

Prevalence of Complications and Clinical Audit of Management of Type 2 Diabetes Mellitus: A Prospective Hospital Based Study

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ABSTRACT

Introduction: Management of type 2 diabetes mellitus (DM) needs multi factorial risk reduction strategies like weight reduction, blood pressure (BP) control and lipid profile regulation, along with glycaemic control. These strategies should be implemented very early in the course of the disease to prevent both microvascular and macro vascular complications.

Aim: To find out the prevalence of diabetic complications and to audit the management of glycaemia, blood pressure and serum lipids in the outpatient diabetes clinic in a hospital located in Western U.P.

Materials and Methods: A prospective study conducted in a tertiary referral teaching hospital, on 105 patients with type 2 diabetes mellitus (mean age 52.84 ± 1.02 years) who attended the diabetic clinic during June 2014 to April 2015, who had undergone screening for complications. Main outcome measures: Weight, height, body mass index (BMI), blood pressure, fasting and post prandial blood sugars, glycated hemoglobin, serum lipids and presence of diabetic microvascular as well as macrovascular complications. Mean of various clinical and biochemical parameters were compared in patients with and without complications.

Results: The mean age of patients was estimated as 52.84 ± 1.02 years. Fifty six percent of patients were males. Average BMI was 28.61 ± 0.28 kg/m². Most of them had abdominal obesity. The average duration of diabetes was 8.39 ± 0.6 years. The average of systolic blood pressure (SBP), diastolic blood pressure (DBP), HbA1C, FBS, PPBS, LDL, HDL and triglyceride were estimated as 129.1 ± 1.49 mm Hg, 84.85 ± 0.94 mm Hg, $6.99 \pm 0.08\%$, 141.33 ± 2.12 mg/dl, 214.51 ± 3.11 mg/dl, 155.66 ± 2.07 mg /dl, 40.07 ± 0.38 mg/dl, 236.53 ± 3.31 mg/dl respectively based on 105 patients. Amongst micro vascular complications; retinopathy, neuropathy and nephropathy were documented in 51.4, 77.14 and 30.47% diabetes patients respectively. The prevalence of coronary artery disease, stroke and gangrene were 42.85, 12.38 and 3.80% respectively.

Conclusion: The prevalence and risk of the complications of type 2 DM significantly increased with age of patients, duration of diabetes, fasting blood sugar and LDL levels. The awareness regarding monitoring of target BP and lipid profile is needed beyond the glycaemic control, amongst patients and health care providers.

Keywords: Diabetes care, Management goals, Macrovascular complications, Microvascular complications

INTRODUCTION

Diabetes mellitus (DM) is emerging as an epidemic worldwide, of which 97% patients are known to have type- 2 insulin -resistant diabetes, which is strongly associated with visceral obesity. Its management includes not only blood sugar control but also regulation of other risk factors like body weight, blood pressure (BP) and lipid profile. National and international guidelines are available wherein the targets for management of these risk factors have been specified [1,2]. The UK Prospective Diabetes Study (UKPDS) has suggested that every 1% reduction in glycated haemoglobin (HbA1c) was associated with a 37% decrease in microvascular disease and 14% reduction in myocardial infarction (MI) [3]. Another long-term, target-driven study has shown that the control of multiple risk factor in patients with type 2 diabetes was associated with 50 % decrease in the risk of cardiovascular and microvascular events [4]. In nationwide surveys from USA, UK and South East Asia have reported that only 50% diabetics attain target HbA1c of <7% [5-7]. A study from USA which was conducted during 1999-2000 has reported that the targets achieved in management of diabetes were sub optimal and only 40% attained target BP whereas 36% diabetics had ideal low density lipoprotein (LDL) [5].

AIM

The aim of this investigation was to audit the targets achieved in management of type 2 DM and to study the prevalence of complications of type 2 DM in a tertiary care hospital of Western U.P.

MATERIALS AND METHODS

A prospective hospital based cross-sectional study on type 2 diabetic patients was conducted at a tertiary care hospital in Rohilkhand region- Western U.P. Amongst 398 out patients registered in diabetic clinic during 11 month study period (June 2014 – April 2015); 105 patients who met following criteria were included in the study.

Inclusion criteria

1. Type 2 DM was diagnosed on the basis of plasma glucose criteria i.e. either the fasting blood sugar (FBS) >125 mg/dL, or 2-h post prandial blood sugar (PPBS) >200 mg/dl, or blood sugar after 2 hrs of 75-g oral glucose tolerance test (OGTT) >200 mg/dl, or HbA1c >6.5%. The patients with classic symptoms of hyperglycemia or hyperglycemic crisis, who had a random plasma glucose ≥ 200 mg/dl, were considered as diabetic. [1,2].
2. Patients who consented to get screened for complications of type 2 DM, were considered for inclusion in this study.
3. Patients with good treatment and dietary compliance who came for regular follow-up.

Exclusion criteria

The patients having the following features were not included in this study-

1. Those suffering from Type-1 DM.
2. Diabetic patients with pregnancy/ gestational diabetes.
3. Patients who did not give consent for detailed screening/ evaluation.

4. Patients who had poor treatment compliance and follow-up. All the patients under the study were first subjected to a detailed history and examination including calculation of body mass index (BMI). Assessment for glycaemic control was done by FBS (10 hr fasting) / PPBS estimation which was estimated by glucose oxidase-peroxidase method (GOD-POD) [8].

HbA1C was determined directly (without measurement of total hemoglobin) by immunoturbidimetric method [9]. Serum total cholesterol was measured by cholesterol oxidase-phenol aminoantipyrine (CHOD-PAP) method [10]. Serum triglycerides were measured by GPO-PAP method [11].

High density lipoprotein (HDL) and LDL cholesterol estimations were done by assay based on Poly vinyl sulphonic acid and polyethylene glycolmethyl ether coupled classic precipitation method with improvement in using optimized quantities of PVS-PEGME and selected detergent [12].

Opinion from the Ophthalmologist was taken regarding the presence of retinopathy which was diagnosed by direct ophthalmoscopy. Monofilament test was done to detect the neuropathy. Presences of microproteinuria, gross proteinuria, abnormal kidney function were noted for ascertaining the incidence of nephropathy. Patients in coronary artery disease (CAD) group had a history of angina, MI and/or ECG finding of ischemia / infarction / left bundle branch block (LBBB). Cerebro vascular accident (CVA) was defined in patients with history suggestive of stroke involving significant MRI changes. Only patients who had overt gangrene or skin changes in lower extremities were considered. Special attention was paid regarding the awareness of diabetic complications and targets in management of DM amongst patients. This information was collected using a pre-tested questionnaire. The guidelines laid down by ICMR (2005) in collaboration with WHO were used to classify the targets in the patients [Table /Fig-1] [2].

STATISTICAL ANALYSIS

Mean and standard error were estimated for all clinical and metabolic parameters. The mean of each parameter of the group with the complication was compared to that of without complication using 'Independent sample T test' by SYSTAT V 13 statistical software.

ETHICAL CONSIDERATIONS

The study was carried out after the approval of the College Ethical Committee. An informed written consent was sought from the patients or relatives who were included in this study.

RESULTS

Our study was a cross-sectional hospital based study, conducted on 105 OPD patients with diabetes, who were screened for complications and had a good follow-up. The mean age of patients was estimated as 52.84 ± 1.02 years. Fifty six percent of patients were males. Average BMI was 28.61 ± 0.28 kg/m². Most of them had abdominal obesity. The average duration of diabetes was 8.39 ± 0.6 years. The average of systolic blood pressure (SBP), diastolic blood pressure (DBP), HbA1C, FBS, PPBS, LDL, HDL and triglyceride were estimated as 129.1 ± 1.49 mm Hg, 84.85 ± 0.94 mm Hg, $6.99 \pm 0.08\%$, 141.33 ± 2.12 mg/dl, 214.51 ± 3.11 mg/dl, 155.66 ± 2.07 mg /dl, 40.07 ± 0.38 mg/dl, 236.53 ± 3.31 mg/dl respectively based on 105 patients.

Amongst microvascular complications, retinopathy, neuro-pathy and nephropathy were documented in 51.4, 77.14 and 30.47% diabetes patients respectively. Comparison of various parameters in the groups with and without microvascular complications have been given in [Table/Fig-2].

The prevalence of coronary artery disease, stroke and gangrene were 42.85, 12.38 and 3.80% respectively. [Table/Fig-3] describes the comparison between various parameters in groups with and without macro vascular complications. In both micro and macro

vascular complication groups, the prevalence of complications correlated significantly ($p < 0.01$) with patient's age, duration of diabetes (DurrnDM) and LDL levels.

The patients were classified as having good control (who attained the targets), fair control and poor control [Table/Fig-4].

All patients seemed to be interested in control of blood sugar only whereas, the control of BP and/or lipid profile was not their priority. Probably because majority of patients had poor knowledge/ awareness about the target blood sugar, lipid profile and BP in management of Type 2 DM.

DISCUSSION

This study was conducted with an aim to audit the diabetes management and study prevalence of complications in our set up. HbA1C, BP, weight and lipid profile monitoring is most important aspect in diabetic care. A multicentric study (Diab care asia) conducted in 1998 reported that only 7.8% patients got their HbA1c tested. Another epidemiological study (DEDICOM) in 2005 also reported that HbA1c was estimated in only 13% patients [13,14] thus indicating a poor awareness of HbA1c testing. However HbA1c is now gaining popularity and has been accepted widely for monitoring as well as diagnosis of DM [1,2]. The awareness regarding monitoring of lipid profile and ideal BP is still lacking amongst patients and health care providers.

Amongst 398 diabetics attending our clinic only 105 gave their consent for the study. 73% patients did not wanted complete screening for complications, mainly due to ignorance, lack of time or financial support. Many of them were not included as they came for infrequent follow up and were inclined for herbal/ alternative medicine for management of their diabetes.

Amongst the study group, 75-80% belonged to lower/lower middle socio-economic status as well as rural background. Most of the patients were ignorant about the targets in management of DM while only a few (approx. 10 %) knew about role of weight management and control of BP and lipid profile in preventing complications of Type 2 DM. These findings are in accordance with the DEDICOM study done on 819 patients; where only 32% patients had BP measurement and 16% patients had their lipid profile done [14]. It has also been reported that only 43.4% patients got their BP checked, 5.6% had their kidney function test done and 4.2% had their lipid profile measurement done. Eye check-up was done on 7.6% patients and 47.6% came for 4 or more follow-up in a year [15].

The target FBS and HbA1C was achieved by 7.6 and 13.3% patients respectively. Most of the patients were on 2-3 oral hypo glycaemic agents but still could not achieve the target of HbA1C. Inadequate control of HbA1C (>7) was seen in 76, 50 and 55% patients from multi centric studies conducted at U.K, USA and Asia respectively [5-7]. Prevalence of patients achieving the optimal target HbA1C (<7) was observed in 46, 26.3, 31.4 and 45% patients from Brazil, Thailand, Pakistan and India [16-

S I . No.	Parameter	Ideal (Target)	Satisfactory (Fair)	Unsatisfactory (Poor)
1.	FBS (mg/dl)	80-110	111-125	>125
2.	PPBS (mg/dl)	120-140	140-180	>180
3.	HbA1C (%)	<7%	7-8%	>8%
4.	BP (mmHg)	<130/80	<140/90	>140/90
5.	Body Mass Index (kg/m ²)	20-23	-	-
6.	Total cholesterol (mg/dl)	<180	-	-
7.	LDL (mg/dl)	<100	-	-
8.	HDL (mg/dl)	>45	-	-
9.	Triglyceride (mg/dl)	<150	-	-

[Table/Fig-1]: Targets in management of Type 2 Diabetes Mellitus (ICMR Guidelines, 2005) [2]

Complications Parameters	Neuropathy			Retinopathy			Nephropathy		
	Present (81)	Absent (24)	p-value	Present (54)	Absent (51)	p-value	Present (32)	Absent (73)	p-value
Age (years)	55.53 ± 1.05	43.79 ± 1.82	p<0.01	57.37 ± 1.22	48.05 ± 1.39	p<0.01	58.56 ± 1.50	50.34 ± 1.21	p<0.01
Durn DM (years)	10.00 ± 0.74	2.95 ± 0.49	p<0.01	11.85 ± 0.93	4.72 ± 0.56	p<0.01	14.21 ± 1.16	5.83 ± 0.57	p<0.01
SBP (mm Hg)	130.18 ± 1.82	125.66 ± 2.11	0.207	131.57 ± 2.41	126.58 ± 1.68	0.096	132.75 ± 2.62	127.57 ± 1.80	0.112
DBP (mm Hg)	85.26 ± 1.12	83.50 ± 1.69	0.437	85.40 ± 1.37	84.27 ± 1.29	0.551	85.21 ± 1.78	84.69 ± 1.11	0.801
BMI	28.61 ± 0.29	29.24 ± 0.55	0.303	28.81 ± 0.37	28.70 ± 0.35	0.523	28.68 ± 0.54	28.79 ± 0.29	0.774
HBA1C (%)	6.94 ± 0.008	7.17 ± 0.22	0.267	7.10 ± 0.11	6.87 ± 0.12	0.181	7.24 ± 0.15	6.88 ± 0.10	0.054
FBS (mg %)	142.00 ± 2.50	139.08 ± 3.90	0.566	146.87 ± 3.21	135.47 ± 2.51	p<0.01	151.12 ± 4.51	137.04 ± 2.15	p<0.01
PPBS (mg %)	216.83 ± 5.99	206.34 ± 9.47	0.375	225.42 ± 8.15	201.70 ± 5.57	0.024	237.75 ± 11.72	204.19 ± 4.82	p<0.01
LDL (mg/dl)	159.17 ± 2.20	143.83 ± 4.52	p<0.01	161.27 ± 2.92	149.72 ± 2.74	p<0.01	164.06 ± 3.85	151.98 ± 2.35	p<0.01
HDL (mg/dl)	40.09 ± 0.42	40.00 ± 0.90	0.914	39.64 ± 0.52	40.52 ± 0.55	0.252	39.37 ± 0.75	40.38 ± 0.44	0.227
TRIG (mg/dl)	239.48 ± 3.55	226.58 ± 7.96	0.102	239.70 ± 4.25	233.17 ± 5.12	0.327	242.68 ± 5.50	233.84 ± 4.09	0.220

[Table/Fig-2]: Comparisons of means of various parameters in the group with and without microvascular complications

Complications Parameters	Gangrene			CAD			CVA		
	Present (104)	Absent (101)	p-value	Present (45)	Absent (60)	p-value	Present (13)	Absent (92)	p-value
Age (years)	65.00 ± 2.88	52.36 ± 1.03	0.018*	57.71 ± 1.39	49.20 ± 1.28	0.001**	63.15 ± 2.15	51.39 ± 1.05	p<0.01**
Durn DM (years)	17.50 ± 2.46	8.02 ± 0.64	0.001	11.93 ± 1.07	5.73 ± 0.61	p<0.001**	14.07 ± 2.11	7.58 ± 0.64	p<0.01**
SBP (mm Hg)	137.75 ± 2.78	128.81 ± 1.54	0.255	130.55 ± 2.74	128.10 ± 1.63	0.420	129.53 ± 3.55	129.09 ± 1.62	0.923
DBP (mm Hg)	94.00 ± 5.41	84.49 ± 0.94	0.054	84.55 ± 1.30	85.08 ± 1.33	0.784	87.84 ± 2.77	84.43 ± 1.00	0.236
BMI	26.07 ± 0.65	28.86 ± 0.26	0.041*	28.80 ± 0.42	28.73 ± 0.32	0.723	27.76 ± 0.80	28.89 ± 2.59	0.098
HBA1C (%)	8.05 ± 0.32	6.95 ± 0.08	0.013*	7.12 ± 0.12	6.90 ± 0.11	0.202	7.36 ± 0.27	6.94 ± 0.08	0.100
FBS (mg %)	164.75 ± 5.15	140.40 ± 2.14	0.027	145.80 ± 3.14	137.98 ± 2.81	0.068	154.23 ± 5.96	139.51 ± 2.21	0.022*
PPBS (mg %)	297.75 ± 37.66	211.19 ± 4.86	0.001	227.20 ± 9.31	204.84 ± 5.28	0.028*	260.92 ± 21.65	207.89 ± 4.62	p<0.01**
LDL (mg/dl)	176.50 ± 11.28	154.84 ± 2.08	0.045*	163.62 ± 3.37	149.70 ± 2.35	p<0.001**	166.84 ± 7.76	154.08 ± 2.07	0.043*
HDL (mg/dl)	37.25 ± 0.62	40.18 ± 0.39	0.143	39.91 ± 0.62	40.20 ± 0.48	0.711	40.00 ± 1.41	40.08 ± 0.39	0.941
TRIG (mg/dl)	271.25 ± 20.62	235.15 ± 3.29	0.036*	244.80 ± 4.96	233.33 ± 4.30	0.030*	251.28 ± 10.68	234.43 ± 3.43	0.092'

[Table/Fig-3]: Comparisons of means of various parameters in the group with and without macrovascular complications

* significant (p<0.05), ** highly significant (p<0.01)

Month	Parameter	FBS	PPBS	HbA1C	BMI	LDL	BP
Patient without complication (n=24)	Ideal/Good	5	2	2	3	2	7
	Satisfactory/Fair	9	7	9	18	3	9
	Unsatisfactory/Poor	10	15	13	3	19	8
Patient with complication (n=81)	Ideal/Good	3	3	12	10	3	14
	Satisfactory/Fair	9	17	22	42	2	46
	Unsatisfactory/Poor	69	61	47	29	76	21
All patients (n=105)	Ideal/Good	8	5	14	13	5	21
	Satisfactory/Fair	18	24	31	60	5	55
	Unsatisfactory/Poor	79	76	60	32	95	29

[Table/Fig-4]: Achievement of targets of various clinical and biochemical parameters

19] respectively. The reason for higher prevalence of optimal target control in India could be due to the fact that this study was conducted recently and with the advent of time, the awareness for HbA1C could be increasing amongst patients as well as health professionals.

Ideal BMI was observed in 11.4% patients [Table/Fig-4] which could be attributed to poor awareness in patients about weight management as a control measure in diabetes. The situation seems to be improved in Brazil where target BMI has been reported to be achieved in 24% patients [16]. The mean systolic (SBP) and diastolic (DBP) blood pressures were observed to be 129.15 ± 1.49 and 84.85 ± 0.94 mm Hg respectively in our study which seemed to be fairly controlled. This could be probably due to the fact that most of the patients were already on one or two antihypertensives at the time of interview. In a study from Brazil, it was seen that optimum SBP and DBP were attained in 28.5 and 19.3% patients respectively [16]. In a similar study conducted at Australia, 60% diabetics had optimal control of BP (<130/80 mmHg) [20].

In our study, 4.7% patients had attained optimal control of LDL (<100 mg/dl), 4% patients had optimal control of triglyceride (<150 mg/dl) and 48% patients had optimal control of HDL (>40 mg/dl). The LDL levels were poorly controlled (>100 mg/dl) in our population because of lack of awareness about control of lipid profile and poor compliance of hypolipidemic drugs. In a multicentric trial on 5400 patients from 178 centers across India, 48.74% patients in urban settings attained optimal control of LDL (<100 mg/dl) [21] which is quite contrasting to our values observed on patients belonging to rural settings. Amongst microvascular complications; retinopathy, neuropathy and nephropathy were documented in 51.4, 77.14 and 30.47 % diabetes patients respectively. The prevalence of coronary artery disease, stroke and gangrene were 42.85, 12.38 and 3.80% respectively. The prevalence of complications exhibited significant ($p < 0.01$) correlation with patient's age, duration of diabetes and LDL levels, in both micro and macro vascular groups.

A similar study in South India on new onset type 2 diabetics showed prevalence of neuropathy (16%), retinopathy (20%), nephropathy (34%), CAD (25%), peripheral vascular disease (PVD-11%) and CVA (8%). These results suggest that diabetic complications start even before overt hyperglycemia is seen and some other factors like dyslipidemia and metabolic syndrome may also be responsible for these complications [22]. In this study age, duration of type 2 DM and high LDL had highly significant ($p < 0.01$) bearing on almost all complications of Type 2 DM, except gangrene [Table/Fig-2,3]. Our results were in accordance with other similar studies [3,22,23].

There was a highly significant ($p < 0.01$) association of FBS with retinopathy, nephropathy and CVA (stroke). A significant ($p < 0.05$) effect of PPBS was observed on microvascular complications. HbA1C did not exhibit any effect on micro or macro vascular complications probably because most of the patients were on 2-3- oral medications and mean blood sugar remained to be under control. These observations were not in accordance with other reports because the patient sample size and duration of follow-up in our study was limited.

CONCLUSION

The prevalence and risk of the complications of type 2 DM significantly increased with age of patients, duration of diabetes, fasting blood sugar and LDL levels. Hence, FBS, HbA1C and lipid profile should be aggressively managed early in the disease to prevent life threatening complications like coronary artery disease and stroke. Educating the type 2 diabetics about the disease and targets in its management is of prime importance and there is a need to develop a national programme regarding management of diabetic dyslipidemia especially for the rural masses.

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