ORIGINAL ARTICLE

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Evaluating the relationships of hypoglycaemia and HbA1c with screening-detected diabetes distress in type 1 diabetes

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Summary

Aims: To explore the relationship between diabetes distress, glucose control and awareness of hypoglycaemia in adults with type 1 diabetes.

Methods: We performed a cross-sectional study using data collected from 280 consecutive type 1 diabetes patients who used a routine clinic consultation tool that recorded HbA1c, hypoglycaemia awareness (measured using the Gold score) and diabetes distress (measured using the Diabetes Distress Scale 2 [DDS2]). We assessed correlations between DDS2 and HbA1c and DDS2 and Gold score and performed an ordinal regression analysis to identify factors contributing to distress.

Results: Diabetes distress was significantly correlated with HbA1c ($r = .319$, $P < .001$) and Gold score ($r = .258$, $P < .001$) independently and with synergistic effect. Female gender was also associated with diabetes distress, while age, BMI, duration of diabetes, severity of complications and use of CSII pumps were not. Occurrence of severe hypoglycaemia (SH) episodes increased with Gold score in a linear manner throughout the scale.

Conclusions: This study has identified new evidence of a significant, independent relationship between diabetes distress measured by the DDS2 and reduced awareness of hypoglycaemia in people with type 1 diabetes. It also demonstrates that diabetes distress is significantly associated with HbA1c and female gender independently. The DDS2 identifies distress associated with both hypo- and hyperglycaemia and can be a useful screening tool. Additionally, the occurrence of SH increases with increasing Gold score.

KEYWORDS
diabetes distress, hypoglycaemia, psychological aspects, type 1 diabetes

1 | INTRODUCTION

For adults with type 1 diabetes, NICE recommends aiming for a target HbA1c of <48 mmol/mol (6.5%) without significant hypoglycaemia.[1] Achieving these levels requires a number of self-care behaviours, such as frequent capillary blood glucose testing, and those who attend self-care education courses (eg, Dose Adjustment For Normal Eating; DAFNE) have better glycaemic control.[2,3] However, the demands of diabetes self-management do place a burden on the person with diabetes, and this can contribute to "diabetes distress."[4] This is the specific

psychological burden that people experience when living with diabetes.[5] It can be related to many factors of coping with type 1 diabetes, such as negative social perceptions, physician-related distress, eating distress, fear of complications and managing treatment regimens.[6] In both type 1[7,8] and type 2 diabetes,[9,10] cross-sectional studies have consistently identified an association between diabetes distress and HbA1c. This may be mediated through an association between diabetes distress and reduced implementation of self-care behaviours,[10,11] and therefore, distress is a barrier to improving diabetes control.[5,11] However, the association is likely to be bidirectional, with high HbA1c results also contributing to distress. Where diabetes distress may have been misdiagnosed as depression in the past,[12] there is increasing recognition that they are related but independent phenomena.[8]

Hypoglycaemia and the fear it generates are often considered to be important barriers in achieving optimal glucose levels. The avoidance of hypoglycaemia is also likely to be reliant on the implementation of self-care behaviours, such as blood glucose testing and insulin dose adjustment. However, there are very little published data on the relationship between hypoglycaemia and diabetes distress. In type 1 diabetes, Fisher et al[7] identified, using qualitative interviews, that fear of hypoglycaemia can contribute to diabetes distress. However, there are no data investigating the relationship between screening-detected diabetes distress and hypoglycaemia awareness, or that assess the complex relationship of diabetes distress with both hypoglycaemia risk and glycaemic control simultaneously.

The objectives of this study were to identify any relationships of routinely screened diabetes distress with hypoglycaemia awareness and HbA1c in a population of people with type 1 diabetes.

2 | METHODS

2.1 | Data collection

Data were collected from 296 consecutive adult patients attending 2 teaching hospital diabetes clinics in London, UK, for appointments
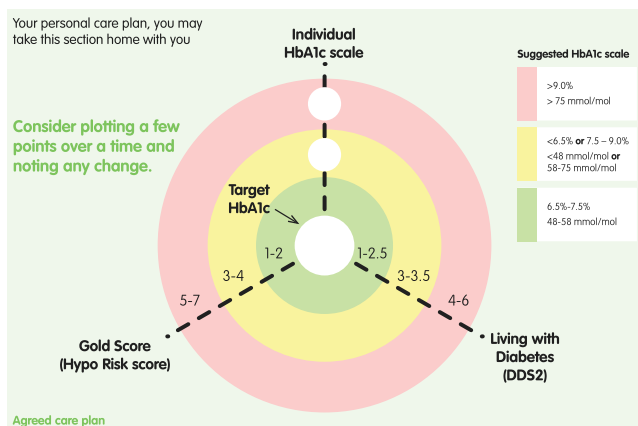

FIGURE 1 Diagram in the Type 1 Consultation tool (T1C), used to demonstrate 3 aspects of diabetes management to patients: HbA1c, hypoglycaemia risk and diabetes distress.[13] Note: Some stratification cut-offs differ from those used in this study

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Novelty statement

- This study was performed involving adults with type 1 diabetes attending 2 London tertiary diabetes clinics.
- With higher HbA1c, the proportion of people with high diabetes distress increases.
- With decreased hypoglycaemia awareness, diabetes distress increases except for those with complete loss of awareness, who have relatively lower diabetes distress.
- A significant proportion of people who achieve target HbA1c with minimal hypoglycaemia do so at the expense of significant diabetes distress.
- The risk of recurrent severe hypoglycaemia (SH) increases in a liner fashion with increasing Gold score.

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regarding type 1 diabetes. Both clinics are tertiary referral clinics which include a high proportion of people referred due to problematic control or complications. These clinics routinely screen for diabetes distress and collect data on HbA1c and hypoglycaemia risk during consultations using a clinic pro forma—the Type 1 Consultation (T1C) tool (Appendix S1).[13] They use this tool to initiate care pathways for elevated diabetes distress, hypoglycaemia awareness or elevated HbA1c, and a disclaimer was given advising patients that data provided may be used for audit purposes. The results are marked on a multicoloured 3-scale diagram to enable feedback to the patient and explain the relationship between HbA1c, hypoglycaemia risk and diabetes distress as part of the consultation (Figure 1). Several other patient characteristics are also recorded on the T1C. Consecutive completed consultation tools were audited for all patients who attended the clinics between September 2015 and March 2016, although incomplete consultation tools were excluded and no data were collected on these people.

2.2 | Glycaemic control

Laboratory HbA1c taken on the day prior or same day as the clinic consultation was used to measure glycaemic control. In line with UK National Diabetes Audit criteria, <58 mmol/mol (7.5%) was used as a marker of reasonable control.[14] Therefore, HbA1c results were classified as on-target if <58 mmol/mol (7.5%), moderately raised if 58-68 mmol/mol (7.5%-8.4%) and severely raised if ≥69 mmol/mol (8.5%).

2.3 | Hypoglycaemia

Each person answered the Gold score,[15] a 7-point Likert scale question validated for identifying impaired awareness of hypoglycaemia (IAH),[16] which is a risk factor for severe hypoglycaemia (SH).[17] Gold score 1-2 demonstrates normal awareness of hypoglycaemia, Gold score 3-4 identifies moderate awareness and Gold score >4 identifies IAH, according to the original authors' stratification.[15] The self-reported number of SH episodes in the preceding year was also

recorded, defined as "hypoglycaemia which you were unable to treat by yourself."

2.4 | Diabetes distress

The Diabetes Distress Scale 2 (DDS2) was used to screen for diabetes distress. This scale was developed by Fisher et al[18] and is the average score of 2 Likert scale questions, each scored 1 to 6:

> Please consider the degree to which each of the 2 items below may have distressed or bothered you in the last 4 weeks:
>
> 1. Feeling overwhelmed by the demands of living with diabetes
> 2. Feeling that I am often failing with my diabetes routine.

It has been shown to correlate with various markers of diabetes management in type 1[19] and type 2 diabetes.[10] As there is no strong evidence for particular cut-off points in type 1 diabetes for DDS2, this study stratified diabetes distress groups using tertiles of the DDS2 results found. Therefore, distress was classified as low with DDS2 score <2.5, moderate with a score 2.5-3.5 and high with a score ≥4.

2.5 | Analyses

Descriptive statistics were used to describe relationships between the 3 parameters being investigated. Pearson and Spearman rank correlations were used to evaluate the associations DDS2 scores held with HbA1c and Gold score, respectively. An ordinal regression analysis was also used to assess the strength of association between DDS2 scores and other variables. SPSS version 19 was used for these analyses.

3 | RESULTS

A total of 296 completed T1Cs were assessed, which represents >80% of the people seen in these clinics during the time period. Fifteen duplicates were excluded and 1 person was excluded as HbA1c was invalid due to recent blood transfusions. Therefore, data are presented here from 280 people. Sample characteristics are shown in Table 1.

Diabetes Distress Scale 2 scores were normally distributed, and mean DDS2 score was 3.2.

Mean HbA1c was 68 mmol/mol (8.4%), with 31.1% of people having moderately raised HbA1c and 42.5% with severely raised HbA1c.

21.8% of people had at least 1 SH episode within the past year with 13.6% having had 2 or more severe hypos. 63.2% had Gold score of 1-2 (normal awareness), 21.4% scored 3-4 (moderate awareness), and 15.4% had Gold score >4 (IAH).

Histograms for DDS2 score, HbA1c and Gold score in this sample are shown in Fig. S1.

HbA1c and DDS2 raw score correlations revealed that HbA1c was significantly associated with screening-detected diabetes distress (r = .319, P < .001). With increasing HbA1c, from on-target to moderately and severely raised, the proportion of people with low diabetes distress decreased overall (43%, 24% and 25%, respectively) and the proportion with high diabetes distress increased (23%, 26% and 48%, respectively). This is shown in Figure 2A.

TABLE 1 Sample characteristics

Gender (male)	42.5%
CSII pump	61.6%
Mean age (y) (SD)	43.3 (±15.6)
Mean diabetes duration (y) (SD)	24.6 (±12.9)
Mean BMI in kg/m^2 (SD)	29.4 (±4.3)
Presence of complications (%)	
No complications	37
Minimal changes[a]	32
Functional organ damage[b]	31

[a]eg, microalbuminuria/background retinopathy/neuropathy without complications.
[b]eg, CKD/visual loss/neuropathy with complications.

Diabetes Distress Scale 2 scores correlated overall with Gold score (r = .257, P < .001). The proportion of people screened as having high diabetes distress increased from 27% to 72% as Gold scores increased from 1 to 6, but those with complete loss of awareness (Gold score 7) had similar levels of diabetes distress as those with normal awareness (Figure 2B).

The proportion of people with recurrent SH increased from 6.2% in those with normal awareness (Gold score 1-2) to 20% in those with moderate awareness (Gold score 3-4) and almost 35% in those with IAH (Gold score > 4) (Figure 3).

The overlap of people who had severely raised HbA1c, high diabetes distress and/or IAH was assessed. 48% of those who had severely raised HbA1c also had high diabetes distress. 58% of those who had IAH also had high diabetes distress. 67% of those who had both severely raised HbA1c and IAH had high diabetes distress. 74% of those with high diabetes distress also had severely raised HbA1c or IAH.

Of those who had on-target HbA1c <58 mmol/mol (7.5%) and normal awareness, 32.6% reported moderate diabetes distress and 8.7% reported high diabetes distress. 4.1% of those with high diabetes distress had on-target HbA1c and normal awareness, compared to 32.5% of those with low diabetes distress.

On independent t testing, there was no significant difference in mean HbA1c (68 mmol/mol [8.4%] vs 70 mmol/mol [8.5%], P = .38), Gold score (2.63 vs 2.66, P = .87) or DDS2 scores (3.19 vs 3.20, P = .92) between those with and those without continuous subcutaneous insulin infusion (CSII) pumps, respectively.

On ordinal regression analysis of DDS2 scores involving HbA1c, Gold score, age, gender, duration of diabetes, BMI, severity of complications and use of CSII, only HbA1c (odds ratio 1.56), Gold score (odds ratio 1.48) and female gender (odds ratio 1.68) were significantly associated with increasing diabetes distress (Table 2).

4 | DISCUSSION

4.1 | Main findings

The main findings of our study are the association of diabetes distress with reduced awareness of hypoglycaemia and the intriguing finding
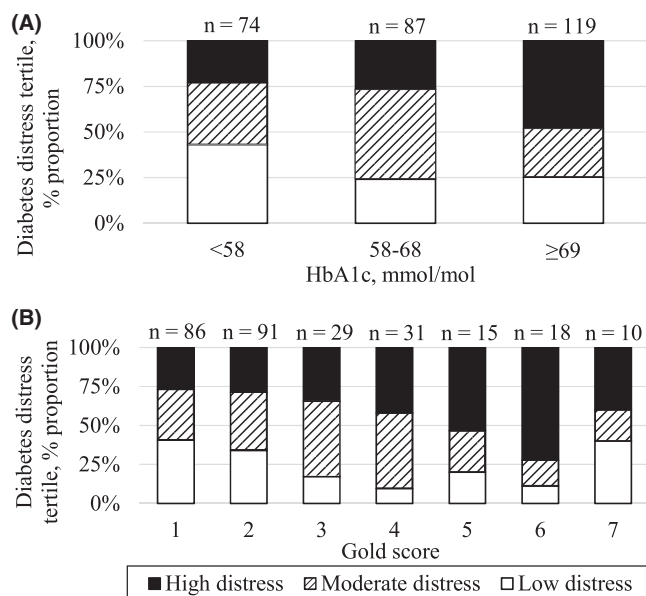
FIGURE 2 Relative proportions of diabetes distress tertiles, based on DDS2 scores, against HbA1c (A) and impairment of hypoglycaemia awareness measured by the Gold score (B)
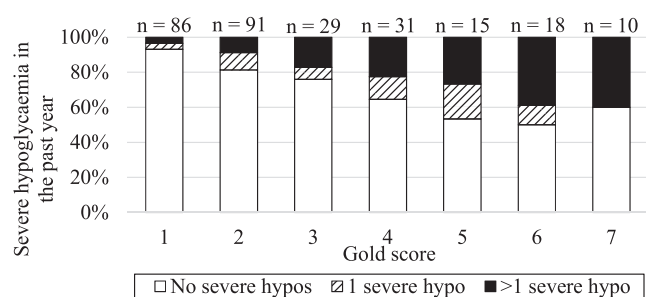

FIGURE 3 Occurrence of severe hypoglycaemia (SH) episodes in the preceding year, against patient-reported Gold score

that those with complete unawareness of hypoglycaemia (Gold score 7) have a relatively low level of diabetes distress. Our data confirm a previously documented relationship between raised diabetes distress and raised HbA1c, but we also find considerable overlap between those with raised HbA1c, IAH and diabetes distress.

Another novel finding was the linear relationship between decreasing hypoglycaemia awareness, as reported using the Gold score, and the proportion of people reporting >1 episode of SH (Figure 3). This is of practical importance, as >1 SH would preclude the person from driving as per current regulations in the UK and EU. It helps to validate the self-reported Gold score as a clinically relevant marker of risk related to hypoglycaemia in a type 1 population treated with modern therapies.

The interaction between those with the highest tertile of diabetes distress, severely raised HbA1c or IAH shows that while 48% of those with raised HbA1c have the highest degree of diabetes distress, those who also have problematic hypoglycaemia are even more likely to experience severe distress (67%), suggesting a link between high glucose variability and diabetes distress. In this study, we did not have continuous blood glucose data recorded to explore that further. It was

TABLE 2 Results of an ordinal regression analysis of the independent influence of multiple variables on diabetes distress as measured by the Diabetes Distress Scale 2 (DDS2)

Variable	Odds ratio	Significance	95% confidence limits
HbA1c (%)	1.56	$P < .001$	1.33-1.83
Gold score	1.48	$P < .001$	1.29-1.70
Age (y)	0.85	$P = .069$	0.97-1.001
Duration of diabetes (y)	1.00	$P = .954$	0.99-1.02
BMI (kg/m^2)	1.03	$P = .215$	0.98-1.09
Complication severity[a]	1.03	$P = .853$	0.76-1.39
CSII pump	0.91	$P = .703$	0.58-1.44
Female gender	1.68	$P = .02$	1.07-2.63

[a]Patients classed as no complications, minimal changes (eg, microalbuminuria/background retinopathy/neuropathy without complications) or functional organ damage (eg, CKD/visual loss/neuropathy with complications).

also interesting to find that a significant proportion of people who had on-target control with normal awareness did so at the expense of psychological distress. It may be speculated that for some people, an element of distress may be an adaptive strategy which assists their ability to self-manage; however, for many of these people, addressing diabetes distress is likely to benefit their psychological well-being.

4.2 | Comparison with wider literature

Optimal diabetes control is achieving as close to target HbA1c as possible without excessive or problematic hypoglycaemia. It may often be the balance between high and low blood glucose readings that leads to distress, and evaluating one without the other can be misleading. Many people may have raised HbA1c due to fear of hypoglycaemia or due to high glucose variability with swings between high and low glucose levels.

The DAWN2 study[20] previously published some data associating diabetes distress with hypoglycaemia in type 1 diabetes. Here, SH episodes were associated with diabetes distress, based on self-reported data. A paper by Hessler et al[21] recently demonstrated increased diabetes distress (measured by T1-DDS) is associated with increases in HbA1c over time, but longitudinal monitoring of the occurrence of hypoglycaemia episodes was not performed. Our finding showing that diabetes distress is correlated with decreased awareness is as expected, but the low levels of distress seen in those with complete unawareness is an interesting finding. We speculate that this may represent the lack of concern around hypoglycaemia identified by Rogers et al[22] in qualitative interviews with people with IAH, possibly mediated by reduced regional brain activation in response to hypoglycaemia.[23] These changes can be interpreted as a lack of anxiety, stress and food-seeking behaviour in response to hypoglycaemia, and a lack of deactivation of areas involved in pleasure and reward. The small sample size of 10 people with the most severe IAH (Gold score = 7)

should be noted however, as this may have contributed to this result and puts a limitation onto its reliability.

Using ordinal regression analysis, we found raised HbA1c, decreased hypoglycaemia awareness and female gender are independently associated with elevated screening-detected diabetes distress. However, other factors such as age, duration of diabetes and severity of complications were not (Table 2). Previous studies have reported that diabetes distress is higher in younger people, those with shorter duration of diabetes and those with higher complication severity;[7,19] however, these analyses did not correct for other variables such as HbA1c, and therefore, these factors may not be independently associated with distress.

4.3 | Strengths and limitations

Diabetes Distress Scale 2 was used to assess distress in these clinics rather than the longer PAID,[5] DDS17,[24] or T1-DDS[7] questionnaires. It has been shown to correlate well with the longer versions,[19] and its brevity assists its inclusion into regular clinical practice. However, the use of DDS2 carries some limitation as it is unable to measure different sources of distress like the DDS17 and T1-DDS.

Another factor important to be aware of is that the clinics included in this study were tertiary referral clinics with a greater-than-average proportion of people with either problematic hypoglycaemia or raised HbA1c. An audit of our whole type 1 diabetes clinic population found mean HbA1c was 61 mmol/mol (7.7%); however, this study sample from these tertiary clinics had a mean HbA1c of 68 mmol/mol (8.4%). Also, 26.4% of this sample achieved HbA1c <58 mmol/mol (7.5%), in comparison with 29.2% of the overall type 1 population in the National Diabetes Audit.[14] This should be taken into consideration when interpreting these results and may explain why the mean DDS2 score in our study was 3.17 compared to 2.3 in a study carried out by Strandberg,[25] who recruited patients from a general endocrinology clinic. Our study is also limited by the inability to provide data on the <20% of people who attended their clinic appointment but chose not to complete the T1C and were therefore excluded from the audit process. This may have allowed a degree of ascertainment bias.

In type 2 diabetes, a cut-off score of ≥3 on the DDS2 has been defined as a marker of significant distress that would interfere with self-management efficacy resulting in raised HbA1c.[10,18] However, in those populations there was a plateau between DDS2 scores 3 and 4 in type 2 diabetes.[10] In type 1 diabetes however, this does not appear to be the case. Joensen et al reported linear relationships between DDS17 scores and clinical outcomes including HbA1c in type 1 diabetes, and they noted that DDS2 scores correlated closely with DDS17 scores in their study.[19] Our study does not assess the overall pattern of the relationship between the DDS2 and clinical outcomes; however, it has demonstrated that the DDS2 can be used effectively in type 1 diabetes as a routine screener of diabetes distress that correlates with important clinical outcomes. Our study is also limited by investigating 1 point in time, and further research is required to assess the association between diabetes distress and the change in HbA1c and hypoglycaemia awareness over time.

4.4 | Recommendations

We believe that measuring diabetes distress in the consultation and placing it in the context of HbA1c or hypoglycaemia awareness is a key way to engage people in a discussion about what may be contributing to their diabetes-related psychological distress. Our care pathway, the T1C (Appendix S1),[13] suggests the use of the full DDS17 or T1-DDS when elevated scores on the DDS2 are identified to facilitate a fuller conversation about sources of distress for individual people. We believe this has helped to encourage the use of therapeutic strategies that incorporate attempts to reduce diabetes distress in people with type 1 diabetes. Diabetes distress does not often change over time without intervention,[26] but there is existing evidence in type 1[6] and type 2[27] diabetes that intervention-driven reduction in diabetes distress is associated with improvements in HbA1c. Fisher et al suggest that reduction of distress can be achieved by clinicians simply listening, understanding, acknowledging and normalizing diabetes distress,[28] and use of a screening tool such as the DDS2 in consultations may facilitate this. Structured education in self-management, such as DAFNE, has been shown to significantly reduce diabetes distress.[29]

4.5 | Summary

In conclusion, this study adds to the current knowledge around the relationship between suboptimal HbA1c and diabetes distress by considering the interaction of hypoglycaemia awareness. Moderate awareness, when the person gets some but not all the warnings of hypoglycaemia, is associated with increasing diabetes distress, but once all warning signs are lost, diabetes distress seems to be lower. We also showed that in a significant proportion of those with raised HbA1c, increased hypoglycaemia risk due to IAH may also contribute to their diabetes distress. We have also demonstrated evidence of an increase in the risk of severe hypos with increasing Gold score. Multivariate analysis identified associations between diabetes distress and HbA1c, reduced hypoglycaemia awareness and female gender independently from other factors. We conclude that the Diabetes Distress Scale 2 is a useful tool that can be used routinely to gauge diabetes distress in type 1 diabetes and indicates those in which this may be an important factor in clinical outcomes.

AUTHOR CONTRIBUTIONS

PJT and PC participated in the design of the study and undertook data collection. PJT, FE, LS, NHP, JS and PC were involved in the development and implementation of the T1C which facilitated data collection. PJT performed data analysis and wrote the manuscript. PC and JS

reviewed, edited and approved the manuscript. SA provided advisory support throughout the project. PJT is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

CONFLICT OF INTEREST

There are no relevant conflict of interests reported regarding the authors of this study.

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SUPPORTING INFORMATION

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