Original Article

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A Study of Microvascular Complications in Patients with Newly Diagnosed Type II Diabetes Mellitus in a Tertiary Care Hospital, Moradabad

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Abstract

Background: Diabetes mellitus is a metabolic syndrome which has reached epidemic levels in both developed and developing parts of the modern world. With rising prevalence of obesity, physical inactivity and other related metabolic syndromes, the incidence and prevalence of type II DM is sharply increasing along with the related complications. Type II diabetes mellitus is related with macrovascular and microvascular complications, latter being usually overt. In fact, in many cases the type II diabetes often reaches clinical attention due to the microvascular complications. The common microvascular complications including diabetic retinopathy, diabetic nephropathy and sensory neurological deficits are a common cause of morbidity associated with type II diabetes. Aim: The frequency of microvascular complications in newly diagnosed cases of Type II diabetes mellitus. **Subjects and Methods:** More than 200 patients newly diagnosed cases of type II DM were included in the study conducted in Medicine Department of our Institution following approval from IEC and after obtaining written & informed consent. The frequency of the microvascular complications including diabetic retinopathy, diabetic nephropathy and diabetic sensory neuropathy was calculated utilizing various tests and clinical examination along with presence of hypertension and smoking, latter are known factors in increasing the severity of the type II diabetes related morbidities. Appropriate statistical methods and tools were used to find out the statistical significance of various observations. **Observations and Results:** Significant number of patients in our study were in 41-60yrs age group with male predominance. Majority were obese and more than three-fourth had deranged HbA1c levels of >6.5. Significant number of patients had hypertension and were smokers that showed statistical correlation with increased incidence of microvascular complications in the corresponding subgroup. Significant proportion of patients in our study group were detected with microvascular complications in form of diabetic retinopathy, diabetic nephropathy and sensory neuropathy. **Conclusion:** Since the incidence of microvascular complications including retinopathy, nephropathy and sensory neuropathy is quite high in newly diagnosed patients of Type II diabetes mellitus, hence clinical & laboratory tests directed to their diagnosis should be included in the screening protocol of such patients. As these tests are inexpensive, hence their inclusion may go a long way in reducing the microvascular complication related morbidity in type II diabetes mellitus patients.

Keywords: Microvascular complications, type II Diabetes Mellitus

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Introduction

Diabetes Mellitus

DM has emerged as a common and important general medical disease. In patients with T2DM, lack of insulin from the pancreas or low insulin usage prompts high blood glucose levels.Eastern Medical College Journal The worldwide load attributed to this disease was a hundred and ten millions during the ’90s, and it was stretched out to augment to roughly double by 2010.[1]

DM is divided into Type (most typically in adolescence, characterized by the pancreatic tissue not being able to produce adequate amounts), Type 2 diabetes and Gestational diabetes.[2]

In T2DM (also called a non-pancreatic deficiency), insulin conveys in ordinary or even high wholes, yet body cells’ reaction to insulin is flawed, provoking insulin block. Insulin

block is a biochemical state where cells dismiss the adequate use of the insulin produced.[3,4] The main pathophysiological reason for T2DM is the disappointment of pancreatic β cells. It is the incapability of these cells that prompts inadequate outflow of insulin resulting in an expanded insulin obstruction in the target tissues such as liver, fat tissues, and muscles. Most of the people are determined to have T2DM only when they have problems related to the complications of diabetes.[2,4]

"Normally, diagnosis of diabetes is ascertained depending upon levels of blood glucose, assessed either with measurement the fasting plasma glucose (FPG) levels or the 2-hour plasma glucose (2-h PG) level after a 75-g oral glucose tolerance test (OGTT)."[2,5,6]It was only recently, that the American Diabetes Association (ADA) proposed the usage of Glycosylated Haemoglobin which corresponds to glycated haemoglobin, to be included in the supported strategy to achieve better avowing of diabetes.[4,5,7] "The Glycosylated Haemoglobin cut-off concentrations for ailment confirmation as advised by the American Diabetes association in 2012; and updated in 2018 are: under 5.7% (regular); 5.7% to 6.4% (prediabetes); 6.5% or higher (diabetes)."[2,4,5]

The current plan type 2 DM is that it remembers triple varieties from the standard for the start of hyperglycemia,

1. Impaired pancreatic insulin discharge,
2. Peripheral protection from insulin action happening primarily in liver, muscle, and
3. Excessive hepatic glucose yield.

As a progressing ailment, it leads to various complication broadly categorized in to vascular and nonvascular. Vascular abnormalities are furthermore subdivided into microvascular (affecting the small vessels) or macrovascular (affecting large, major vessels). Persistent hyperglycemia remains the critical reason for little vascular entanglements.[8]

Microvascular consequences comprise of tactile framework hurt (neuropathy), renal incompetence (nephropathy), and eye hurt (retinopathy). Whereas large vessel entanglements consist of cardiovascular disease, stroke, and periphery vascular disorder.

Visual lack is chiefly the eventual outcome of diabetic retinopathy and clinically massive macular edema.[9–11] Even up to amazingly late stages, DR is usually asymptomatic

Diabetic neuropathy has a critical association with foot ulceration and danger of amputation. DN can impact various pieces of both the periphery and the tangible autonomic frameworks. DPN and DAN regularly match.[2]

DN's signs will range from an indistinct reduction of the sense of temperature in the feet to destruction of the heart. The most frequently perceived involvement of diffuse DPN is distal and sensorimotor polyneuropathy.[8] Unmistakable insufficiencies start distally in the cut off points and progress proximally, achieving the customary "stockingglove" scattering. From the outset, unobtrusive annihilation of small fibers can achieve a sense of changed temperature acknowledgment, paresthesias, dysesthesias, just as neuropathic torture. With neuropathy development, colossal nerve strands similarly become harmed, which achieves diminished light touch and proprioception sensations and finally muscle inadequacy.[12] DAN impacts various structures, including the gastrointestinal system (gastroparesis, the runs, stoppage) and the genitourinary structure.[12]

Diabetic Nephropathy clinically portrays constant proteinuria of more than 500 mg/day in a diabetic patient. Two critical features adding to the pathology of human diabetic neuropathy are nerve fiber degeneration and gross infections of the veins giving them. The pore size of the glomerular basement layer increases as Nephropathy progresses, causing proteinuria, accompanied by replication of mesangial cells until an extracellular structure and glomerular sclerosis expansion, reaching a reinforcing renal cap.[2] The release of 30 to 300 mg/g creatinine is represented by micro-albuminuria. "CKD can be gathered into 5 stages reliant on eGFR: $\geq$ 90 (stage 1), 6089 (stage 2), 4059 (stage 3A), 3044 (stage 3B), 1529 (stage 4), and < 15 (stage 5) ml/min/1.73m^2."[2,6,13]

The DCCT evaluate if simple glycemic control in patients with DM diminishes the repeated earnestness of small vascular inconveniences. The genuine benchmark bunch achieved lower Glycosylated Haemoglobin levels than the ordinary benchmark gathering, and patients follow up for about a period of 6.5 years.[14]

AIM

- To study the occurrence of micro-vascular complications in newly diagnosed type 2 diabetes mellitus patients.

Objectives

- To study the Micro-vascular complications namely - Diabetic Retinopathy, Diabetic Nephropathy, Diabetic Neuropathy in patients with newly diagnosed type 2 Diabetes.
- To correlate incidence of micro-vascular complications with patient characteristics {age, sex, BMI, glycosylated haemoglobin levels, obesity, smoking, hypertension, alcohol intake} in order to look for associated possible risk factors.

Subjects and Methods

This observational, hospital-based, study was carried out on newly diagnosed cases of type II Diabetes mellitus in the Department of Medicine of our Institution over a period of 12 months following approval of Institutional Ethics committee

and after obtaining an informed consent according to the following criteria:

Inclusion Criteria

All Type 2 Diabetic Patients diagnosed within the past 6 months.[3]

Exclusion Criteria

- Type 1 Diabetes Mellitus patients.
- Women with Gestational Diabetes

After obtaining each patient's medical history, family history, and treatment if any, the patients were examined for the microvascular complications. Stratification of the subjects was done based on patient characteristics {age, gender, BMI, smoking, alcohol use, hypertension, HbA1c levels} to assess and attempt to find a correlation with possible associated risk factors.

Case Definitions

Newly diagnosed type 2 DM: patients who have been diagnosed with type 2 diabetes mellitus within the past 6 months [As Per American Diabetes Association Guidelines-symptomatology or taking Anti diabetic medication with Random Plasma Glucose >/= 200mg/dl Or Fasting Blood Glucose Levels >/= 126 Mg/dl Or Hba1c >/=6.5%].[5,8]

● Assessment of Retinopathy by ophthalmological examination included fundoscopy and measurement of visual acuity.

Non proliferative Diabetic Retinopathy (NPDR)- microaneurysms, small 'dot and blot' haemorrhages, 'splinter' haemorrhages, intraretinal microvascular abnormalities (IRMA) and 'cotton wool' spots. The presence of lesions in various degrees determines whether the NPDR is 'mild', 'moderate', 'severe' and 'very severe'.

Proliferative Diabetic Retinopathy (PDR)-

Neovascularization - elsewhere (NVE) -On optic disc (NVD).[15,16]

● Assessment of Neuropathy by looking for abnormal/decreased- Vibration perception to a 128-Hz tuning fork Pressure sensation with a Semmes-Weinstein monofilament.

● Assessment of Ankle reflex by a percussion hammer.

● Nerve Conduction Studies carried out when required.[13]

- The release of 30 to 300 mg/g creatinine is represented by micro-albuminuria. "CKD can be gathered into 5 stages reliant on eGFR: ≥ 90 (stage 1), 6089 (stage 2), 4059 (stage 3A), 3044 (stage 3B), 1529 (stage 4), and < 15 (stage 5) ml/min/1.73m^2."

Routine Investigations included CBC, FBS, PPBS, HbA1c, KFT, LFT, Lipid Profile,

Blood Pressure Measurement, Urine Routine

Microscopic Examination, Chest X ray, ECG

Results

Age distribution:

Out of 214 patients in our study, maximum number (23.36%) of patients were clustered in 51-60yrs followed by 41-50yrs with minimum number i.e. 0.93% in 81-90 yrs.

Gender distribution:

Majority of the patients in our study were male (n=128, 59.81%). This clearly indicate higher incidence of newly diagnosed diabetes in males.

Distribution based on Body Mass Index (BMI)

In our study around half of the patients were overweight (50.93%) followed by obese (29.44%) with fewer being underweight or normal. Mean and standard deviation is 35.67±17.20 with a significant p value of 0.0038.

Distribution based on Glycosylated Haemoglobin levels:

Out of 214 patients in our study, nearly 80% had Glycosylated Haemoglobin levels of >6.5, with 29% showing levels >9.5.

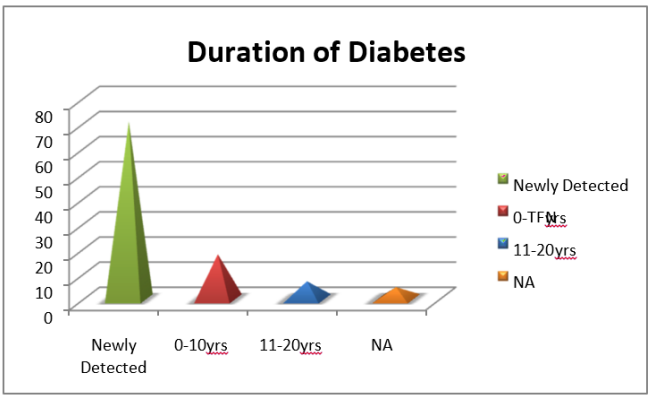

Figure 1: Duration of Diabetes

Hypertension in newly diagnosed diabetics:

Out of 214 patients, 114 had hypertension and remaining 100 patients do not have. The frequency of neuropathy between diabetic patients that had a history of hypertension and those who did not, t-test was significant (p value: 0.0416).

Smoking:

In our study, 105 patients had history of smoking. Most of the people who smoked were males. The prevalence of retinopathy between diabetic people who smoked and diabetic people who did not smoke was statistically significant (p-value: 0.0119).

Table 1: Urine Albumin Creatinine Ratio

Stages of nephropathy	Urine dipstick for protein	Urine ACR (mg/mmol)	24-hour urine collection for albumin	No. of patients	Percentage
Normal	Negative	<2	<30 mg/day	49	22.90
Micro-albuminuria	Negative	2-20	30-300 mg/day	113	52.80
Overt	Positive	>20	>300 mg/day	43	20.09
		>67	>1,000 mg/day	0	0
NA				9	4.21
Mean ± Std. dev.	42.8±44.56				
P value	0.0982				

Stages of Diabetic Nephropathy: Urine Albumin Creatinine Ratio:

From [Table 1] we can see that the urine albumin-creatinine ratio (ACR) out of total 214 patients, 22.90% for less than 2 mg/mmol, 52.80% were within 2-20, 20.09% for more than 20 mg/mmol and 4.21% are not applicable. Here the mean is 42.8 and standard deviation is 44.56 (p value-0.0982). This disparity is found not to be statistically important under traditional standards.

Diabetic Retinopathy:

Diabetic retinopathy (DR) is the commonest microvascular complication and leading cause of blindness in diabetics. 42.06% patients on Indirect Ophthalmoscopic examination of the fundus, were diagnosed with mild NPDR, 21.49% patients had moderate NPDR, and 8.41% of patients with severe NPDR. 23.83% patients were diagnosed with no Diabetic retinopathy and 4.21% were not applicable. This was statistically significant (p value 0.0398).

Diabetic Neuropathy

Diabetic Neuropathy was studied using two tools, namely lower limb numbness/ tingling and altered Sensory Testing using a Simmes-Weinstein Monofilament.

Up to 142/214(66.36%) patients had clinically significant bilateral lower limb numbness/tingling as well as altered Monofilament Sensory Testing which was not

statistically significant.

Discussion

In our study, maximum patients were in 51-60yrs age group followed by 41-50yrs. Zoungas, S. et al,[17] (2014) stated that "There has been a stagnant data confusion on age, age at diabetes diagnosis, diabetes duration, and vascular events. The mean age (±SD) was 65.8 ± 6.4 years with the mean age at diagnosis was 57.8 ± 8.7 years, and the definition for diabetes was 7.9 ± 6.4 years. The probability of full-scale macrovascular events, microvascular events and end-of-life were associated with the diabetes spectrum, while age (or age at diagnosis confirmation) was simply associated with the risk of large-scale vascular events and passing-through. No relation between duration, age, and probability of large-scale vascular accidents or deaths (both p>0.4) attributed to diabetes."[18]

In our study, majority of patients (128/214) were males comprising of 59.81%. This clearly shows gender wise males are more frequently suffering from newly diagnosed diabetes but this is not statistically significant as by Bharti Prakash, et al (2018) who stated that the pervasiveness of microvascular complexities increments with age, term, weight list (BMI), hereditary, and poor glycemic control.[19]

In our study 50.93% patients were overweight while 29.44% were obese with mean and standard deviation of 35.67±17.20. Deepak Kumar Garg (2019) in their study had Type 2 diabetes mellitus and BMI below 18.5 kg/m2, a factor for evaluation as of late disease in patients.

Data analyses revealed in our study that 28% of patients in our sample had diabetic nephropathy at the time of the initial diagnosis of diabetes. Elmokashfi T Albala (2018) in their study on newly discovered diabetics found that the mean Glycosylated Haemoglobin in males was 11.88% ±0.43 and in females 13.26% ±0.66%.[18]

In our study, 114/214 had hypertension. The rate of neuropathy between diabetic patients that had a history of hypertension and those who did not have a history of hypertension using the t-test was statistically significant (p value: 0.0416). according to Z. Anwer (2011), most of these patients have strikingly exacerbated hazard small vascular and huge scope vascular complexities.[20]

There were 105 smoker patients in our study with majority being men. The frequency of retinopathy between diabetic people who smoke and diabetic people who did not smoke demonstrated a statistically significant. Mariola Śliwińska-

Table 2: Diabetic Retinopathy (on fundus examination)

Diabetic Retinopathy	No. of patients	Percentage
Mild NPDR	90	42.06
Severe NPDR	18	8.41
Moderate NPDR	46	21.49
No DR	51	23.83
NA	9	4.21
Total	214	
Mean ± Std. dev.	42.8±31.87	
P value	0.0398	

Mossoń (2017) in their study on smoker diabetics have confirmed an expanded predominance and a greater danger of early passing related to macrovascular inconveniences' progression.[21] Furthermore, smoking add to the pathogenesis of type 2 diabetes.

Out of 214 patients, 29.44% (66) patients had a history of consuming alcohol. Alexei Volaco et al (2018) revealed U shaped correlation between alcohol consumption and DM and its problems.[22]It has been suggested that ingestion of moderate amount of alcohol may reduce the risk of developing diabetes mellitus and may be associated with improved metabolic control, a decrease in some microvascular complications (retinopathy and nephropathy) and a decrease in mortality and macrovascular events.

In our study, the distribution of urine albumin-creatinine ratio (ACR) revealed 22.90% <2 mg/mmol, 52.80% were within 2-20, 20.09% >20 mg/mmol and 4.21% are not applicable. Rahman MA (2016) revealed that micro-albuminuria is an early marker of diabeter nephropathy. It is more affected by a familial tendency to hypertension in diabetic people paying little heed to an embodiment of raised BP.[23]

Significant number of patients (>75%) in our study revealed diabetic retinopathy (DR).

A. Abdollahi et al (2006) in their study stated that diabetic retinopathy commonest complexities of T2DM.[24]

In our study, significant number of patients (66.36%) had clinically significant bilateral lower limb numbness/tingling. V Bansal (2006) also demonstrated distal-adjusted neuropathy is the commonest (75%).

In our study the Altered Monofilament Sensory Testing was found to be present in 142 i.e. 66.36% of patients and absent in 62 (28.97%). And those with other causes of neuropathy subsequently diagnosed were 10 i.e. 4.62%. This disparity is found not to be statistically important under traditional standards.

Conclusion

The current study reiterates the emphasis on the fact that a major chunk of patients present with clinically significant morbidity related to the disease or its complications in one way or other, at diagnosis and for years before diagnosis. Our analysis indicated a higher incidence of retinopathy, followed by neuropathy and nephropathy; in newly diagnosed T2DM patients.

This highlights the imperative need for aggressive screening to recognize microvascular complications as early as possible, and to stop or delay the development of complications. It can be conclusively said that BMI can also be duly responsible for elevated micro-vascular risks in newly diagnosed diabetes patients.

Thereby according to our analysis, in order to solve this issue, an appropriate screening system and proper monitoring of diabetes should be carried out. Diabetic clinics should actively support newly diagnosed type 2 diabetic patients even with non-significant ACR. By using conventional criteria we found out that most of the patients show an altered Monofilament Sensory Testing for detection of Diabetes Mellitus thus confirming the presence of Diabetic Neuropathy; and the most commonly seen microvascular complication was Diabetic Retinopathy. History of smoking or alcohol increased the risk quite significantly in diabetics.

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