# Occurrence and Predictors of Diabetes Distress in Adult Patients with Type 2 Diabetes from North India

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## **Abstract**

**Introduction:** There is limited data regarding the prevalence and predictors of diabetes distress in Indians with type 2 diabetes (T2D). The study aimed to determine the occurrence and predictors of diabetes distress in adult persons with T2D. **Methods:** In a cross-sectional study, persons with T2D on pharmacotherapy for at least 1 year were evaluated. They were administered three questionnaires namely- Diabetes Distress Scale-17, Patient Health Questionnaire-9, and Morisky Medication Adherence Scale-8. Clinically meaningful data regarding diabetes complications, anthropometry, and biochemical parameters were recorded. **Results:** Two hundred persons completed the study (mean age 57 ± 9.89 years, 59% males). Overall 140 (70%) of the patients had diabetes distress (mean DDS score ≥2). Clinically significant diabetes distress (CSDD) that requires a physician's attention (mean DDS score ≥3) was seen in 75 (37.50%) of the study participants. The mean HbA1c was significantly higher in participants with CSDD (10.24 ± 2.01 vs. 7.85 ± 1.14; P = <0.001). Both microvascular [retinopathy (28% vs. 5.60%;  $P \le 0.001$ ), neuropathy (28% vs. 0%;  $P \le 0.001$ ), nephropathy (32% vs. 6.40%;  $P \le 0.001$ )] and macrovascular (CAD 24% vs. 4.80%;  $P \le 0.001$ ) and (CVA 6.67% vs. 1.60%; P = 0.059) complications were significantly correlated with CSDD. Medication adherence was significantly lower in patients with CSDD (p=<0.001). An increased number of insulin injections increased BMI and HbA1c, and the presence of nephropathy were independent predictors of CSDD. **Conclusion:** Diabetes distress is a common co-morbid condition in persons with T2D. CSDD had a significant correlation with poor glycaemic control, higher BMI, presence of nephropathy, and higher number of insulin injections.

**Keywords:** Depression, diabetes, diabetes complications, diabetes distress, quality of life, type 2 diabetes

## INTRODUCTION

Type 2 diabetes (T2D) is a chronic condition characterized by long-term treatment, weight gain, diet changes, fear of insulin injections, hypoglycemia, and complications. Diabetes distress is an emotional response characterized by anxiety, discomfort, and dejection. It leads to poor glycaemic control, lower adherence to antihyperglycemic regimens, and deficit in self-care behavior, increasing the risk of long-term complications and poor quality of life. A review analyzing 46 studies in South Asian adults from low- and middle-income countries reported diabetes distress prevalence ranging widely from 18.0% to 76.2%. Among the psychosocial issues, depression is another common issue in T2D and it is very important to differentiate s distress and depression.

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In several studies, diabetes distress is more strongly and independently related to behavioral and clinical measures of T2D management than depression.<sup>[5,6]</sup>

It is important to address the psychological needs of the patients of T2D. However, the majority of guidelines focus only on the medical aspects. Despite high prevalence, diabetes distress is often underreported and untreated in persons living with T2D.

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There is limited data regarding the prevalence and causes of diabetes distress in Indian persons living with T2D highlighting unique social challenges of T2D management. The aim of the study was hence to determine the occurrence and predictors of diabetes distress and its association with glycaemic control, complications of T2D, and adherence to antihyperglycemic medications, in adult patients with T2D from North India.

## MATERIALS AND METHODS

A cross-sectional study was conducted in the out-patient department (OPD) of the Endocrinology and Medicine clinic of Maharaja Agrasen Hospital, Punjabi Bagh, New Delhi (400 bedded, teaching, super specialty hospital serving patients from both urban and rural areas). This study was approved by the Institutional Ethics Committee.

#### **Inclusion criteria**

Consenting consecutive adult persons with T2D attending Medicine and Endocrine OPD, aged ≥18 yrs and ≤75 yrs with diagnosis of at least one-year duration at the time of enrolment, on antidiabetic medication and/or on insulin therapy (those requiring medical intervention for the correction of glycemia) for at least 1 year and with absence of diagnosis of depression/anxiety before the diagnosis of T2D (not on any antidepressant or anxiolytics medication), were screened for the study.

#### **Exclusion criteria**

Excluded participants were individuals with diabetes other than T2D (type 1 diabetes, pancreatic diabetes, secondary diabetes, gestational diabetes), and persons with current psychiatric disorder (having diagnosed depression on anti-depressants or anxiolytics treatment or other psychiatric medications).

## **Method of data collection**

The study and its procedure were explained to all the eligible participants in detail and written informed consent was obtained who were willing to participate. The study was conducted between January 2019 and March 2019.

The diagnosis of T2D was done according to ADA (American Diabetes Association) criteria.[8] Clinical assessment and laboratory investigations of participants were done as per routine clinical practice as per the institutional protocol. Detailed information about demographic parameters, the current therapeutic regime, presence of micro or macrovascular complications were taken and data was used for analysis. In addition to self-reporting the illness, health-related information was gathered from the medical records of the participants. Anthropometric parameters were recorded following standard techniques and due precautions. The fasting blood samples were taken, after ensuring a minimum of 8 hours of overnight fasting for the estimation of plasma glucose and serum lipids. Plasma glucose estimation was done by the glucose oxidase method.<sup>[9]</sup> Glycated hemoglobin (HbA1c) was estimated by high-pressure liquid chromatography. [9] HbA1c ≥7% was taken as an indicator of poor glycemic control. Serum total cholesterol and triglycerides were estimated by standard enzymatic procedures and HDL cholesterol by direct assay method.<sup>[10]</sup> LDL-C was derived from Friewald's equation from the above lipid parameters.

Below mentioned 3 questionnaires were administered to all the study participants by the first author in the interview sheet fashion and responses given by participants were recorded.

- 1. Diabetes Distress Scale-17 (DDS-17)
- 2. Patient Health Questionnaire-9 (PHQ-9)
- 3. Morisky Medication Adherence Scale-8 (MMAS-8).

DDS-17 was used for the diagnosis of diabetes distress as they have shown to be the most popular, reliable, and sensitive to detect distress in T2D patients.[11] DDS includes 17 items measuring four dimensions: emotional burden (EB, 5 items), physician-related distress (PD, 4 items), regimen-related distress (RD, 5 items), and diabetes-related interpersonal distress (ID, 3 items). These items use a six-point Likert scale ranging from 1 (no distress) to 6 (high distress). A total score is calculated by adding the 17 items and dividing the sum by 17. Higher scores indicate greater distress. For all analyses related to diabetes distress, the mean score of DDS-17 was taken into consideration in the present study. A score of  $\leq 2$  is considered as no distress. A score of  $\leq 2$ is considered as having diabetes distress. However, a mean score of≥3 is considered clinically significant diabetes distress (CSDD) or high distress worthy of clinical attention. [12] All the correlations and other analyses related to diabetes distress have been done with CSDD in our study.

PHQ-9 questionnaire was used to assess the prevalence and severity of depression among adult patients with T2D. The PHQ-9 patient health questionnaire is the module of depression which scores each of the nine DSM-4 (Diagnostic and Statistical Manual of Mental Disorder) criteria as zero for not at all, to 3 for almost every day. PHQ-9 score is used as follows 0–4 no depression, 5–9 mild depression, 10–19 moderate depression, and 20–27 severe depression. [13]

The MMAS-8 is a self-reported measure of adherence to antihyperglycemic medications in chronic diseases like T2D. It has been proven reliable and valid, with eight items formulated to avoid a "yes-saying" bias. [14] The scale uses yes/no responses for questions 1–7 and a 5-point Likert scale for item 8. The scoring system rates each response as 1 and 0 for no responses, except for question 5 (did you take your diabetic medicine yesterday?) and item 8 (How many times do you have difficulty remembering to take all your medications?). The total score ranges from 0 to 8, and the scores are categorized into below adherence (<6), medium adherence (6–8), and high medication adherence (8). A copy of all these 3 scales has been provided as supplementary file 1.

#### Sample size calculation

The sample size was calculated using the formula, n = 4pq/L2, where n was the required sample size, P was the estimated prevalence of diabetes distress (0.36 as per the study by Perrin *et al.*, [15] q was 1 - p (0.64), and L was Loss % (Loss of information) =19.6%. The sample size came out to be 188, which was rounded to 200.

## Statistical analysis

Statistical Analysis was performed with the help of Epi Info (TM) 7.2.2.2. EPI INFO is a trademark of the Centers for Disease Control and Prevention (CDC).[16] Descriptive statistics were used to summarize continuous variables such as (PHQ-9 scores, and MMAS-8 scores), and the results were presented as means  $\pm$  standard deviations (SD). For categorical variables (retinopathy, nephropathy, neuropathy), proportions and frequencies were reported. For continuous variables (PHQ-9 and MMAS-8 scores), an independent samples t-test was conducted to compare the mean values between the two groups (CSDD and non-CSDD). Levene's test was used to assess the assumption of homogeneity of variances. The test of proportion was used to calculate the Standard Normal Deviate (Z) for comparing differences in proportions between groups, while associations between categorical variables were assessed using the Chi-square ( $\chi^2$ ) test.

Logistic regression analysis was used to examine the association between diabetes distress and the occurrence of complications (retinopathy, nephropathy, and hypoglycemia) while controlling for potential confounders. The strength of associations was expressed as Odds Ratios (ORs) with corresponding 95% confidence intervals (CIs). A *P* value of <0.05 was considered statistically significant for all analyses, indicating that the results were unlikely to be due to chance.

#### **Ethical aspect**

The study was performed by the principles of the Declaration of Helsinki and was approved by the institutional ethics committee of Maharaja Agrasen Hospital, Punjabi Bagh, Delhi, India (Ref. No.: MAH/ADMN/IEC/2018/March/1, dated 03/04/2019). Written informed consent was taken from all study participants.

### RESULTS

268 consecutive persons living with T2D between 18 and 75 years of age were screened. 42 participants were excluded because they did not match the inclusion criteria and 24 persons did not give consent for the study. 2 did not fill full proformas and hence were excluded from the analysis. In the final analysis, 200 persons were included.

The mean age (mean  $\pm$  SD) of the participants was 57  $\pm$  9.89 years. Out of the total participants, 118 (59%) were males. 91.51% of the participants were married with a spouse living. 60% had graduation as their minimum educational qualification and 60% were employed. 3.53% of the participants self-reported their current habit of smoking; while 13.57% reported current significant alcohol intake.

The duration of T2D was >10 years among 60.50% of the patients. Mean ( $\pm$ SD) fasting blood glucose (FBG), post-prandial blood glucose (PPBG), and HbA1c of study participants were 146.43  $\pm$  39.50 mg/dL, 216.52  $\pm$  56.07 mg/dL and 8.75  $\pm$  1.91 respectively. The diabetes-related microvascular

complications nephropathy, retinopathy, and neuropathy were seen in 16%, 14%, and 10.53% of participants, respectively; while a history of coronary artery disease (CAD) and cerebrovascular accident (CVA) was reported in 12% and 3.51% of participants respectively. Some form of diabetes education in the past from their physician or diabetes educator was reported to be received by 73.54 percent of the study participants.

## **Diabetes distress in study participants**

Overall, 140 (70%) of study participants had diabetes distress. CSDD (DDS-17 mean Score  $\geq$  3) was observed in 75 (37.50%) of the study participants. All the further correlations and other analyses related to diabetes distress have been done with CSDD in our study. Of the individual component of diabetes distress, 51% of the total participants had EB; 49.58% had RD; 16.01% had ID; and 14.53% had PD.

### Glycemic control and diabetes distress

The mean HbA1c was significantly higher in participants with CSDD as compared to those without CSDD ( $10.24 \pm 2.01$  vs.  $7.85 \pm 1.14$ ;  $P \le 0.001$ ) [Table 1]. Also, FBG ( $165.88 \pm 45.45$  vs.  $134.76 \pm 30.08$ ;  $P \le 0.001$ ) as well as PPBG ( $244.21 \pm 71.33$  vs.  $199.90 \pm 35.58$ ; P < 0.001) were significantly higher in participants with CSDD as compared to those without CSDD. CSDD had a significant correlation with the duration of diabetes ( $P \le 0.001$ ).

#### **Complications of diabetes and Diabetes distress**

All microvascular complications [retinopathy (28% vs. 5.60%;  $P \le 0.001$ ), nephropathy (32% vs. 6.40%;  $P \le 0.001$ ), and neuropathy (28% vs. 0%;  $P \le 0.001$ )] were significantly high in participants with CSDD [Table 2].

CAD was also significantly high in participants with CSDD (24% vs. 4.80%;  $P \le 0.001$ ). The history of CVA was also significantly higher in participants with CSDD (6.67% vs. 1.60%; P = 0.059).

## **Depression and diabetes distress**

Regarding depression overall 70 (35%) of the participants had depression, 53 (26.52%) of participants had mild depression, 14 (7%) had moderate and only 3 (1.52%) subjects had severe depression as assessed by PHQ-9. Overall, 22.57% of participants had both CSDD and depression; 12.52% had only depression but no CSDD and 15% had only CSDD but no depression. There was a significant correlation between depression severity and CSDD of the patients ( $p \le 0.001$ ). The mean PHQ-9 score was significantly higher in subjects with CSSD (6.04 ± 3.93 vs. 2.98 ± 2.89;  $P \le 0.001$ ).

#### Adherence to medication and diabetes distress

Regarding adherence to antihyperglycemic medications as assessed by MMAS-8 score, 34.51% of participants had low adherence, 29.54% had moderate and only 36% had high adherence to the treatment. Overall, low medication adherence was significantly higher in subjects with CSSD (P = < 0.001). MMAS-8 score was significantly lower in participants with

Table 1: Comparison of clinical and biochemical parameters in type-2 diabetes patients with or without clinically significant diabetes distress (CSDD)

Parameter	Participants with CSDD (n=75) Mean±SD or n (%)	Participants without CSDD $(n=125)$ Mean $\pm$ SD or $n$ $(%)$	P	
Age (in years)	58.15±10.79	56.30±9.27	0.201	
Males	32 (42.67%)	86 (68.80%)	0.000	
Married	60 (80.00%)	123 (98.4%)	< 0.001	
Duration of diabetes				
1-5 years	9 (12.00%)	34 (27.20%)	0.005	
6-10 years	10 (13.33%)	26 (20.80%)		
>10 years	56 (74.67%)	65 (52.00%)		
BMI	27.89±4.17	26.70±2.93	0.019	
SBP	$127.07 \pm 18.07$	126.16±16.00	0.711	
DBP	78.27±7.42	78.88±8.15	0.597	
FPG	165.88±45.45	$134.76\pm30.08$	< 0.001	
PPPG	244.21±71.33	199.90±35.58	< 0.001	
HbA1c	$10.24\pm2.01$	7.85±1.14	< 0.001	
Hemoglobin	12.01±1.70	12.35±1.51	0.143	
SGOT	40.20±20.07	37.14±15.60	0.230	
SGPT	44.92±24.30	$40.80 \pm 18.11$	0.173	
Serum creatinine	1.10±1.14	$0.82 \pm 0.11$	0.007	
eGFR	82.15±33.53	97.60±21.99	< 0.001	
Serum uric acid	7.28±3.65	5.46±2.02	< 0.001	
Serum total cholesterol	184.63±53.28	$178.98 \pm 43.27$	0.414	
Serum LDL-C	$126.29\pm40.00$	117.14±34.99	< 0.001	
Serum HDL-C	44.44±10.93	41.86±11.34	0.116	
Serum triglyceride	178.23±56.46	153.16±58.71	0.003	
Participants doing SMBG	64 (85.33%)	75 (60.00%)	< 0.001	
On Insulin therapy	43 (57.33%)	14 (11.20%)	< 0.001	
Number of classes of OHAs				
≤2	35 (46.67%)	53 (42.40%)	0.556	
>2	40 (53.33%)	72 (57.60%)		

\*BMI: body mass index; SBP-systolic blood pressure; BP-diastolic blood pressure; FBG-fasting plasma glucose; PPBG-postprandial plasma glucose; HbA1c-glycated haemoglobin; SGOT- Serum glutamic oxaloacetic transaminase; SGPT- Serum glutamic pyruvic transaminase; eGFR- estimated glomerular filtration rate; LDL-C- low-density lipoprotein cholesterol; HDL-C- high-density lipoprotein cholesterol; SMBG-self monitoring of blood glucose; OHAs-oral hypoglycaemic agents

CSSD as compared to those without CSSD ( $4.29 \pm 1.48$  vs.  $7.17 \pm 1.09$ ;  $P \le 0.001$ ). In our study, there was a significant relationship between insulin therapy and CSDD among study participants ( $p \le 0.001$ ). A significantly high number of participants were on insulin therapy among those who had CSDD as compared to those without CSDD (57.33% vs. 11.20%;  $P \le 0.001$ ). More participants with CSSD had episodes of clinical hypoglycemia in the last 1 year (33.33% vs. 12.00%;  $P \le 0.001$ ). The scores of the DDS-17, PHQ-9, and MMAS-8 for all the participants have been provided in Supplementary File 2.

#### **Predictors of diabetes distress**

Binary logistic regression was assessed with all the variables likely to influence diabetes distress (age, sex, smoking, alcohol use, education, duration of diabetes, number of oral diabetes medications used per day, number of hypoglycemia events per year, number of insulin injections per day, HbA1c, body mass index (BMI), presence of end-organ damage like CAD, CVA, neuropathy, nephropathy, retinopathy, number

of self-monitoring of blood glucose per week and diabetes education). Variables with P values less than 0.2 were included in the final model [Table 3]. Age (0.079), gender (0.093), number of insulin injections per day (<0.001), CAD (0.084), nephropathy (0.015), retinopathy (0.061), BMI (0.05), and HbA1c < 0.001) had P value <0.2 and were included in multivariate binary regression. Binary logistic regression analysis revealed an increase in the number of insulin injections per day, an increase in BMI and HbA1c, and the presence of nephropathy were significantly associated with increased occurrence of CSDD.

## DISCUSSION

Our study found a high prevalence of CSDD in North Indian adults with T2D, which was linked to poor glycemic control and higher diabetes complications. CSDD was associated with increased insulin therapy and lower medication adherence. Increased number of insulin injections, BMI, HbA1c, and nephropathy were independent predictors of CSDD.

Table 2: Comparison of end-organ damage, hypoglycemia, depression parameters, and medication adherence in type-2 diabetes patients with or without clinically significant diabetes distress (CSDD)

Parameter	Participants with CSDD $(n=75)$	Participants without CSDD ( $n=125$ )	Statistics		
	Mean $\pm$ SD or $n$ (%)	Mean $\pm$ SD or $n$ (%)	DF	Chi-sq	P
Retinopathy	21 (28.00%)	7 (5.60%)	1	19.5349	< 0.001
Nephropathy	24 (32.00%)	8 (6.40%)	1	22.8571	< 0.001
Neuropathy	21 (28.00%)	0 (0.00%)	1	NA	NA
CAD	18 (24.00%)	6 (4.80%)	1	16.3636	< 0.001
CVA	5 (6.67%)	2 (1.60%)	1	3.5628	0.059
Participants who had Episodes of hypoglycaemia in last 1 year	25 (33.33%)	15 (12.00%)	1	13.3333	0.003
Depression					
Absent	30 (40.00%)	100 (80.00%)	3	33.3485	< 0.001
Mild	35 (46.66%)	18 (14.40%)			
Moderate	8 (10.67%)	6 (4.80%)			
Severe	2 (2.67%)	1 (0.80%)			
PHQ-9 score	$6.04\pm3.93$	$2.98\pm2.89$			< 0.001
Medication adherence					
Low	61 (81.33%)	8 (6.40%)	2	119.374	< 0.001
Moderate	11 (14.67%)	48 (38.40%)			
High	3 (4.00%)	69 (55.20%)			
MMAS-8 score	4.29±1.48	7.17±1.09			< 0.001

<sup>\*</sup>DF: Degrees of Freedom, Chi-sq: Chi-square; CAD-coronary artery disease; CVA-cerebrovascular accident; PHQ-9-patient health questionnaire-9; MMAS-8-Morisky medication adherence scale-8

Table 3: Summary Statistics of Odds Ratios for Various Risk Factors based on clinically significant diabetes distress (CSDD) by using multivariable stepwise backward logistic regression analysis

Parameter	Odds	95% Confid	95% Confidence Limits		
	Ratio	Lower	Upper		
Age (Years)	0.945	0.887	1.007	0.079	
Gender	0.391	0.13	1.17	0.093	
Number of OHAs	1.709	0.612	4.769	0.306	
Number of Insulin Inj per day	23.000	5.591	94.623	< 0.001	
Number of hypoglycemia in last 1 year	0.332	0.074	1.49	0.15	
CAD	5.723	0.793	41.322	0.084	
CVA	1.052	0.116	9.522	0.964	
Nephropathy	7.194	1.467	35.266	0.015	
Retinopathy	4.067	0.936	17.675	0.061	
Number of SMBG per week	0.521	0.105	2.587	0.425	
Diabetes education	0.945	0.217	4.115	0.94	
BMI	1.146	1.000	1.314	0.05	
HbA1c	2.934	1.847	4.662	< 0.001	

<sup>\*</sup>BMI: body mass index; HbA1c-glycated haemoglobin; SMBG-self monitoring of blood glucose; OHAs-oral hypoglycaemic agents

In our study, the prevalence of CSDD was 37.5%, which is comparable to what is reported in previous studies (18-35%). [17,18] The EB (51%) and RD (49.5%), as depicted in previous literature also, were high in our study. [19] Chronic diseases like diabetes often cause apprehension, discomfort, and difficulty in adjusting to a new lifestyle and daily drug use. Like in our study, other studies have also shown poor glycemic control to be associated with diabetes distress. [3,7] Studies have clearly shown diabetes distress to be a better predictor of poor glycemic control than depression in persons with T2D. [6] Diabetes complications have been consistently

shown to predict diabetes distress in individuals with T2D in several previously published studies. [3,7,19] A study of 1862 T2D patients found that those with high distress had higher levels of HbA1c than those without distress (7.4% vs. 7.1%,  $P \le 0.001$ ) and higher odds of diabetic neuropathy (adjusted odds ratio, 1.63;  $P \le 0.002$ ). This trend was seen to persist throughout the 3-year follow-up and was associated with younger age, female gender, longer duration of diabetes, and higher carbohydrate intake (all P < 0.05). [20]

In our study, 35% of the patients had depression out of which the majority had only mild depression. Previous studies have shown that diabetes patients are often not clinically depressed but distressed about their condition. Diabetes distress is related to depression but is distinct. Studies have assessed both depression and diabetes distress simultaneously to study their relationship.<sup>[21,22]</sup> In our study, 22.5% of patients had both distress and depression, 12.5% of patients had only depression but no distress, and 15% of patients had only distress but no depression. A recently published cross-sectional, observational study in Saudi Arabia found that 48.5% of individuals experience diabetes distress, with physical symptoms, poor quality of life, depression, and anxiety being significant predictors.<sup>[23]</sup> Also, a good partner and family support are critical to better glycemic control, and general and psychological well-being of people living with T2D.<sup>[24]</sup>

Our study revealed that increased obesity (BMI) is a significant predictor of CSDD. Obesity is linked to end-organ damage, sleep apnea, and impaired sleep, poor quality of life, and diabetes distress. [25] Additionally, increased hypoglycemia and insulin injections contribute to CSDD. The severity of diabetes distress is influenced by the underlying disease state and phobia related to insulin pricks. Modern injectable combination therapies could help reduce needle prick counts, providing greater freedom and mobility, potentially reducing diabetes distress and improving quality of life. [26]

Previous studies have also shown lower medication adherence to be associated with diabetes distress. Effective diagnosis and management of comorbid diabetes can improve glycemic control, reduce complications, and enhance quality of life. [19,27] Diabetes distress has shown to be more prevalent in individuals aged  $\leq$ 45 years, those with >8% HbA1c, insulin therapy patients, and those with treatment interruptions. [28] Other studies have shown diabetes distress to be more common in younger, females, uneducated individuals, those with higher BMI, poor glycemic control, and those with longer diabetes duration. [25,29] Significant negative associations have been observed with dietary control, glucose management, and healthcare use (P < 0.01). [30]

A few limitations of this study need to be mentioned. First, the lack of evaluation of a control group is a limitation of this study. The inclusion of limited participants, single-center settings, and interview sheet-based questionnaires may introduce bias and limit generalizability. However, the study has enough power to demonstrate that the sample size was sufficient to detect significant associations, particularly between HbA1c and CSDD, as well as to identify other predictors. Multicentre studies involving a large number of subjects are further needed to validate our findings.

#### CONCLUSION

Our study demonstrated diabetes distress to be a common co-morbid health problem in adults with T2D from North India. CSDD was significantly correlated with a longer duration of diabetes, poor glycemic control, lower medication adherence, and higher diabetes complications. Increased number of insulin injections, BMI, HbA1c, and nephropathy predicted CSDD. Timely diagnosis and effective management of diabetes distress can improve glycemic control, and medication adherence, decrease complications, and improve quality of life in persons living with T2D.

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## **Authors contribution**

DK, DD and SC conceived the presented research idea. JG and SM were involved in research conduction and data acquisition. LG and RK performed the computations and manuscript writing. All authors contributed to the article and approved the submitted version.

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Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

#### **Data availability statement**

Datasets generated during the current study are available from the corresponding author upon reasonable request.

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## THE DIABETES DISTRESS SCREENING SCALE

**DIRECTIONS:** Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 2 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 2 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
2. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6

## **DDS**

**DIRECTIONS:** Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1. Feeling that diabetes is taking up too much of my mental and physical energy every day.	1	2	3	4	5	6
2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1	2	3	4	5	6
3. Feeling angry, scared, and/or depressed when I think about living with diabetes.	1	2	3	4	5	6
4. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1	2	3	4	5	6
5. Feeling that I am not testing my blood sugars frequently enough.	1	2	3	4	5	6
6. Feeling that I am often failing with my diabetes routine.	1	2	3	4	5	6
7. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1	2	3	4	5	6
8. Feeling that diabetes controls my life.	1	2	3	4	5	6

	Not a Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
9. Feeling that my doctor doesn't take my concerns seriously enough.	1	2	3	4	5	6
10. Not feeling confident in my day-to-day ability to manage diabetes.	1	2	3	4	5	6
11. Feeling that I will end up with serious long-term complications, no matter what I do.	1	2	3	4	5	, 6
12. Feeling that I am not sticking closely enough to a good meal plan.	1	2	3	4	5	6
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	1	2	3	4	5	6
14. Feeling overwhelmed by the demands of living with diabetes.	1	2	3	4	5	6
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1	2	3	4	5	6
16. Not feeling motivated to keep up my diabetes self management.	1	2	3	4	5	, 6
17. Feeling that friends or family don't give me the emotional support that I would like.	1	2	3	4	5	6

## **DDS17 SCORING SHEET**

## **INSTRUCTIONS FOR SCORING:**

The DDS17 yields a total diabetes distress scale score plus 4 sub scale scores, each addressing a different kind of distress. To score, simply sum the patient's responses to the appropriate items and divide by the number of items in that scale. The letter in the far right margin corresponds to that item's subscale as listed below. We consider a mean item score of 3 or higher (moderate distress) as a level of distress worthy of clinical attention. Place a check on the line to the far right if the mean item score is  $\geq 3$  to highlight an above-range value.

We also suggest reviewing the patient's responses across all items, regardless of mean item scores. It may be helpful to inquire further or to begin a conversation about any single item scored 3 or higher.

Total DDS Score:			
	a. Sum of 17 item scores.		
	b. Divide by:	<u>17</u>	
	c. Mean item score:		≥ 3
A. Emotional Burden	:		
	a. Sum of 5 items (1, 3, 8, 11, 14)		
	b. Divide by:	<u>5</u>	
	c. Mean item score:		≥ 3
B. Physician-related	Distress:		
•	a. Sum of 4 items (2, 4, 9, 15)		
	b. Divide by:	4	
	c. Mean item score:		≥ 3
C. Regimen-related I	Distress:		
	a. Sum of 5 items (5, 6, 10, 12, 16)		
	b. Divide by:	<u>5</u>	
	c. Mean item score:		≥ 3
D. Interpersonal Dist	ress:		
		3	
	c. Mean item score:		≥ 3
D. Interpersonal Dist	<ul><li>a. Sum of 3 items (7, 13, 17)</li><li>b. Divide by:</li></ul>		≥ 3

## Patient Health Questionnaire-9

Over the last two weeks, how often have you been bothered by any of the	e following problems?
Little interest or pleasure in doing things?	Not at all Several days More than half the days Nearly every day
Feeling down, depressed, or hopeless?	Not at all Several days More than half the days Nearly every day
Trouble falling or staying asleep, or sleeping too much?	Not at all Several days More than half the days Nearly every day
Feeling tired or having little energy?	Not at all Several days More than half the days Nearly every day
Poor appetite or overeating?	Not at all Several days More than half the days Nearly every day
Feeling bad about yourself - or that you are a failure or have let yourself or your family down?	Not at all Several days More than half the days Nearly every day
Trouble concentrating on things, such as reading the newspaper or watching television?	Not at all Several days More than half the days Nearly every day
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual?	Not at all Several days More than half the days Nearly every day
Thoughts that you would be better off dead, or of hurting yourself in some way?	Not at all Several days More than half the days Nearly every day
Total = /27	
Depression Severity: 0-4 none 5-9 mild 10-14 moderate 15-19 modera	tely severe 20-27 severe

It scores each of the nine DSM-IV criteria as "0" (not at all) to "3" (nearly every day).

## **Morisky Medication Adherence Scale-8 (MMAS-8-Items)**

Below is a list of statements. Please indicate the extent to which you agree or disagree with them by circling the number of the appropriate box. There are no right or wrong answers. Please give honest answers; otherwise the result would not be valid.

Regarding your diabetes treatment,

	Yes	No
1. Do you sometimes forget to take your medication?		
2. People sometimes miss taking their medication for reasons other than		
forgetting. Over the past two weeks, were there any days when you did not take		
your medication?		
3. Have you ever cut back or stopped taking your medication without telling		
your doctor because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring your		
medication?		
5. Did you take all your medications yesterday?		
6. When you feel like your symptoms are under control, do you sometimes stop		
taking your medication?		
7. Taking medication every day is a real inconvenience for some people. Do you		
ever feel hassled about sticking to your treatment plan?		
8. How often do you have difficulty remembering to take all your medication?		
o Never/Rarely		
Once in a while		
o Sometimes		
o Usually		
o All the time		

Scores of Patient Health Questionnaire-9 (PHQ-9), Morisky Medication Adherence Scale-8 (MMAS-8), and Diabetes Distress Scale-17 (DDS 17) for all the participants

S.No	PHQ-9 Score	MMAS-8	DDS 17 Score	S.No	PHQ-9 Score	MMAS-8	DDS 17 Score
1	9	4.25	3.06	51	3	5	3.12
2	11	7	2.6	52	1	6	1.88
3	7	7	2.18	53	1	6	2.12
4	0	6	1.59	54	2	4	3.06
5	5	2	3.12	55	7	5	3.12
6	4	8	1.94	56	3	7	1.59
7	4	7	1.71	57	6	5	3.24
8	2	8	1.53	58	2	8	2.71
9	9	5	3.12	59	3	7	3.06
10	5	8	1.88	60	1	8	1.24
11	12	4	3	61	2	8	1
12	3	8	1.35	62	1	8	1.53
13	3	3.25	3.06	63	1	8	1.88
14	5	8	2.35	64	9	5	3.29
15	5	8	2.41	65	0	8	1.59
16	10	7	2.71	66	2	7	2.65
17	11	2.75	3.35	67	1	6	2.35
18	2	8	2.65	68	5	4	4.12
19	4	6	2.65	69	12	7	3.71
20	1	4	2.65	70	9	2	3
21	9	6	3.18	71	1	4	2.41
22	8	3	3.18	72	0	8	1.29
23	8	8	2.24	73	0	8	1.53
24	19	5	3.24	74	3	5	3.47
25	4	8	1.24	75	2	6	2.18
26	2	7	1.82	76	2	3	3.12
27	8	5	3.24	77	1	8	2.71
28	2	7	2.24	78	1	8	1.29
29	6	6	2.88	79	3	4	3.12
30	15	8	2.18	80	2	7	2.53
31	3	4	3.12	81	1	2	3.12
32	8	8	1.41	82	0	5	1.71
33	7	2	3.88	83	1	8	2.41
34	3	3.75	3.82	84	2	8	1.53
35	2	7	2.18	85	4	7	2.47
36	8	2.25	4.18	86	0	7	3.88
37	2	6	2.59	87	4	8	2.06
38	8	3	3.12	88	8	8	2.18
39	2	6	2.12	89	3	4	3.12
40	4	8	2.06	90	2	7	1.53
41	5	7	2.71	91	5	5	3.06
42	3	3	3.47	92	8	6	2.12
43	8	4.75	3.35	93	0	8	1.29
44	0	8	1.71	94	3	8	2.47
45	4	8	2.24	95	20	2	3.35
46	2	8	1.94	96	9	3.75	3.12
47	4	5	3.47	97	0	3	1.94
48	3	7	1.88	98	3	7	2.71
49	2	6	2.35	99	6	8	3.06
50	3	8	1.18	100	5	4	3.47

S.No	PHQ-9 Score	MMAS-8	DDS 17 Score	S.No	PHQ-9 Score	MMAS-8	DDS 17 Score
101	0	8	1.12	151	2	8	1.53
101	1	8	2.06	152	4	7	2.47
102	3	6	2.24	153	0	7	
	5	5			4		3.88
104			3.12	154		8	2.06
105	2	7	2.47	155	8	8	2.18
106	6	4	3.82	156	3	4	3.12
107	1	8	1.88	157	2	7	1.53
108	3	7	3.12	158	5	5	3.06
109	10	8	1.71	159	8	6	2.12
110	1	8	1.59	160	1	6	2.12
111	5	6	3.06	161	2	4	3.06
112	1	8	1.88	162	7	5	3.12
113	3	8	1.76	163	3	7	1.59
114	2	5	2.18	164	6	5	3.24
115	3	4	3.29	165	2	8	2.71
116	2	6	1.88	166	3	7	3.06
117	2	8	1.94	167	1	8	1.24
118	9	7	3.35	168	2	8	1
119	4	4	3.12	169	1	8	1.53
120	3	7	2.18	170	1	8	1.88
121	11	6	3.12	171	9	5	3.29
122	3	8	2	172	0	8	1.59
123	2	8	1.47	173	2	7	2.65
124	3	3	3.12	174	1	6	2.35
125	4	2	3	175	5	4	4.12
126	1	6	1.65	176	12	7	3.71
127	0	8	1.82	177	9	2	3
128	3	6	2	178	1	4	2.41
129	9	4	3.82	179	0	8	1.29
130	11	6	2.88	180	0	8	1.53
131	5	8	1.88	181	3	5	3.47
132	12	4	3	182	2	6	2.18
133	3	8	1.35	183	2	3	3.12
134	3	3.25	3.06	184	1	8	2.71
135	5	8	2.35	185	1	8	1.29
136	5	8	2.41	186	3	4	3.12
137	10	7	2.71	187	2	7	2.53
138	11	2.75	3.35	188	1	2	3.12
139	3	3	3.12	189	0	5	1.71
140	4	2	3	190	1	8	2.41
141	1	6	1.65	191	4	8	2.06
142	0	8	1.82	192	8	8	2.18
143	3	6	2	193	3	4	3.12
144	9	4	3.82	194	2	7	1.53
145	11	6	2.88	195	5	5	3.06
146	5	8	1.88	196	8	6	2.12
147	12	4	3	197	1	6	2.12
148	3	8	1.35	198	2	4	3.06
149	0	5	1.71	199	7	5	3.12
150	1	8	2.41	200	3	7	1.59