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Prevalence of diabetes distress among type 2 diabetes mellitus patients in India: a systematic review and metaanalysis

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ABSTRACT

Introduction: The burden of type 2 diabetes mellitus (T2DM) in India is on the rise, with projections indicating a staggering 134 million cases by 2045. Managing T2DM demands strict adherence, often resulting in mental strain and burnout. Diabetes distress (DD), a unique psychological burden, significantly affects motivation and self-care, contributing to increased morbidity and mortality.

Material and Methods: This study was conducted by doing a comprehensive literature search using PubMed (MEDLINE) and EMBASE databases for studies published from their inception to 14th August 2023 by using relevant keywords. The protocol is registered in PROSPERO and adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. Selected articles were meticulously screened based on predetermined inclusion and exclusion criteria. Joanna Briggs Institute (JBI) Critical Appraisal scale for cross-sectional study was used for assessing the study quality. Data analysis was done by using Jamovi 2.3.24 software

Results: Following the systematic search and screening process, 10 cross-sectional studies were identified, comprising a total of 2,107 Type 2 Diabetes Mellitus patients. All studies employed the Diabetes Distress Scale-17 (DDS-17) for measurement. The prevalence of DD varied, ranging from 8.45% to 61.48%. The pooled prevalence of DD in T2DM patients in India was estimated at 33% (95% CI: 21%–45%) with substantial heterogeneity observed ($l^2 = 97.33\%$, P < 0.001). While an asymmetric funnel plot suggested potential publication bias, sensitivity analysis reinforced the robustness of our findings.

Conclusion: Policymakers, clinicians, and researchers can leverage these insights to prioritize the psychological well-being of T2DM patients, ultimately improving their overall health outcomes. This study aligns with the Sustainable Development Goals (SDGs) and India's national health policy, emphasizing the urgency of screening and treating diabetes-related distress by 2025.

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Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both (Holt et al., 2017). The global prevalence of DM has risen dramatically from 4.7% in 1980 to 8.5% in 2014, with the proportion of type 2 diabetes mellitus (T2DM) accounting for around 90% of all diabetes cases (Ogurtsova et al., 2017).

India has witnessed exponential growth in the prevalence of T2DM over the past few decades, from 5.0% in 1980 to 7.3% in 2000, and further escalating to 8.8% in 2014 (Anjana et al., 2017). The International Diabetes Federation (IDF) estimates the number of people with diabetes in India to be 77 million in 2019, projected to rise to 134 million by 2045 (Barman et al., 2023; Saeedi et al., 2019).

This rising burden imposes a substantial economic impact on patients, healthcare systems, and society. A systematic review done in 2020 included 32 studies that reported the mean direct cost of diabetes mellitus in India. It reported an expense ranging from ₹3949 per annum to ₹45,792 per annum (Oberoi & Kansra, 2020). A study done by Kansra and Oberoi (2023) in Punjab found the expenditure on diabetes care in 2021 is ₹34,100 for the median annual direct cost and ₹4200 for the indirect cost (Kansra & Oberoi, 2023).

DM patients have twice the risk of mortality as compared to Non-DM patients, this is due to complications caused by DM: Microvascular Complications (retinopathy, nephropathy, and neuropathy) and Macrovascular Complications (cardiovascular disease, cerebrovascular disease, and stroke) (Mokhtari et al., 2019). Also, the increase in mortality and complications in T2DM after COVID-19 has further aggravated stress/ fear among T2DM patients (Khunti et al., 2022).

Worldwide 28% of T2DM patients have different severity of depression and 14.5% of T2DM patients have major depressive disorder (Khaledi et al., 2019; Wang et al., 2019). While in developing countries, depression in T2DM patients varies from 34 to 54% (Hussain et al., 2018; Pashaki et al., 2019; Roy et al., 2012).

T2DM requires a lot of restraint and discipline which can lead to mental fatigue, stress, or burnout (Natesan et al., 2016; Thakur, 2015). It causes a lot of stress on the patients as well as the caregivers because of its restrictive diet, lifestyle/physical activity, complications arising due to T2DM, and financial constraints/burden because of medicines/ treatment (Neilson et al., 2021).

Diabetes distress (DD) refers to psychological distress specific to people living with diabetes. It can encompass a wide range of emotions such as feeling overwhelmed by the demands of self-management required through adherence to diet, exercise, and medications. It encompasses feeling overwhelmed by the daily self-management demands, fear of complications, hypoglycemia, interpersonal difficulties and access to care (Adriaanse et al., 2008; Fisher et al., 2014; Gonzalez et al., 2016; Pouwer, 2009).

High levels of DD have been associated with suboptimal glycemic control, self-care deficits, impaired quality of life, increased healthcare costs and risk of complications (Fisher et al., 2007; Gonzalez et al., 2008; 2016; Perrin et al., 2017).

Rates of DD have been reported to range between 18 and 35% globally (Fisher et al., 2007). In Malaysia, the prevalence of DD was found to be 37.4% using the Problem Areas

in Diabetes (PAID) scale (Tan et al., 2018). Data on the prevalence of DD among T2DM patients in India is limited. A study from Chennai reported the prevalence of DD to be 61.3% (Natesan et al., 2016). There remains a need to comprehensively evaluate the burden of DD across India to inform policies and interventions aimed at addressing the psychosocial aspects of diabetes care.

This systematic review and meta-analysis aim to determine the pooled prevalence of DD among T2DM patients across India. The findings will highlight the significance of DD as a critical but under-recognized issue, providing evidence to advocate for routine screening and management integrated into standard diabetes care.

Material and methods

Current Systematic Review and Meta-analysis was planned to estimate the burden/ prevalence of diabetes distress (DD) among type 2 diabetes mellitus (T2DM) patients in India.

The study protocol is registered in PROSPERO (Registration id: CRD 42023445374). We have used the checklist provided in Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) for protocol development (Page et al., 2021).

Search strategy and selection criteria

We have searched PubMed (MEDLINE) and EMBASE for all the relevant articles that were published by using the keywords '(Diabetes Distress) AND (India OR Indian) AND (Proportion OR Frequency OR Prevalence OR Incidence OR Incident OR Burden)'. The time frame for the literature search was explicitly specified, encompassing articles published since 2010 up until 14 August 2023. This comprehensive approach ensured the inclusion of relevant literature on our research topic within the accessible resources. Free-full text articles available in the English language were shortlisted for our study.

Study selection

Articles found in both databases were downloaded and imported into Zotero software. They were merged together, and duplicate entries were filtered by one author (AS). Shortlisted articles were screened by going through their title and abstract following the inclusion and exclusion criteria of the study by two authors (RS and AP).

Study inclusion criteria: 1. Studies that are observational study, cross-sectional study, multicentric study, or comparative study; 2. Studies reporting the diabetes distress in Adult (> 18 years) Type 2 Diabetes Mellitus Patients; 3. Studies published in English.

Study exclusion criteria: 1. Studies that are Interventional Study, Meta-Analysis, Clinical Study, Case Series/Report, Laboratory Studies on Animals; 2. Studies reporting the diabetes distress in children or any other type of diabetes; 3. Studies measuring other kinds of depression or mental disorders other than diabetes distress.

Articles were assessed and selected for full-text screening based on their relevance to the research question 'Prevalence of Diabetes Distress among Type 2 Diabetes Mellitus

patients in India'. If there was any confusion about any study, it was selected for full-text screening.

Authors RS and AP did the full-text review. Articles that had clear information about the outcomes were selected for data extraction and analysis. Those studies which didn't have clear or complete information like methodology, outcomes, and results were excluded. If there was any disagreement about any study, it was resolved by consulting MHR and AS.

Data from the shortlisted articles were extracted into data summary tables in the following format which included: author, publication year, study design, number of T2DM patients, mean age of the study participants, male and female participants, DD scale used, and DD present in T2DM patients. The above-mentioned data was entered in Jamovi 2.3.24 software for analysis. If any discrepancy in data extraction was found, it was discussed amongst the other authors and was resolved. (MHR and AS).

Study quality assessment (risk of bias assessment)

Joanna Briggs Institute (JBI) Critical Appraisal scale for cross-sectional study was used to assess the quality of the study of the shortlisted article independently by the two authors (AS and MHR); any disagreement or discrepancy was settled by discussing with other authors (RS and AP).

The checklist was used to assess the quality of the study methodology and to look for the possibility of any bias in the study such as in its design, methodology, and analysis. No modifications were done in the checklist for the assessment of the risk of bias (Santos et al., 2018).

Statistical analysis

Statistical analyses were done by using Jamovi 2.3.24 software. Pooled prevalence of DD in T2DM patients was calculated by using Random-effect model with a 95% confidence interval (CI) and presented in Forest plot. The statistical heterogeneity among studies was assessed by I^2 statistic. Funnel plot was used to assess the dissymmetry. To assess the reliability of our study sensitivity analysis was performed by excluding studies one by one.

Ethics statement

Ethical approval is not applicable as our study does not involve human participants and the data used in the study was from individually published studies that were ethically approved.

Results

Study selection

After using the keywords defined in our study, applying filter for free full-text and English language we found 133 and 71 articles in PUBMED and EMBASE respectively. All the search results were imported into Zotero software by one author (AS) to remove

duplicate entries. After removing 15 duplicates, we had 142 articles identified for our study. Two authors (RS and AP) screened the articles by title and abstract screening based on the inclusion and exclusion criteria of our study. Out of 142 articles, 49 articles were shortlisted for full-text screening. Shortlisted articles were screened by going through their title and abstracts following the inclusion and exclusion criteria of the study by two authors (RS and AP) as mentioned in the methodology. Articles were assessed and selected for full-text screening based on their relevance to the research question. If there was any confusion about any study, it was selected for full-text screening. 36 records were excluded because of the reasons such as the study is not measuring DD, not done on T2DM, data not clear. After full-text screening 13 articles were identified for data extraction, from which only 10 articles' data was obtained (Gahlan et al., 2018; Gupta et al., 2022; Natesan et al., 2016; Panda et al., 2022; Patra et al., 2021; Ratnesh et al., 2020; Roy et al., 2018; Sasi et al., 2013; Sumana et al., 2021; Vidya et al., 2021). 3 articles were excluded from data analysis as they reported DD and other kinds of depression together. Figure 1 explains the process of screening and selection of articles in our study.

Study characteristics

All the selected articles in our study are of cross-sectional design and have used the Diabetes Distress Scale – 17 (DDS-17) to measure DD. A total of 2,107 T2DM patients were included in all the studies. The smallest and largest sample size was 122 and 546, respectively. The prevalence of DD in T2DM patients varied from 8.45% to 61.48% in the selected articles. Other study characteristics of the study are presented in Table 1. The pooled prevalence of DD in T2DM patients in India was 33% (21% – 45%) which is shown in Figure 2 with statistically significant heterogeneity between studies ($I^2 = 97.33\%$, P < 0.001). Analysis of proportions by using the Freeman-Tukey Double Arcsine Transform is done in the included studies (Figure 3). Asymmetric funnel plot indicated publication bias might exist.

Sensitivity analysis was done to find any outlier/article that is influencing the results of our study. Sensitivity analysis was performed by excluding studies one by one and the results are shown in Table 2. The results of sensitivity analysis tell us that none of studies alone had an impact on the overall prevalence of DD reported in our study.

Study quality assessment

The quality of the study (risk of bias) was assessed by using 8-item JBI critical appraisal checklist for cross-sectional studies of all the studies and is summarized in Table 3. All the studies have clearly defined their objectives, study setting, study subjects, inclusion criteria, measurement method, statistical analysis and outcomes.

Discussion

This systematic review and meta-analysis provide key information on the burden of DD among T2DM patients across India. The pooled prevalence of 33% indicates that DD is highly prevalent and suggests that a significant proportion of individuals with T2DM in

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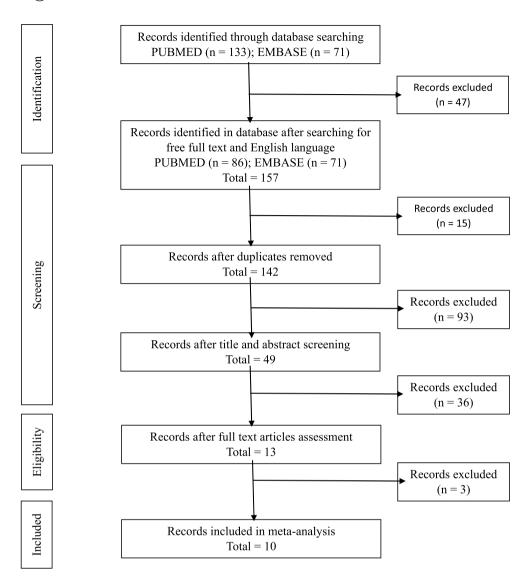


Figure 1. PRISMA Flowchart.

India experience diabetes-related psychological distress yet remains an under-recognized issue in the context of diabetes care. Our study findings is consistent with previous studies conducted in similar settings and reinforces the consistent presence of DD as a critical aspect of T2DM management in India (Gahlan et al., 2018; Gupta et al., 2022; Natesan et al., 2016; Panda et al., 2022; Patra et al., 2021; Roy et al., 2018; Sumana et al., 2021).

This highlights the need to integrate routine screening and management of DD within the Indian healthcare system to improve overall diabetes outcomes. The Indian Council of Medical Research's INDIAB study reported poor control of modifiable risk factors, with only 25.3% of T2DM patients achieving recommended HbA1c targets (Unnikrishnan et al., 2014).

								DD	DD
	Type of	Sample	Mean				DD	Burden	Prevalence
First author	study	Size (N)	Age	SD	Male	Female	Scale	(n)	(%)
Sasi ST, 2013	Cross-sectional	546	55.44	NR	303	243	DDS-17	219	40.11
Natesan S, 2016	Cross-sectional	122	NR	NR	85	37	DDS-17	75	61.48
Gahlan D, 2018	Cross-sectional	189	54.26	11.38	44	145	DDS-17	34	17.99
Roy M, 2018	Cross-sectional	250	47.8	8.34	138	112	DDS-17	62	24.80
Ratnesh et al., 2020	Cross-sectional	250	54.67	10.1	165	85	DDS-17	49	19.60
Sumana K, 2021	Cross-sectional	142	53.94	12.25	79	63	DDS-17	12	8.45
Vidya K, 2021	Cross-sectional	140	NR	NR	82	58	DDS-17	82	58.57
Patra S, 2021	Cross-sectional	200	51.34	NR	127	63	DDS-17	83	41.50
Gupta S, 2022	Cross-sectional	133	48.2	7.7	105	28	DDS-17	68	51.13
Panda BK, 2022	Cross-sectional	135	NR	NR	85	50	DDS-17	17	12.59

Table 1. Characteristics of included studies in the meta-analyses to determine the prevalence of diabetes distress in people with T2DM.

Note: NR - Not Reported.

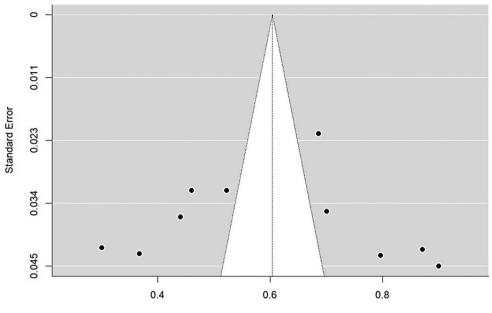
1 st Author, Publication year	Prevalence of DD	Weight Prevalence (95% CI)			
Sasi ST, 2013	H a ll	10.17% 0.40 [0.36, 0.44]			
Natesan S, 2016	⊢ ⊷⊣	9.77% 0.61 [0.53, 0.70]			
Gahlan D, 2018	HEH	10.08% 0.18 [0.13, 0.23]			
Roy M, 2018	H∎H	10.09% 0.25 [0.19, 0.30]			
Ratnesh, 2020	⊨ ≣ ⊣	10.12% 0.20 [0.15, 0.25]			
Sumana K, 2021	H B H	10.14% 0.08 [0.04, 0.13]			
Vidya K, 2021		9.82% 0.59 [0.50, 0.67]			
Patra S, 2021	⊢ ∎-1	9.96% 0.41 [0.35, 0.48]			
Gupta S, 2022	_ 	9.79% 0.51 [0.43, 0.60]			
Panda BK, 2022	⊦∎⊣	10.07% 0.13 [0.07, 0.18]			
RE Model		100.00% 0.33 [0.21, 0.45]			
	i , , , , , , , , , , , , , , , , , , ,				
Heterogenicity; I2 = 97.7%; p <0.001	0 0.2 0.4 0.6 0.8				

Figure 2. Forest-plot reporting Prevalence of DD in T2DM.

Also, it is comparable to prevalence rates reported in other developing countries like Pakistan (18–54%) and Iran (30–65%) using the DDS-17 scale (Shayeghian et al., 2015). The wide range reflects differences in social support systems, access to care and other psychosocial factors influencing DD.

Addressing DD through counseling, peer support and cognitive behavioral therapy could significantly enhance patients' self-efficacy and ability to manage lifestyle changes central to diabetes control (Mash et al., 2014; Winkley et al., 2020).

However, there remain barriers to translating these recommendations into practice within the Indian healthcare settings. A qualitative study found that physicians experience difficulties in detecting and managing psychosocial problems due to limited consultation time, lack of dedicated counselors and sparse validated screening tools (Gulabani et al., 2008). To enable assessment of DD, linguistically validated and culturally adapted



Double Arcsine Transformed Proportion

Figure 3. Funnel plot: Double Arcsine Transform proportion for the heterogeneity of the study.

Excluding	Pooled Prevalence	/ ²	
Sasi ST, 2013	0.33 (0.19–0.46)	97.71%	
Natesan S, 2016	0.30 (0.19-0.42)	97.42%	
Gahlan D, 2018	0.35 (0.22-0.48)	97.76%	
Roy M, 2018	0.34 (0.21-0.48)	97.87%	
Ratnesh et al., 2020	0.35 (0.22-0.48)	97.73%	
Sumana K, 2021	0.36 (0.24-0.48)	97.25%	
Vidya K, 2021	0.31 (0.19-0.43)	97.56%	
Patra S, 2021	0.33 (0.19-0.46)	97.98%	
Gupta S, 2022	0.31 (0.19-0.44)	97.85%	
Panda BK, 2022	0.36 (0.23-0.48)	97.6%	
Total	0.33 (0.21–0.45)	97.7%	

Table 2. Sensitivity Analysis for finding the outlier in the studies.

screening tools like the Type 2 Diabetes Distress Assessment Scale (T2-DDAS) are recommended (Fischer et al., 2022). Integrating community health workers and telemedicine can help overcome shortages in specialized providers, thereby improving access to psychosocial care (Mash et al., 2014).

At the policy level, India's National Programme for Prevention and Control of Diabetes, Cardiovascular Disease and Stroke (NPCDCS) advocates establishing diabetes clinics at primary care facilities and strengthening capacity building of healthcare professionals (Ministry of Health and Family Welfare, Government of India, 2023). Our findings reinforce the need to incorporate routine DD screening and management into the program's recommended protocols and care pathways. Overall, concerted efforts by policymakers, professional bodies and diabetes advocacy groups are required to recognize and address the high burden of DD among T2DM patients in India.

				Were				
	Were the	Were the	Was the	objective,			Were the	
	criteria for	study	exposure	standard		Were	outcomes	
	inclusion	subjects	measured	criteria		strategies to	measured	Was
	in the	and the	in a valid	used for	Were	deal with	in a valid	appropriate
	sample	setting	and	measurement	confounding	confounding	and	statistical
	clearly	described	reliable	of the	factors	factors	reliable	analysis
Studies	defined?	in detail?	way?	condition?	identified?	stated?	way?	used?
Panda BK	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Gupta S	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Patra S	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Vidya K	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sumana K	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ratnesh	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Roy M	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Gahlan D	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Natesan S	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sasi ST	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 3. Risk of bias assessment (JBI critical appraisal checklist for cross-sectional studies) for assessing the quality of the studies.

Strength and limitations

This study has certain strengths and limitations that must be acknowledged. Substantial heterogeneity was observed in the meta-analysis ($I^2 = 97.33\%$) reflecting the diverse nature of the included studies, which encompasses variations in study designs, participant demographics, and methodological differences. This heterogeneity highlights the complex interplay of factors influencing DD and underscores the need for tailored interventions that consider individual and cultural nuances.

The presence of publication bias, as indicated by the asymmetric funnel plot, warrants attention. It suggests a potential bias toward the publication of studies with statistically significant results. However, all studies have specified and defined their eligibility criteria, study setting, recruitment process, scale used, outcome measurement and statistical analysis. After assessing each study, we feel that for the current findings, the samples were representatives of the target population even though the heterogeneity was high.

Our sensitivity analysis confirmed the robustness of our findings, as no single study disproportionately influenced the overall results. This strengthens the credibility and reliability of our estimates, offering confidence in the reported pooled prevalence.

The unavailability of access to databases such as SCOPUS, Web-of-Science, and Cochrane Library constrained our literature search. Free full-text articles or openaccess articles are only included in our studies. These limitations have been transparently acknowledged.

Conclusion

Our study contributes valuable insights into the prevalence of DD among T2DM patients in India. These findings underscore the need for a holistic approach to diabetes care, recognizing the psychological impact alongside the physical aspects of the condition. Addressing DD through targeted interventions is crucial to improving overall health outcomes in this population. 10 👄 R. SINHA ET AL.

Screening of DD can be implemented at the community level through Non-Communicable Disease (NCD) Clinics by using validated scales like the T2-DDAS. This allows for early identification of distress and tailored counseling or therapy to enhance selfmanagement abilities.

At the policy level, incorporating routine psychosocial assessments and DD management into the standard of care protocols of NPCDCS is recommended. Awareness campaigns, capacity building of healthcare professionals and engagement of community health workers will be vital to translate these policies into practice.

Overall, a coordinated response by all stakeholders including policy makers, professional bodies, researchers and patient advocacy groups is required to recognize and mitigate the high burden of DD among T2DM patients in India.

Disclosure statement

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Data availability statement

Not Applicable; data used in analysis in the study is present in Table 1.

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