ORIGINAL ARTICLE

PREVALENCE OF DIABETIC COMPLICATIONS IN NEWLY DIAGNOSED TYPE 2 DIABETES PATIENTS IN PAKISTAN: FINDINGS FROM NATIONAL REGISTRY

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Background: This study was conducted to assess the prevalence of micro- and macrovascular complications in patients with newly diagnosed type 2 diabetes (T2DM) in Pakistan. **Methods:** In this multicentre, observational, cross-sectional disease registry, patients (aged ≥18 years) who were diagnosed at enrolment with T2DM, defined by fasting blood glucose (FBG) ≥126 mg/dL and/or glycated haemoglobin (HbA1c) ≥6.5%, were enrolled. Microvascular complications were ascertained by objective examination while macrovascular complications were identified from patients' medical history. Descriptive statistics were used for data analysis. **Results:** Data from 891 patients were analysed in the study. Mean [±standard deviation (SD)] HbA1c, FBG, and random blood glucose were 9.9% (±2.2%), 193.4 (±74.0) mg/dL, and 294.3 (±72.7) mg/dL, respectively. Obesity (n=689, 77.3%) and familial history of diabetes (n=575, 64.3%) were the most common risk factors for T2DM. Overall prevalence of micro- and macrovascular complications was 68.6% [n=611, 95% confidence interval (CI): 65.4–71.5] and 9.0% (n=80, 95% CI: 7.3–11.0), respectively. Neuropathy, nephropathy, and retinopathy were reported in 59.6% (95% CI: 56.3–62.8), 24.4% (95% CI: 21.6–27.2), and 15.9% (95% CI: 13.7–18.5) of the patients, respectively. Oral antidiabetic agents and insulin were prescribed to 839 (94.2%) and 140 (15.7%) patients, respectively. All study patients received education on T2DM management, mostly from the investigators, and also from diabetes educators and nurses. **Conclusions:** The prevalence of micro- and macrovascular complications of T2DM is high, indicating a delay in diagnosis of disease. In order to counter the burden of diabetic complications, optimum strategies for screening of the general population are required.

Keywords: Type 2 diabetes mellitus; Complications; Retinopathy; Neuropathy; Nephropathy; Myocardial infarction; Stroke; Acute coronary syndrome; Peripheral arterial disease; Pakistan

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a global health concern affecting almost 425 million people[1] and the sixth leading cause of deaths worldwide[2]. The burden of disease is predicted to increase at a higher rate in low-to-middle income countries in Asia, Middle East, and Africa[3] thereby posing serious implications for healthcare resource utilization, quality of life, and T2DM-associated mortality. According to the International Diabetes Federation (IDF), at present 7.5 million people in Pakistan are afflicted with T2DM giving a national age-standardized prevalence of 8.3%.[1] Other studies conducted in Pakistan in between 1995 and 2014 have shown the prevalence of T2DM to be between 8.0% and 14.0%, depending on regional variations, urban versus rural sampling, and criteria used for diagnosis.[4–13]

Type 2 diabetes mellitus is a slow yet progressive disease and is often asymptomatic for a number of years before diagnosis. Recent estimates reveal that approximately half of those with diabetes are as yet undiagnosed; and the proportion, at 61.5%, is high in Pakistan. It has also been reported that by the time of diagnosis, T2DM has already set in for 4–7 years.[14] The resultant chronic hyperglycaemia is a major contributor to vascular dysfunction and the ensuing diabetic complications. These are categorized as 'microvascular' when small blood vessels are impaired or 'macrovascular' when the arteries are damaged.[15] The former affects the eye (retinopathy), kidney (nephropathy), and the nervous system (neuropathy) while macrovascular complications result in a host of cardiovascular disorders such as myocardial infarction (MI), angina, stroke, and peripheral arterial disease (PAD). The outcomes of these vascular complications include loss of vision, end stage kidney disease, diabetic ulcers, limb amputations, disability, lowered quality of life, substantially higher healthcare costs, and death. Depending on various factors such as duration of disease, presence of other risk factors and comorbidities, as well as environmental and genetic factors, most patients with T2DM are at a risk of presenting concomitant diabetic complications at the time of diagnosis. A substantial burden of T2DM in

terms of mortality, human productivity, quality of life, and associated costs is posed by management of diabetic complications.

Owing to its presence in the "diabetes hotspot", these findings have significant implications in context of Pakistan. The changing landscape of the country in terms of westernized lifestyle, rapid urbanization, and lack of education and health awareness adds to the existent burden of T2DM in Pakistan. Moreover, obesity, a major risk factor for diabetes, is rapidly emerging into an epidemic.[16] While stringent measures are required in order to counter this major health challenge, a key obstacle to this has been lack of nationwide data from Pakistan on various aspects of T2DM, especially on diabetic complications. The main goal of this study was to evaluate the prevalence of micro- and macrovascular complications in newly diagnosed T2DM patients visiting specialized outpatient diabetes centres in Pakistan. The study also aimed at ascertaining the current real-world approaches to management of newly diagnosed T2DM patients in outpatient settings.

MATERIAL AND METHODS

The reported study was a national, multicentre, cross-sectional, observational disease registry conducted across 25 centres in 20 cities in Pakistan in between September 2015 and October 2016. Centres were selected from a list using a simple random sampling method and invited to participate in the study from a list of 84 specialized diabetes centres with facilities for diabetes screening as well as detecting diabetic complications.

In context of the study, T2DM was characterized, as per the ADA 2015 guidelines,[17] as fasting blood glucose (FBG) ≥126 mg/dL or HbA1c ≥6.5%. A patient was considered to have newly diagnosed T2DM if he/she had random blood glucose (RBG) values ≥200 mg/dL at screening and FBG ≥126 mg/dL and/or HbA1c ≥6.5% on a confirmatory laboratory test.

The study was conducted according to the principles laid down by the Declaration of Helsinki (1968) and its subsequent amendments as well as Good Epidemiological Practice. Moreover, the study was conducted with approval of respective institutional review board (IRB)/ independent ethics committees (IECs) at study centres and was in full compliance with local and national laws in Pakistan.

Individuals visiting the study sites who were ≥18 years of age, presented with newly diagnosed T2DM based on ADA 2015 criteria,[17] and were willing to provide an informed consent were invited to participate in the study. Presentment of type 1 diabetes or previously diagnosed T2DM, gestation diabetes, or continuing antidiabetic therapy served as exclusion criteria. Approximately 40 patients were recruited consecutively at each study site.

Patient data collected included anthropometrics, socioeconomic profile, T2DM profile including familial history, classical symptoms, and glycaemic parameters, as well as prevalence of diabetic complications; risk factors and comorbidities, and diabetes management strategies including lifestyle alterations, initiation of anti-diabetic treatment, and patient education.

Diabetic complications assessed were of microvascular as well as macrovascular origin. The prevalence of microvascular complications, including retinopathy, nephropathy, and peripheral neuropathy, was estimated by objective evaluation at the time of enrolment. Presence of retinopathy was assessed by performing ophthalmoscopy on both eyes. Incidence of nephropathy was confirmed by estimating urinary microalbumin and creatinine levels. A comprehensive Diabetic Foot Examination comprising visual inspection, monofilament examination, pinprick sensation, ankle reflexes, and an optional estimation of the Ankle Brachial Pressure Index (ABPI) was conducted to establish presence of peripheral neuropathy. The prevalence of macrovascular complications, including myocardial infarction (MI), stroke, angina, and peripheral arterial disease (PAD), was estimated based on patients' medical history. Analysis of blood samples for glycaemic parameters (HbA1c and FBG) and urine samples for microalbumin and creatinine levels was done at Aga Khan laboratory, Karachi.

Data from a previously published global study[18] was used for calculation of sample size. In their study, *Shaw et al*[18] reported a prevalence of 31.0% for diabetic retinopathy, the lowest for any of the microvascular complications estimated in the study. Considering this to be the minimum captured prevalence in our study with a 95% confidence level and a margin of error of 3.0%, as well as accounting for missing information in 10.0% of study patients, the sample size was calculated to be 1000 patients.

Descriptive statistics were used for analysis of study data. The primary endpoint of prevalence of micro- and macrovascular complications was described using proportions and percentages with their 95% confidence intervals (95% CI). The secondary endpoints of classical and other symptoms of T2DM and prescribed anti-diabetic therapies were described using distribution of percentages; while glycaemic parameters of FBG and HbA1c were described by mean and standard deviation (SD).

RESULTS

Our study recruited a total of 958 patients during a 2-month recruitment period at each site and data from 891 patients who met the inclusion criteria are presented in this article. Data from 67 patients were excluded either because laboratory reports had not been provided or urinary microalbumin and/or creatinine values were not estimated at enrolment.

Patient characteristics are summarized in table-1. The study population comprised more males (56.0%) and had a mean (±SD) age of 47.7 (±10.6) years. The mean (±SD) height, weight, body mass index (BMI), and waist circumference were 161.9 (±11.9) cm, 76.5 (±15.2) kg, 29.1 (±5.8) kg/m^2, and 98.9 (±14.8) cm, respectively. Over 3/4th of the cohort were overweight (characterized by BMI >25 kg/m^2) and 79.4% of the males and 94.4% of the females had waist circumference ≥90 cm and ≥80 cm, respectively.

Mean (±SD) HbA1c, RBG, and FBG were 9.9% (±2.2 %), 294.3 (±72.7) mg/dL, and 193.4 (±74.0) mg/dL, respectively. All study patients had RBG ≥200 mg/dL and FBG ≥126 mg/dL while HbA1c ≥6.5% was reported in 883 (99.1%) patients.

Almost 40.0% of the study population presented a history of classical symptoms of diabetes and the commonly reported complaints included extreme fatigue (n=620, 69.6%), polyuria (n=581, 65.2%), nocturia (n=541, 60.7%), and polydipsia (n=528, 59.3%). The most prevalent risk factors for diabetes were obesity (n=689, 77.3%), a familial history of diabetes (n=575, 64.3%), and sedentary lifestyle (n=435, 48.8%).

The majority of patients (n=708, 79.5%) were urban residents and a substantial proportion (n=330, 37.0%) were unskilled people. Education level of the patients had a notable disparity with only 138 (15.5%) patients reporting a university/higher education while almost half (n=435, 48.8%) of the patients were either illiterate or had received primary education. The presence of microvascular complications was confirmed in 611 (68.6%, 95% CI: 65.4–71.5%) patients (Table-2). Retinopathy was reported in 142 (15.9%) patients. In patients with retinal alterations, approximately 1/5th of the changes observed were proliferative by nature (right eye: 27 out of 134 patients; left eye: 24 out of 131 patients).

Nephropathy, characterized by a urinary albumin-to-creatinine ratio ≥30 mg/g, was identified in 217 (24.4%) patients. Diabetic neuropathy, based on one or more positive findings from physical, neurological, and/or vascular examination, was detected in 531 (59.6%) patients. The most common findings from the Diabetic Foot Examination are given in Table-2. It is interesting to note that ankle-brachial pressure index (ABPI) was estimated in only 114 (12.7%) patients; although, this assessment was optional.

Macrovascular complications were reported in 80 (9.0%, 95% CI: 7.3–11.0) patients (Table-2). The most commonly observed macrovascular complication was angina, reported in 46 (5.2%, 95% CI: 3.8-6.8) patients, followed by MI (n=29, 3.3%, 95% CI: 2.3–4.6), PAD (n=20, 2.2%, 95% CI: 1.5-3.4), and stroke (n=18, 2.0%, 95% CI: 1.3-3.2).

Details of anti-diabetic treatment prescribed to the study patients is given in table-3. Oral antidiabetics (OADs) were the anti-diabetic treatment of choice, prescribed in 839 (94.2%) of the patients, either alone (n=732, 82.2%) or in combination with insulin (n=107, 12.0%). In patients treated with OAD alone, the preferred regimen was a combination of 2 OADs (n=368, 41.3%), followed by a single agent regimen (n=274, 30.8%) and a combination of >2 OADs (n=90, 10.1%). Biguanides were prescribed in 791 (88.7%) patients, either as a single agent or in combination with other OADs and/or insulins. The most common OAD regimens as a single agent, as a combination of 2 OADs, and as a combination of >2 OADs were biguanides (n=243, 27.2%), biguanides+sulfonylureas (n=274, 30.7%), and biguanides + sulfonylureas + DPP-4 inhibitors (n=84, 9.4%), respectively.

Insulin was prescribed in 140 (15.7%) patients, either singly (n=33, 3.7%) or in combination with OADs (n=107, 12.0%). Long-acting insulin analogue (basal insulin) and premixed human insulin 70/30 (premix insulin) were the most widely prescribed insulins, recommended in 52 (5.8%) and 46 (5.2%) patients, respectively. When prescribed singly, the most preferred insulin was premix insulin (n=23, 2.6%) while the most common insulin-OAD combination reported was basal insulin + biguanides (n=25, 2.8%). The main reasons for prescribing OADs, as reported by the investigators, were – to achieve better glycaemic control (n=744, 83.5%), to lessen the risk of hypoglycaemia (n=568, 63.7%), and for cost-effectiveness (n=523, 58.7%) (Table-4). Likewise, the most common reasons for prescribing insulins were reportedly – to achieve better glycaemic control (n=137, 15.4%), to lessen the risk of hypoglycaemia (n=69, 7.7%), and to facilitate treatment adherence (n=57, 6.4%). Nearly all (n=863, 96.9%) patients were recommended dietary management and exercise in addition to their anti-diabetic treatment.

All study patients received education towards managing their T2DM. In most patients, it was the investigators themselves who imparted the education (n=560, 62.9%) or diabetes educators were called upon to provide counselling (n=327, 36.7%). Almost all patients received education on lifestyle modification (n=886, n=99.4%) and disease management (n=874, 98.1%). Patient education on self-monitoring of blood

glucose and management of hypoglycaemia was also substantially high, reported in 768 (86.2%) and 696 (78.1%) patients, respectively. Patients (n=796, 89.3%) were also advised to test their blood glucose levels daily (n=312, 35%) and weekly (n=202, 22.7%). In addition, patients were also advised to attend the next consultation in an average (±SD) of 14.8 (±8.3) days.

Table-1: Patient characteristics and medical history at enrolment (n=891)

	n (%)
Age in years, mean (SD)	47.7 (10.6)
Gender	
Male	499 (56.0)
Female	392 (44.0)
BMI in kg/m^2, mean (SD)	29.1 (5.8)
<23 kg/m^2	95 (10.7)
≥23 kg/m^2 – ≤25 kg/m^2	107 (12.0)
>25 kg/m^2	689 (77.3)
WC in cm, mean (SD)	98.9 (14.8)
Males with Waist circumference ≥90 cm	396 (79.4)
Females with Waist circumference ≥80 cm	370 (94.4)
Systolic blood pressure in mmHg, mean (SD)	131.6 (16.3)
Diastolic blood pressure in mmHg, mean (SD)	84.3 (9.4)
HbA1c %, mean (SD)	9.9 (2.2)
HbA1c ≥6.5%	883 (99.1)
Fasting blood glucose in mg/dL, mean (SD)	193.4 (74.0)
Fasting blood glucose ≥126 mg/dL	891 (100.0)
Random blood glucose in mg/dL, mean (SD)	294.3 (72.7)
Random blood glucose ≥200 mg/dL	891 (100.0)
Classical symptoms of diabetes presented at enrolment	
Extreme fatigue	620 (69.6)
Polyuria	581 (65.2)
Nocturia	541 (60.7)
Polydipsia	528 (59.3)
Polyphagia	419 (47.0)
Risk factors and comorbidities	
Obesity (BMI >25 kg/m^2)	689 (77.3)
Familial history of diabetes	575 (64.3)
Sedentary lifestyle	435 (48.8)
Hypertension	367 (41.2)
Smoking	234 (26.3)

Table-2: Microvascular and macrovascular complications existent at time of type 2 diabetes mellitus diagnosis (n=891).

	n (%)	CI 95%
Micro vascular complications		
Retinopathy	142 (15.9)	13.7–18.5
Proliferative changes in right eye	27 (20.1)	
Proliferative changes in left eye	24 (18.3)	
Neuropathy (foot examination)	531 (59.6)	56.3–62.8
Foot inspection		
Dryness of skin	404 (45.3)	
Cracked skin	275 (30.9)	
Discoloration/Pigmentation	146 (16.4)	
Neurological assessment		
Vibration absent	157 (17.6)	
Monofilament examination sensation absent	103 (11.6)	
Temperature sensation abnormal	74 (8.3)	
Vascular assessment		
Dorsalis pedis pulse absent	57 (6.4)	
Posterior tibialis pulse absent	48 (5.4)	
Nephropathy	217 (24.4)	21.6–27.2
Macro vascular complications		
Angina	46 (5.2)	3.8–6.8
Myocardial infarction	29 (3.3)	2.3–4.6
Peripheral arterial disease	20 (2.2)	1.5–3.4
Stroke	18 (2.0)	1.3–3.2

Table-3: Pharmacological treatment prescribed for Type 2 diabetes mellitus (n=891).

	n (%)
Oral antidiabetic	839 (94.2)
Only Oral antidiabetic	732 (82.2)
Single Oral antidiabetic	274 (30.8)
Biguanides	243 (27.2)
Sulfonylureas	21 (2.4)
DPP-4 inhibitors	10 (1.1)
Two Oral antidiabetic	368 (41.3)
Biguanides + Sulfonylureas	274 (30.7)
Biguanides + Dipeptidyl peptidase-4 inhibitors	84 (9.4)
Three Oral antidiabetic	90 (10.1)
Biguanides + Sulfonylureas + Dipeptidyl peptidase-4 inhibitors	84 (9.4)
Biguanides + Sulfonylureas + Thiazolidinediones	3 (0.3)
Insulin	**140 (15.7)**
Only insulin	33 (3.7)
Premix insulin	63 (7.1)
Premixed analogue insulin	17 (1.9)
Premixed human insulin (70/30)	46 (5.2)
Basal insulin	57 (6.4)
Long-acting insulin analogue	52 (5.8)
Intermediate-acting human insulin	5 (0.6)
Prandial insulin	5 (0.6)
Short-acting insulin analogue	3 (0.3)
Rapid-acting insulin analogue	2 (0.2)
Basal insulin + prandial insulin	14 (1.6)
Prandial insulin + premix insulin	1 (0.1)
Oral antidiabetic **+ Insulin**	**107 (12.0)**
Biguanides + basal insulin	25 (2.8)
Biguanides + premix insulin	21 (2.3)

Table-4: Reasons for prescribing pharmacological treatment (n=891).

Reason for prescribing	oral antidiabetic	Insulin
	n (%)	
Better glycaemic control	744 (83.5)	137 (15.4)
Less hypoglycaemia	568 (63.7)	69 (7.7)
Accessible	531 (59.6)	47 (5.3)
Less chances of weight gain	527 (59.1)	34 (3.8)
Cost-effective	523 (58.7)	43 (4.8)
Ease of adherence to therapy	479 (53.8)	57 (6.4)
Once a day therapy	74 (8.3)	37 (4.2)
Less immunogenic	-	27 (3.0)
Better quality	-	46 (5.2)

DISCUSSION

In this real-world, nationwide study, we discovered that a substantial proportion of our study patients had developed diabetic complications, especially of microvascular nature, at the time of detection of T2DM. At almost 60.0% prevalence, diabetic neuropathy was the most commonly observed microvascular complication, although the prevalence of nephropathy and retinopathy, at 24.4% and 15.9%, respectively, was also considerable. Macrovascular complications were reported in 9.0% of the patients, with prevalent angina in >5.0%. The average values of glycaemic parameters – RBG, FBG, and HbA1c – were notably high. Almost 40.0% of the patients had classical symptoms of T2DM at the time of enrolment and the most common risk factor was obesity. The mainstay of anti-diabetic treatment was OAD agents, largely biguanides, either singly or in combination. The insulinization rate was 15.7% and premix insulin was preferred over other types.

The disparities in prevalence of T2DM and its management in various parts of the world make it somewhat tedious to estimate the prevalence of diabetic complications in the general population. This is especially applicable to newly diagnosed T2DM patients since the detection of disease depends on a number of factors such as availability of health resources for screening, physician and patient awareness and education, and the socioeconomic status of the country. The prevalence of micro- and macrovascular complications in the international, multicentre A1CHIEVE study (n=66,726) was reported to be 53.5% and 27.2%, respectively.[19] In contrast, a cross-sectional study of approximately 7000 newly diagnosed T2DM patients in Denmark revealed a prevalence of micro- and macrovascular complications of 12.0% and 17.0%, respectively (6.0% of the patients had both).[20] Such variabilities are also reflected in specific diabetic complications as well. Different studies have cited the prevalence of diabetic neuropathy in the range of 2.4–52.0%.[14,20–23] The only statistic for Pakistan comes from a hospital-based study conducted by Lakhiar *et al* which found the prevalence of neuropathy in newly diagnosed T2DM patients to be 32.7%.[24] In comparison, the

prevalence of neuropathy was substantially higher in our study. Prevalence rates of diabetic retinopathy have been estimated to be in between 6.0% and 20.0% in studies from outside Pakistan[14,20,21,25–28] and in between 12.8% and 15.0% in studies conducted in Pakistan[29–31] and our reported rate of 15.9% is in agreement with this range. Similarly, our observed prevalence rate for diabetic nephropathy (24.4%) corroborates previously reported rates between 3.0% and 37.0%.[14,20,21] A small but nevertheless noteworthy proportion of our patients also presented macrovascular complications, angina being the most prevalent. However, the prevalence of these complications was within range of previously reported findings.[14,20,21,32]

The importance of glycaemic control in the management of T2DM cannot be stressed enough. Data from the ADVANCE trial which studied >11000 patients has shown that for every 1.0% increase in HbA1c level over the threshold of 7.0%, the risk of a micro- or macrovascular event or death rises by approximately 40.0%.[33] A similar observation was made by Ali *et al* in study conducted in Pakistan; patients with poor glycaemic control were reported to have more severe microvascular complications.[34] Furthermore, large-scale studies such as the UKPDS,[35] ADVANCE,[36] and VADT[37] have provided ample evidence of the benefit of tight glucose regulation on impeding the progress of microvascular complications in T2DM patients. Hence, early detection and timely intervention hold the key to easing the burden of diabetic complications. However, it is equally important to understand the real-world scenario in a developing country such as Pakistan when formulating strategies for combating the diabetes epidemic. The socioeconomic and demographic profile of Pakistan is heterogeneous and includes urban zones within a largely rural area. Healthcare facilities which could run screening camps and mass awareness programs are mostly limited to large cities, out of reach of a substantial fraction of the population who reside in the underdeveloped areas. Moreover, lower education and income levels also negatively impact a patient's willingness to seek medical help when symptoms of T2DM appear or undergo regular screening to identify the disease in early stage. These factors will have to be taken into consideration when building policies and guidelines for early detection of T2DM in Pakistan. Given the restrictive costs as well as the need for well-trained manpower for running effective screening programs, alternative strategies could be adopted. Recently, the concept of diabetes risk score has been tested in studies for detection of T2DM through the use of a simple, non-invasive, and inexpensive algorithm.[38,39] The utility of such easy-to-perform assessments have also been demonstrated in the Pakistani setting[40, 41] and holds the potential to be an effective tool in early detection of T2DM in Pakistani patients.

Despite the clinically relevant findings of our study, it does have certain inherent limitations. Being a cross-sectional study, we could essentially only gather a snapshot of the prevalence of diabetic complications in our patients. Hence, we could not establish the effectiveness of contemporary treatment practices of T2DM in managing these complications. In addition, we limited the study population to newly diagnosed T2DM patients in order to suit the goal of the study and it was therefore not possible to ascribe a temporal nature to the development of T2DM and its complications. Lastly, our study was conducted in urban settings and hence our data is probably not reflective of the situation in rural settings.

However, our study revealed that in the Pakistani setting, the prevalence of diabetic complications, especially those of microvascular nature, at the time of detection of T2DM, are substantial. We hope that our findings provide the impetus to direct the focus of health authorities, policy makers, and health care providers in Pakistan on developing appropriate strategies for increasing disease awareness as well as for detecting T2DM at an earlier stage. Further studies will be required to optimize resources and strategies to neutralize the burden of T2DM epidemic in Pakistan.

AUTHORS' CONTRIBUTION

FU, BA, NJ: Data Collection and interpretation, write-up.

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