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Research Article

PERIPHERAL NEUROPATHY- AN EARLY MARKER OF MICROVASCULAR COMPLICATIONS IN NEWLY DIAGNOSED TYPE 2 DIABETES MELLITUS

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Diabetes mellitus (DM) leads to increased morbidity and mortality as a consequence of macro- and micro-vascular complications.

A B S T R A C T

Background- Diabetes mellitus (DM) leads to increased morbidity and mortality as a consequence of macro- and micro-vascular complications. Diabetic neuropathy is considered as one of the most common long term, complications of diabetes mellitus and is clinically present in 30-50% of all diabetic patients. The clinical and electro-physiological evidence of diabetic peripheral neuropathy is estimated to be about 70% in both type-I and type-II diabetes mellitus. Here we evaluate the presence of microvascular complications in newly diagnosed diabetic patients.

Materials And Methods- This observational study was performed in Department of Medicine at SRMSIMS, Bareilly for duration of 16 months (1st January 2018 to 30th April 2019) on newly diagnosed type 2 diabetes mellitus as per ADA Criteria (within 3 months) patients with age more than 18 years who were attending medicine OPD and medicine wards and who had confirmed consent and were fit to the inclusion criteria were recruited for this study.

Results- The present study revealed that neuropathy develops at the time of diagnosis of diabetes in 55.8% patients and should be regularly screened for. Diabetic neuropathy. Diabetic retinopathy was found only in 13.7 % patients whereas Evidence of Nephropathy was found only in 4.9% of the patients.

Conclusion- Early diagnosis of peripheral neuropathy, patient education and treatment prevents moribound complications like neuropathy related foot ulcers, diabetic foot, falls etc. Patients presenting with recent onset diabetes should also screened for diabetic neuropathy along with nephropathy and retinopathy

INTRODUCTION

Diabetes mellitus is a heterogeneous group of metabolic disorders characterized by hyperglycemia with disturbances of carbohydrate, fat and protein metabolism caused by either lack of insulin secretion or decreased sensitivity of the tissues to insulin.[i]

Diabetes mellitus (DM) leads to increased morbidity and mortality as a consequence of macro- and micro-vascular complications.[ii] Type 2 DM is characterized by insulin resistance, with or without insulin deficiency that induces organ dysfunction. According to the ICMR – INDIAB study, there are 62.4 million people living with diabetes in India.

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T2DM is a progressive disease and hampers the quality of life of the patients due to micro and macrovascular complications.[iii]

Criteria for Newly Diagnosed Type 2 Diabetes Mellitus[iv]

As per the ADA Guidelines patients diagnosed with diabetes mellitus according to following criteria within **3 months** of presentment to the OPD/ Hospital.

- Symptoms of diabetes plus random blood glucose concentration ≥11.1 mmol/L (200md/dl) or
- Fasting plasma glucose ≥ 7.0 mmol/L (126mg/dl) or
- Two hour plasma glucose ≥ 11.1 mmol/L (200mg/dl) during an oral glucose tolerance test.
- HbA1c> 6.5
- Microvascular complications of Diabetes are :

- Peripheral Neuropathy
- Diabetic Retinopathy
- Diabetic Nephropathy

Diabetic neuropathy is one of the most common long term, complications of diabetes mellitus and is clinically present in 30-50% of all diabetic patients. The electro-physiological evidence of diabetic peripheral neuropathy is estimated to be about 70% in both type-I and type-II diabetes mellitus[v]

Distal symmetrical polyneuropathy (DSPN) is a symmetrical, length-dependent sensorimotor polyneuropathy attributable to metabolic and microvessel alterations as a result of chronic hyperglycemia exposure and cardiovascular risk covariates.

According to San Antonio Convention, main groups of neurological disturbances in diabetes mellitus include: [vi]

1. Subclinical neuropathy, determined by abnormalities in electrodiagnostic and quantitative sensory testing.
2. Diffuse clinical neuropathy and distal symmetric sensorimotor and autonomic syndromes.
3. Focal syndromes.

Classification of Diabetic Neuropathy[vii]

Generalised neuropathies	Focal or multifocal neuropathies
1.Distal symmetric polyneuropathy • Large fibre sensory • Small fibre painful sensory • Subclinical neuropathy 2.Acute painful diabetic neuropathy 3.Autonomic neuropathy	1.Compressive focal neuropathies • Carpal tunnel syndrome • Femoral, sciatic, ulnar, peroneal neuropathy 2.Non compressive focal and multifocal neuropathies • Mononeuritis multiplex • Cranial neuropathies

Diabetic neuropathy can manifest as combination of both positive (painful) symptoms like electrical sensation, squeezing, constricting, throbbing, freezing or knife like and negative (no painful) symptoms like asleep, dead, numbness or loss of touch or pain sensations. So the diagnosis of DPN can be made after careful clinical examination and excluding the other common forms of neuropathy like CIDP, vitamin B12 deficiency, hypothyroidism and uremia which can occur in diabetic patients by appropriate investigations.[viii],

Unfortunately, despite decades of research, there are no modifiable treatments for diabetic neuropathy other than improved lifestyle and diabetes control.[ix] A Cochrane review of all available clinical studies reveals that rigorous glucose control can decrease the incidence of diabetic neuropathy in Type 1 DM but has little to no effect in T2D despite more than 10 years of improved glucose control.[x]

AIMS AND OBJECTIVES

To study the microvascular complications in early diabetics.

MATERIAL AND METHODS

This observational study was performed in Department of Medicine at SRMSIMS, Bareilly for duration of 16 months (1st January 2018 to 30th April 2019) on newly diagnosed type 2 diabetes mellitus (within 3 months) patients with age more than 18 years who were attending medicine OPD and medicine wards and who were confirmed consent and fit to the inclusion criteria were recruited for this study.

Inclusion Criteria

- ✓ Age>18 Years
- ✓ Newly Diagnosed Type 2 Diabetes Mellitus Patients (Diagnosed within 3 Months)
- ✓ Not on Any Treatment for DM

Exclusion criteria

- ✓ Age<18 Years
- ✓ Long Standing DM> 3 Months
- ✓ Gestational Dm/ Steroid Induced DM/ Conditions requiring long Term Steroids
- ✓ Chronic diseases like CHF/ CKD/ COPD/ Malignancies
- ✓ Patients with History of Alcoholism, Thyroid Disorder, B12 Deficiency, Drugs Causing Peripheral Neuropathy like Cisplatin, Amiodarone, Disulfiram, Phenytoin, Hydralazine

A total of 117 patients were screened, 7 declined to participate in the study and 08 were not fit according to inclusion criteria and finally 102 patients were recruited with type 2 DM were found fit according to inclusion criteria.
The NCS instrument used for this study was computerized RMS Aleron 201 Code BK-3/01 Machine.

OBSERVATION AND RESULTS

Of 102 newly diagnosed type 2 diabetes patients, 63 (61.8%) were male and 39 (38.2%) female patients. Maximum patients belonged to age group of 41-50years (32.35%) with Mean age 48.52 ± 10.95 and Range 25-77 Years. (Table 1)

Table 1 Distribution of patients on the basis of age and sex

Age Group (Years)	Total (n=102)	Sex	
		Male (n=63)	Female (n=39)
≤30 Years	7 (6.86%)	6	1
31- 40 Years	22 (21.57%)	12	10
41 - 50 Years	33 (32.35%)	17	16
51- 60 Years	31 (30.39%)	24	7
>60 Years	9 (8.8%)	4	5
Total	102	63	39

Table no 2 shows the anthropometric characteristics of the study population. Mean age of the study population was 48.52 ± 10.95 years and Range 25-77 Years. Mean age in males was 48.52 ± 11.5 and 48.51 ± 10.14 years in females. The mean weight and height in the population was 71.1 ± 10.78 kg and 164.28 ± 7.34 cm respectively. Mean BMI was 26.45 ± 4.37 Kg/m^2, In males the mean BMI was 25.59 ± 3.91 Kg/m^2 while in females it was 27.85 ± 4.75 Kg/m^2.

Table 2 Anthropometric characteristics of study patients

Characteristics	Newly diagnosed Diabetes Patients (n=102)				
	Total (n=102)	Male (n=63)		Female (n=39)	
	Mean +/- S.D (n=102)	Mean +/- S.D.	Range	Mean +/- S.D.	Range
Age (years)	48.52 ± 10.95	48.52 ± 11.5	25-77	48.51 ± 10.14	30-72
Height (cm)	164.28 ± 7.34	166.67 ± 6.95	154-185	160.41 ± 6.29	148-178
Weight(kg)	71.1 ± 10.78	70.82 ± 9.95	47-88	71.54 ± 12.12	48-90
BMI (kg/m^2)	26.45 ± 4.3	25.59 ± 3.91	14.61-33.18	27.85 ± 4.75	19.14-35.16

Table no. 3a and 3b shows the Pulse, Blood pressure and lab investigations of the study population. Mean Pulse rate in the study population was 84.48 ± 8.78 beats/ minute and Systolic Blood pressure (SBP) was 127.31 ± 11.2 mmHg and Diastolic Blood pressure (DBP) 81.15 ± 7.82 mmHg. There was no history of hypertension in the study population.

Mean Total leucocyte count(TLC) was 6373.24 ± 1985.76 /cumm and hemoglobin (hb) was 12.27 ± 0.89 gm%.

Urea and Creatinine values were 33.3 ± 21.49 mg/dl and 0.92 ± 0.49 mg/dl respectively. Deranged renal profile was found only in 5 patients (4.9%), i.e. eGFR<90ml/min/1.73m^2

Fasting and Post prandial blood sugar levels are 187.88 ± 53.64 mg/dl and 273.28 ± 83.77 mg/dl respectively whereas HbA1C levels were 9.23 ± 2.29 %

Fasting lipid profile values showed Total Cholesterol 199.36 ± 65.41 mg/dl , Triglycerides (TG) 234.11 ± 129.06 mg/dl LDL levels 98.87 ± 40.46 mg/dl and HDL levels of 34.58 ± 12.71 mg/dl

Table 3a Pulse and Blood Pressure of the study subject

Vitals		Sample size	Mean ± SD	Median	Range	Inter quartile Range
Pulse (bpm)		102	84.48 ± 8.78	86	64-110	76 – 90
Blood pressure (mmHg)	SBP	102	127.31 ± 11.2	130	100-160	120 – 130
	DBP	102	81.15 ± 7.82	80	60-100	80 – 90

Table 3b Lab Investigations of the study subject

	Sample size	Mean ± SD	Median	Range	Inter quartile Range
Hb(gm%)	102	12.27 ± 0.89	12.25	10.5-14.6	11.600 - 12.800
TLC (/cumm)	102	6373.24 ± 1985.76	5800	3600-11000	4600 – 7850
Urea (mg/dl)	102	33.3 ± 21.49	28	11-170	20 – 41
Creat (mg/dl)	102	0.92 ± 0.49	0.8	0.3-3.9	0.600 - 1.100
FBS (mg/dl)	102	187.88 ± 53.64	180	116-453	150 – 202
PPBS (mg/dl)	102	273.28 ± 83.77	245	137-530	204 – 321
T. Chol (mg/dl)	102	199.36 ± 65.41	196	117-402	148 – 248
TG (mg/dl)	102	234.11 ± 129.06	212	154-1023	158 – 302
HDL(mg/dl)	102	34.58 ± 12.71	36	10-92	28 – 42
LDL (mg/dl)	102	98.87 ± 40.46	100	90-200	96 – 120
VLDL (mg/dl)	102	47.33 ± 21.7	45	10-101	30 – 60
HbA1C (%)	102	9.23 ± 2.29	8.6	6.8-16.9	7.700 - 10.300

Of the 102 patients screened Tingling Sensation was the predominant symptom present in 24 patients (23.53%) followed by burning sensation which was 2.94 %. Foot ulcers and feeling of numbness were absent in all the patients. None of the patients had motor or autonomic symptoms .

Table no 4 shows the clinical pattern of neuropathy based on clinical examination (n=26). Most common neuropathy found was sensory neuropathy (n=16) followed by Mixed type (n=6) and Motor type (n=2) of neuropathy.

Pattern of involvement showed that lower limb involvement was more common (n=23) followed by upper limb (n=2). No evidence of cranial neuropathy was found on clinical examination.

Table 4 Clinical pattern of neuropathy

Type of Neuropathy		No of patients (n=26)
Type of neuropathy	Sensory	18
	Motor	2
	Mixed	6
Involvement Pattern	Upper Limb	2
	Lower limb	23
	Both	1
Cranial Neuropathy		00

We found evidence of Neuropathy on Nerve Conduction Studies (NCS). NCS was done in all the patients (n=102) and we found presence of neuropathy in 57 patients (55.8%) out of 102 patients screened. 44.2% patients did not have evidence of neuropathy at the time of diagnosis of type 2 diabetes mellitus. Table no. 5 & 5.1 shows the type and pattern of neuropathy in the study subjects. We found that sensory neuropathy was in majority 31 (54.39%) of patients followed by mixed type in 22 (38.60%) patients and motor was only in 4 (7.02%) patients. Pattern of involvement showed that lower limb involvement was most common 36 (63.16%) patients followed by both upper and lower limbs were 11 (19.30%) patients and upper limb were only 10 (17.54%) patients. EPS type shows that the axonal type of neuropathy was most common 43 (75.44%) patients while demyelinating was only in 14 (24.56%) patients. The pattern of nerve involvement shows that poly-neuropathy was most common in 42 (73.68%) patients while mono-neuropathy was only in 13 (12.7%) patients out of which Carpal tunnel syndrome (CTS) comprised of 6 patients(10.53%) and mononeuritis multiplex was found in 2 (3.51%) patients only. Femoral, sciatic, ulnar, peroneal neuropathy and Cranial nerve involvement was not found in any of the patients.

Table 5 Type of neuropathy on the basis of NCS

Type of neuropathy		No of patients (n=57)	Percentage
Type of Neuropathy	Motor	4	7.02%
	Sensory	31	54.39%
	Mixed	22	38.60%
Pattern of Involvement	Upper limb	10	17.54%
	Lower limb	36	63.16%
	Both	11	19.30%
EPS Type	Axonal	43	75.44%
	Demyelinating	14	24.56%

Table 5.1 Pattern of Neuropathy

	Type	No of patients (n=57)	Percentage
Pattern of Neuropathy	Distal Symmetric polyneuropathy	42	73.68%
	Mononeuropathy	7	12.28%
	Mononeuropathy-CTS	6	10.53%
	Femoral, sciatic, ulnar, peroneal neuropathy	00	00
	Mononeuropathy-Peroneal Neuropathy	00	00
	Mononeuritis multiplex	2	3.51%
	Cranial Neuropathy	00	00

Table no 6 shows the Fundus findings of the study population. Out of 102 patients screened only 14 patients (13.7%) had evidence of diabetic retinopathy and all the patients had Non Proliferative Diabetic Retinopathy (NPDR)

Table 6 Fundus findings of Study population

Fundus	Newly Diagnosed Diabetes Patients (n=102)
Normal	88 (86.2%)
Abnormal- NPDR	14 (13.7%)

DISCUSSION

Diabetic neuropathy (DN) is one of the most common long term, complications of diabetes mellitus, and is clinically present in 30-50% of all diabetic patients. The clinical & electro-physiological evidence of diabetic peripheral neuropathy is expected to be about 70% in the both type-I & type-II diabetes mellitus.[v]

The cause of DPN though remains unknown but ischaemic, & metabolic components are implicated. Hyperglycaemia induces vascular changes, which increases endothelial vascular resistance and reduces nerve blood flow. Hyperglycaemia also causes depletion of nerve myoinositol through a competitive uptake mechanism. Moreover, activation of the polyol pathway in the nerve through enzyme aldose reductase leads to the accumulation of sorbitol and fructose in the nerve and induces nonenzymatic glycosylation of structural nerve proteins. Hyperglycemia also causes oxidative stress and generation of ROS species. Activation of protein kinase C has been linked to vascular damage in DN. These changes result in abnormal neuronal, axonal, and Schwann cell metabolism, which result in impaired axonal transport. Endoneural hypoxia is produced by increased vascular resistance and reduced blood flow in the nerve. Hypoxia leads to further capillary damage, which in turn aggravates disturbance in axonal transport and reduced Na-K ATPase activity leading to axonal atrophy and impairment of nerve conduction.[xi]

This present study has found a higher incidence of peripheral neuropathy in newly diagnosed type 2 DM (55.8%). Many studies in India have shown different prevalence rates of peripheral neuropathy in newly diagnosed Type 2 Diabetes mellitus due to different diagnostic criteria, variable sample size, the difference in mean age at diagnosis and ethnicity. These findings were similar to the Indian study done by Battula P *et al*[xii] reported 60% prevalence of neuropathy in the diabetic patients.

In a study done by Dutta A *et al*.[xiii], the prevalence of peripheral neuropathy in newly diagnosed diabetes mellitus was 29%. Another study by H K Gill *et al*.[xiv] showed a prevalence of 30% based on presence of an abnormality in NCS whereas another Indian study by Sosale A *et al*.[xv] demonstrated a lower incidence of peripheral neuropathy of only 13.15%. Another Indian study conducted by Pandey AK & Pandit A[xvi] reported the prevalence of neuropathy among newly diagnosed type 2 diabetes mellitus patients was 33.3% while Bhuyan AK & Appaiah S[xvii]**Error! Bookmark not defined.** reported the overall prevalence of peripheral neuropathy among newly diagnosed type 2 diabetes mellitus patients was 68.75%. Ashok S *et al*, had reported the neuropathic prevalence about 19.1%. An Irani study conducted by kiani J *et al*, suggests that their study population have prevalence of 45.7% which is fewer lesser than present study.[xviii] Mythili A *et al* study using nerve conduction suggest that the prevalence of neuropathy is about 71%, this percentage is very near to our present study.[xix]

In the present study, sensory involvement was in majority 31 (54.39%) of patients followed by mixed type of neuropathy in 22 (38.60%) patients and motor involvement was only in 4 (7.02%) patients in type of neuropathy on NCS. Pattern of involvement showed that the lower limb was most commonly involved in 36 (63.16%) patients followed by both upper and lower limb that was in 11 (19.30%) patients and upper limb involvement was in 10 (17.54%) patients. EPS shows the axonal involvement was most common in 43 (75.44%) patients while demyelinating was only in 14 (24.56%) patients. EPS shows that distal symmetrical poly-neuropathy was most common in 42 (73.68%) patients while mono-neuropathy was only in 15 (26.3%) patients out of which Carpal tunnel syndrome was in 6 patients and mononeuropathy multiplex in 2 patients.

These findings were similar with the study conducted by **Mohan G *et al***[xx] whereas on NCS sensory motor (mixed) type was seen in maximum number of patients i.e. 64 (64%) followed by pure sensory in 18 (18%) and pure motor in 2 (2%) patients. 80 (80%) had axonal type of neuropathy followed by demyelinating type in 3 (3%). Another Indian study was done by Kakrani AL *et al*[xxi] reported distal symmetrical (80%) polyneuropathy is most common form of diabetic neuropathy and NCV performed on 50 patients of diabetic neuropathy out of which all patients i.e. 100% had involvement of lower limb and only 24 patients i.e. 48% had involvement of upper limb also which is similar to present study.

The present study revealed that neuropathy develops at the time of diagnosis of diabetes in 55.8% patients and should be regularly screened for. Diabetic neuropathy. Diabetic retinopathy was found only in 13.7 % patients whereas Evidence of Nephropathy was found only in 4.9% of the patients.

Early diagnosis of peripheral neuropathy , patient education and treatment prevents moribound complications like neuropathy related foot ulcers, diabetic foot, falls etc.
Patients presenting with recent onset diabetes should also screened for diabetic neuropathy along with nephropathy and retinopathy

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