Original article:

Study of Prevalence, Knowledge of Diabetic Complications and its associated factors amongst patients attending OPD: Hospital based Cross sectional study

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Abstract

Background: Diabetes is a chronic disease, leading to many complications include micro vascular (nephropathy, retinopathy, and neuropathy) and macro vascular (stroke, myocardial infarction, and coronary artery disease) with co morbidities leads to a substantial decrease in the patients' quality of life as well as socio-economic implications. It is a chronic disease with considerable impact on health status and quality of life and it is considered an urgent public health issue because it has a pandemic potential.

Objectives: The main aim of this study was to determine diabetic complications and its associated factors. It also aimed to assess the knowledge of diabetic patients about the related complications.

Material and Methods: A descriptive, observational, cross sectional study was conducted in the diabetes clinics of various tertiary care hospitals across North India. The study population included all the Type 2 diabetic subjects who attended the clinic from November 2017 to April 2018. 360 subjects were selected by systematic random sampling. A pre-designed and pre-tested schedule was used for data collection. Data were collected regarding socio-demographic characteristics and duration of diabetes. In laboratory profile HbA1C levels were estimated. The data were analyzed using statistical software SPSS 20.Proportions and Chi-square test were used for analysis.

Results: Out of 360 diabetic patients, 140 (39%) had one or more complications while 220 (61%) did not have any complications. It was found that cardiovascular complications were present in 120 (33.3%) patients, cerebrovascular complications were present in 35 (9.7%) patients, peripheral vascular disease was present in 25 (7%) patients, while 50 (14%) patients were having diabetic nephropathy, 130 (36.1%) patients were having diabetic neuropathy and 110 (30.5%) patients were suffering from diabetic retinopathy. Significant association was found between the complications with religion, socio-economic status, duration of diabetes, HbA1C.Also, significant association was found between duration of diabetes and HbA1C levels with each of the individual complications.

Conclusion: Early diagnosis, periodic screening .and blood sugar control may help to reduce the complications of Type 2 diabetes.

Keywords: Nephropathy, neuropathy, retinopathy, Type 2 Diabetes Mellitus.

Background:

Diabetes mellitus (DM) appears to be a global epidemic and increasingly a major non-communicable disease threatening both affluent and non-affluent society [1, 2]. More than 170 million people worldwide have diabetes, and this figure is projected to more than double by the year 2030, if the current trend is allowed to continue further [3].Diabetes is one of the commonest and non-communicable disease remains highly prevalent with an increasing incidence globally. It is classified under three major groups, namely, type 1, type 2, and gestational diabetes [4]. World health organization defined diabetes mellitus (DM) as a metabolic disorder of multiple etiology characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both [5].

According to the International Diabetes Federation, Type 2 diabetes accounts for 85% to 95% of all diabetes in high income countries and may account for an even higher percentage in low- and middle income countries. Type 2 diabetes is a common condition and a serious global health problem [4]. Type 2 diabetes mellitus is a multidimensional health problem with important consequences owing to its increasing prevalence, chronicity and complications that cause disability, decreased health-related quality of life (HRQOL) and premature death [6]. Diabetes is a chronic disease, leading to many complications include micro vascular (nephropathy, retinopathy, and neuropathy) and macro vascular (stroke, myocardial infarction, and coronary artery disease) with co morbidities leads to a substantial decrease in the patients' quality of life as well as socio-economic implications [7]. It is a chronic disease with considerable impact on health status and quality of life and it is considered an urgent public health issue because it has a pandemic potential [8].

Adequate knowledge of diabetes is a key component of diabetic care. Many studies have shown that increasing patient knowledge regarding disease and its complications have significant benefits with regard to patient compliance to treatment and to decreasing complications associated with disease [9].

Aim and Objectives:

The main aim of this study was to determine diabetic complications and its associated factors. It also aimed to assess the knowledge of diabetic patients about the related complications.

Materials and Methods:

(i)   **Study Design:** It was a cross sectional study conducted in OPD of different tertiary care hospitals across North India.

(ii)   **Sample size:** The estimated sample size was calculated by the formula:

$$4 \text{ P Q} / \text{ L}^2; \text{ where}$$

P=Prevalence of disease/complication under study;

Q= (100-P)

L=Absolute error (ie.5% at 95% confidence interval)

A hospital based study by Rema et al. in South India showed prevalence of 34.1% retinopathy[7]. This prevalence has been taken for sample size calculation as literature review have shown this prevalence to be maximum. With 95% confidence limit and 5% absolute error, the sample size was 359.

Sample size = $4 \times 34 (100\text{-}34)/5^2$ So the sample size is calculated as 359

(iii) **Methodology:** The study was carried out in a minimum of 360 established type 2 diabetes patients, who will be visiting the clinic for treatment during the time period of November 2017 to April 2018 (6 months). The purpose and other details of the study will be discussed with the patients. An oral consent will be taken from all the participating patients, prior inclusion in the study.

(iv) **Inclusion criteria:** Diagnosed cases of Type 2 Diabetes who are willing to give informed consent to participate in the study were included.

(v) **Exclusion criteria:** Diagnosed diabetic patients who do not wish to participate were excluded. Those who were unable to reply verbal questions as well as mentally retarded and unconscious patients were also excluded from the study. Pregnant and lactating females were excluded because of safety reasons.

(vi) **Procedure:** Once the consultation by the physician was over, the prescriptions were reviewed and the patients were be interviewed using structured questionnaire (open question method). Type 2 diabetic patients were interviewed with a pre-designed and pre-tested schedule. Details regarding socio-demographic parameters such as age, sex, religion, socio-economic status of family (B.G. Prasad scale) was taken. History regarding duration of diabetes was also taken. Detailed clinical examination and relevant biochemical investigations was done. For diagnosis of Type 2 Diabetes Mellitus international standards (WHO 1999) were followed.(fasting plasma glucose $\geq$ 7.0 mmol/L or 126mg/dl and/or 2 hours postprandial plasma glucose or casual plasma glucose $\geq$ 11.1 mmol/L or 200mg/dl. The cut-off for HbA1C was taken as per WHO guidelines according to which good glycaemic control was defined as HbA1C of <7%, while 7%-8% range is acceptable and >8% was poor glycaemic control. On every visit, information regarding the use of medicines was given to the patients. The information which was recorded included patients demographic details like age, sex, body weight, height, major disorders, co-morbid conditions, family history, number of medicines prescribed, classes of medicines prescribed, complications and investigations.

(vii) **Definition of Outcome: The complications of diabetes : 1**. **Micro vascular Complications -** Retinopathy - Nephropathy - Neuropathy **2. Macro vascular Complications –** Coronary Heart Disease Peripheral Vascular Disease Cerebrovascular Disease Cardiovascular complications was diagnosed using the Minnesota criterion [8]. CT scan reports along with clinically diagnosed cases of cerebrovascular accidents will be used for diagnosis of cerebrovascular complications [9]. History of intermittent claudication or absence of one or more peripheral pulses in the feet, presence of ulcer or amputation was used to define peripheral vascular disease [10]. Presence of microalbuminuria (urinary albumin ranging from 30-300mg/day), macroalbuminuria or elevated serum creatinine was used to define diabetic nephropathy[11].Diabetic neuropathy[12]was diagnosed if there is bilateral absence of ankle jerks or bilateral loss of sensation to touch, pain and temperature. For diagnosis of diabetic

retinopathy[13], fundoscopy was done. All the reports were scrutinized by experts and expert opinion will be sought for reaching at a diagnosis.

(viii) **Statistical Analysis:** The differences in proportions were compared by unpaired t-test where appropriate. Statistical significance was set for $p < 0.05$. All statistical analysis was performed using SPSS version 17.0.

Results:

Out of 360 diabetic patients, 140 (39%) had one or more complications while 220 (61%) did not have any complications. It was found that cardiovascular complications were present in 120 (33.3%) patients, cerebrovascular complications were present in 35 (9.7%) patients, peripheral vascular disease was present in 25 (7%) patients, while 50 (14%) patients were having diabetic nephropathy,130 (36.1%)patients were having diabetic neuropathy and 110 (30.5%) patients were suffering from diabetic retinopathy.

It was found that complications were present in 16.7% and 22.3% patients in both ≤50 years and >50 years age group respectively. 23.7% of males and 13.3% of females were having complications. The presence of complications were more in Hindu patients (30.5%) compared to Muslims. Complications were more common in patients belonging to class 4 socio-economic status(25%),followed by those belonging to class 3(11.1%) and class 5(2.7%)socio-economic status respectively, while patients belonging to class 1 and class 2 socio-economic status were not presenting with any complications. The presence of complications were mostly seen in patients who are suffering from Type 2 diabetes for 5-15 years(26.5%)while it was 12.5% for patients who have diabetes for more than 15 years and patients suffering from diabetes for <5 years did not present with any complications. Complications were more frequently present in patients with HbA1C level 7%-8%, followed by 12.5% in patients with HbA1C level >8% while only 7% patients with HbA1C level <7% were presenting with complications. It was found that the association of complications were statistically significant (p<.005) with religion, socio-economic status, duration of diabetes and glycated haemoglobin levels(HbA1C) (Table 1)

Characteristics	Complications		P value
	Present	**Absent**	
Age			
<50	60 (16.7%)	120 (33.3%)	χ^2=1.027
>50	80 (22.3%)	100 (27.7%)	p value=0.31
Total	140 (39%)	220 (61%)	
Sex			
Male	90 (25%)	115 (32%)	χ^2=4.25
Female	50 (14%)	105 (29%)	p value=0.39
Total	140 (39%)	220 (61%)	
Religion			
Hindu	110 (30.5%)	140 (38.8%)	χ^2=11.7
Muslim	25 (7%)	70 (19.4%)	p value=0.001
Others	05 (1.5%)	10 (2.7%)	
Total	140 (39%)	220 (61%)	
Socio economic status			
Class 1	0 (0.0%)	30 (8.3%)	χ^2=230
Class 2	0 (0.0%)	110 (30.5%)	p value= 0.0001
Class 3	40 (11.1%)	80 (22.3%)	
Class 4	90 (25%)	0 (0.0%)	
Class 5	10 (2.7%)	0 (0.0%)	
Total	140 (39%)	220 (61%)	
Duration of Diabetes			
<5 years	0 (0.0%)	190 (52.7%)	χ^2=268
5-15 years	95 (26.5%)	30 (8.3%)	p value=0.0001
>15 years	45 (12.5%)	0 (0.0%)	
Total	140 (39%)	220 (61%)	
Hba1c			
<7%	25 (7%)	220 (61%)	χ^2=258
7-8%	70 (19.5%)	0 (0.0%)	p value=0.0001
>8%	45 (12.5%)	0 (0.0%)	
Total	140 (39%)	220 (61%)	

Table 1: Association of complications of Type 2 diabetes mellitus with various characteristics.

Among the patients suffering from diabetes for 5-15 years, 19.5% had cardiovascular complications, 1.4% had cerebrovascular complications while none of the patients had peripheral vascular disease. Diabetic nephropathy, neuropathy and retinopathy were found in 7%, 25% and 16.7% patients respectively. Again, among the patients suffering from diabetes for more than 15 years, 14% patients had cardiovascular complications, 8.3% patients had cerebrovascular complications while 7% of the patients had peripheral vascular disease. Diabetic nephropathy, neuropathy and retinopathy were found in 7%, 11.1% and 14% patients respectively. The association between duration of diabetes and cardiovascular complications, cerebrovascular complications, peripheral vascular disease, diabetic nephropathy, neuropathy and retinopathy were statistically significant. ($p<.005$) HbA1C was <7% in 4% patients with cardiovascular complications and 9.7% and 7% patients of diabetic neuropathy and retinopathy respectively. None of the patients with cerebrovascular complications, peripheral vascular disease and diabetic nephropathy had HbA1C level <7%. HbA1C was 7%-8% in 16.7% patients with cardiovascular complications, 1.4%patients with cerebrovascular complications, 7% patients with diabetic nephropathy, 19.5% patients with diabetic neuropathy and 11.1% patients with diabetic retinopathy. None of the patients with peripheral vascular disease had HbA1C level between 7%-8%.In the patients with HbA1C level >8%,cardiovascular complications were seen in 12.5% patients, cerebrovascular complications were seen in 8.3% patients, diabetic nephropathy and diabetic neuropathy were seen in 7% patients each while diabetic retinopathy is seen in 12.5% patients. 7% of the patients with peripheral vascular disease had HbA1C level between >8%.The association between HbA1C level and cardiovascular complications, cerebrovascular complications, peripheral vascular disease, diabetic nephropathy, neuropathy and retinopathy were statistically significant.($p<.005$) (Table 2)

Characteristics	Different types of complications					
Duration of Diabetes in years	Cardio vascular complications (%)	Cerebro vascular complications (%)	Peripheral vascular disease (%)	Diabetic nephropathy (%)	Diabetic neuropathy (%)	Diabetic retinopathy (%)
<5	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
5-15	70 (19.5)	05 (1.4)	0 (0.0)	25 (7)	90 (25)	60 (16.7)
>15	50 (14)	30 (8.3)	25 (7)	25 (7)	40 (11.1)	50 (14)
Total	120 (33.3)	35 (9.7)	25(7)	50 (14)	130 (36.1)	110 (30.5)
P value	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
Hba1c						
<7%	15 (4)	0 (0.0)	0 (0.0)	0 (0.0)	35 (9.7)	25 (7)
7-8%	60 (16.7)	5 (1.4)	0 (0.0)	25 (7)	70 (19.5)	40 (11.1)
>8%	45 (12.5)	30 (8.3)	25 (7)	25 (7)	25 (7)	45 (12.5)
Total	120 (33.3)	35 (9.7)	25(7)	50 (14)	130 (36.1)	110 (30.5)
P value	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001

Table 2: Association of different types of complications with the various characteristics

Complication	Participants response		
	Yes	**No**	**Don't know**
Hypertension	100 (27.7%)	50 (13.8%)	210 (58.3%)
Heart disease	30 (8.3%)	30 (8.3%)	300 (83.3%)
Hypoactive sexual arousal	60 (16.7%)	30 (8.3%)	270 (75%)
Arousal disorder	100 (27.7%)	40 (11.1%)	220 (61.1%)
Sexual pain disorder	0 (0%)	30 (8.3%)	330 (91.6%)
Retinopathy	50 (13.8%)	40 (11.1%)	270 (75%)
Nephropathy	30 (8.3%)	60 (16.7%)	270 (75%)
Diabetic foot	200 (55.5%)	50 (13.8%)	110 (30.5%)
Neuropathy	120 (33.3%)	60 (16.7%)	180 (50%)

Table 3: Response of Diabetic patients on complications of diabetes.

Table 3 shows the proportion of participants' response on the knowledge on diabetic complications. The most common diabetic complication known by diabetic patients was diabetic foot (55.5 %), followed by neuropathy (33.3 %), hypertension (27.7%), arousal disorder (27.7 %), hypoactive sexual arousal (16.7%), retinopathy (13.8%), heart disease (8.3%), and nephropathy (8.3 %) In general higher proportions of them were not knowledgeable on diabetic complications. Out of 360 patients surveyed, 330 (91.6%) had no knowledge on sexual pain disorder, 300 (83.3 %) had no knowledge on heart disease, 270 (75 %) had no knowledge on nephropathy, neuropathy 180 (50%), arousal disorder 220 (61.1%), retinopathy 270 (75%), hypoactive sexual arousal 270 (75%) and diabetic foot 110 (30.5 %) (Table 3).

Discussion:

The present study showed that the prevalence of macrovascular and microvascular complications among the diabetic patients were 39%.Significant association was found between these vascular complications with religion, socio-economic status, duration of diabetes and HbA1C levels. Though there are limited studies showing the association of complications of Type 2 diabetes with the above mentioned characteristics, one study has found significant association with complications and duration of diabetes and HbA1C levels[10]. Among the diabetic patients with complications, cardiovascular complications were present in 33.3% patients, cerebrovascular complications were present in 9.7% patients, peripheral vascular disease was present in 7% patients, while 14% patients were having diabetic nephropathy,36.1% patients were having diabetic neuropathy and 30.5% patients were suffering from diabetic retinopathy. Both cardiovascular complications and diabetic retinopathy were more in patients sufferingfrom diabetes for 5-15 years and HbA1C levels ranging between 7%-8%.All the associations were found to be statistically significant. The prevalence of cerebrovascular disease, peripheral vascular disease and diabetic nephropathy were more in patients suffering from diabetes for more than 15 years, higher levels of HbA1C and the associations were statistically significant. Diabetic neuropathy was more in patients having diabetes for more than 15 years and HbA1C levels 7%-8% and the associations were statistically significant. Ramachandran et al.[11] also revealed a high prevalence(30.1%) of coronary heart disease in a study conducted in South India. The prevalence of

stroke and peripheral vascular disease was found to be 0.9% and 4.1% respectively (Ramachandran et al.)[12].Another study have shown the prevalence of cerebrovascular disease to be 6.9%(9).Studies have shown that the prevalence of peripheral vascular disease is as low as 2.3% among diabetic patients[13] .Another study showed the prevalence of peripheral vascular disease to be 4% among Indian patients with Type 2 diabetes[14]. The higher prevalence of cerebrovascular complications and peripheral vascular disease in this study may be due to the fact, that the study was conducted in diabetes clinic of a tertiary care hospital which is a specialized centre. Significant association was found between duration of diabetes and peripheral vascular disease in studies conducted by Raman et al[15]inIndore and Ramachandran et al.[16] in South India. However no significant association was found with glycaemic control in these studies[15].The prevalence of nephropathy in the form of microalbuminuria was found to be 19.7% by Ramachandran et al.[16]in Chennai and 26.6% by Gupta et al.[17] in New Delhi. A wide variation in the prevalence of diabetic nephropathy was also found in WHO multicentric study of vascular disease[18] (2.4% in Hong Kong,23% in Delhi and 37% in Oklahoma,USA).This geographic variation may be attributed to difference in genetic as well as socio-economic,cultural and environmental factors of different ethnic groups. Diabetic nephropathy was found to have significant association with duration of diabetes in studies conducted by Mohan et al.[17]and Verghese et al.[19]. Also, increased prevalence of diabetic nephropathy has been found in patients with increased glycosylated haemoglobin in studies by Viswanathan et al[20] and Gupta et al.[21].A study has shown the prevalence of neuropathy among diabetic patients to be 30.1%. The study conducted by Rema et al[7] in South India, found the prevalence of retinopathy to be 34.1% among diabetics.The prevalence of retinopathy was found to be 23.7% in the study conducted by Ramachandran et al.[20] in Chennai. The association between diabetic retinopathy and duration of diabetes was found to be statistically significant in both the studies. Studies conducted in different settings[7,21] also revealed the increased prevalence of diabetic retinopathy with poor glycaemic control.

Conclusion:

The following study has shown that among the diabetic patients 39% were suffering from complications. It is seen that the complications were more in those suffering from diabetes for a long duration and having a poor glycaemic control. Thus early screening, regular blood glucose monitoring along with HbA1C estimation and control of blood sugar level by lifestyle modification and treatment may help to reduce the morbidity and mortality of Type 2 diabetes in the form of vascular complications.

Higher proportion of the T2D patients did not have adequate knowledge on diabetic complications. Male gender, high income earners, higher level of education, and longer duration of T2D were significantly associated with degree of understanding for diabetic complications. It is incumbent on healthcare giver to provide early diabetic education regarding causes, management and preventive measures of diabetic complications. Organizing health education programmes as well as health outreaches on preventives measures such as adjusting to lifestyle and dietary modifications will enhance the level of knowledge of diabetic complications among diabetic patients.

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Limitations:

Although it was a multi centre hospital based study but with a relatively small study population, so results cannot be generalized to the entire population.

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