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The National Diabetes Registry in India

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ABSTRACT

Currently available data is limited in estimating the demography of Type 2 Diabetes Mellitus (T2DM) patients and hence this study helps in understanding the disease profile, associated complications, comorbidities, treatment paradigms and socio-economic impact in T2DM patients across India. A multicenter, observational, non-interventional, 6 month follow-up registry was conducted in 26 states across India involving 2944 T2DM patients between 18-75 years of age. Detailed medical history, profile of patients, diet patterns and lifestyle methods were captured. The laboratory parameters like FBG, PPBG and HbA1c were captured at enrolment, 3rd and 6th months. Out of total 2944 patients, data of 2849 (96.77%) patients were considered for analysis. The mean age of patients with diabetes was 52.9 years with mean diabetes duration of 5.8 years. About 1/4th of diabetics were hypertensive (24.05%) and majority was from the upper middle socio-economic strata (42.6%). About 15.8% patients were never advised lifestyle modifications and non-pharmacological interventions during the physician interaction. Metformin was the most commonly used oral hypoglycemic drug (58.53%) followed by glimepiride (35.87%); whereas a combination of metformin and glimepiride was used in 16.98% patients. Good glycemic control (HbA1c<7%) is observed only in 20.8% and 23.4% patients at 3rd and 6th months. Non-compliance to diabetic diet is found in 8% individuals. The most common cause of non-compliance is lack of motivation (5.54%), lack of information (2.28%), busy job schedules (1.94%) and financial reasons (1.56%). The one diabetes registry helps in understanding the T2DM patient flow, comorbid conditions and compliance to therapy from Indian perspective.

Keywords: Type-2 Diabetes Mellitus, HBA1c, FBG, PPBG

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INTRODUCTION

The prevalence of type-2 diabetes mellitus (T2DM) is increasing worldwide major contribution from China and India which in the present scenario called as Chindia [1]World Health Organization (WHO) estimates that nearly 347 million people all over the world suffer from diabetes and this number is likely to be doubled by 2030.[2,3] In the year 2002, 32 million Indians were suffering from diabetes[4] and the International Diabetes Federation (IDF) estimates that the number of diabetics in India can rise to 109 million by the year 2030.[5] There has been an increase in the prevalence of diabetes among rural population in India.[6]

Results of a national study conducted by the ICMR (ICMR-INDIAB) which assessed the prevalence of diabetes and pre-diabetes (impaired fasting glucose and/or impaired glucose tolerance) in urban and rural India, have been published in 2011[7,8]. This report presented data representing nearly 18.1 per cent of the nation's population which indicate the rapid progression of the diabetes epidemic across the nation. The authors report that currently 62.4 million people live with diabetes, and 77.2 million people are on the threshold with pre-diabetes in India.

Thus, as a first step towards better management of Indian diabetics, this national diabetes patient registry was planned to understand the patient demography, associated complications and comorbidities, treatment paradigms and socio-economic aspects in diabetics. It was expected that the data obtained via this patient registry would help the clinicians make informed targeted decisions during management of diabetes in Indian population. This was a 6 month, observational, non-interventional program which served as a national diabetes database across India.

Objectives

The primary objective of the registry was to create a database to understand the patient profile, demography, disease profile, associated complications, comorbidities, treatment paradigms and socio-economic aspects of T2DM across India. The additional objectives were to understand different aspects in T2DM management (dietary control, lifestyle modification and pharmacotherapy), treatment preferences, parameters used for monitoring glycemic control, to correlate the blood glucose levels (fasting and post-prandial) with HbA1c, and to assess the compliance and change in clinical and laboratory parameters in diabetics over 6 months' period.

MATERIALS AND METHOD

Study design and sites

This was a multicenter, observational, non-interventional, registry program in 200 diabetes clinics/centers across India with a planned sample size of 3000 T2DM patients. Being a non-

interventional registry program, no formal sample size calculation was performed. The study protocol, informed consent documents, case report form (CRF) and all study related documents were approved by the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) of the respective sites. All participating investigators ensured that the study was conducted in full conformity with the principles of the Declaration of Helsinki, International Conference on Harmonization- Good Clinical Practice (ICH-GCP) guidelines, and Indian Council of Medical Research (ICMR) and Indian GCP guidelines.

Study population

A total of 2944 male and female patients between 18 to 75 years of age having T2DM patients were enrolled from the 148 participating sites after obtaining written informed consent. All patients visited the study sites for their routine consultation and follow-up. Enrolled patients had to be diagnosed of T2DM and receiving therapy for a minimum 6 months period prior to enrollment. Patients with type-1 diabetes mellitus, juvenile diabetes and those requiring hospital admission at for any cause at the time of screening were excluded. Pregnant women and women with gestational diabetes were excluded.

Assessments and schedule

All patients underwent a detailed medical history, socio-economic status, co-morbidities and demography assessment at screening. Detailed clinical examination was done for all patients at screening and follow-up. No laboratory assessments were done for the study purpose. However, the data for blood hemoglobin (Hb), fasting blood glucose (FBG) and post-prandial blood glucose (PPBG) and glycosylated hemoglobin (HbA1C) was captured for patients if done. Details about the diet and lifestyle methods (diet, exercise, smoking and alcohol) practiced by the patients, and the anti-diabetic (generic) medications used by them was captured. Methods used for monitoring glycemic control and compliance to medication and Self-Monitoring of Blood Glucose (SMBG) was also captured at screening and during follow up visits.

Patient assessments were repeated after 3 and 6 months after enrolment.

Statistical methods

All enrolled patients constituted the analysis population and descriptive statistics is presented for the parameters. Categorical variables were summarized with the frequency and percentage of patients in each category. Continuous variables were summarized with number of patients; mean, Standard Deviation (SD), minimum, median, and maximum values. Shift tables are provided comparing the baseline visit status against each post-baseline visit status.

RESULTS AND DISCUSSION

A total 2849 (96.77%) completed the study and 95 (3.23%) patients discontinued the study (79 lost to follow-up; 15 failed to comply study requirements, and one woman was excluded due to pregnancy).

Demography

Table-1 presents the demography, co-morbid conditions and detailed patient profile of the enrolled patients, whereas age (yrs.), duration of diabetes (yrs.), body mass index (BMI), waist-hip ratio (WHR) and glycemic indices at enrollment are shown in table-2. Males comprised of 57% and females 43% of all diabetics. Majority of the patients (81%) were Hindu by religion, and were from Tamil Nadu (13.1%), Kerela (12.3%) and Maharashtra (11.6%). The geographical distribution of patients is shown in table-3. About one in four diabetics were hypertensive (24.05%) and majority of patients were from the upper middle socio-economic strata (42.6%).

Table 1: Demographic characteristics and profile of patients enrolled

	All Enrolled (N=2944)		All Enrolled (N=2944)
Gender, n (%)		**Occupation, n (%)**	
▪ Male	1677 (57%)	▪ Unemployed	1271 (43.2%)
▪ Female	1267 (43%)	▪ Unskilled worker	60 (2%)
Smoking status, n (%)		▪ Semi-skilled worker	157 (5.4%)
▪ Never smoked	2532 (86%)	▪ Skilled worker	274 (9.4%)
▪ Current smoker	287 (69.7%)	▪ Clerk/Shop owner/ Farmer	507 (17.2%)
▪ Past smoker	412 (14.0%)	▪ Semi-Profession	175 (6%)
Alcohol intake, n (%)		▪ Profession	500 (17%)
▪ Never	2622 (89.1%)	**Monthly family income (INR), n (%)**	
▪ Current	235 (73.0%)	▪ ≤1600	87 (3%)
▪ Past	322 (10.9%)	▪ 1601–4809	67 (2.2%)
Education, n (%)		▪ 4810–8009	261 (8.8%)
▪ Illiterate	165 (5.6%)	▪ 8010–12019	506 (17.2%)
▪ Middle school	376 (12.8%)	▪ 12020–16019	429 (14.6%)
▪ High school	612 (20.8%)	▪ 16020–32049	934 (31.8%)
▪ Intermediate/diploma	335 (11.4%)	▪ ≥32050	660 (22.4%)
▪ Graduate or post-graduate	1146 (39%)	**Socio-economic status, n (%)**	
▪ Professional	310 (10.6%)	▪ Lower	21 (0.8%)
Co-morbid conditions, n (%)		▪ Lower/Upper lower	514 (17.4%)
▪ Hypertension	708 (24.05%)	▪ Middle/Lower middle	788 (26.8%)
▪ Dyslipidemia	210 (7.13%)	▪ Upper	364 (12.4%)
▪ Hypothyroidism	90 (3.06%)	▪ Upper Middle	1257 (42.6%)
▪ CAD	64 (2.17%)		
▪ Other	363 (12.33%)		

Table 2: Age and laboratory profile of patients at enrollment

	N	Mean (±SD)	Median (Min, Max)
Age (yrs.)	2944	52.9 (±10.55)	53.0 (1.8, 75)
Duration of diabetes (yrs.)	2944	5.8 (±5.31)	4.0 (0.1, 37)
BMI (kg/sq.m)	2941	26.5 (±4.80)	26.0 (1.4, 63)
Waste hip ratio (WHR)	2924	1.0 (±0.10)	1.0 (0, 2)

Hb (mg/dl)	1166	4502.7 (6007.16)	14.0 (7, 17000)
FBG (mg/dl)	2261	152.9 (58.46)	140.0 (1, 540)
PPG (mg/dl)	1900	215.8 (76.28)	200.0 (34, 860)
HbA1c (%)	1509	8.1 (1.67)	7.8 (5, 18)

Table 3: Geographical origin of patients enrolled

Origin state, n (%)	All Enrolled (N=2944)	Origin state, n (%)	All Enrolled (N=2944)
Tamil Nadu	386 (13.1%)	Chhattisgarh	59 (2.00%)
Kerala	361 (12.3%)	Rajasthan	56 (1.90%)
Maharashtra	341 (11.6%)	Odisha	42 (1.43%)
Madhya Pradesh	237 (8.05%)	Uttarakhand	39 (1.32%)
Gujarat	237 (8.05%)	Assam	26 (0.88%)
Andhra Pradesh	207 (7.03%)	Bihar	9 (0.31%)
Karnataka	203 (6.90%)	Himachal Pradesh	5 (0.17%)
Uttar Pradesh	188 (6.39%)	Arunachal Pradesh	3 (0.10%)
Delhi	182 (6.18%)	Chandigarh	1 (0.03%)
West Bengal	134 (4.55%)	Goa	1 (0.03%)
Punjab	84 (2.85%)	Jammu & Kashmir	1 (0.03%)
Haryana	80 (2.72%)	Jharkhand	1 (0.03%)
Telangana	60 (2.04%)	Tripura	1 (0.03%)

Physical examination

Abnormalities were observed in 2.24% patients in general examination 3.53% patients in nervous system, 0.58% patients in head and ENT examination, 1.05% patients in cardiovascular system, 1.02% patients in respiratory system, 0.48% patients in gastrointestinal system, 0.65% patients in musculoskeletal system and 0.44% patients in genitourinary system. No dermatological abnormalities were observed in any of the patients.

Diet and lifestyle methods

The diet and lifestyle modifications suggested to the diabetes patients are shown in table-4. It is noteworthy that about 89.6% patients were advised exercise as a non-pharmacological intervention, 84.8% patients were suggested smoking cessation, and 84.2% were recommended alcohol cessation.

Table 4: Dietary and lifestyle modification of the patients

	All Enrolled (N=2944)
Diabetic diet, n (%)	
▪ Low carbohydrate diet	1255 (42.6%)
▪ Low fat diet	1238 (42%)
▪ Prescribed at this visit	485 (16.4%)
▪ Very low calorie liquid diet	165 (5.6%)
▪ Never on diet	126 (4.2%)
▪ Meal replacement	113 (3.8%)
▪ Other	1059 (36%)
Exercise, n (%)	
▪ Prescribed exercise in the past	2064 (70.2%)
▪ Prescribed exercise at the current visit	573 (19.4%)
▪ Never prescribed exercise	307 (10.4%)

	All Enrolled (N=2944)
Smoking, n (%)	
▪ Never prescribed cessation of smoking	449 (15.2%)
▪ Prescribed cessation of smoking in the past	266 (9%)
▪ Never smoked	133 (4.6%)
▪ Prescribed cessation of smoking at this visit	59 (2%)
Alcohol intake, n (%)	
▪ Never prescribed cessation alcohol intake	463 (15.8%)
▪ Prescribed cessation alcohol intake in the past	194 (6.6%)
▪ Never drink alcohol	133 (4.6%)
▪ Prescribed cessation alcohol intake at this visit	47 (1.6%)

Anti-diabetic drugs and other medication

The anti-diabetic drugs and other medications used by the patients is shown in table-5. Metformin is the most commonly used oral hypoglycemic drug (58.53%) followed by glimepiride (35.87%); whereas a combination of metformin and glimepiride is used in 16.98% patients. Triple drug therapy is used in 4.86% patients and insulin in 9.21% patients. The most common concomitant medications prescribed were methylcobalamin and rosuvastatin (1.8% each) followed by telmisartan (1.5%), atorvastatin (1.4%), metoprolol (0.8%), multivitamins with minerals (0.7%), thyroxine (0.7%), pregabalin (0.6%), olmesartan (0.6%), amlodipine (0.5%) and losartan (0.5%).

Glycemic parameters

The glycemic parameters are shown in table-6. There is a reduction in all three glycemic parameters from baseline to 3 and 6 months. Good glycemic control (target HbA1c<7%) was observed in 20.6%, 20.8% and 23.4% patients at baseline, month-3 and month-6 respectively.

Table 5: Antidiabetic medications and other medications used

	Overall (N=2944)		Overall (N=2944)
Anti-diabetic medication, n (%)		**Anti-hypertensive, n (%)**	
▪ Metformin (MF)	1723 (58.53%)	▪ Telmsartan (TL)	43 (1.46%)
▪ Glimepiride (GM)	1056 (35.87%)	▪ Metoprolol	23 (0.78%)
▪ MF + GM	500 (16.98%)	▪ Olmesartan (OL)	17 (0.58%)
▪ Voglibose	447 (15.18%)	▪ Amlodipine (AM)	15 (0.51%)
▪ Insulin	271 (9.21%)	▪ Losartan	15 (0.51%)
▪ Pioglitazone (PG)	228 (7.74%)	▪ TL + AM	13 (0.44%)
▪ Vildagliptin	205 (6.96%)	▪ OL + Hydrochlorothiazide	12 (0.41%)
▪ MF + GM + PG	143 (4.86%)	**Lipid lowering, n (%)**	
▪ Gliclazide	122 (4.14%)	▪ Rosuvastatin (RS)	53 (1.8%)
▪ Sitagliptin	117 (3.97%)	▪ Atorvastatin	40 (1.36%)
		▪ RS + Fenofibrate	10 (0.34%)
Hormonal Preparations, n (%)		**Multivitamins with minerals, n (%)**	20 (0.68%)
▪ Thyroxine	19 (0.65%)	▪ Multivitamin	11 (0.37%)
Anti-Neuropathies Drug, n (%)		▪ Multivitamins and minerals	20 (0.68%)

	Overall (N=2944)		Overall (N=2944)
Anti-diabetic medication, n (%)		**Anti-hypertensive, n (%)**	
▪ Pregabalin	18 (0.61%)	▪ Methylcobalamin	53 (1.8%)

Table 6: Glycemic parameters at baseline and over 6 months follow-up

	FBG (mg/dl)	PPBG (mg/dl)	HbA1c (%)
Baseline	Mean (SD)		
▪ n	2261	1900	1509
▪ Mean (SD)	152.9 (58.46)	215.8 (76.28)	8.1 (1.67)
▪ Median (Min, Max)	140.0 (1, 540)	200.0 (34, 860)	7.8 (5, 18)
Month 3			
▪ n	2168	1854	1302
▪ Mean (SD)	134.9 (44.48)	185.3 (52.32)	7.6 (4.04)
▪ Median (Min, Max)	123.5 (12, 412)	180.0 (7, 522)	7.2(1, 147)
Month 6			
▪ n	2090	1764	1255
▪ Mean (SD)	127.5 (39.73)	175.5 (46.45)	7.3 (1.02)
▪ Median (Min, Max)	118.0 (60, 396)	168.0 (72, 436)	7.1 (3, 15)
Change from baseline			
Month 3			
▪ n	1907	1562	1094
▪ Mean (SD)	-19.5 (41.34)	-32.4 (62.96)	-0.5 (4.43)
▪ Median (Min, Max)	-10.0 (-302, 207)	-20.0 (-714, 186)	-0.3 (-12, 140)
Month 6			
▪ n	1843	1497	1043
▪ Mean (SD)	-26.3 (48.87)	-40.5 (72.60)	-0.8 (1.44)
▪ Median (Min, Max)	-16.0 (-310, 251)	-28 (-722, 282)	-0.5 (-11, 6)

Compliance

Patient adherence to anti-diabetic therapy was observed in 71.0%, 75.4% and 77.2% patients at baseline, 3 months and 6 months respectively. Compliance to SMBG was observed in 25.2%, 29.4% and 35.2% patients at baseline, 3 months and 6 months respectively. The dietary compliance was observed in only 44.4%, 55.6% and 59.0% patients at baseline, month 3 and month 6 respectively. Non-compliance to anti-diabetic treatment was found in 4.4%, 2.6% and 1.8% patients at baseline, month 3 and month 6 respectively. Non-compliance to SMBG was found in 5.6%, 4.0% and 3.0% patients at baseline, month 3 and month 6 respectively. Similarly, non-compliance to diabetic diet was found in 8.0%, 5.8% and 5.6% patients at baseline, month 3 and month 6 respectively. Remaining patients had moderate compliance to respective modalities.

The most common cause of non-compliance was the lack of motivation (5.54%), lack of information (2.28%), busy job schedules (1.94%) and financial reasons (1.56%).

DISCUSSION

This observational registry database of 2944 patients provides an overview of T2DM profile in Indian population. The primary analyses of our study showed that the mean duration of

diabetes was 5.8 (5.31) years, which is shorter compared to an earlier reported India subset data of the Diabcare Asia study, where the mean duration of diabetes was longer (10.0 ± 6.9 years).[9] Similarly, in another cross-sectional study conducted in India about assessment of diabetes empowerment reported a longer diabetic duration of 10.1 (7.7) years in a regional Indian population.[10] The shorter duration of diabetes in our registry probably indicates an increase in the newly diagnosed cases of diabetes in recent period. However, in a patient profiling study in 100 lean T2DM Indian patients (BMI <19 kg/sq.m.), the mean age of the patient was reported to be 53 years (range 32-75 years) and the duration of diabetes was 51.7 months (range 5-180 months) which is similar to our observations.[11] The mean age of T2Dm in the present study was 52.9 years (range 1.8-75 years). The BMI observed in our study was smaller compared to an earlier reported Indian data (26.5 (4.80) kg/sq.m and 28.43 (3.75) kg/sq.m respectively).[12] However, the WHR observed in our study (1.0 (0.10)) is higher compared to those reported in this earlier study (0.98 (0.01)).(12) A relatively lower BMI combined with a higher WHR possibly due to truncal obesity in the Indian diabetes patients which could be attributed to the changes in diet and lifestyle in this decade.[13]

Development of diabetes mellitus has been reported be about 2.5 times more likely in persons with hypertension than their normal counterparts.[14] A review on diabetes mellitus and associated hypertension, vascular disease, and nephropathy provides evidence that prevalence of hypertension in diabetic persons is increasing which suggests that these two conditions frequently coexist.[15] However, hypertension was reported in 24.05% patients in the present study, which seems to be surprisingly low considering the fact that all the study subjects were diabetic. This is in contrast to the high overall prevalence of 33.8% hypertension reported in urban population in a systematic review.[16,17] In our study most of the patients were from upper middle class (42.6%) and middle/lower middle class (26.8%) whereas in a cross-sectional study descriptive study conducted in India with a population of 103 diabetic patients showed that around 66% patients belonged to the lower socio-economic class, 26.2% belonged to the middle class and 7.7% belonged to the upper socio-economic class.[18] A study conducted in Canada in diabetic patients describing association of socio-economic status with diabetes prevalence also showed that low income was associated with a higher prevalence of diabetes and diabetes related complications.[19] An epidemiological study conducted in Europe suggested that diabetes was less prevalent in people with good education and people who belonged to upper class.[20] The possible explanation for this observation could be a greater awareness of health and diabetes amongst upper socioeconomic strata due to education and social status leading to a better dietary control along with regular exercise.

A systematic review compared 8 trials which were randomized controlled trials of exercise and diet interventions of at least six-month duration and reported diabetes incidence in people at risk for T2DM. The review considered the following groups, an exercise plus diet (2241 participants) and a standard recommendation arm (2509 participants). Two studies had a diet only (167 participants) and exercise only arm (178 participants). The results of the review revealed that exercise plus diet interventions reduced the risk of diabetes and also showed favorable effects on weight and body mass index reduction, waist-to-hip ratio and waist circumference.[21] The secondary analyses presented the lifestyle and dietary modification in our study revealed that the majority of the patients were on low carbohydrate diet (42.6%).

Metformin was the most commonly prescribed medication in our study (58.5%) followed by glimepiride (35.9%). The American Diabetes Association (ADA) also recommends Metformin as the preferred initial pharmacological agent for type 2 diabetes if not contraindicated and if tolerated.[22] Metformin has adequate evidence supporting its efficacy and safety, it is inexpensive, and reduces the risk of cardiovascular events.[23] A prospective, cross-sectional, observational survey carried out in 100 diabetic patients showed that metformin was the most common individual medication to be prescribed in 31.6% patients followed by glimepiride 20.3%; which is similar to our study [20]. These findings reflect that metformin (biguanides) and sulfonylureas are still the choice of most physicians for treatment of T2DM,[24] and also that glimepiride is the most preferred sulfonylurea for management of T2DM. The use of insulin is also reported in 9.21% patients with T2DM which suggest that many T2DM patients remain uncontrolled on oral agents and require insulin therapy which could be attributed to primary or secondary failure to the oral antidiabetic drugs

Good glycemic control was observed in only 20% of patients with the current anti-diabetic medication used, whereas poor glycemic control was observed in about 40.2% patients at enrollment. However, there were reductions seen in FBG, PPBG and HbA1C from baseline values at screening and also after 3 and 6 months. Although this was an observational, non-interventional study, inclusion in the study after obtaining informed consent should have possibly increased the awareness of the patients towards their disease leading to improved glycemic control. Also, the poor glycemic control in over 40% patients suggest neglect and poor disease awareness amongst Indian patients. Results of a phase-1 study in diabetics in India in 14,277 participants reported good glycemic control in 31.1% of urban and 30.8% of rural patients.[13] Therefore, the results of both these studies reveal a poor glycemic control which are unacceptable by any healthcare standards. These results call for improvement in the patient counselling and awareness activities and more efforts by both clinicians and patients to achieve a greater glycemic control to prevent macrovascular and microvascular

complications of T2DM in long-term. More frequent follow-up and monitoring of glycemic control is required in Indian diabetes patients.

This study provide useful data for the development of better diabetes management strategies. However, the study follow-up duration was short and the study did not estimate the diabetes complications despite the longitudinal nature of study. Further, long-term follow-up studies are needed to assess the incidence and prevalence of diabetes complications.

CONCLUSION

Despite design limitations of the study, the study provides some valuable information on the demographic characteristics and treatment modalities in patients with diabetes across India. Hypertension is the most common comorbid condition in Indian T2DM patients. Majority (43.2%) of Indian T2DM patients are unemployed and 42.6% belong to the upper middle income group. Metformin and glimepiride are the most preferred oral anti-diabetic drugs.

DECLARATION

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