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Original Research Article

Assessment of risk factors, complications and treatment patterns of diabetic patients in India

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ABSTRACT

Background: Early identification of risk factors and comorbidities is essential for optimizing treatment strategies in diabetes. The diabetes in India (DIAB India) study aims to evaluate risk factors, glycemic status, comorbidities, and initial management choices in newly diagnosed T2DM
Methods: A retrospective, observational, multicenter study was conducted with a large cohort of 19,230 patients pan India. Data was collected from patient health records and meticulously stored into a standard format. Demographic data (age, gender, weight, height, risk factors, and blood pressure), clinical presentation (family history, complications, glycemic indices, and comorbidities), and choice of management were recorded and used for analysis.
Results: Obesity and family history were most common risk factors for T2DM and were significantly correlated with its severity ($p<0.001$). The most common comorbidity was neuropathy (59.8%) followed by nephropathy (27%) and CV events (25%). Obese patients have higher mean hemoglobin A1c (HbA1c) of 8.4%, fasting blood glucose (FBG) (160 mg/dL), and postprandial blood glucose (PPBG) (233.6 mg/dL) compared to non-obese. Both single and combination therapies led to significant improvements in HbA1c (Single: pre- 7.47, post-6.87; Combination: pre-8.26, post-7.13), FBG (Single: pre-138.94, post-118.89; Combination: pre-161.21, post-128.2), and PPBG (Single: pre-200.88, post-163.83; Combination: pre-235.10, post-177.87) levels after treatment, with combination therapy showing greater reductions across all markers ($p<0.001$). The improvement in glycemic control was greater in patients who followed dietary advice ($p<0.001$).
Conclusions: Obesity and family history were the most common risk factors contributing to diabetes in the newly diagnosed Indian patients. The comorbidities usually associated with diabetes are identified as neuropathy and cardiovascular conditions. While dietary measures are not widely used, significant improvement in glycemic status is reported using pharmacotherapy (monotherapy or combination). Choice of pharmacological and non-pharmacological treatments should be tailored to patient preferences, demographics, comorbidities, age, and other factors.

Keywords: Diabetes mellitus, Newly diagnosed, Risk factors, Prevalence, Glycemic status, India

INTRODUCTION

Diabetes mellitus is a chronic condition representing a major health concern for healthcare across the world. Type-2 diabetes mellitus (T2DM) is the most common type of diabetes increasing the burden on healthcare due to its high prevalence.[1] According to a 2019 report from the world health organization (WHO), diabetes constitutes the ninth leading non-communicable cause of mortality, contributing to approximately 1.6 million global deaths.[1,2] The rate of incidence of T2DM is on the rise across the world, with over 463 million individuals presenting with T2DM worldwide in 2019 that is expected to reach 578 million in 2030.[3] Among these, patients with T2DM from India and China will contribute large proportion of patients to the global diabetic population, with greater than 75% of cases expected to reside in these 2 countries by 2025.[4]

India currently has accounts for second highest number of diabetic patients, with more than 77 million active cases of T2DM which is estimated to rise up to 134.2 million by 2045.[5] The situation is further exacerbated by rising obesity rates, increased comorbidities, and a doubling of diabetes management costs in India.[6] Furthermore, comorbidities such as cardiovascular conditions, lipid metabolic disorders, kidney dysfunction, and hypertension deteriorate the diabetic patient's condition.[7,8] A comprehensive assessment of the prevalence and severity of comorbidities in T2DM patients is crucial for effective management and informed treatment decisions. Consequently, preventive measures are vital to improving both health outcomes and financial well-being.

Effective management of diabetes requires early glycemic control. However, substantial disparities in T2DM prevalence, incidence, and outcomes among different population groups in India complicate the management of diabetes.[9]Furthermore, diabetes presents with the challenges of economic burden, systemic complications, and low therapeutic efficacy in patients. Traditional management strategies include oral hypoglycemic drugs, insulin therapy, and behavioral modifications such as changing diet intake and regular physical excercise.[10] Unfortunately, modern medicine faces a range of challenges, including patient resistance to existing treatments, a higher incidence of side effects, insufficient effectiveness in managing related complications, and the rising costs of newly developed drugs.[10]

The outpatient department (OPD) serves as a critical gateway for the diagnosis, management, and monitoring of T2DM. While OPD acts as a primary source of routine medical care, treatment, and engagement of patients with healthcare professionals regarding diabetes, many patients receive ineffective recommendations on controlling blood glucose levels and clinical inertia.[11] Hence, OPDs represent a strategic vantage point for studying the demographic patterns and clinical manifestations of T2DM across the Indian population.

As most of the data on the management of diabetes is derived from Western countries, and Indian researchers have predominantly focused on single-center studies, an overview of demographic characteristics and management approaches in Indian T2DM patients is lacking. Therefore, a nationwide, multicentre analysis was necessary to capture the heterogeneity of T2DM across different healthcare facilities in India. By investigating T2DM across multiple OPDs, the study aims to identify demographic factors, clinical profiles, and management practices prevailing in India. The DIAB INDIA study aims to evaluate risk factors, glycemic status, and comorbidities of newly diagnosed T2DM. Additionally, the study aims to analyze the outcomes of the initial management choices of clinicians in T2DM patients and provide evidence-based strategies for prevention, early intervention, and holistic patient care.

METHODS

Study design and population

The DIAB INDIA study is a retrospective, multicenter, cross-sectional, observational study conducted to assess the demographic profile, glycemic status, and initial management strategies for T2DM patients. The study population comprises patients with newly diagnosed T2DM across various hospitals, clinics, and healthcare institutes in India. Data was retrospectively collected by physicians, diabetologists, and endocrinologists using a standardized data capture form. The selection of patients was entirely at the discretion of the treating physician, with no additional evaluations or investigations conducted to obtain data for this study.

Data collection

The following retrospective data was collected using the standardized data capture protocol for each patient included in the study: 1) Patient diagnosis, 2) Demographic data including age, gender, weight, height, risk factors (physical inactivity, smoking, alcohol consumption), and blood pressure, 3) Clinical assessment of the condition, familial medical history, existing complications, and comorbid disease condition, 4) Pharmacological approach and dietary recommendations 5) Changes in glycemic status like glycated hemoglobin A1c (HbA1c), fasting blood glucose (FBG), postprandial blood glucose (PPBG)) before and after treatment.

Statistical analysis

SAS 9.4 and SPSS (version 27) were used for statistical analysis. Descriptive statistics were employed initially to understand the frequency and proportions of various factors, such as the prevalence of comorbid conditions at diagnosis and the proportion of patients on different antidiabetic medications and dietary plans. For inferential statistics, one-way ANOVA was utilized to examine the relationship between BMI categories and the severity of diabetes, indicated by markers like HbA1c, FBG, and PPBG. ANOVA was crucial in comparing means across the BMI categories, confirming a statistically significant relationship between obesity and higher HbA1c levels. Similarly, independent samples t-tests were used to assess differences in diabetic markers between two independent groups, such as smokers vs. non-smokers or those with vs. without a family history of diabetes. Additionally, a paired samples t-test was applied to compare pre- and post-treatment values for HbA1c, FBG, and PPBG within the same group of patients. Throughout the analysis, the 95% CI ensured the statistical validity of findings.

Ethical considerations

As per the directives of the Indian council of medical research (ICMR) "ethical guidelines for biomedical research on human participants," this study presents less

than minimal risk. Approval from the institutional ethics committee (IEC) was obtained prior to the study's commencement. As this study is retrospective and does not involve patient identifiers, a waiver of informed consent was sought from the EC. The confidentiality of each study patient was maintained throughout the study. Identifying information was accessible only to the relevant study personnel and, if necessary, to the ethics committee and regulatory bodies. Limited personnel including the IEC, sponsor, quality assurance teams, and regulatory agencies had access to the case record forms throughout the duration of the study maintaining strict patient confidentiality.

RESULTS

Patient demographics

Patient demographic data is presented in Table 1. The mean age of the patients was 58.31 (15.30) years. Of the 19,230 patients included, 12111 (63%) were male, and 7119 (37%) were female. The average height was 159.82 (31.48) cm, and the mean weight was 74.51 (14.37) kg. Physical inactivity was reported in 28.3% of patients, while 19.8% reported alcohol intake and 13.0% used tobacco. The mean systolic blood pressure was 141.31 (27.83) mmHg, and the mean diastolic blood pressure was 94.93 (21.92) mmHg.

Clinical characteristics

A significant proportion of patients had already developed complications at the time of diagnosis. The most common complications were neuropathy (59.8%), followed by nephropathy (27.0%), coronary artery disease (25.0%), stroke (19.0%), and retinopathy (17.1%) (Table 2). Obesity was correlated with a higher severity of T2DM. Patients in the obese category (>25 kg/m²) had the highest mean HbA1c of 8.4% (1.4), fasting blood glucose (FBG) of 160.0 mg/dL (54.5), and postprandial blood glucose (PPBG) of 233.6 mg/dL (76.6). In contrast, underweight patients had significantly lower values ($p<0.001$) with HbA1c of 8.0% (1.6), FBG of 146.0 (59.7) mg/dL, and PPBG of 193.5 (91.9) mg/dL.

Smoking and family history were both significantly correlated with the severity of T2DM (Table 4). Smokers had a higher mean HbA1c of 8.2% (1.4) and PPBG of 238.8 mg/dL (79.6) compared to non-smokers, who had HbA1c of 8.1% (1.4) and PPBG of 224.4 mg/dL (90.3) ($p<0.001$). Similarly, patients with a family history of diabetes had higher HbA1c 8.2% (1.4) and PPBG of 234.0 mg/dL (82.4), compared to those without a family history (HbA1c: 7.9% (1.4), PPBG: 221.3 mg/dL (93.2)), with significant p values ($p<0.001$ for both).

Treatment modalities

Most patients (77.1%) were initiated on combination antidiabetic therapy, while 22.9% were started on single medication therapy (Table 5). HbA1c levels were found to significantly improve after treatment, with patients on single therapy showing a reduction from 7.47% to 6.87%, and those on combination therapy improving from 8.26% to 7.13% ($p<0.001$). This highlights the efficacy of both single and combination therapies in managing glycemic levels.

A detailed pre-post analysis of glycemic markers assessed the impact of single versus combination antidiabetic therapy. Both single and combination therapies led to significant improvements in HbA1c, FBG, and PPBG levels after treatment, with combination therapy showing greater reductions across all markers. The differences between pre- and post-treatment values were statistically significant ($p<0.001$).

Dietary plans

The patients followed diverse dietary plans (Table 6). A significant proportion of patients followed a regular diet (61.4%), with 40.5% adhering to low-carb diets. The improvement in glycemic control was greater in patients who followed dietary advice, with a significant reduction in FBG and PPBG levels across groups ($p<0.001$).

Table 1: Patient demographics and clinical presentation.

Variables	Mean	SD
Age (in years)	58.31	15.30
Gender N (%)		
Male	12111	63.0%
Female	7119	37.0%
Height (cm)	159.82	31.48
Weight (kg)	74.51	14.37
Physical inactivity N (%)		
Yes	5436	28.3%
No	13794	71.7%
Alcohol intake N (%)		
Yes	3800	19.8%
No	15430	80.2%
Tobacco use N (%)		
Yes	2492	13.0%
No	16738	87.0%
Systolic blood pressure (mmHg)	141.31	27.83
Diastolic blood pressure (mmHg)	94.93	21.92
HbA1c	8.3	1.4
Duration of diabetes (yrs)	7.3	4.1

Table 2: Proportion of diabetic patients having existing comorbidities.

Conditions	Count	Percentages (%)
Neuropathy	11502	59.8
Retinopathy	3282	17.1
Stroke	3654	19.0
CAD	4810	25.0
Nephropathy	5183	27.0

Table 3: Correlation of obesity with severity of T2DM.

Class	N	HbA1c %			FBG mg/dl			PPBG mg/dl		
		Mean	SD	P	Mean	SD	P	Mean	SD	P
Underweight (<18.5 kg/m^2)	1693	8.0	1.6	0.001	146.0	59.7	0.001	193.5	91.9	0.001
Normal BMI (18.5-22.9 kg/m^2)	6900	7.9	1.4		153.4	50.9		222.4	98.0	
Over weight (23.0 -24.9 kg/m^2)	6970	8.2	1.3		159.2	52.3		237.0	81.0	
Obese (>25 kg/m^2)	3667	8.4	1.4		160.0	54.5		233.6	76.6	

Table 4: Correlation of smoking status and family history with severity of T2DM.

Variables	N	HbA1c (%)			FBG (mg/dl)			PPBG (mg/dl)		
		Mean	SD	P	Mean	SD	P	Mean	SD	P
Smoking status										
Yes	3790	8.2	1.4	0.001	158.5	51.8	0.001	238.8	79.6	0.001
No	15440	8.1	1.4		155.5	53.4		224.4	90.3	
Family history										
Yes	9040	8.2	1.4	0.001	158.1	50.7	0.001	234.0	82.4	0.001
No	10190	7.9	1.4		154.4	55.1		221.3	93.2	

Table 5: Correlation of single of combined therapy with HbA1c, FBG, and PPBG.

Markers	Timepoint	Single, (n=4398, 77.1%)			Combination, (n=14832, 22.9%)			P on delta between groups
		Mean	SD	P	Mean	SD	P	
HbA1c (%)	**Pre**	7.47	1.40	0.001	8.26	1.37	0.001	0.001
	Post	6.87	1.08		7.13	1.08		
FBG (mg/dl)	**Pre**	138.94	61.03	0.001	161.21	49.33	0.001	0.001
	Post	118.89	48.30		128.20	39.73		
PPBG (mg/dl)	**Pre**	200.88	105.10	0.001	235.10	81.34	0.001	0.001
	Post	163.83	77.45		177.87	61.42		

Table 6: Patient distribution based on diet plan.

DIET plan	Count	Percentages (%)
Regular diet	11813	61.4
Low-carb diets	7790	40.5
Weight watchers	4803	25.0
The DASH diet	2271	11.8
Intermittent fasting	3731	19.4
Information not available	1042	5.4

DISCUSSION

The DIAB INDIA study is a retrospective, observational, multicentric, Indian study including diabetic patients to investigate the risk factors, glycemic status, comorbidities, and initial management choices in T2DM patients. The severity of diabetes was assessed by various glycemic parameters like HbA1c, FBG, and PPBG which was found to be higher in obese patients, smokers, and in patients with a familial history of diabetes. Furthermore, neuropathy was the most common complication associated with diabetes. The improvement in HbA1c levels was better in combined drug therapy with a higher reduction from baseline than in monotherapy. Dietary changes including low carbohydrate diet, controlled calorie intake, DASH diets, and intermittent fasting positively improved glycemic outcomes. As the prevalence of diabetes is increasing in India, it is important to understand these factors, empowering physicians to make evidence-based decisions.

According to the demographic data collected, a significantly higher proportion of the patients were male. Although the data is collected retrospectively, the high number of men enrolled indirectly indicates the predisposition to developing diabetes in men. This finding is in line with other studies.[12,13] Recent ICMR-INDIAB reports of 2023 state that, diabetic prevalence was 12.1% in Indian men, while lower in Indian women (10.7%).[12] Furthermore, according to global estimates, there are 17.7

million more diabetic males than females, with a prevalence of 10.8 and 10.2% respectively.[5] The higher prevalence of diabetes among male patients may be attributed to adverse dietary habits and behavioral modifications such as skipping breakfast and the habit of taking mid-meal snacks, thereby contributing to hypertension, metabolic imbalance, and increased BMI, both of which are established risk factors for the development of diabetes.[13,14]

The mean age of the present population with diabetes was over 55 years, indicating a higher incidence in older individuals. With the advancing age, energy homeostasis is impaired leading to abnormal carbohydrate metabolism. Furthermore, elderly patients are more susceptible to insulin deficiency with an increased risk of insulin resistance.[15] ICMR data identified a peak prevalence of diabetes at the age of 60, with a decreasing prevalence.[16] This can be attributed to the reduced life expectancy in the diabetic population after developing serious morbidities such as renal failure, cardiovascular diseases, and retinal complications.[17] These comorbidities significantly increase mortality rates, thereby contributing to the lower prevalence of diabetes in individuals over 60 years of age.[17]

The present study identified obesity, smoking, and family history as significant risk factors. While non-modifiable predictors of diabetes such as age, familial history, race, and genetic variants play a significant role in the progression of the disease. The increasing incidences of diabetes across the globe are primarily due to the elevation of modifiable risk factors. These factors include lack of physical activity, insufficient sleep, consumption of high calorie/fat diets, and sedentary behavior.[2] A shift in diet, like increasing the intake of processed foods and beverages with high sugar content, and reduced consumption of fruits and vegetables, contributes to the elevated risk of developing diabetes.[2] Glycemic control attained through diet directly improves glycemic status. Existing literature reports a predisposition toward diabetes in adults consuming high-meat and low-plant-based diets.[13] A plausible explanation for this correlation is the elevated levels of saturated fats and cholesterol in egg yolk, fish, and chicken.[18] A healthy diet combined with a sedentary lifestyle and lack of activities still increases the risk of diabetes. Therefore, dietary management should be recommended with physical exercise for optimal glycemic control. Therefore, a shift in prevention strategies is required, focusing on modifiable factors rather than non-modifiable risk factors.

The present study demonstrates that regular intake of alcohol and smoking further aggravates the risk of diabetes. This finding is in alignment with the results of Maddatu et al which reported a positive correlation between smokers and diabetes.[19] Dalal et al observed significantly higher levels of HbA1c in smokers compared to the non-smoking population.[1] Smoking elevates the level of reactive oxygen species (ROS) in cells, and activates the inflammatory response, causing mitochondrial dysfunction.[19–22] Less than 20% of the present patient population consumed alcohol. However, in patients drinking alcohol, it may serve as a significant risk factor. Chronic alcohol intake induces a persistent inflammatory response in the pancreas, which can impair pancreatic function and disrupt insulin secretion, potentially contributing to diabetes.[23]

Obesity was correlated with a higher severity of T2DM. The results of the current study demonstrate that patients in the obese category (>25 kg/m²) had the highest mean HbA1c of 8.4%, FBG of 160.0 mg/dL, and PPBG of 233.6 mg/dL. In contrast, underweight patients showed significantly lower values ($p<0.001$) of HbA1c, FBG, and PPBG. Dalal et al reported that 53.11% of the obese population participating in the study was diagnosed with diabetes.[1] WHO states that 44% of the global diabetic population is obese, with a presumed doubling of diabetes due to obesity in the following year. This indicates approximately 55 million obesity-related diabetic patients by 2025.[24-26] With the increasing prevalence of diabetes among the obese population, the term diabesity has been introduced. Furthermore, there is a 7-fold increase in mortality in diabetic patients who are obese.[27] Obesity causes elevated levels of metabolites such as triglycerides, hormones, pro-inflammatory molecules, and non-esterified fatty acid molecules that collectively cause insulin resistance.[28] Furthermore, obese men are at an even higher risk of diabetes due to differences in fat distribution in the body. In men, fat is predominantly stored in the liver and the abdominal region. Conversely, in women, fats accumulate in the thighs and hips. This visceral fat storage in the liver and muscles impairs the physiological pathways that regulate glucose levels, making men more prone to developing diabetes with relatively less weight gain.[13,29] Therefore, managing obesity with weight loss goals along with antidiabetic medications promises higher diabetic control.

The use of a combination of antidiabetic medications provided a higher reduction in HbA1c, FBG, and PBGG serum levels than monotherapy, underscoring the effectiveness of using combination therapy for better glycemic control in T2DM patients. However, baseline and post-treatment HbA1c, FBG, and PBGG levels in combination therapy remained higher than those observed in patients on single therapy. This demonstrates the use of combination drugs for more severe diabetes cases. The UK prospective diabetes study (UKPDS) demonstrated a consistent reduction in the percentage of patients maintaining HbA1c levels below 7% with monotherapy over the 10-year follow-up period.[30] This finding indicates that long-term monotherapy may not be adequate for sustained hyperglycemia management. The rationale behind this is the progressive nature of diabetes, particularly T2DM, which causes a gradual decrease in the functionality of β cells. With the progression of the

disease, glycemic control worsens leading to more pronounced symptoms.[31] As a result, monotherapy may be insufficient for achieving optimal glycemic control with combination therapy providing improved results by targeting multiple metabolic pathways. Combination therapy acts through their synergistic or complementary actions and potential to counteract drug resistance.[32] Therefore, pharmacological management using multiple drugs is a better option for patients with multiple comorbidities, drug resistance, or suboptimal glycemic control.

The present study is the one of the largest retrospective studies on diabetes in India as per the authors knowledge. Due to the multicentric data collection, the results of the study are inclusive of various demographics, socioeconomic status, geographical regions, and economic status. Therefore, the results of the study can be generalized to Indian patients and used by regulatory authorities.

Certain limitations of the study must be acknowledged. First, the study did not analyze the various drugs used in India and their specific clinical outcomes. Second, the inclusion of the participants by physicians is subject to selection bias. Third, there is a lack of data on the duration of diabetes and symptom resolution in patients. Fourth, a critical aspect of diabetes, the health-related quality of life (HRQoL) of the patients was not considered in the present study which must be employed in future studies.

CONCLUSION

The Indian diabetic population is rising, causing a significant healthcare burden. Obesity, family history were identified as the common risk factors in diabetic Indian patients. Major comorbidities associated with diabetes were neuropathy and cardiovascular conditions. While dietary measures showed significant improvement in glycemic parameters, they were not widely adopted. Significant reductions in glycemic indices were reported using pharmacotherapy (monotherapy or combination). The present large-scale retrospective study provides critical findings specific to the Indian population with potential to redefine diabetes prevention and management strategies. Identifying modifiable risk factor in the patients and taking active steps to reverse them using behavioral and pharmacological therapies can significantly improve patient outcomes and achieve better glycemic control.

Future clinical trials are required to investigate the role of various drugs and behavioral strategies in diabetes management and symptom resolution among Indians.

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