23)	30% (10/33)
> 10	23% (11/47)	22% (11/51)	17% (4/23)	24% (8/33)
Level of education		*		*
Primary school	2% (1/47)	28% (14/51)	9% (2/23)	46% (15/33)
Middle school	15% (7/47)	6% (3/51)	13% (3/23)	24% (8/33)
College/High school	34% (16/47)	24% (12/51)	30% (7/23)	9% (3/33)
University	49% (23/47)	43% (22/51)	48% (11/23)	21% (7/33)
Diabetes complications				
No Complication	60% (28/47)	63% (32/51)	70% (16/23)	64% (21/33)
Retinopathy	9% (4/47)	4% (2/51)	0% (0/23)	6% (2/33)
Cardiovascular	159% (7/47)	14% (7/51)	17% (4/23)	6% (2/33)
Nephropathy	2% (1/47)	6% (3/51)	0% (0/23)	6% (2/33)
Neuropathy	23% (11/47)	24% (12/51)	13% (3/23)	21% (7/33)
Foot problem	13% (6/47)	8% (4.51)	4% (1/23)	9% (3/33)
Mean CES-D score (Depression)	9.7 ± 7.8	11.6 ± 8.9	7.3 ± 8.1	14.3 ± 13.0
High level of depression (CES-D ≥ 16)	13% (6/46)	24% (12/49)	22% (5/23)	40% (13/33)
Mean PAID total score (0–100)	28 ± 23	34 ± 22	30 ± 23	39 ± 24
Mean ITAS total score	52 ± 10	56 ± 9	54 ± 9	53 ± 13

*$P \leq 0.01$, comparing men and women within the same hospital.

In the present study, we found that 48–68% of the participants agreed to some extend that taking insulin indicates a personal failure, which is in concert with findings from the DAWN study, where 58% of the patients agreed with a comparable statement [7,14]. Requiring insulin therapy is linked to a sense of personal failure, possibly fuelled by common physician practice worldwide, where the prospect of insulin therapy is used as a kind of threat to motivate better patient cooperation [6]. In the present study a substantial number of patients (43–60%) stated that insulin therapy would cause family and friends to be more concerned about them, whereas Polonsky *et al.* [6] did not report this response, possibly related to differences in culture [15,16].

Patients with higher levels of depression, scored highest on the ITAS item 'Managing insulin injections takes a lot of time and energy'. The fact that depressed patients tend to view insulin injections as (too) complex and burdensome, is in line with our expectations, as depression is characterized by low energy, cognitive difficulties, low outcome expectancies and self-esteem [8]. Also, patients with a low education believed insulin therapy to be difficult and demanding, drawing attention to the importance of diabetes knowledge and a correct understanding of the pathophysiology and treatment of Type 2 diabetes. The fact that the DAWN study [7] did not find a relationship between education and negative attitudes towards insulin may be related to a difference in measurement. Where we used a comprehensive questionnaire, Peyrot and colleagues only asked about perceived efficacy of insulin and self-blame for needing insulin.

Another interesting finding is more patients (40%) with a high depression score responded that insulin causes weight gain than those reporting less negative affect (12–14%) In the UKPDS, patients taking insulin indeed gained 4 kilograms more than those on diet, over a period of 10 years [4]. Although modern insulin analogues may have a less profound effect on weight than NPH [17], worries about gaining weight are not unrealistic. The fact that depressed patients were the most worried about the weight issue is in line with the depressive realism hypothesis, which posits that depressed people are often more accurate in their perceptions and judgements than non-depressed people are [18].

There are several limitations that need to be mentioned. First, as our data have been collected in two Turkish outpatient clinics in Istanbul, it is important to emphasize that the results might not be representative for other diabetes patients in or outside Turkey. Generally the more complex diabetes patients

Table 2 Percentages of subjects who responded to each ITAS item with 'somewhat agree' or 'strongly agree', for each of the patients with different CESD scores: 0–15 (low/moderate), 16–23 (high depressive symptoms), 24 or more (severe depressive symptoms)

	CES-D scores		
Item content	0–15	16–23	24+
n	*113*	*21*	*15*
1-Taking insulin means I have failed to manage my diabetes with diet and tablets.	51%	48%	68%
2-Taking insulin means my diabetes has become much worse.	41%	29%	40%
3-Taking insulin helps to prevent complications of diabetes.	52%	52%	80%
4-Taking insulin means other people see me as a sicker person.	42%	57%	53%
5-Taking insulin makes life less flexible.	43%	38%	53%
6-I'm afraid of injecting myself with a needle.	43%	48%	53%
7-Taking insulin increases the risk of low blood glucose levels (hypoglycaemia).	29%	43%	33%
8-Taking insulin helps to improve my health.	56%	52%	40%
9-Insulin causes weight gain.	12%	14%	40%
10-Managing insulin injections takes a lot of time and energy.	10%	19%	47%**
11-Taking insulin means I have to give up activities I enjoy.	14%	14%	20%
12-Taking insulin means my health will deteriorate.	22%	24%	13%
13-Injecting insulin is embarrassing.	4%	0%	20%*
14-Injecting insulin is painful.	11%	14%	20%
15-It is difficult to inject the right amount of insulin correctly at the right time every day.	27%	29%	53%
16-Taking insulin makes it more difficult to fulfil my responsibilities (at work, at home).	26%	10%	40%
17-Taking insulin helps to maintain good control of blood glucose.	58%	57%	53%
18-Being on insulin causes family and friends to be more concerned about me.	43%	43%	60%
19-Taking insulin helps to improve my energy level.	40%	24%	33%
20-Taking insulin makes me more dependent on my doctor.	34%	43%	53%

*$P \leq 0.05$; **$P \leq 0.01$.

Table 3 Multiple linear regression analyses: associations between a negative appraisal of insulin therapy (total ITAS score), and 1) sociodemographic variables, depression and diabetes-specific emotional distress (PAID survey) in 154 insulin-naive outpatients with type 2 diabetes mellitus

	Model 1 Sociodemographic			Model 2 Sociodemographic and depression			Model 3 Sociodemographic, depression, diabetes-specific distress		
	Beta	*t*	*P*	Beta	*t*	*P*	Beta	*t*	*P*
I Sociodemographic (enter)									
Female sex	0.07	0.81	0.419	0.04	0.53	0.656	0.04	0.45	0.657
Low education	0.15	1.74	0.084	0.14	1.68	0.098	0.11	1.30	0.196
Age (years)	–0.04	–0.39	0.694	–0.02	0.05	0.797	0.11	1.20	0.231
Duration diabetes (years)	–0.07	–0.79	0.432	–0.11	–1.30	0.208	–0.10	–1.15	0.254
II Depressed mood (enter)									
Depression symptoms (CES-D)				0.20	2.30	0.023	0.02	0.25	0.806
III Diabetes-specific emotional distress									
Problem Areas In Diabetes Survey (PAID)							0.39	4.12	0.001
Adjusted R^2		0.04		0.07			0.17		
F-change		1.44		5.31			16.98		
P-value (*F*-change)		0.227		0.023			0.001		

are referred to university hospitals, and the patients in our study were also relatively highly educated.

Secondly, as the design of our study is cross-sectional, we cannot infer conclusions regarding causality. Yet, it does seem plausible that depression contributes to a more negative attitude towards the use of insulin, rather than the reverse. Furthermore, longitudinal studies are needed to investigate whether lower levels of depression are predictive of a more successful change to insulin therapy. Thirdly, we did not collect data for the patients who refused or were unable to participate

because of reading problems or illiteracy. As a result of this we have no clear indication if or how the non-response could have influenced our results. However, we want to emphasize that the non-response was rather low (30%).

In sum, we can conclude that higher levels of depression and diabetes-specific emotional distress are associated with a significantly more negative appraisal of insulin therapy. Future prospective studies are needed to test whether depression and diabetes-distress are associated with actual postponing insulin therapy and subsequent worsening of glycaemic control.

Competing interests

Nothing to declare.

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