

Prevalence of undiagnosed type 2 diabetes mellitus in Pakistan: Results of SCREEN-diabetes disease registry

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Abstract

Objective: To estimate the prevalence of undiagnosed diabetes in patients visiting the primary care physicians for any reason in urban outpatient settings.

Methods: This national, multicentre, non-interventional disease registry was conducted from October 2011 to August 2013 across Sindh and Punjab provinces of Pakistan and comprised randomly selected health centres with qualified general practitioners. Patients aged 45 years or more and willing to have a random blood sugar screening test were selected. They were screened on American Diabetes Association risk factors. Fasting blood glucose and glycated haemoglobin of patients with random blood sugar ≥ 200 mg/dL were checked and those with values ≥ 126 mg/dL or $\geq 6.5\%$ respectively were considered newly-diagnosed type 2 diabetes mellitus (T2DM). They were followed up three months later.

Results: There were 8,250 patients with a mean age of 53.2 ± 8.1 years, and mean body mass index of 27.3 ± 5.3 kg/m². The prevalence of undiagnosed diabetes in patients visiting primary care physicians for any reason was 525 (6.4%). Overall, 484 (92.2%) of the newly-diagnosed type 2 diabetes mellitus were advised lifestyle modification, 460 (88.1%) were put on oral anti-diabetic drugs, and insulin was initiated in 50 (9.5%) patients. There was a mean decrease of $1.6 \pm 1.6\%$ in glycated haemoglobin and 41.9 ± 56.8 mg/dL in fasting blood glucose from baseline to the three-month follow-up.

Conclusion: The burden of undiagnosed diabetes in Pakistan was found to be considerable. With proper management, significant improvement was shown.

Keywords: Complications, Diabetes mellitus-type 2, Glycated haemoglobin, Pakistan, Management, Prevalence. (JPMA 68: 1171; 2018)

Introduction

Diabetes is a potentially disabling chronic disease which has transformed into a major public health challenge to health care systems worldwide. According to International Diabetes Federation (IDF), 34.6 million people from the Middle East and North Africa (a region inclusive of Pakistan) are living with diabetes and it has been estimated that by the year, 2035 there will be a 96.2% increase in the prevalence rate of diabetes in this region.¹ Pakistan alone has a national prevalence of 12% for type 2 diabetes mellitus (T2DM).²

Untreated or poorly controlled diabetes leads to serious micro and macro-vascular complications, which increases the risk of premature death in patients with diabetes.³ There is a high burden of microvascular complications among Pakistani people with diabetes, as evident by the frequency of their prevalence to name a few, retinopathy 58.0%, neuropathy 39.6%, and nephropathy 61.4%.⁴

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The financial burden of diabetes and its associated complications increases the overall healthcare expenditure in these patients. The annual mean healthcare expenditure on an individual in Pakistan for diabetes was estimated to be Pakistani rupees (PKR) 11,580 or (US\$ 197).⁵ It has also been estimated that diabetes caused 87,354 adult deaths in Pakistan in the year 2013.¹

According to IDF, 26.8% people with diabetes in Pakistan are under the age of 40 years and a further 49.6% are between 40 and 59 years of age.¹ Thus, the burden of diabetes translates into a large impact in the economically productive segments of population and shows a trend of early diabetes development in the population.

Early diagnosis followed by sufficient physical activity, moderate weight reduction, and pharmacological interventions can substantially control blood glucose levels and the complications associated with diabetes, even in high risk patients.⁶ However, timely initiation of appropriate treatment is often impeded by the hidden demographic burden of diabetes in Pakistan, which has

been estimated to have more than 3 million undiagnosed cases of diabetes.¹ A pilot study showed that for each known case of T2DM there are approximately 1.7 cases of undiagnosed T2DM and 2.5 cases of impaired glucose tolerance (IGT) in the local population.²

American Diabetes Association (ADA) recommends screening for diabetes and pre-diabetes in individuals above 45 years of age and/or body mass index (BMI) of ≥ 25 kg/m².⁶ Risk factors for developing T2DM vary across populations but usually include high levels of physical inactivity, first degree relatives with diabetes patient, hypertension ($\geq 140/90$ mm of Hg), previous diagnosis of IGT or impaired fasting glucose (IFG), a history of gestational diabetes (GDM) and cardiovascular diseases.^{6,7} However, the absence of proper infrastructure for diabetes screening and high-risk group identification, hamper early diagnosis of diabetes.⁸ Lack of public awareness and knowledge on symptoms of diabetes and poverty are other notable healthcare challenges in Pakistan.⁹⁻¹¹

According to a study, increased screening activity at the level of general practitioners (GPs) can result in a 35.0% higher chance of being diagnosed with diabetes.¹² Early detection of undiagnosed diabetes, timely initiation of treatment and self-management education can help in reducing diabetes-related complications, prevent or delay disease progression and improve quality of life in patients with T2DM.^{13,14} Treatment starts with lifestyle modification, diet and exercise along with hypoglycaemic drugs like metformin, if necessary.¹⁵ For patients with micro-and macro vascular complications, treatment would include lowering of blood glucose level along with reduction in hypertension, hyperlipidaemia and other co-morbidities.

A comprehensive overview of the Pakistani healthcare system suggests a high burden of undiagnosed diabetes which is in line with other nations in South Asia.¹⁶ The demographic burden of undiagnosed diabetes represents a hidden negative variable in diabetes management initiatives. At the level of healthcare systems it stymies public health interventions by under representing the scale of the challenge posed by diabetes and by holding the potential to skew currently observed trends in patient populations. At the individual level, failure to detect diabetes can result in a significant clinical, psychosocial and financial burden. Early detection of diabetes is an important aspect of diabetes

management as evidenced by the considerable improvements in outcomes with management initiated after early diagnosis.¹³ However, sufficient evidence from a large-scale study to substantiate the routine screening of patients visiting primary healthcare settings is lacking in Pakistan. The current study was planned to collate nationwide data on the prevalence of undiagnosed T2DM in patients visiting the primary care physician (PCP) for any reason in outpatient settings of major cities of Pakistan. This study was aimed at helping healthcare providers in identifying undiagnosed patients with T2DM and help them achieve good glycaemic control. Secondary objectives of the study included documenting the management of newly-diagnosed T2DM patients for the first three months and to assess the change in glycated haemoglobin (HbA1c) and fasting blood glucose (FBG) levels from baseline to a follow-up visit 3 months after treatment initiation.

Subjects and Methods

This national, multicentre, non-interventional disease registry was conducted from October 2011 to August 2013 across Sindh and Punjab provinces of Pakistan and comprised randomly selected health centres with qualified general practitioners. The study was approved by the Review Board of Civil Hospital, Karachi, and the Dow University of Health Sciences (DUHS), Karachi. Written informed consent was obtained from all the participants.

The prevalence of diabetes in Pakistan was estimated at 12%.⁶ Assuming a margin of error of 0.65% with a 95% level of significance, a sample of 9,602 individuals was required to be screened in order to obtain a pool of approximately 1,000 T2DM patients. Thus, a sample size of 10,000 patients was proposed. This sample size was also adequate to detect a 1% change in HbA1c (9.1 to 8.1%) in three months based on data from the registry for assessing oral anti-diabetic drugs (OAD) usage in diabetes management (REASON) study conducted in South-Asia in 2006.¹⁷

A total of 100 centres with qualified general practitioners were randomly selected to recruit patients at each of the selected sites. Finally, patients were recruited from 84 sites in 12 cities. Patients aged 45 years or more, willing to have a random blood sugar (RBS) screening test and to provide informed consent were included in the study. Patients with previously known diabetes and pregnant women were excluded.

The sequence of procedures during the study was

divided into six phases: Phase-0 was PCP clinic visit for any ailment and evaluation of eligibility for screening; Phase-1 was the administration of a screening questionnaire based on 10 risk factors excluding ethnicity, as defined by the ADA; Phase-2 was RBG testing at the PCP clinic; Phase-3 was measurement of FBG and HbA1c in patients with RBG ≥ 200 mg/dL in Phase-2. Patients with FBG ≥ 126 mg/dL or only HbA1c $\geq 6.5\%$ were considered newly diagnosed T2DM; Phase-4 was initiation of diabetes management interventions in newly-diagnosed patients according to PCP discretion; and Phase-5 was follow-up visit to the PCP at the end of the 3rd month for FBG and HbA1c measurement. Patients with FBG ≥ 126 mg/dL or HbA1c $\geq 6.5\%$ at Phase-3 were confirmed as newly-diagnosed T2DM patients with previously undiagnosed diabetes.

For the study, patients were required to make two visits; visit 1 was to undergo conduct phase 0-4, and visit 2 for phase 5. The two visits were 3 months apart.

Demographic features like age, gender and physical characteristics were observed along with ADA-defined risk factors for diabetes. The glycaemic parameters of FBG and HbA1c of patients with newly-diagnosed diabetes were also analysed. All data was collected and recorded on paper-based case report forms (CRF). Categorical variables were reported as percentages and continuous variables were reported as means with standard deviations. Paired t-test was used to determine mean change in FBG and HbA1c values over three months. McNemar's test was used for comparing the proportions of patients with glycaemic controls at baseline and at three months stage.

Results

Of the 9,341 included initially, 1,091(11.67%) were excluded for various reasons (Figure). The remaining 8,250(88.32%) were screened. They had a mean age of 53.2 ± 8.1 years and mean BMI of 27.3 ± 5.3 kg/m². Among the patients 4,620 (56.0%) were males and 6,216(75.3%) were overweight (≥ 23 kg/m²) (Table-1). The most common risk factors of T2DM were BMI ≥ 23.0 kg/m² in 6,216(75.3%) cases, physical inactivity 4,534(55%), and family history 4,495(54.5%) were positive.

Patients with at least one positive risk factor numbered 6,216(75.3%) and they were subjected to RBG testing at the investigator's clinic, of whom 693(7.4%) patients had an RBG ≥ 200 mg/dL with a mean of 275.5 ± 73.3 mg/dL. In these 693 patients, FBG and HbA1c higher than predefined cut-offs were found in 445(84.8%) and 500(95.2%) patients, respectively. Of the total 8,250

Table-1: Demographic physical characteristics and risk factors for diabetes in patients screened on ADA risk factors.

Variables	N=8250, n (%)	Mean(SD)
Age (years)		53.2(8.1)
Gender (Male)	4,620 (56)	
BMI (kg/m ²)		27.3(5.3)
Screening phase-risk factors		
BMI ≥ 23.0 kg/m ²	6,216 (75.3)	-
Usual physical inactivity	4,534 (55.0)	-
Family history of T2DM	4,495 (54.5)	-
HTN ($\geq 140/90$ mm Hg or on therapy for HTN)	3,390 (41.1)	-
Low HDL cholesterol (<35 mg/dL) and/or a high TG level (≥ 250 mg/dL)	1,342 (16.3)	-
History of cardiovascular disease	903 (10.9)	-
Previous identified HbA1c $\geq 5.7\%$, IFG† or IGT	231 (2.8)	-
History of GDM or delivery of a baby weighing >4.08 kg	230 (2.8)	-
Acanthosisnigricans	204 (2.5)	-
Women with PCOS	72 (0.9)	-

BMI= body mass index, HTN=systemic hypertension, HDL=high density lipoprotein, IFG=impaired fasting glucose, TG= triglyceride, GDM=gestational diabetes mellitus, IGT=impaired glucose tolerance, PCOS=polycystic ovarian syndrome, ADA=American diabetes association, T2DM=type 2 diabetes mellitus.

Table-2: Glycaemic parameters of patients newly diagnosed with type 2 diabetes mellitus.

Glycaemic parameters	n=525, n (%)	Mean(SD)
FBG (mg/dL)	-	186.9(66.1)
FBG ≥ 126	445 (84.8)	-
FBG <126	79 (15.0)	-
Missing FBG values	01 (0.2)	-
HbA1c(%)	-	9.4(1.9)
HbA1c ≥ 6.5	500 (95.2)	-
HbA1c <6.5	12 (2.3)	-
Missing HbA1c values	13 (2.5)	-

FBG=fasting blood glucose, HbA1c=glycated haemoglobin.

patients screened, 525(6.36%) were identified with either elevated FBG or HbA1c. The mean FBG and HbA1c of these patients were 186.9 ± 66.1 mg/dL and $9.4 \pm 1.9\%$, respectively (Table-2).

After diagnosis, 484 (92.2%) patients were advised lifestyle modification, including diet and exercise. OADs were prescribed to 460(88.1%) patients and/or insulin to 50(9.5%). The most commonly prescribed OADs were Biguanide to 347(66.1%) patients and Sulphonyl urea to 341(64.9%) (Table-3).

Overall, in patients reporting for a follow-up visit, irrespective of the per-protocol 3-month duration, a mean reduction of 41.9 ± 56.8 mg/dL($p < 0.01$) in FBG and

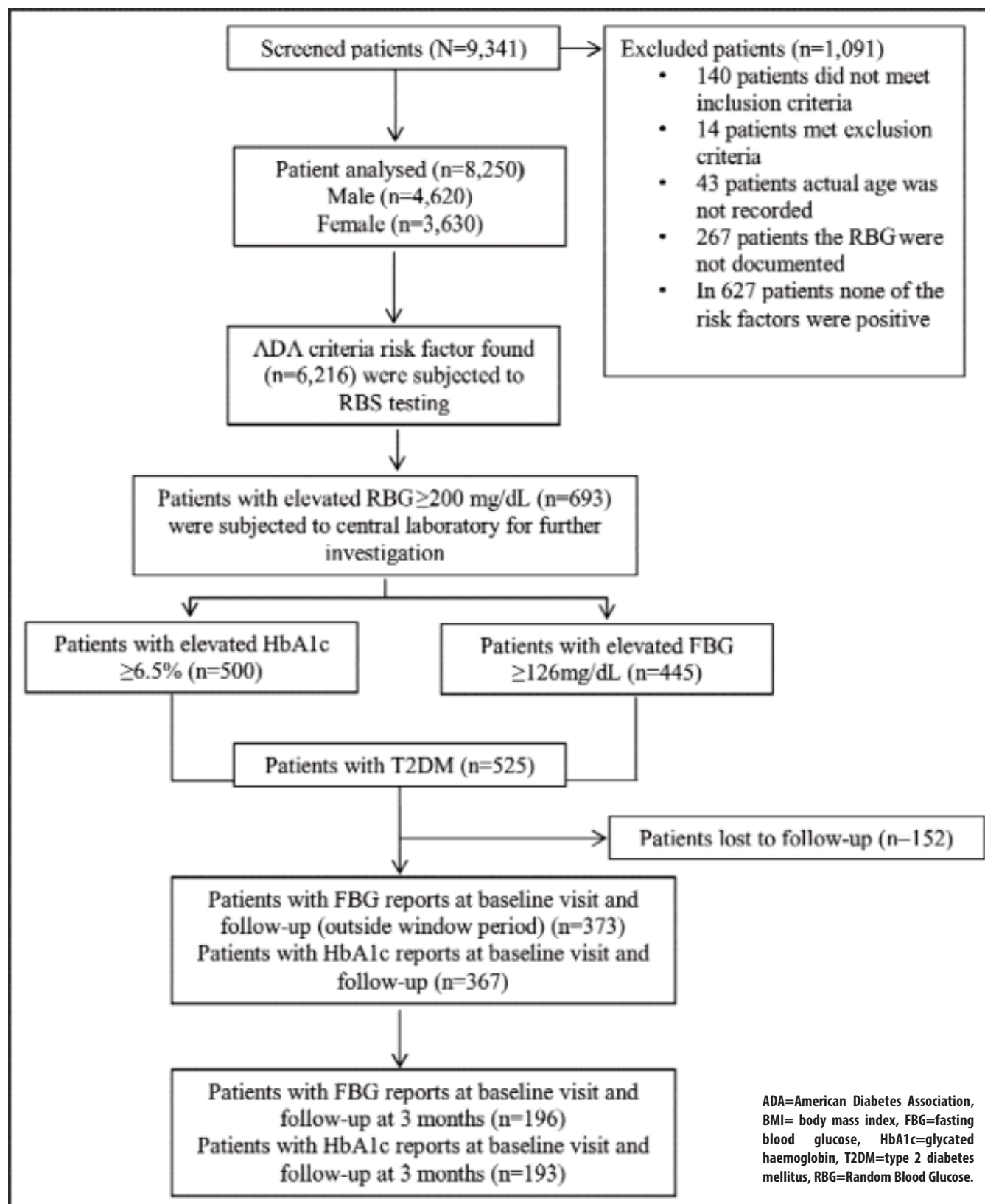


Figure: Flow Diagram of Patient disposition.

1.6±1.6% ($p<0.01$) in HbA1c was observed in 373(71%) and 367(69.9%) patients, respectively. Among 196(37.3%) patients who had their follow-up at 3 months±2 weeks, a significant ($p<0.01$) decline in mean FBG from 178.2±56.1 at baseline to 133.4±40.6 mg/dL at endpoint was observed. Also a significant ($p<0.01$) increase in the proportion of patients with FBG <126 mg/dL was observed from 14% at baseline to 53% patients at the endpoint. A significant ($p<0.01$) decline in mean HbA1c level was observed from 9.1±1.9% at baseline to 7.5±1.4% at the end point in 193(36.5%) patients who had HbA1c data both at baseline and 3 months ±2 weeks. There was a significant ($p<0.01$) increase from 3.6% to 20.7% in the proportion of patients whose HbA1c was <6.5% at the end of the second visit (Table-4). Out of the 525 patients managed

therapeutically, only 1(0.19%) serious adverse event was reported as death from brain haemorrhage. The reporter/investigator considered this unrelated as the patient had a history of hypertension.

Discussion

This disease registry was conducted to determine prevalence rate of undiagnosed T2DM patients in Pakistan. The prevalence of undiagnosed diabetes in patients visiting PCPs for any reason in outpatient setting in major cities of Pakistan was 6.4%. The three common risk factors reported were BMI ≥ 23.0 kg/m², physical inactivity, and family history of T2DM. The newly diagnosed T2DM patients were advised lifestyle modification along with OAD. Biguanide and Sulphonyl urea were the most commonly prescribed OADs. Therapeutic intervention was started with two OADs in 45.1% patients and insulin in 9.5% patients. There was a mean decrease of 1.6% in HbA1c and 41.9mg/dL in FBG at 3 months follow-up visit compared to baseline values.

The results of the present study are consistent with earlier pilot studies conducted in Pakistan which reported a diabetes prevalence of 5.1% in men and 6.8% in women, and 6.3% of undiagnosed diabetes in urban and rural population, respectively.^{18,19} In the present study the estimated prevalence of undiagnosed T2DM was 6.4% in patients visiting PCPs for any reasons in outpatient setting. The prevalence of undiagnosed diabetes in Pakistan is also in line with data from other developing countries with high-risk populations like India 7.2%, and China 9.8%.^{16,20} This may be explained in terms of similarities in the prevalence of risk factors between Indian and Pakistani populations or the rapid urbanisation in China. There also seems to be a direct relationship between high prevalence rates of undiagnosed diabetes and strong diabetes management initiatives — a study from Germany, a

Table-3: Management of patients newly diagnosed with type 2 diabetes mellitus.

Management	n=525, n (%)
Life style modification	484 (92.2)
Diet	10 (1.9)
Exercise	2 (0.4)
Diet+exercise	473 (90.1)
Missing information	40 (7.6)
On medication	525 (100)
On OAD	460 (88.1)
Any 1 OAD	205 (39.4)
Any 2 OAD	237 (45.1)
>2 OAD	7 (1.3)
Type of OAD	525 (100)
(Biguanide)	347 (66.1)
(Sulphonylurea)	341(64.9)
Thiazolidinediones	6 (1.1)
Alpha glucosidase inhibitor	9 (1.7)
Missing information on OAD	11 (2.3)
On fixed dose combination	11 (2.1)
Sulphonylurea/Biguanide	11 (2.1)
On insulin	50 (9.5)

T2DM=type 2 diabetes mellitus, OAD= oral anti-diabetic drugs.

Table-4: Mean change in FBG and HbA1c from baseline to follow-up visits in patients newly diagnosed with type 2 diabetes mellitus.

Glycaemic Parameters	Fasting blood glucose (mg/dL)				HbA1c (%)			
	n	Mean(SD)	Mean difference	p value	n	Mean(SD)	Mean difference	p value
Baseline visit	196	178.2(56.1)	44.8	<0.01	193	9.1(1.9)	1.6	<0.01
Follow-up visit at 3rd month (±2 weeks)		133.4(40.6)				7.5(1.4)		
Baseline visit	177	187.6(66.7)	39.0	<0.01	174	9.4(1.9)	1.6	,0.01
Follow-up visit outside 3 month (±2 week) period (between 4-7 months)		148.6(57.9)				7.8(1.7)		
Baseline visit	373	182.7(61.4)	41.9	<0.01	367	9.2(1.9)	1.5	<0.01
Follow-up visit of patients with available FBG reports at any time after baseline visit		140.8(50.2)				7.7(1.6)		

T2DM=type 2 diabetes mellitus, FBG=fasting blood glucose, HbA1c=glycated haemoglobin.

country with a nationwide disease management programme for T2DM,²⁰ reported a prevalence of 0.9% of undiagnosed diabetes.²¹ Similarly, the prevalence of undiagnosed diabetes in Ireland has been reported at 2.8% for patients aged ≥ 45 years;²² Ireland has a comprehensive National Diabetes Programme (NDP) as part of its healthcare system.²³

Diabetes education plays an important part in promoting disease diagnosis; low diabetes awareness is known to be associated with low rates of diagnosis.²⁴ Diabetes awareness through education programmes is also known to be associated with significantly improved glycaemic control in newly diagnosed diabetes patients.²⁵ Thus, while therapeutic interventions and periodic screening form one aspect of the medical management of diabetes, cost-effective public awareness initiatives represent a simple method to promote effective diabetes management. Data from the current study shows the need for an effective diabetes management policy focussing equally on medical and educational interventions.

Regular physical activity is important in patients with T2DM not only to improve glucose control and a variety of cardiovascular risk factors, but also to improve functional capacity and a sense of well-being.²⁶ In the present study, 83.3% of T2DM patients had history of physical inactivity, 38.5% had a BMI of >30 kg/m², 53.0% had a BMI range of 25 - 29.9 kg/m², however, only 8.6% patients had a BMI <25 kg/m². Lifestyle modifications including diet and exercise along with therapeutic intervention were advised to 90.1% patients. Studies have reported that short-term benefits for diabetes might be achieved by practicing mild physical activity.²⁷ However, in light of the reports on rising trend of unhealthy dietary and lifestyle patterns in Pakistan, counselling and effective lifestyle modifications should be promoted in order to increase patient adherence and compliance, especially for high-risk patients.^{28,29} A considerable proportion of the study population were prescribed OAD; Biguanide metformin to 66.1% and Sulphonyl urea to 57.1% for diabetes management. This is in line with a study from India, where metformin was the most frequently prescribed drug for monotherapy with OAD prescribed to 40.5% of the study population. In the same study, glimepiride and metformin were the most frequently prescribed anti-diabetic drug combinations prescribed 76.3% of the study population.³¹ Inclusion of metformin with lifestyle modifications has been recommended by ADA and American Association of Clinical Endocrinologists (AACE) in the initial

management of T2DM patients.²⁶

Initiation of insulin therapy is recommended when OADs along with lifestyle modifications fails to achieve the required glycaemic control²⁶ or directly after diagnosis when HbA1c is high ($\geq 9.0\%$).³¹ Even though a therapy-wise breakdown of baseline HbA1c trends is unavailable, almost every 1 in 10 patients were initiated on insulin, demonstrating direct insulinisation in this population. Though all currently available therapies lower glucose and HbA1c levels, the magnitude of reductions is variable. The variable drug action profile is an important modulator of drug effectiveness in patients, and should be carefully considered while selecting treatment regimens for an individual with T2DM.³² Available evidence stresses the importance of regular monitoring of blood glucose and HbA1c levels, with a view to adjust medications in three-month intervals to optimise the management of T2DM.³³

In the present study, a mean decrease of 1.6% (1.6) in HbA1c and 41.9(56.8 SD) mg/dL in FBG level was observed after 3 months of treatment in a population that was previously not screened for diabetes. Diabetes screening is known to be associated with significant glycaemic control in sub-continental populations.¹³ T2DM is often associated with microvascular complications which include retinopathy, neuropathy and nephropathy.³⁴⁻³⁶ Macrovascular complications like cardiovascular, cerebral and peripheral vascular disease are also associated with uncontrolled blood glucose level.^{37,38} As seen in United Kingdom Prospective Diabetes Study (UKPDS), HbA1c reduction is associated with significant benefits in terms of reduced secondary complications, with a 1.0% HbA1c reduction being related to 21.0% decrease in risk of any end point or death related to diabetes and 37.0% decrease in risk of microvascular complications.³⁸ Thus, early detection and treatment initiation in diabetes not only improves glycaemic control but also helps avoiding a considerable burden of secondary complications in the future.

The current study demonstrates the considerable prevalence of undiagnosed cases of T2DM in health seeking patients visiting PCPs for any reason, in a large sample. This is expected to inform policy discourse on public health strategies to combat diabetes and provide rationale for early and appropriate screening of diabetes in high risk populations. Furthermore, the present study is the first to record early/direct insulinisation in newly-diagnosed T2DM patients in Pakistan. However, the

predominantly urban setting and the health-seeking sample in which the study was conducted limits the interpretation of data in the context of the Pakistani population as a whole and may also underestimate the overall undiagnosed diabetes burden. The glycaemic benefits demonstrated in the study are limited to the study population due to the variability of the prescribed therapies.

Conclusion

Pakistan has a considerable prevalence of undiagnosed diabetes in patients visiting PCP for any reason. However, timely initiation of individualised treatment has the potential to prevent or delay diabetes complications and associated negative outcomes. This study showed a significant decrease in HbA1c and FBG in newly diagnosed diabetes patients. The considerable prevalence of undiagnosed diabetes and the benefits of timely interventions in newly diagnosed patients suggest the need for a comprehensive, national diabetes management programme, focusing on both clinical and educational interventions.

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