CLINICAL STUDY

A Hospital-based Observational Study of Type 2 Diabetic Subjects from India

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ABSTRACT

Aim: The aim of this study was to describe the profile of the subjects with type 2 diabetes mellitus (T2DM) to obtain a clear picture from Western India, that would help in management of diabetes. **Methods:** An observational study was conducted with newly diagnosed 622 type 2 diabetic subjects attending Dept. of Diabetology, All India Institute of Diabetes and Research and Yash Diabetes Specialties Centre (Swasthya), Ahmedabad during the period from August 2006 to January 31, 2009. Subjects completed an interviewer-administered comprehensive questionnaire, which included variables such as sociodemographic presenting symptoms, risk profile (hypertension, obesity, dyslipidemia and glycemic status), family history of diabetes, physical activity and behavioral profile. Blood pressure, body mass index (BMI), glycosylated hemoglobin (HbA1c) and fasting lipid profile were measured. Descriptive and bivariate analyses were carried out using SPSS version 11.5. **Results:** A total of 622 T2DM cases with mean age (years) 47.7 ± 10.9 were studied. Of these, 384 (62%) were male. The majority of T2DM subjects were obese (68%) and 67% had positive family history of diabetes. Renal dysfunctions and vision impairment were found in 10% (62/622) and 9% (57/622), respectively in T2DM subjects. The mean HbA1c level was 9.02% ± 1.67 and good glycemic control (HbA1c level <7%) was achieved only in 7.4% T2DM subjects. The Chi-square (χ^2) analysis showed that higher BMI (≥25 kg/m^2) is significantly associated with hypertension among T2DM subjects ($p < 0.01$). There were statistically significant differences between male and female study subjects with respect to mean age, BMI, waist and hip circumference and mean low-density lipoprotein (LDL) level ($p < 0.05$). **Conclusions:** The present study revealed that obesity, family history of diabetes, dyslipidemia, uncontrolled glycemic status, sedentary lifestyles and hypertension were more prevalent in T2DM subjects. Hence, the overall risk profile was very poor and needs improvement. The characterization of this risk profile will contribute in defining more effective and specific strategies for screening and controlling T2DM in Western India.

Keywords: Type 2 diabetes mellitus, obesity, polyuria, glycemic status, dyslipidemia, India

Type 2 diabetes mellitus (T2DM) is a chronic, debilitating disease characterized by insulin resistance, impaired insulin secretion and hyperglycemia. It is the most prevalent metabolic condition and one amongst major health and socioeconomic problems worldwide.[1-3] It represents more than 90% of total prevalence of diabetes in the world[4] and is responsible for 9% of the global mortality corresponding to four million deaths per year. Since, the onset is insidious, there is an average delay of 3-5 years in diagnosis. By the time, the condition is diagnosed, minimal changes responsible for micro- and macrovascular complications are already present. This issue is further compounded by untreated diabetes because of ignorance or inaccessibility to treatment. Untreated diabetes may result in limb amputation, blindness, kidney failure and neuropathy. T2DM is also associated with 4-fold increase risk of cardiovascular events and risk factor for doubling the risk of cardiovascular death.[5-7]

The prevalence of T2DM has been rising worldwide and globally more than 180 million people are suffering from it. In particular, developing countries are facing an epidemic of T2DM.[8,9] The major global burden comes from India and China, where more than 75% of diabetic subjects will live in 2025.[4] India, like many other developing countries, has witnessed a rapid epidemiological transition in the last two decades. Coupled with this, there has been a dramatic improvement of the Indian economy in terms of per capita income. These dramatic changes have had a great impact on urbanization and lifestyle of the Indians and as a result diabetes mellitus has become the main public

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health problem. It is amenable to change through early recognition at the individual level and surveillance at the population level. Studies showed that India is facing 3-fold rise of prevalence of diabetes in urban (from 5% to 15%) as well as in rural (2% to 6%) areas.[10,11] India had the largest number of the diabetic subjects with 31.7 million cases of T2DM in India.[3,12] This is further compounded by the epidemic of obesity and increase in the cost of diabetes management by 2-folds.[13] Therefore, prevention is also important from monetary point of view. Misra et al reported that increasing awareness of risk factors and how to prevent them should be emphasized in the population.[14] Apart from this, the lifestyle modifications (physical exercise, diet control, etc.) are appropriate measures in prevention of diabetes. Furthermore, to control and prevent T2DM epidemic, it must be approached in an appropriate, socioeconomically and culturally relevant manner but very little data are available from western part of India to support this and for prevention of diabetes it is also vital to know the profile of diabetics.

To describe the profile of type 2 diabetic subjects from Western India.

METHODS

A hospital-based observational study was conducted during August 2006 to January 2009 in Ahmedabad district of Gujarat State. Ahmedabad is the largest district of Gujarat with an approximate population of 5 million. The city is famous for medical tourism because of its wide network of cost-effective tertiary care hospitals catering the population of not only from Gujarat but also from neighboring states and even from abroad.

To be included in this study, subjects had to be newly diagnosed cases of diabetes mellitus (diagnosed within last 6 months), attending the Dept. of Diabetology, All India Institute of Diabetes and Research and Yash Diabetes Specialties Centre (Swasthya) during the study period for first time and willing to participate in the study. A sample size of 660 was decided so as to study at least 20% of newly diagnosed cases, based on the data review of the Dept. of Diabetology, which revealed that at least 100 subjects (newly diagnosed) presented every month, hence during the study period there would be 3,000 subjects. The calculated minimum sample size was inflated by 10% to account for anticipated dropouts.

After satisfying the case definition and obtaining informed consent (written consent from literate subjects and a verbally informed consent from illiterate subjects), 709 subjects were enrolled through simple random sampling method. After explaining the details of the study, a comprehensive case history was recorded on a semi-structured, close-ended proforma. The basic data on age, sex, education, occupation, smoking and tobacco chewing status, alcohol consumption, diet and physical activity were collected from all the subjects. All subjects were also interviewed regarding history of hypertension and other comorbid conditions and a general physical examination was done. All anthropometric measurements were recorded using standardized procedures. These subjects also underwent various clinical tests like urinalysis (first morning urine sample for evaluation of microalbuminuria), blood tests for complete hemogram, plasma glucose, glycosylated hemoglobin (HbA1c), renal function tests and lipid levels. The blood samples were collected after ensuring 12 hours of overnight fasting. Total cholesterol (TC), triglycerides (TG) and high-density lipoprotein cholesterol (HDL-C) levels were estimated in serum. Low-density lipoprotein cholesterol (LDL-C) was calculated using the Friedewald formula (LDL-C [mg/dL] = Non-HDL-C - TG/5).[15]

For analysis, the current smokers and ex-smokers were categorized in the 'ever smoker' group. Similarly, the current tobacco chewer and ex-tobacco chewer were categorized in the 'ever tobacco chewer' group. Ever smoker and ever tobacco chewer groups were considered as tobacco user. Current alcohol users were defined as subjects who had consumed alcohol at least once in last 1-month period. The main occupational level was divided into three categories: Low (e.g., skilled workers, household workers and retired); medium (e.g., desk jobs) and high (e.g., professionals and businessmen). Physical activity was categorized as sedentary (sitting, standing and driving for most of the day, cooking, light cleaning, light yard work, slow walking and other major activities involve sitting); moderate (an occupation that includes lifting, lots of walking or other activities that keep you moving for several hours qualifies as moderately active) and heavy (heavy manual labor, a very active lifestyle, dancer or very active sports played for several hours almost daily, an elite athlete in training or an extremely active lifestyle - both at work and at play and sport or activity lasting for several hours, almost daily). Blood pressure (BP) was recorded, after the subjects had rested for at least 5 minutes. Two readings were taken 5 minutes apart and mean of two was considered as the BP. Hypertension was diagnosed based on

drug treatment for hypertension or if the BP was >130/80 mmHg according to Joint National Committee-7 (JNC-7) criteria.[16,17] The diagnosis of diabetes mellitus was done using criteria established by the American Diabetes Association.[18] Either a fasting plasma glucose (FPG) level >7.0 mmol/L or ≥126 mg/dL after a minimum 12-hour fast, or 2-hour post glucose level (oral glucose tolerance test [OGTT]) >11.1 mmol/L or ≥200 mg/dL on more than one occasion, with symptoms of diabetes. In the absence of information from medical records, self-reported cases were confirmed by establishing the criteria of regular treatment with antidiabetic drugs or by performing a 2-hour OGTT. Impaired glucose tolerance (IGT) was defined as FPG level of 100 mg/dL (5.6 mmol/L) but <126 mg/dL (7.0 mmol/L) or 2-hour OGTT of ≥140 mg/dL (7.8 mmol/L) but <200 mg/dL (11.1 mmol/L). National Cholesterol Education Program (NCEP) guidelines were used for definition of dyslipidemia[19] as presence of ≥1 abnormal serum lipid concentration like hypercholesterolemia, high LDL-C, hypertriglyceridemia and low HDL-C. Body mass index (BMI) values were defined according to the recommendations of Indian Council of Medical Research (ICMR) for Indians. A study subject was considered to be obese if BMI was ≥25 kg/m^2, overweight when BMI was 23-24.9 kg/m^2.[20] The criteria for glycemic status were <7% (good control), 7-8% (suboptimal control), 8-9% (inadequate control) and >9% (uncontrolled).[21]

The study protocol was approved by the Institutional Review Board (IRB) of All India Institute of Diabetes and Research.

Statistical Analysis

Data were entered in Excel sheet and cleaned, validated and analyzed using SPSS version 11.5. Quantitative variables were summarized using mean and standard deviation while categorical variables were tabulated using frequencies and percentages. Student *t*-test was used to test the significance of differences between mean values of two continuous variables. Chi-square (χ^2) test was carried out to test the difference between two or more groups. The probability (p) level of < 0.05 was considered significant.

RESULTS

A sample of 709 diabetic subjects was enrolled. Of 709 study subjects, 622 had T2DM. Hence, further analysis was performed on 622 T2DM subjects.

Sociodemographic: Sociodemographic characteristics of the study sample are shown in Table 1. Eighty-four percent (521/622) of the subjects were Hindus and almost all study subjects were literate. The sample comprised of 384 males and 238 females. Type 2 diabetics were evenly distributed in the study sample in four quartiles of age with mean age 47.70 ± 10.94 years. Around a third of the study sample had high level of occupation (37%).

Table 1. Sociodemographic Characteristics of the Type 2 Diabetic Subjects from India

Characteristics	Number (n = 622)	Percentages (%)*
Age (years) (mean ± SD)	47.70 ± 10.94	
Upto 40	164	27
41-48	170	27
49-55	150	24
>55	138	22
Sex		
Male	384	62
Female	238	38
Marital status		
Never married	22	4
Ever married	600	96
Religion		
Hinduism	521	84
Islam	51	8
Christianity	19	3
Others	31	5
Education		
Nil	03	1
Primary school	18	3
Secondary school	105	17
College	420	67
Professionals (CA, MBBS, etc.)	76	12
Occupation level		
Low	281	45
Medium	112	18
High	229	37

*All percentages rounded to whole numbers.

Presenting complaints/symptoms: The study subjects had classic diabetic symptoms such as nocturia 44% (273/622), polyuria 31% (192/622) and polydypsia 23% (145/622). However, 9% (57/622) study subjects presented with vision impairment (Table 2).

Table 2. Presenting Symptoms of Type 2 Diabetic Subjects from India

Characteristics	(n = 622)	Percentages (%)*
Nocturia (Yes)	273	44
Polyuria (Yes)	192	31
Polydipsia (Yes)	145	23
Vision impairment (Yes)	5	79
Itching of private parts (Yes)	50	8
Tingling (Yes)	136	22
Weight loss (Yes)	165	27
Weakness (Yes)	365	59
Leg pain (Yes)	155	25
Burning micturition (Yes)	68	11
Skin complaint (Yes)	59	10
Numbness (Yes)	39	6
H/O impotence (Yes)	28	5

*All percentages rounded to whole numbers.

Behavioral profile: Our findings showed that 28% (173/622) subjects had some form of habits; 9% (56/622) subjects were smoker, 20% (121/622) subjects were chewing tobacco and 8% (51/622) subjects were consuming alcohol. A large number of study subjects (84%) reported sedentary lifestyle (Table 3).

Risk profile: Very few study subjects (7%) had good glycemic control (HbA1c <7%). Two-thirds of the study population had positive family history for diabetes. Our findings showed a mean BMI of 27.06 ± 4.57. According to BMI, only 16% of the studied sample was of normal weight; the majority was either over weight (23.0-24.9 kg/m^2) or obese (BMI ≥ 25 kg/m^2). Microalbuminuria was found in 10% (62/622) T2DM subjects. Dyslipidemia and hypertension among T2DM was 78% and 47%, respectively (Table 3). There were statistically significant differences between male and female study subjects with respect to mean age (male = 46.93 ± 11.11, female = 48.95 ± 10.53), mean BMI (male = 26.47 ± 4.34, female = 28.02 ± 4.78), mean waist circumference (male = 93.12 ± 10.47, female = 88.96 ± 9.53), mean hip circumference (male = 98.46 ± 8.83, female = 101.69 ± 12.52) and mean LDL level (male = 119.20 ± 31.23, female = 127.73 ± 38.15) at $p < 0.05$ (Table 4). BMI was significantly associated with hypertension among T2DM subjects ($p < 0.001$) (Table 5).

DISCUSSION

Diabetes mellitus is a major public health problem worldwide. Its prevalence is on the rise in many parts

Table 3. Profile of Clinical and Other Associated Factors of Type 2 Diabetic Subjects from India

Characteristics	Number (n = 622)	Percentages (%)*
HbA1C (mean ± SD)	9.02 ± 1.67	
Glycemic status		
<7% (good control)	46	7
7-8% (suboptimal control)	159	26
8-9% (inadequate control)	163	26
>9% (uncontrolled)	254	41
Family history of diabetes		
Present	417	67
BMI group		
Underweight (<18.5 kg/m^2)	11	1
Normal (18.5-22.9 kg/m^2)	99	16
Overweight (23.0-24.9 kg/m^2)	92	15
Obese (≥25.0 kg/m^2)	420	68
Microalbuminuria	62	10
Lipid		
Dyslipidemia	487	78
Hypertension		
Present	289	47
Mode of onset		
Acute	446	72
Subacute	145	23
Insidious	31	5
Physical activity		
Sedentary	525	84
Moderate	89	14
Heavy	8	1
Diet control	103	17
Other diabetic treatments (excluding diet) (Yes)	219	35
Smoking (Yes)	56	9
Years of tobacco smoking (mean ± SD)	11.46 ± 9.27	
Tobacco chewing (Yes)	121	20
Years of tobacco chewing (mean ± SD)	12.37 ± 8.61	
Alcohol (Yes)	51	8
Years of alcohol drinking (mean ± SD)	9.68 ± 7.64	

*All percentages rounded to whole numbers.

Table 4. Study Population Characteristics, Clinical and Laboratory Findings by Sex among Type 2 Diabetic Subjects from India

Characteristics	Mean ± SD		P value
	Male	Female	
Age	46.93 ± 11.11	48.95 ± 10.53	0.026
BMI	26.47 ± 4.34	28.02 ± 4.78	0.000
Waist circumference (cm)	93.12 ± 10.47	88.96 ± 9.53	0.000
HIP circumference (cm)	98.46 ± 8.83	101.69 ± 12.52	0.000
Blood pressure			
SBP (mmHg)	128.30 ± 16.43	129.60 ± 17.54	0.354
DBP (mmHg)	84.87 ± 9.13	83.41 ± 9.19	0.054
HBA1c	9.07 ± 1.74	8.93 ± 1.55	0.333
Lipid profile			
Cholesterol (mg/dL)	194.82 ± 39.24	201.00 ± 46.98	0.079
HDL (mg/dL)	41.17 ± 5.28	40.91 ± 6.10	0.575
LDL (mg/dL)	119.20 ± 31.23	127.73 ± 38.15	0.003
Triglycerides (mg/dL)	182.49 ± 123.31	169.87 ± 140.23	0.242
VLDL (mg/dL)	36.04 ± 18.46	32.03 ± 12.62	0.004

Table 5. Factors Associated with Hypertension among T2DM Subjects from India

Factors	Hypertension		X^2	P value
	Yes	No		
Age (years)				
Upto 40	67	97	6.86	0.076
41-48	73	97		
49-55	74	76		
>55	75	63		
BMI				
≥25 kg/m^2	222	198	21.25	0.000
<25 kg/m^2	67	135		
Physical activity				
Sedentary	246	279	0.21	0.659
Moderate to heavy	43	54		
Lipid profile				
Dyslipidemia	220	267	1.4	0.242
Normal	69	66		
Family history (diabetes)				
Positive	205	212	3.7	0.054
Negative	84	121		
Glycemic status				
<7% (good control)	24	22	5.449	0.142
7-8% (suboptimal control)	65	94		
8-9% (inadequate control)	86	77		
>9% (uncontrolled)	114	140		

of the developing world and India is no exception. Individuals with T2DM are considered as high priority as they are potential candidates for rapid evaluation to prevent and halt the progression of the complications.

This study presents observational data from large number of subjects with diabetes attending Dept. of Diabetology, All India Institute of Diabetes and Research and Yash Diabetes Specialties Centre, Ahmedabad. To the best of our knowledge, no such type of profiles has been reported from Western India. Nonetheless, literature regarding prevalence of diabetes is available from South and North India.[22-26] Our main motivation for this analysis was to obtain the risk profile so that we can prevent or decrease the burden of T2DM in Western India.

This study found that T2DM is a major burden in Western India, which is consistent with a study by Simon.[4] Our study population had a negligible proportion of illiterate T2DM subjects. This finding was expected given that our sample was drawn from a tertiary care hospital located in an urban area. Many factors like family history of diabetes mellitus, age, overweight/obesity, hypertension and lack of physical exercise have already been identified.[27] In the present study, most subjects with T2DM were found to be obese. This complements various studies.[28-31] Obesity was also associated with family history of diabetes in Indian population.[32] Dyslipidemia and hypertension were also related with family history of diabetes through BMI.[30,33] This study also identified BMI as predictor for hypertension among T2DM subjects and the role of BMI has been previously described.[27] Our study could not demonstrate significant association

between physical activity, dyslipidemia and controlled glycemic status with hypertension among T2DM subjects. However, age and family history of diabetes are marginally significant.

Although diet control is the cornerstone in the management of T2DM but only 17% of the studied sample was on diet therapy. Achieving good glycemic control in diabetes subjects has proven a real challenge to the healthcare providers. It has been documented in studies that self care among T2DM subjects improved glycemic control and reduced complications.[34,35]

In this study, only 7% subjects had good glycemic control, which is different from various studies such as a Swedish survey, which found that 34% of type 2 diabetic subjects had good glycemic control,[36] study by Al-Maskari et al, which found that 38% T2DM of subjects had good glycemic control[37] and study by Al-Kaabi et al, which reported 31% of subjects had good glycemic control.[21]

The possible explanation may be that our study sample consisted of newly- diagnosed T2DM subjects drawn from a tertiary care hospital and nonadherence to interventions may have contributed to uncontrolled glycemic status[38] and these subjects may have had T2DM since many years as evident from the complications such as renal dysfunction in 9% and vision impairment in 10% subjects of T2DM.

LIMITATIONS

Several potential limitations should be considered in interpreting the results of this study. First, the study is limited by cross-sectional design so temporality (cause-and-effect relationships) cannot be established but it can provide a clear snapshot of the current situation and may help in developing improvement in management and in designing future studies to explore further. Second, this is a hospital-based study from a urban set up, which may not be representative and applicable to general population. However, this could provide a reasonably precise and reliable estimate of risk profile of T2DM in Western India. Lastly, we tried our level best to include newly diagnosed subjects but we are not sure that all subjects were newly diagnosed because we have relied on the subjects.

CONCLUSION AND RECOMMENDATION

The present study is directed at providing the profile of the T2DM subjects from Western India as an impetus for further exploration of the sociocultural and subject-related factors affecting the outcomes of T2DM care that in turn will lead to redefining of the diabetes control and preventive strategies. The present study revealed that obesity, family history of diabetes, dyslipidemia, uncontrolled glycemic status, sedentary lifestyles and hypertension were highly prevalent in T2DM subjects. Hence, the overall risk profile was very poor. The findings of this study also provide an early indication for development of complications of T2DM.

Based on our findings, we recommend that appropriate management of T2DM subject requires a number of steps.

- Uncontrolled glycemic status, dyslipidemia and vision impairment should be taken care by conducting early screening for complications, frequent check-ups and follow-ups.
- Lifestyle modification interventions like control of body weight through diet and exercise should be emphasized for prevention of T2DM.
- Early approach for prevention of onset and progression of diabetic complications can be achieved with reduction in HbA1c level.

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