A new perspective on diabetes distress using the type 2 diabetes distress assessment system (T2-DDAS): Prevalence and change over time

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A B S T R A C T

Aims: To establish cut-points and thresholds for elevated diabetes distress; document change over time; and define minimal clinically important differences (MCID) using the new Type 2 Diabetes Distress Assessment System (T2-DDAS).

Methods: A national sample of adults with type 2 diabetes completed the T2-DDAS CORE distress scale and the 7 T2-DDAS SOURCE distress scales at baseline and 6-months. Scores were computed separately for insulin- and non-insulin users. Spline regression models defined CORE cut-points and SEM formulas defined MCID. A rational "threshold" approach defined elevated SOURCE scores.

Results: 471 participants (205 insulin, 266 non-insulin) completed both assessments. Analyses yielded ≥2.0 as the cut-point for both elevated CORE and elevated SOURCE. Prevalence of elevated CORE was 61.8 % (69.9 % over 6 months). Elevated SOURCE scores varied from 30.6 % (Stigma/Shame) to 76.4 % (Management); 87.5 % indicated at least 1 elevated SOURCE score. Most (77.1 %) reported multiple elevated SOURCES. 81.8 % with elevated CORE distress at baseline remained elevated at 6 months. MCID analyses yielded +/− 0.25 as significant change. Few differences between insulin- and non-insulin users occurred.

Conclusions: Elevated CORE distress is highly prevalent and persistent over time; most participants reported multiple SOURCES of distress. Findings highlight the need for comprehensive assessment of diabetes distress.

1. Introduction

Diabetes distress (DD) refers to the often unacknowledged emotional burden that is experienced when managing a chronic, challenging disease like diabetes over time. DD is highly prevalent and has been significantly linked with poor glycemic control, reduced medication taking, poorly managed diet, and low physical activity, pointing to its significant clinical impact. Although assessing and addressing DD has been included as part of general diabetes management guidelines, there remains a need for more contemporary, comprehensive and reliable DD assessment tools that yield actionable information for use in both research and clinical practice. Most of the major tools currently in use were developed decades ago and, unfortunately, they do not reflect recent changes in social standards, medications, and devices, or address the modern-day stresses of health care access and stigma.

In a recent report, we suggested that there has been a longstanding "mismatch" between how DD is defined and the way it is assessed. Though all of the definitions of DD share a singular focus on a core emotional experience that derives from struggling with diabetes over time, this widely accepted definition contrasts with how DD traditionally has been assessed. The assessment of the central emotional experience of DD often has been combined and conflated with a range of DD sources and contributors (e.g., frustration with one's self-care regimen, concerns about hypoglycemia, health access). Therefore, the way in which DD is commonly defined (as a singular, core emotional experience) and how it is commonly measured (as a sum across sources or contributors to distress) do not match.

To address this mismatch, we developed and validated the Type 2...
Diabetes Distress Assessment System (T2-DDAS) for adults with type 2 diabetes. The T2-DDAS includes a Core measure that precisely characterizes the intensity of the emotional DD experience and a set of Sources measures that identifies the key contributors or specific sources of distress. The seven Sources are: management demands, healthcare provider, hypoglycemia, long-term health, interpersonal issues, shame/stigma and healthcare access.

Our goals in this paper are to expand upon the earlier findings by examining the properties of T2-DDAS over time, documenting stability and change without intervention, establishing cut-points and thresholds to denote elevated DD, and defining minimal clinically important differences (MCID). Specifically, we address the following questions. First, what cut-points and thresholds for the Core and Source scales should be used to indicate elevated DD? Second, using these markers, what is the point-prevalence (at baseline) and cumulative prevalence of elevated Core and Source DD over 6 months? Third, how stable are Core and Source DD over time? Fourth, what is a reliable MCID for the Core scale and how much change occurs over time using this metric?

2. Subjects, materials and methods

2.1. Procedure

Details about the initial T2-DDAS development and validation have been presented previously. Briefly, participants were recruited from the Taking Control of Your Diabetes (TOCOYD) Research Registry, an online platform of individuals recruited primarily from TOCOYD’s 1-day diabetes education events in the United States. Participants were ≥ 21 years old, read English, and diagnosed with T2D ≥ 1 year. Qualitative interviews with 11 T2D adults and 10 clinicians informed the development of DD-related phrases that were then converted into survey items. A national sample of respondents with T2D was asked to complete a brief eligibility questionnaire, electronic consent, and a survey battery online, including the T2-DDAS. Six months after the initial (baseline) assessment, participants completed a similar online survey. Participants received a $40 electronic gift card for participation at each of the two timepoints. The research protocol was approved by Ethical and Independent Review Services.

2.2. Measures

Demographic measures included age, gender, race/ethnicity, education (years), living with a partner, and duration of diabetes. Diabetes status included self-reported HbA1C value within 6 months, body mass index (BMI; calculated from self-reported weight and height), current form of insulin delivery if taking insulin (pump vs. multiple daily injections), current use of continuous glucose monitoring (CGM) (yes/no), and number of diabetes complications (yes/no from a list of 8). The 29-item T2-DDAS consists of a Core scale (8 items, alpha = 0.94) and 7 Source scales (21 items: 3 items for each of the 7 Source scales) (alphas = 0.73 to 0.90). Items are scored on a 5-point Likert-type scale: 1 = “not a problem”, 2 = “a little problem”, 3 = “a moderate problem”, 4 = “a serious problem”, and 5 = “a very serious problem.”

2.3. Data analysis

Descriptive statistics included reviews of item and scale distributions for the sample as a whole and split by insulin users and non-insulin users. Analyses of variance (ANOVA) or chi-square analyses, as appropriate, were conducted to test for differences between dropouts and retained participants on baseline respondent characteristics. For the 6-month Management Source score, one item missing due to data entry error was imputed from the baseline item values using multiple imputation by chained equations (MICE) method. Two approaches were adopted to examine stability and change in the Core DD scale: determination of a cut-point to define elevated Core DD, and calculation of MCID. To determine the cut-point, a spline regression model was specified using nonlinear regression procedures in RStudio for Windows (RStudio Team, 2020). This analysis estimated where a knot occurred along the distribution of the Core DD score that reflected a change in its linear relationship with HbA1C. Then, two separate linear regression models were performed to test for the significance of linear slopes below and above that cut point. For Core DD MCID, we employed the SEM small effect formula [1*(SD * y/(1 – α))], and utilized the standard deviation and Cronbach’s alpha from the baseline scale to calculate the prevalence of participants who scored ≥ 1 MCID, ≥ 1 MCID, or remained within 1 MCID over 6 months.

Based on previous strategies, we utilized a non-statistical, “threshold approach” for defining elevated Source DD for several reasons. First, there is no clear rationale for identifying a relevant criterion variable (e.g., HbA1c) to define elevated Source DD. Source scales only allow the respondent to report the origins or contributors to their DD—a way for them to indicate which DD Sources are problematic and to what degree. Second, because each elevated Source score occurs within the context of the other Source scores, each score should not be considered individually, but only in the context of the number, level and configuration of all other Source scores. Third, this approach focuses on how the scales should be used: they were developed to facilitate a clinical conversation and to direct intervention. Placing each elevated Source score in the context of the others provides a setting for that conversation to begin. Given these considerations, we defined elevated Source scores as “thresholds,” rather than hard, statistically-defined markers. Consequently, we set the Source scale thresholds conservatively at ≥ 2.0, which indicates at least “a little problem,” reduces the risk of false negative findings, and provides commonality with the 2.0 cut-point used for the Core score.

All analyses were conducted for the overall sample as well as stratified by insulin use.

3. Results

3.1. Respondent characteristics

Of the 770 T2D Registry participants who were screened at baseline, 599 (77.8 %) met eligibility criteria (258 insulin users; 341 non-insulin users) and completed the baseline assessment. The 6-month assessment retained 471 of the original 599 respondents (78.6 %). Retained participants were significantly more likely to be non-Hispanic white, better educated, and CGM users, compared to those who did not complete the 6-month assessment (all p < .05). Analyses included data only from participants who completed both assessments. Mean age was 62.59 (SD = 10.32) years, and 65.1 % were female (Table 1). Most participants were non-Hispanic white (71.1 %) and had received some post-high school education (78.4 %). Some baseline characteristics significantly differed by insulin use: compared to non-insulin users, insulin users tended to have lower income, less oral medication use, longer diabetes duration, higher BMI, more complications, and higher HbA1C (all p < .05).

3.2. Cut-point analysis

Using HbA1C as the dependent variable, results of spline regression procedures, indicated a knot at a Core DD score of 1.75. A test for a quadratic relationship was nonsignificant. This cut-point, rounded to 2.00, was used to establish two participant groups: those with Core DD score < 2.00 and those with Core DD score ≥ 2.00. In piecewise regression models, significant linear relationships were found between the Core DD score and HbA1C values above the cut-point (R² = 0.076, B = 0.51 [SE = 0.09], t = 5.32, p < .001) but not below the cut-point (R² = 0.001, B = 0.17 [SE = 0.18], t = 0.93, p = .353) (Fig. 1). Additionally, there was a significant difference in mean HbA1C between those below and above the 2.0 Core DD cut-point (below cut-point = 6.78 (SD = 0.86); above
Participant characteristics at baseline (N = 471).

<table>
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<th>Insulin users M (SD) or % n = 205</th>
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<td>62.38 (9.44)</td>
<td>62.86 (11.37)</td>
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<td>Gender (% female)</td>
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<td>62.2 %</td>
<td>49.6 %</td>
<td>78.5 %</td>
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<td>30.65 (8.47)</td>
<td>35.16 (9.10)</td>
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<td>3.73 (2.32)</td>
<td>4.68 (2.18)</td>
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<td>HbA1C (%)</td>
<td>7.18 (1.19)</td>
<td>6.93 (1.01)</td>
<td>7.50 (1.32)</td>
</tr>
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</table>

* Significant between-group difference (p < .05).

Fig. 1. Linear relationship between baseline HbA1C and Core DD score below and above 2.00 cut-point (N = 471).

3.3. Prevalence of DD

Table 2 summarizes the baseline prevalence and 6-month cumulative prevalence of elevated Core DD (using the 2.0 cut-point) and Source DD scores (using the 2.0 threshold). Baseline prevalence of elevated Core DD was 61.8 % and 6-month cumulative prevalence was 69.9 %. The prevalence of elevated baseline Source DD across the 7 scales varied from 30.6 % (Stigma/Shame) to 76.4 % (Management). Prevalence rates at 6 months were similar to baseline for Core DD (69.9 %) and Source DD, with a small but significant change in prevalence only for Long-Term Health & Complications (76.0 % at baseline to 80.5 % at 6 months) (p < .01). Baseline prevalence rates were similar for insulin users and non-insulin users for both the Core and Source scales. Thus, the prevalence of both Core and Source scale DD were quite high at both baseline and 6 months, with relatively little change over time.

To explore these findings further, we calculated a score that reflected the number of DD Sources that reached the ≥2.0 threshold for each respondent (range = 0–7). The mean number of elevated DD Sources reported was 3.52 (SD = 2.30) at baseline and 3.38 (SD = 2.31) at 6-month follow-up; 87.5 % of all respondents indicated at least 1 elevated DD Source at baseline and 87.9 % reported similarly at 6-month follow-up, with no differences between insulin users and non-insulin users. Only 12.5 % reported no elevated DD Sources. The percentages reporting 1 to 7 DD Sources at baseline, respectively, were 10.4 %, 13.8 %, 15.5 %, 10.8 %, 13.2 %, 8.1 %, and 15.7 %, with no differences between insulin and non-insulin users. Of those reporting ≥1 elevated Source score, nearly half (45.4 %) reported between 1 and 3, and about half (54.6 %) reported 4 or more. The correlations between the number of elevated DD Sources with the Core DD score and with HbA1C at baseline were 0.71 (p < .001) and 0.25 (p < .001), respectively, suggesting that the larger the number of elevated DD Sources reported, the higher the Core emotional distress and the poorer the glycemic management.

3.4. Stability and change in DD across the cut-point over time

Table 2 shows changes in DD over time. Of those below the cut-point on the Core DD score at baseline, 78.9 % remained below it at 6-month follow-up. Similarly, of those who scored above the Core cut-point at baseline, 81.8 % remained above it at 6-month follow-up, with no differences between insulin and non-insulin users. Thus, both non-elevated and elevated Core DD scores remained relatively stable over time for the vast majority of participants.

A similar, relatively stable pattern emerged for each of the Source DD scales. Most people below the threshold at baseline continued below the threshold at 6 months (range = 75.9 % – 91.7 %; Table 2). Also, there was minimal shifting in the Source DD scales over time, with a minority of individuals below the threshold at baseline migrating above the threshold at 6 months (range = 8.3 % – 24.1 %), and a similar minority above the threshold at baseline moving below the threshold at 6 months (range = 7.2 % – 28.5 %). There was little change in the mean number of elevated Source DD scores over time as well (3.52 at baseline vs. 3.38 at 6 months). Thus, despite some variation in elevated distress across the Source DD scales over time, the Sources endorsed by an individual at baseline tended to be similar to those endorsed at 6-months, with the total number and intensity of endorsed elevated Source DD scales remaining about the same over time.

3.5. Minimal clinically important difference (MCID)

MCID refers to a fine-grained analysis of change anywhere along a score distribution – not just at the ≥2.0 cut-point. The mean baseline Core DD score was 2.41 (SD = 1.01; 8 items; alpha = 0.94) and the resulting small effect MCID value was 0.25. This indicates that an increase or decrease of 0.25 along any point along the Core DD scale range marks a significant MCID change. Over time, 19.3 % of the sample
displayed a significant MCID increase, 46.1 % showed no change, and 34.6 % displayed a significant MCID decrease in their Core DD score using this measure. The MCID score was similar for insulin (0.24) and non-insulin users (0.25), with no differences in the percent of each group displaying change over time. These analyses suggest that significant change in at least one MCID along the entire Core DD distribution over time occurred relatively frequently, even though relatively few individuals crossed over the cut-point.

4. Discussion

The first aim of this research was to establish meaningful demarcations for elevated DD for adults with T2D. Spline and piece-wise regression analyses using HbA1C as the criterion indicates a meaningful cut-point for the Core DD score at 2.0. This result is identical to the 2.0 cut-point found with the T1-DDS and DDS, suggesting that even “a little” distress is linked to poorer glycemic outcomes. Furthermore, it, along with the MCID findings, suggests that interventions to reduce DD could be beneficial across the entire DD range, not just for individuals who report elevated DD or HbA1C.

For Source DD, we adopted a “face-valid” approach and set the threshold at ≥2.00. This more rational, applied approach allows for easily identifying the content, number and pattern of distress source(s) and then to use a respondent’s highest Source score(s) as a starting point for a clinical conversation. Reviewing each elevated Source DD scale in the context of the others, rather than as a single indicator, enhances its meaningfulness and applicability in the clinical setting. For example, a single elevated Management Source DD score might be addressed quite differently than if that score occurred in tandem with an elevated Hypoglycemia Source score rather than an elevated Family/Friends Source score. Each would drive a very different kind of conversation and a very different approach to intervention. To enhance the use of the T12-DDAS system, a guide for application of the Core and Source scores in clinical care will be available in the near future.

Our second aim was to identify the baseline prevalence and 6-month cumulative prevalence of elevated Core and Source DD. Baseline prevalence of Core DD is 61.8 % and 6-month cumulative prevalence is 69.9 %, far higher than expected and far higher than reported for other scales for adults with T2D.2,13,21 We suggest that this higher rate is directly linked to how the Core DD scale is defined and constructed. Unlike previously developed measures, which often average items across many different aspects, sources and domains of DD, our Core DD scale reflects only the underlying, unalloyed emotional experience of DD, regardless of source or other content. Focusing exclusively on the essential emotional impact of DD reveals its ubiquity within the T2D community and points to the need for more active clinical attention.

The prevalence of elevated Source DD ranges from 30.6 % to 76.4 %, suggesting that there is considerable variability in reported Sources of DD within our sample, which is one reason that the 7 common Sources are included in the T2-DDAS. Furthermore, the sample displays a broad distribution in the number of elevated DD Sources reported – some respondents report few while others report many. The mean number at baseline is 3.52 (SD = 2.30) and 87.5 % report more than one. These findings suggest that DD for most individuals derives from multiple sources, underscoring the need for a patient-centered approach to intervention.

Regarding stability and change over time, a small minority of adults with T2D in this study crossed the Core cut-point over time either by increasing or decreasing their Core DD scores relative to their baseline assessment. Thus, Core DD by and large remains stable over time without intervention. Similarly, the mean number of elevated Source DD scales endorsed and the percentage of individuals endorsing at least one also remains relatively stable over time (mean at baseline = 3.52, mean at 6-month follow-up = 3.38; percentage at baseline = 87.5 %, percentage at 6-month follow-up = 87.9 %).

MCID provides a more fine-grained analysis of Core DD change over time. The MCID of ±0.25 is similar to previous DD scale statistics; for example, the MCID of the T1-DDS is +/- 0.19.20 About 54 % of the sample included in this study exhibited a change of at least one MCID (+/- 0.25), far higher than what was found in the cut-point analyses. A decrease in at least one MCID over time, however, does not mean that Core DD may no longer be of concern: a reduced Core DD score could still be above or below the cut-point. Hence, including both measures of change can be of value depending on the purpose and goals of assessment.

Overall, there are relatively few differences between insulin users and non-insulin users in all analyses. Where differences occur, they reflect the frequent finding that adults with T2D who use insulin tend to be older with higher HbA1C and with longer diabetes duration than non-insulin users. Thus, both the Core and Source DD scales seem applicable for both T2D populations.

This study has several strengths: it employed a relatively large, national sample and it covered a moderate time period. Several limitations should be kept in mind. First, the sample did not include a sufficient number of non-White adults with T2D to enable a more detailed analysis by race/ethnicity. Second, longer-term stability was not assessed. Thus, it is not clear how changes in life stress and diabetes-related events might influence the findings. Third, we were unable to analyze the numbers, patterns and sequences of endorsed Source DD scores and to link them with personal characteristics at the time of the follow-up
assessment. A larger and more diverse sample would be required to explore this topic comprehensively. Last, since parts of both the baseline and 6-month follow-up assessments occurred during the COVID-19 pandemic, the prevalence and configuration of some DD scores may have been altered relative to the pre-pandemic times.55

5. Conclusions

In conclusion, our findings suggest that elevated Core DD is highly prevalent and that it persists over time if no DD intervention is forthcoming. We also find that concerns about day-to-day diabetes management and complications are the most frequently endorsed DD Sources and that most adults with T2D report multiple sources of DD. Last, there is considerable MCID change across the entire Core DD range over time that is not reflected when looking only at Core DD cut-point. These findings again highlight the need for systematic, comprehensive and repeated assessment of DD in research and to drive patient/provider conversations in clinical care.

CRediT authorship contribution statement

WHP, LF and DH contributed to the conceptual design, supervised data collection and analysis, reviewed and discussed the study results, and wrote the manuscript. LS contributed to the data analytic design. UD and MPN contributed to the conceptual design, reviewed and discussed the study results, and reviewed/edited the manuscript.

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Relevant competing interests: LF has served as a consultant for Eli Lilly and Ascensia. WHP has served as a consultant for Eli Lilly, Novo Nordisk, Sanofi Diabetes Care, Dexcom, Abbott Diabetes Care, Boehringer Ingelheim and Insulet. DH has served a consultant for Eli Lilly. UD is an employee of Analysis Group, the company that received funding for this research from Eli Lilly and Company. MPN is an employee of Eli Lilly and Company.

References