

Original Research Article

Real-world observational study to capture demographic details of newly diagnosed type 2 diabetes mellitus

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ABSTRACT

Background: To understand the demographic profile of newly diagnosed type 2 diabetes mellitus (T2DM) patients and to evaluate the glycaemic status and initial treatment choices in this subset of T2DM patients.

Methods: The ROD-IT-2 study was a real-world, retrospective, cross-sectional, observational study conducted at various centres across India between April 2021 and March 2022. The study outcomes included epidemiology, comorbidities, and management strategies preferred by Indian clinicians in these patients.

Results: Data from 29,550 newly diagnosed T2DM patients were analyzed. The mean age of patients was 53.3 years, and majority were males (65%). Majority of patients (63.85%) were aged 40 to 60 years. More than half (53.11%) of the patients were either overweight (36.65%) or obese (16.76%). The mean glycosylated hemoglobin (HbA1c) was high (8.4%). Most (88.5%) patients had cardio-renal comorbidities. Hypertension was the most common comorbidity (45.7%) followed by dyslipidemia (32.1%). Chronic kidney disease (CKD) was also present in 31.2% patients. In the present study, 9.2% patients presented with microvascular complications at the time of diagnosis. Majority of newly diagnosed patients (79.7%) were treated with combination therapy. In patients who were prescribed dual drug combination therapy, metformin + dipeptidyl peptidase-4 inhibitor (DPP4i) was the preferred combination (42.71%) followed by metformin + sulfonylurea (31.37%).

Conclusions: ROD-IT-2 study showed that mean HbA1c levels in T2DM patients still remain high in our population and cardio-renal comorbidities remain prevalent in newly diagnosed patients. Indian clinicians were found to prefer the combination therapy in newly diagnosed T2DM patients.

Keywords: Diabetes mellitus, Newly diagnosed, Epidemiology, Complications, Management

INTRODUCTION

Diabetes mellitus, a global health problem is a heterogeneous group of metabolic disorders, characterized by elevated levels of glucose in blood. Type 2 diabetes mellitus (T2DM) is predominately characterized by insulin resistance. As per the world health organization (WHO) 2019 report, non-communicable diseases accounted for 74% of deaths globally, of which 1.6 million deaths were related to diabetes, making it the ninth leading cause of mortality worldwide.¹⁻³ Overall, about 374 million people are at

increased risk of developing T2DM.⁴ Predictions for the year 2035 report nearly 592 million deaths due to diabetes, which is expected to rise 700 million by 2045.⁵

Earlier T2DM was considered a disease of the affluent “Western” countries. However, the last decade reported a speedy rise in prevalence of diabetes in low and middle-income countries like India in comparison to high-income western countries.^{1,3}

As per the Indian Council of Medical Research (ICMR)–India DIABetes study, the largest nationally represent-

ative epidemiological survey conducted in India on diabetes and prediabetes, the data from 15 states/union territories of the country reported a prevalence of diabetes ranging from 3.5 to 8.7% in rural and from 5.8 to 15.5% in urban areas.^{6,7} Another interesting observation was higher prevalence of prediabetes versus diabetes in most states, an indication of the presence of a large population, which may become diabetic in the future.⁸ As per the India state-level 2016 disease burden report, the cluster of risk factors contributing to disability-adjusted life years (DALYs) and death due to diabetes may have been contributed by the rapid socioeconomic change including urbanization and industrialization, besides other associated risk factors such as population growth, unhealthy eating habits, and a sedentary lifestyle.⁹⁻¹¹

Comorbidities such as cardiovascular disease (CVD), hypertension, dyslipidemia, and renal insufficiency, among others, are commonly seen in conjunction with T2DM, each with their own risks and challenges, which can impact a patient's overall disease state. Diabetes is associated with both macrovascular and microvascular complications besides mental health, infections, hepatic disorders, cancer and disabilities.^{12,13} The findings of the Chennai Urban Rural Epidemiology Study (CURES) conducted in urban Southern India reported lower prevalence of retinopathy, nephropathy, neuropathy, and peripheral vascular disease but a higher prevalence of CAD when compared with the Western population.¹⁴⁻¹⁶ Understanding the occurrence of the degree of comorbidities in T2DM patients is critical to systematically manage these patients, including the selection of its treatment. There is guideline driven evidence that achieving glycaemic targets reduces the risk of developing T2DM complications. However, many patients, have suboptimal glycaemic control because of issues that include unclear advice on how to achieve these targets as well as clinical inertia. Thus, targeted glycaemic control is recommended.¹⁷ Hence, it is vital to understand the basic demographic pattern of disease and initial management approach for T2DM patients. These data will aid in optimizing management strategies for T2DM.

The current observational study intended to primarily evaluate demographic profile of newly diagnosed T2DM patients and aimed to evaluate the glycaemic status of the patients, and initial choice of management options by clinician in this subset of T2DM patients.

METHODS

Study design

The ROD-IT-2 (Real-world observational study to capture demographic details of newly diagnosed Type 2 diabetes mellitus-2) was a real-world, retrospective, cross-sectional, observational study conducted in India between April 2021 and March 2022. In this study, data was collected from multiple centers including hospitals,

clinics, and health care institutes across India. The respective center physicians, diabetologists, or endocrinologists collected the study data retrospectively in a predesigned data capture form.

The data related to patient's diagnosis, age, gender, history of smoking, family history for T2DM, signs of complication at the time of diagnosis (if any), status of obesity, comorbid disease conditions, glycemic status (glycated hemoglobin (HbA1c), fasting blood sugar (FBG), postprandial blood glucose (PPBG), dietary advice, and the choice of management approach and medications were captured from the medical records. The choice of patient selection was based on treating physician's discretion, and there were no additional evaluation or investigation conducted to capture data in this real-world evidence building observational study.

Outcomes

The study outcomes were the evaluation of common presenting complaints at the time of T2DM diagnosis, the proportion of patients with comorbid conditions, patients who were only managed with lifestyle modifications, patients who already had complication at the time of diagnosis, patients initiated with single antidiabetic medications/combination therapy, patients on several types of diet plan, and patients on various antidiabetic medications. Also, the association of obesity, smoking status, and family history with T2DM, HbA1c with preference of antidiabetic medications and dietary advice with FBG and PPBG were evaluated.

Sample size and statistical analysis

In this real-world study, patients' data was collected retrospectively without any predetermined sample size. The study did not test any hypothesis and only the observations from patient's records were analyzed. The data collected from all the centres across India were compiled and statistical analysis was performed at Lambda Therapeutic Research Ltd., Ahmedabad, India. Demographic and baseline characteristics were summarized using descriptive statistics. Categorical variables were summarized with frequency and percentage. Continuous variables were summarized with count, mean, standard deviation, etc. Graphical presentation of data was done using bar chart as appropriate. Correlation between age and weight, HbA1c and weight was evaluated using Pearson correlation coefficient. HbA1c values were compared between patients with smokers and non-smokers (i.e., smoking history) using independent t test. Statistical analyses were performed using SAS[®] version 9.4 (SAS Institute Inc., USA).

Ethics statement

This retrospective study protocol carried less than minimal risk according to the ICMR 'ethical guidelines

for biomedical research on human participants'.¹⁸ The study was conducted after due approval from independent Bio-smart ethics committee, Ahmedabad, India. This was a retrospective study without patient identifiers; hence, the informed consent of patients was not obtained. There was no confidentiality breach of the data during its analysis and interpretation.

RESULTS

A total of 29,550 patients with newly diagnosed T2DM identified between April 2021 and March 2022 were included in this study. Table 1 details the baseline demographic and certain disease characteristics of study population. Majority of patients (63.85%) in our study were in the age group of 41 to 60 years. The patients had a mean age of 53.3 years, and majority of the patients were males (65%) while females constituted 35% of the population. The mean weight of male patients was 77.5 kg and female patients was 72.2 kg. The mean body mass index (BMI) was 27.37 kg/m². More than half (53.11%) of the patients were either overweight (36.65%, n=10,743) or obese (16.76%, n=4956). Our study showed a high prevalence of smokers in male patients (42.7%) whereas only 2.4% female patients were smokers. About 32.8% patients in our study had consumption of >10 cigarettes per day. The HbA1c was significantly (p<0.0001) high in smokers as compared to non-smokers.

The majority (88.5%) of newly diagnosed T2DM patients in our study had cardio-renal comorbidities. Hypertension was the most common comorbidity (45.7%) followed by dyslipidemia (32.1%). A total of 31.2% patients had CKD, and most of the cases were mild CKD (68.9%). About 6.40% of T2DM patients had coronary artery disease (CAD) and 3.20% patients also found to have heart failure. About 11.5% patients did not report comorbidities (Figure 1).

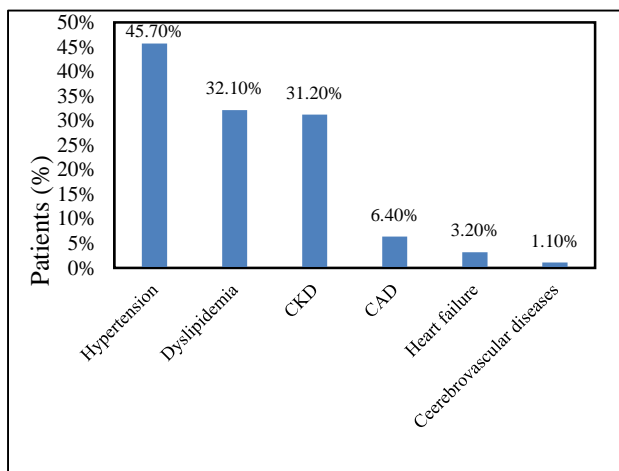


Figure 1: Distribution of patient with their comorbid conditions.
CAD, coronary artery disease; CKD, chronic kidney disease.

Table 1: Baseline demographic and disease characteristics.

Parameters	Values	
Age in years, mean ± SD	53.3±11.2	
Weight status, N (%)		
Underweight	1329 (4.5)	
Normal BMI	12520 (42.37)	
Overweight	10743 (36.36)	
Obese	4954 (16.76)	
Variables	Men	Women
Gender, N (%)	19214 (65)	10336 (35)
Age in years, mean ± SD	53.5±11.3	53.0±10.8
Weight (kg), mean ± SD	77.5±12.0	72.2±12.4
Smoking history (no. of cigarettes smoked per day), N (%)*		
<1	293 (3.60)	
1-5	2494 (30.50)	
6-10	2720 (33.20)	
>10	2682 (32.80)	
Family history of T2DM present, N (%)	16421 (55.7)	
Common presenting complaints, N (%)		
Polyuria	12152 (26)	
Polydipsia	8981 (19.2)	
Polyphagia	7156 (15.3)	
Blurring of vision	3088 (6.6)	
Non healing ulcer	1215 (2.6)	

*Data from 8189 patients. CKD: Chronic kidney disease; SD: Standard deviation.

Correlation between weight and HbA1c

The mean HbA1c was high (8.4%) in the newly diagnosed T2DM patients in the present study. The mean FBG and PPBG levels were also high (172 mg/dL and 258.4 mg/dL, respectively). Obese T2DM patients had higher HbA1c as compared with normal BMI, underweight or overweight patients. Overall, there was no correlation (r=0.2) reported between weight and HbA1c.

Management strategies adopted by Indian clinicians

Indian clinicians were more inclined towards combination therapy for newly diagnosed T2DM patients. Majority (79.7%) of the patients were prescribed combination therapy (Figure 2). As a monotherapy, metformin was the most preferred antidiabetic agent (37.6%). Notably, sodium-glucose cotransporter-2 (SGLT2) inhibitors were prescribed in 12.3% of newly diagnosed T2DM initiated on monotherapy. In patients who were prescribed dual drug combination therapy, metformin + dipeptidyl peptidase-4 inhibitor (DPP4i) was the preferred combination (42.71%) followed by metformin + sulfonylurea (31.37%). In patients who were prescribed triple drug combination therapy, metformin + SU + DPP4i (47.16%) was the preferred combination in the present study. Overall, metformin and DPP-4i were

the most prescribed drugs as monotherapy or as part of combination therapy with various anti-diabetic agents as shown in Figure 3. Low carbohydrate containing diet was the most common (38%) dietary advice given by the clinicians.

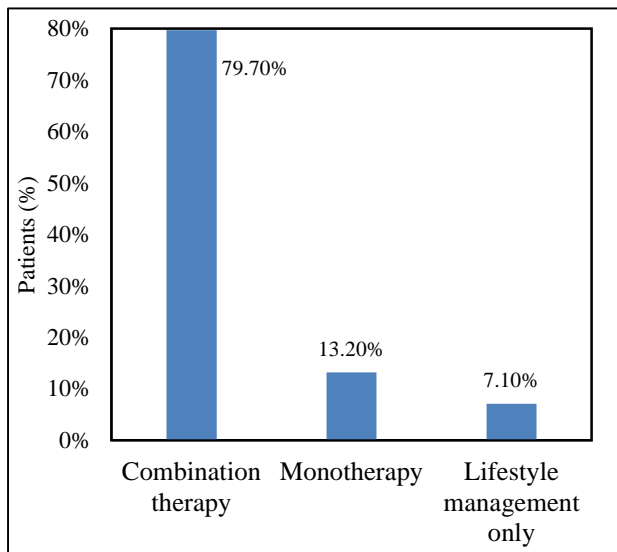


Figure 2: Preference of treatment strategies by clinicians.

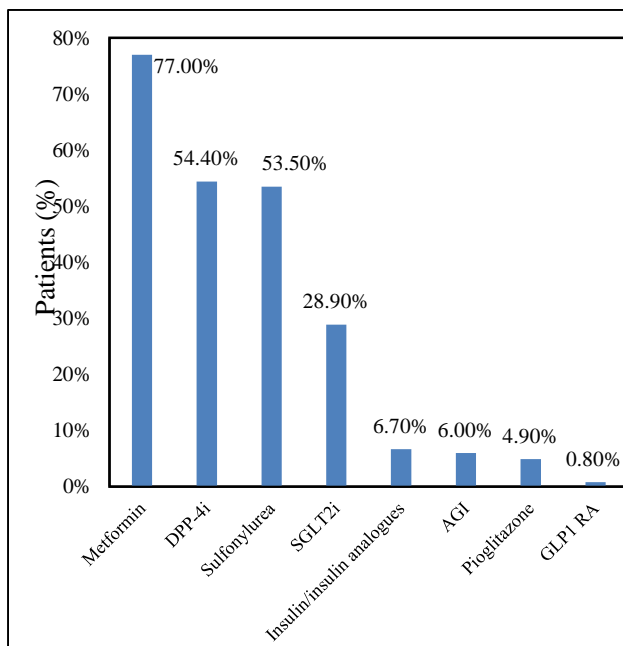


Figure 3: Antidiabetic medications used as monotherapy or combination therapy.

AGI, α -glucosidase inhibitors; DPP-4i, dipeptidyl peptidase-4 inhibitor; GLP1 RA, glucagon-like peptide 1 receptor agonist; SGLT2i, sodium-glucose cotransporter-2 inhibitor.

Microvascular complications in the study population

In the present study, 9.2% patients presented with microvascular complications at the time of diagnosis.

Diabetic neuropathy (35.9%) was the most common complication. Around one fourth of study population also had other microvascular complications like diabetic retinopathy (24.41%) and diabetic foot (23.24%).

DISCUSSION

In India, a significant ($\geq 42\%$) portion of the diabetes population is unaware of their diabetic status, and an overwhelming subset of this population (approximately 45%) is at risk of underdiagnosis of diabetes.¹⁹ The current study reports the results from a large sample of 29,550 patients with newly diagnosed T2DM across India indicating a high prevalence of the disease as well as emphasizes on the unawareness of the disease status in most of the individuals, which is a cause of significant concern. Around one-tenth of T2DM patients in this study presented with microvascular complications at the time of diagnosis. The study highlighted that delayed diagnosis and higher HbA1c at baseline are a cause of concern in this population. The proportion of patients aged <60 years with T2DM in the present study was high. Several evidences suggest that young-onset T2DM has a more aggressive disease phenotype, leading to premature development of complications, with adverse effects on quality of life and unfavourable effects on long-term outcomes, raising the possibility of a future public health catastrophe.²⁰ These findings are in agreement with the ICMR recommendations of routine screening of diabetes in India at 30 years more so in overweight and obese adults.²¹

Our study reported a higher prevalence (53.11%) of T2DM in obese or overweight population, which is in concordance with the WHO data, wherein overweight and obesity accounted for 44% of the diabetes cases and the prevalence of obesity-related diabetes is expected to double to 300 million by 2025.²²⁻²⁴ Highlighting this fact has led to the connotation ‘diabesity’.^{25, 26} Obesity and T2DM together increases the mortality risk by seven-fold.²⁷ In the present study, obese, overweight and surprisingly underweight patients had a higher mean HbA1c compared to patients with normal body mass index, which could be attributed to the lifestyle factors including diet and physical activity and body mass composition.²⁸

The study results are in concurrence to the fact that smoking is a well-established risk factor for diabetes, which is responsible for the production of reactive oxygen species, protein glycation inflammatory molecules, β -cell dysfunction and end-organ protein damage.²⁹ In the present study, smokers had a higher HbA1c when compared to non-smokers, which was statistically significant ($p < 0.0001$).

Diabetes mellitus is the most common cause of CKD, with up to 33.2% of patients with T2DM developing CKD over a 4-year follow-up in a study by De Cosmo et al.³⁰ In addition to diabetes, the prevalence of CKD

increases with the presence of other CV risk factors such as hypertension, hyperlipidemia, and heart failure.^{1,31} The cardiovascular and renal complications share a common underlying pathophysiology, and hence, there is a high prevalence of cardio-renal-metabolic (CaReMe) comorbidities in T2DM patients, suggesting requirement of evaluating multiple risk factors.¹¹ In the present study, about one-third (31.2%) of the newly diagnosed T2DM patients had CKD, and majority of them had associated cardio-renal co-morbidities with hypertension being the most common (45.7%) followed by dyslipidemia (32.1%). From a clinical perspective, the presence of cardio-renal co-morbidities and their essential role in perpetuating the development of adverse outcomes have led to improved risk stratification and potentially guiding treatment options. Recent clinical trials with SGLT2 inhibitors, GLP1 RA, and other agents in patients with T2DM with cardio-renal co-morbidities demonstrated improvements in the patient outcomes.³²⁻³⁴ In the present study, mean HbA1c levels were higher (8.4%) in newly diagnosed T2DM patients. In this real-world study, clinicians were inclined towards utilizing combination therapy in newly diagnosed T2DM patients (~80% of patients). An Indian expert panel has recommended the use of combination therapy with metformin and DPP-4 inhibitors considering cost-effectiveness in Indian T2DM patients with HbA1c >7.5% at diagnosis. Also, American Association of Clinical Endocrinology 2018 consensus statement algorithm recommends metformin plus another agent in patients with HbA1c >7.5% at diagnosis.²¹ Metformin and DPP-4 inhibitors were the preferred anti-diabetic agents in the newly diagnosed T2DM patients as well as patients with microvascular complications. In this study, at time of diagnosis, 9.2% patients presented with microvascular complications. Study limitations included retrospective nature and there may be variations in diagnostic investigations owing to the multicenter type of study.

CONCLUSION

This real-world ROD-IT-2 study reported a higher prevalence of T2DM in men as compared with women more so in the age group between 40 and 60 years. Mean HbA1c levels in this study population was found to be high. Hypertension, dyslipidemia and CKD were most common cardio-renal comorbidities in T2DM patients. Indian clinicians preferred combination therapies to manage T2DM patients. In combination therapy, metformin + DPP4i was the preferred choice followed by metformin + SU. The understanding of the demographics of T2DM and its management parameters will facilitate Indian physicians in optimizing therapeutic strategies.

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Conflict of interest: Dr. Nishant Dalal, Dr. Dixit Patel, Dr. Alok Chaturvedi are employees of Intas Pharmaceuticals Limited, Ahmedabad, Gujarat, India. Ms. Ankita Shah is an employee of Lambda Therapeutic Research Ltd., Ahmedabad, Gujarat, India

Ethical approval: The study was approved by the Institutional Ethics Committee

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