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ASSESSMENT OF SEVERITY OF PERIPHERAL NEUROPATHY IN DIABETIC FOOT IN A TERTIARY CARE HOSPITAL IN KERALA:

Dr Admi V R Karaniyil
Assistant Professor, Department of General Surgery, Azeezia Medical College, Meeyannoor, Kollam, Kerala.

Abstract:
Diabetic neuropathies are among the commonest of all the long term diabetic complications and is the main initiating factor for diabetic foot ulceration (DFU). Epidemiological data on symptomatic diabetic neuropathy which is a common scenario in surgical practice in India remain poor due to inconsistent definitions, poor ascertainment, and a lack of population based studies. This study was aimed to stratify the diabetic foot patients according to their neuropathy severity, type of foot and on quantifying the much morbid painful diabetic neuropathy prevalence in our hospital concomitantly assessing the relationship between symptoms and signs of neuropathy. Over a period of 18 months, an observational study of 120 patients admitted with diabetic foot our college. Patients were stratified according to their severity of neuropathy by Neuropathy Symptom Score (NSS) and Neuropathy Disability Score (NDS) and vascular status by ABPI measurement thereby categorised as Neuropathic, Ischemic and Neuroischemicfoot . Our study showed a high prevalence of neuropathy (81.7%), peripheral vascular disease (70.8%) and infection (77.5%). We also got a significant positive correlation between severity of neuropathy and variables like duration of diabetes ($r = 0.267$, $p = 0.003$) and HbA1c ($r = 0.526$, p8) had painful neuropathic symptoms (NSS $\geq$5), whereas 31.8% of patients without clinical neuropathy (NDS $\leq$2) had painful symptoms .Our study showed worsening clinical neuropathy scores associated with an increasing proportion of patients with ix more severe painful neuropathic symptoms (with $r = 0.753$ and p value <0.001) which challenge the dogma that painful neuropathic symptoms improves as the severity of neuropathy worsens.
Keywords: Diabetic foot; neuropathy severity; painful neuropathy; peripheral vascular disease; infection

Introduction:

Diabetic neuropathies are among the commonest of all the long term diabetic complications and is the main initiating factor for diabetic foot ulceration (DFU) and diabetic foot infection (DFI) which ultimately leads to Lower extremity amputation (LEA). [1] Diabetic neuropathies are heterogenous by their symptoms, pattern of neurologic involvement, course, risk covariates, pathologic alterations, and underlying mechanisms. It has been estimated that every 20 seconds a lower limb is amputated due to complications of diabetes. [2] .Our country India leads the world with largest number of diabetic subjects.However, the quality and even quantity of epidemiological data on symptomatic diabetic neuropathy in India among diabetic foot patients remain poor due to inconsistent definitions, poor ascertainment, and a lack of population based studies. There are only few studies about the Painful Diabetic Neuropathy in diabetic foot which is a common scenario in surgical practise and most surgeons underestimate its prevalence. It is considered to be the cause of considerable morbidity and, under the auspices of the American Academy of Neurology, evidence-based guidelines have been published for the management of this difficult condition. [3] Etiological classification based on neuropathy and ischemia is very crucial in the management of diabetic foot as each type of foot behaves distinctly and treatment protocols of them varies accordingly. Early recognition of neuropathy in diabetic foot is crucial as the literature suggests that the early detection and treatment of diabetic foot complications could reduce the incidence of ulceration and leading to amputation.

AIM AND OBJECTIVES OF STUDY

To study the severity of peripheral neuropathy in diabetic foot ulcers using Neuropathy Symptom Score (NSS) and Neuropathy Disability Score (NDS).

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Materials and Methods:

Study Design: Observational Study

Study Setting:

- Outpatient / Inpatients of Department of General Surgery, Azeezia Medical College, Meeyannoor, Kollam, Kerala

Duration Of Study:

- January 2019- June 2020

Sample Size:

- The following simple formula (Daniel,1999) can be used n =

$$\frac{Z^2 P(1-P)}{d^2}$$

n = sample size

Z = statistic for a level of confidence

p = expected prevalence of peripheral neuropathy

d = precision (20% 0f prevalence when β error is 20%) Z value is 1.96 when α error is 5%

In a recent study by Gershater MA et al [56] among diabetic foot patients the prevalence of neuropathic foot is about 60%.

So substitute the value in the above equation n =

$$\frac{(1.96)^2\ 0.6\ (1-0.6)}{(0.2)^2} = 66.66 = 67$$

So sample size is minimum of 67 patients.

Sample size after 18 months of study= 120 subjects.

Inclusion Criteria:

All patients between 40 to 70 years with diabetic foot attending IP/OP departments of General Surgery and Plastic Surgery.

Exclusion criteria:

- Patients with Type Idiabetes
- Patients with leg ulcers other than diabetic etiology- Traumatic ulcers, Infective ulcers without diabetes ,Malignant ulcers ,Venousulcers
- Patients who do not give consent forstudy.
- Patients with other causes for peripheralneuropathy

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Study Procedure:

ASSESSMENT OF PERIPHERAL NEUROPATHY

The Neuropathy Symptom Score(NSS) is assessed by asking the patient about his various neuropathic symptoms ,asked to say yes/no. Patients were asked about their experience of pain or discomfort in the legs. If the patient described burning, numbness, or tingling, a score of 2 was assigned; fatigue, cramping, or aching scored 1.The presence of symptoms in the feet was assigned a score of 2, the calves 1, and elsewhere a score of 0. Nocturnal exacerbation of symptoms scored 2 vs. 1 for both day and night and 0 for daytime alone. A score of 1 was added if the symptoms had ever woken the patient from sleep. The patients were asked if any maneuver could reduce the symptoms; walking was assigned a score of 2, standing 1, and sitting or lying down 0. The severity of symptoms was graded according to the NSS as follows[3]:
3-4 = mild symptoms

5-6 = moderate symptoms
7-10 =severe symptoms

The (Neuropathy Disability Scoring) NDS[3] is a widely accepted and validated physical examination scoring system used to diagnose neuropathy. Its predictive value and reproducibility are high. The NDS, a composite measure of both large- and small- fibre dysfunction, was assessed using a Neurotip to record awareness of pin-prick

sensation, a 128Hz tuning fork to assess awareness of vibration, Tip therm (instead of warm and cool rods) to assess temperature sensation on the dorsal surface of the foot, and a tendon hammer to record the presence and strength of the Ankle reflex.

Pin-prick perception: A standard Neurotip should be applied just proximal to the toenail on the dorsal surface of the hallux, with just enough pressure to deform the skin. Inability to perceive pinprick over either hallux would be regarded as an abnormal test result.

Vibration perception: A 128 Hz tuning fork is applied at 3 bony sites on the foot, the head of metatarsal, the lateral and the medial malleoli. The patient is asked to describe what he feels. If he/she describes a feeling of vibration, the site concerned is considered normal. If he/she describes anything other than vibrations, the site concerned is considered abnormal.

Ankle reflexes: It can be tested with the patient either kneeling or resting on a couch/table. The Achilles tendon should be stretched until the ankle is in a neutral position before striking it with the tendon hammer. If a response is initially absent, the patient can be asked to hook fingers together and pull, with the ankle reflexes then retested with reinforcement.

Tiptherm examination: The examiner places the two flat surfaces on the tip of the patient's great toe at irregular intervals and asks whether it feels cold or not so cold. The patient is asked to close his eyes during testing. Only if correct answers are given it is presumed that the patient's temperature perception is functioning satisfactorily. The tests were done in an air conditioned room with a temperature range of 20–23°C.

Range of neuropathy score[3]: 0-10
Classification:
0-2= No neuropathy

3-5= Mild neuropathy

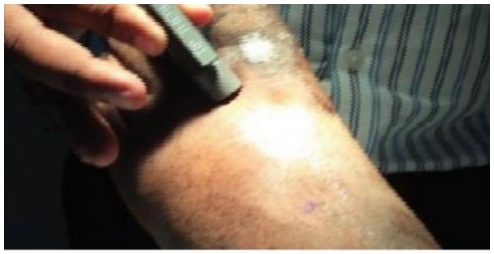
6-8= Moderate neuropathy

≥9= Severe neuropathy

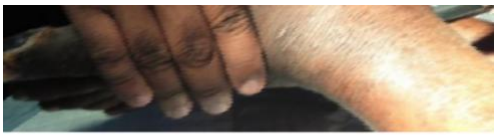
The tables for recording the examination results are included in the proforma.

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

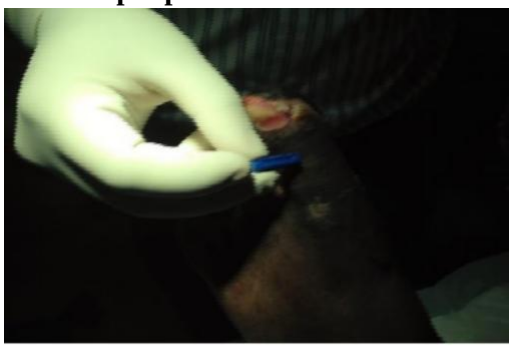
Color plate1;Examining for temperature sensation



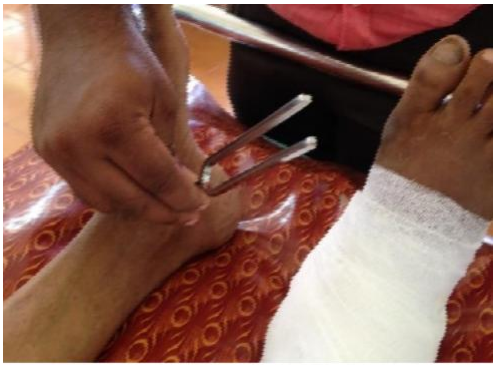
Color plate2; Examining Ankle reflex



Color plate 3; Examining for pin prick sensation



Color Plate 4: Examining for vibration



ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

ASSESSMENT OF PERIPHERAL OCCLUSIVE ARTERIAL DISEASE

Assessment of vascularity using hand held Doppler:

The patient will be at rest 5 to 10 min in the supine position, relaxed. The cuff will be chosen adequately according to the limb size. The width should contour at least 40% of the limb circumference. Similar to the brachial blood pressure measurement, the cuff would be placed around the ankle using the straight wrapping method. The lower edge of the cuff should be 2 cm above the superior aspect of the medial malleolus .An 8- to 10-MHz Doppler probe should be used. Doppler gel will be applied over the sensor. After the Doppler device is turned on, the probe would be placed in the area of the pulse at a 45° to 60° angle to the surface of the skin. The probe would be moved around until the clearest signal is heard. The cuff would be inflated progressively up to 20 mm detect the pressure level of flow signal reappearance. The detection of the brachial blood flow during the arm pressure measurement should also be done byDoppler.

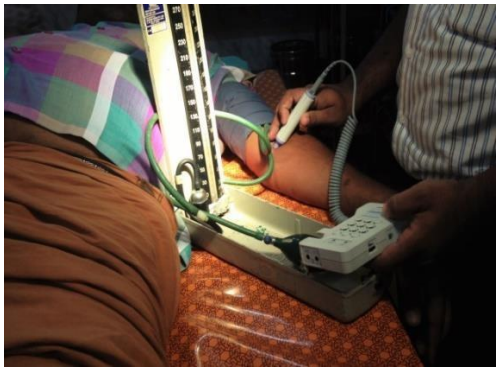
Ankle Brachial Pressure Index= Highest ankle pressure

Highest brachial pressure

ABPI < 0.9 is considered to have PAD[61].

The hand held Doppler is used to detect blood flow using the principles of the Doppler effect. In normal patients the arterial signal has three phases (triphasic), but in the presence of arterial disease this signal becomes biphasic and monophasic (one phase).

Color Plate 5 &6 ;vExamining ABPI using Hand held Doppler



Categorization of diabetic foot[25]:

Ischaemic - ABPI value (<0.9) but the NDS is <2
Neuropathic- NDS is >3 but ABPI value (≥9)
Neuroischaemic- NDS>3 and ABPI value (<0.9).
Patients with atleast moderate symptoms and mild neurologic signs (NSS score ≥5 and NDS score≥3) will be included under painful neuropathycategory[3].

Statistical Analysis :

Statistical Analysis was done using statistical software SPSS Version.1.6. For data analysis appropriate statistical tests like Chi-square, Kruskal Wallis, Pearson correlation and spearman's rho correalation are used which is described in results and analysis part

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Results:

Table 1: Severity of neuropathy by NSS

Severity of neuropathy by NSS	Frequency	Percent
No	5	4.2
Mild	31	25.8
Moderate	40	33.3
Severe	44	36.7
Total	120	100.0

Table 2: Severity of neuropathy by NDS

Severity of neuropathy by NDS	Frequency	Percent
No	22	18.3
Mild	29	24.2
Moderate	53	44.2
Severe	16	13.3
Total	120	100

Table 3: Distribution according to painful diabetic neuropathy (PDN)

PDN	Frequency	Percent
Absent	35	29.2
Present	85	70.8
Total	120	100.0

Table 4: Distribution according to Type of foot

Type of foot	Frequency	Percent
Ischemic	23	19.2
Neuropathic	34	28.3
Neuroischemic	63	52.5
Total	120	100.0

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

COMPARISON OF DIABETIC NEUROPATHY WITH VARIOUS DETERMINANTS.

Table 5. Comparison of Age and Diabetic Neuropathy

Age and diabetic neuropathy			NSS	NDS
Spearman's rho	AGE	Correlation Coefficient (r)	.116	.098
		Significance (p)	.207	.287
		N	120	120

There is positive correlation between increasing age and severity of neuropathy in our studied sample but it is not significant.

Table 6. Comparison of Sex and Diabetic neuropathy

Sex	Severity of neuropathy by NDS				Total
	No	Mild	Moderate	Severe	
M	17 (17.7%)	22 (22.9%)	46 (47.9%)	11 (11.5%)	96
F	5 (20.8%)	7 (29.2%)	7 (29.2%)	5 (20.8%)	24
Total	22	29	53	16	120

Male subjects detected to have higher prevalence of neuropathy (82.3%) when compared to female subjects (79.1%).

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Table 7a- above&b-below. Comparison of Smoking and Diabetic Neuropathy

		NDS										Total
		1	2	3	4	5	6	7	8	9	10	
SMOKING	0	1	7	5	3	3	2	5	9	5		40
	1		1		1	2	4	3	1			12
	2		5	3	3	3	3	2	8	4	2	33
	3		4	1	2	1	1	3	2	2		16
	4	1	3		1	1	3	4	3	2	1	19
Total		2	20	9	10	10	13	17	23	13	3	120

Kruskal-Wallis Test	NSS	NDS
Chi-Square	1.954	1.288
df	4	4
p	.744	.863

No statistically significant association between smoking and severity of neuropathy in our study.

Table 8 a- above & b-below. Comparison of alcohol and neuropathy severity

		NDS										Total
		1	2	3	4	5	6	7	8	9	10	
ALCOHOL	0	1	7	3	5	3	5	7	6	7		44
	1	1	6	2	4	2	5	5	10	5		40
	2		7	4	1	5	3	5	7	1	3	36
Total		2	20	9	10	10	13	17	23	13	3	120

Kruskal-Wallis Test	NSS	NDS
Chi-Square	.884	.263
df	2	2
p	.643	.877

No statistically significant correlation between alcohol and severity of neuropathy in our study

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Table 9 a- above & b-below. Comparison of duration of Diabetes and Diabetic Neuropathy

		NDS										Total
		1	2	3	4	5	6	7	8	9	10	
DOD	1		3	1	4	3	2	2	1			16
	2	1	9	2	3	2	4	8	7	3		39
	3	1	7	5	3	4	7	4	14	6	2	53
	4		1	1		1		3	1	4	1	12
Total		2	20	9	10	10	13	17	23	13	3	120

Spearman's rho		NSS	NDS
DOD (duration of diabetes)	Correlation coefficient (r)	.271	.267
	Significance (p)	.003	.003
	Total (N)	120	120

There is positive correlation between duration of diabetes and severity of neuropathy (r =0.267) and is significant (p =0.003).

Table 10. Comparison of method of diabetic control and Diabetic Neuropathy

		NDS										Total
		1	2	3	4	5	6	7	8	9	10	
MODC	0		3		1	2	1	2	1	4		14
	1	1	3	2	1		2	2	6	1	1	19
	2		9	2	5	4	9	9	6	3	1	48
	3	1	5	5	3	4	1	4	10	5	1	39
Total		2	20	9	10	10	13	17	23	13	3	120

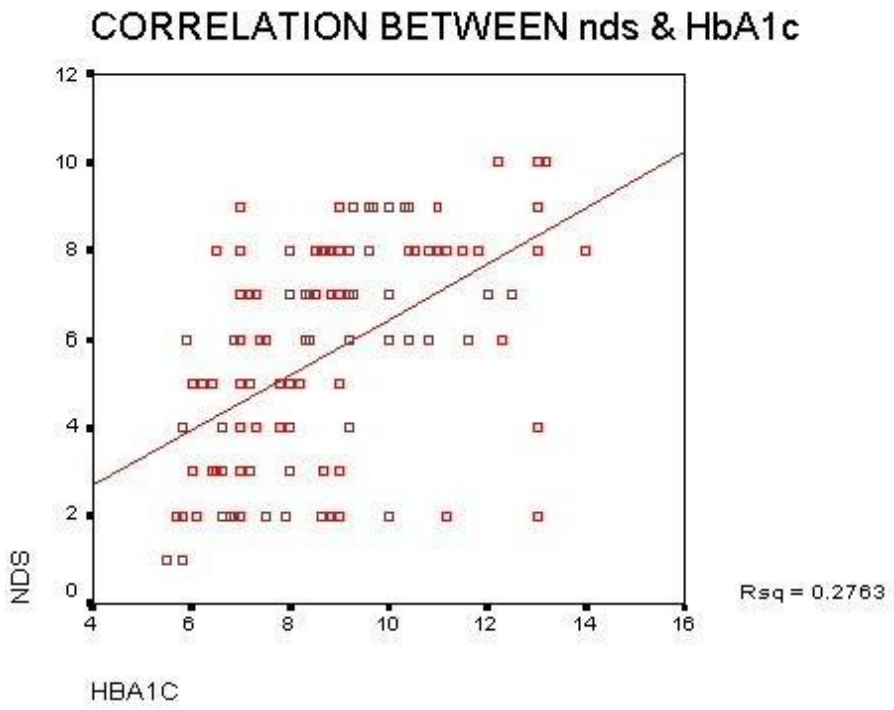
4/16 (25%) patients with severe neuropathy (NDS>8) had no method of diabetic control,2/16 (12.5%) patients were on diet control ,4/16 (25%) patients on oral hypoglycaemic agents and 6/16 (37.5%) patients on insulin. ie: majority of study population with severe neuropathy using Insulin as their method of diabetic control.

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Table 11 & Fig 1: Correlation of HbA1c with NDS

Correlation between NDS and HBA1c	HBA1C	
NDS	Pearson Correlation(r)	.526
	Sig. (p)	.000
	Total (N)	120

There is a significant positive correlation between NDS and HBA1c in our study with r =0.526 and p =<0.001. This sows as the diabetic control worsens the severity of neuropathy rises.



ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Table 12. Comparison of severity of neuropathy by symptoms and by signs scoring.

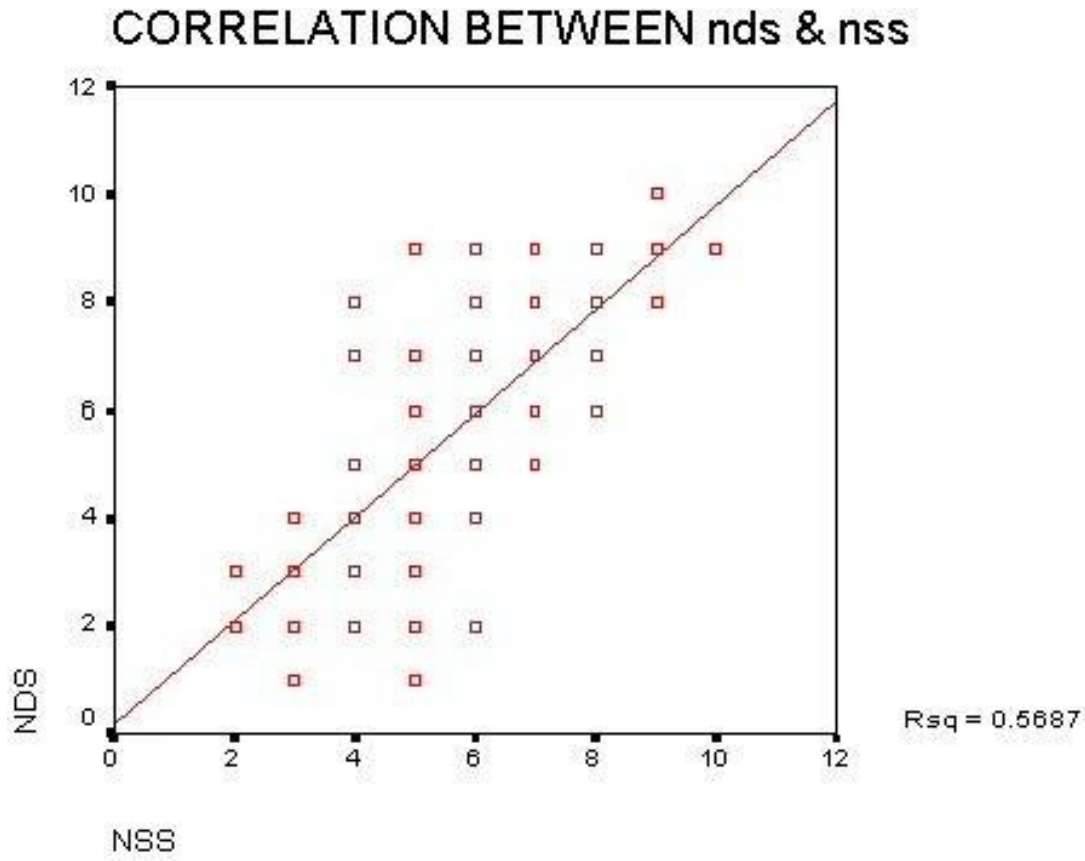
Severity of neuropathy by NSS	Severity of neuropathy by NDS				Total
	No	Mild	Moderate	Severe	
No	3	2	0	0	5 (4.16%)
Mild	12	15	4	0	31 (25.8%)
Moderate	7	10	19	4	40 (33.33%)
Severe	0	2	30	12	44 (36.66%)
Total	22 (18.3%)	29 (24.16%)	53 (44.16%)	16 (13.3%)	120 (100%)

100% (16/16) of diabetic patients with severe clinical neuropathy (NDS>8) had painful neuropathic symptoms (NSS ≥5), whereas only 31.8%% (7/22) of patients without clinical neuropathy (NDS ≤2) had painful symptoms.

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

Table 13 & Fig 2: Correlation between severity of neuropathy by symptoms (NDS) and by signs (NSS).

Correlation between NSS and NDS	NDS	
NSS	Pearson Correlation(r)	0.753
	Sig. (p)	.000
	Total (N)	120



There is strong positive correlation between NSS and NDS with r =.753 and p value <.0001 which shows worsening clinical neuropathy scores associated with an increasing proportion of patients with more severe painful neuropathic symptoms .

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

DISCUSSION

The study found that the overall prevalence of Diabetic Neuropathy by NDS (Neuropathy Disability Scoring), in patients with Diabetic foot ulcer is 81.66%. This is found to be higher when compared to some international studies. Neuropathy was detected in 78% of patients in a study conducted in at Kenyatta National Hospital[4]. In another study by Bowering CK et al[5] neuropathy was found to be 48%. An Indian study conducted by Arijit Chanda et al at St Johns Medical college showed 64.1% prevalence of neuropathy[6] and another study by Shailesh K Shahi et al at SS Hospital, BHU, Varanasi showed 75.25%prevalence[7].We have assessed severity of neuropathy in our study population by NSS and NDS scoring. On assessing with NSS, 115 patients (95.8%) had symptoms suggestive of neuropathy. 31 (25.8%) found to have mild, 40 (33.3%) with moderate and 44 (36.66%) found to have severe symptoms respectively.On assessing with NDS, 98 (81.7%) patients found to have neuropathy and 22 (18.3%) had no neuropathy. 29 (24.2%) patients had mild, 53 (44.2%) moderate, 16 (13.3%) had severe neuropathy respectively.The prevalence of POAD is 70.8% in our study. A study by Huijberts MS et al[8] found that the prevalence of peripheral arterial disease in diabetic foot complications was 63.4%. In a similar study by Boulton AJ et al[9], the prevalence was found to be 54.7%. Kenyatta study[4] featured ischemia in 48.5% of patients. In Eurodiale study the prevalence of POAD in DFU is 49%[10]. A prevalence of 73.33% was found for POAD in the study conducted by Dharmesh et al at SSG Hospital, Vadodara[11].The Eurodiale Study showed 58% prevalence of infection in all ulcer patients admitted to foot centres in Europe.[10]A study by Smith D et al showed 56% of diabetic foot ulcerations to be infected.[12] Another study showed the risk of hospitalization and lower-extremity amputation to be 56–155 times greater for diabetes patients with a foot infection than those without.[13]In our study we got a significant positive correlation NDS and HbA1c values ($p<0.001$, $r = 0.526$). This shows as the glycaemic control worsens the severity of neuropathy rises. Similar results were obtained in a study conducted by Kamron Mohammed[101] which showed HbA1c was significantly higher with loss of vibration sense, neuropathy and high risk foot.PDN (Painful Diabetic Neuropathy) detected in 85 (70.8%) of patients which is a significant cause of morbidity in diabetic patients. In the UK community based population study[3] it was 21%.The high prevalence of PDN in our study may be due to the fact that our study was conducted among Diabetic foot patients whereas the latter in diabeticpatients.Majority of foot we studied came under neuro-ischemic type; 63 (52.5%). 34 (28.3%) had neuropathic and 23 (19.2%) had ischemic foot. In Kenyatta study[4] they were 30.5%, 47.5% and 18% respectively. In another study by Amstrong et al, they were 50%, 35%, and 15% respectively which are comparable to our study.[14]In a study by Gershateretal[15], neuropathic ulcers constituted 59% and neuroischaemic/ischaemic 41%respectively.100% (16/16) of diabetic foot patients with severe clinical neuropathy (NDS>8) had painful neuropathic symptoms (NSS ≥5), whereas 31.8% (7/22) of patients without clinical neuropathy (NDS ≤2) had painful symptoms. In UK study 60% of patients with severe neuropathy had painful symptoms and 26% of patients without neuropathy had painful symptoms.[3] Davies et al also showed that a significant proportion (7.4%) of subjects with PDN using the Toronto Clinical Scoring System had no clinical signs ofneuropathy.[16]OurstudyshowedastrongpositivecorrelationbetweenNSSandNDSwith r=0.753 and p value <.0001 which shows worsening clinical neuropathy scores associated with an increasing proportion of patients with more severe painful neuropathic symptoms and challenge the dogma that painful neuropathic symptoms improvesastheseverityofneuropathyworsens.Similarresultswereobtainedinthe U.K study[3] with r = 0.24 and p <0.0001.This study is a hospital based cross sectional study among diabetic foot patients admitted in surgical wards which limited our sample size, but it provides a brief idea of the importance of assessing the severity of neuropathy in these patients. The high prevalence of neuropathy, ischemia and infection in our diabetic foot patients alarms us for early screening of these risk factors .We also found that PDN (painful diabetic neuropathy) has a high prevalence in our patients. Furthermore, more than one-quarter of our patients (31.88%) without clinical neuropathy on examination had significant painful neuropathic symptoms which implies that a large proportion of the diabetic foot patients are being neglected in the treatment of their

ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

symptoms, and that classic neuropathic, lower-limb symptoms may well be inappropriately considered "nonneuropathic" if there are no concomitant signs of clinical neuropathy. It also emphasizes the need to ask all patients about the occurrence of painful neuropathic symptoms, not just those who have clinical neuropathy. Early detection of this condition provide us an oppurtunity to prevent its progression as there is a general consensus that intensive blood glucose control should be the first step in the treatment of any form of diabetic polyneuropathy.[23] Evidence based guidelines are there for the treatment of this highly morbid condition with various pharmacologic modalities but remains less than satisfactory, and many sufferers experience sub-optimal painrelief.

CONCLUSION

We found a significant positive correlation between duration of diabetes and HbA1c values with severity of neuropathy which shows long standing diabetes and poor glycaemic control heralds the worsening of neuropathic foot. It also emphazises the need for good glycaemic control which may prevent the rapid progression of neuropathy in diabetic foot patients.Majority of foot we studied came under neuro-ischemic type; 52.5% which showing the combined effect of neuropathy and ischemia in development of diabetic foot. It also signifies the need for individual assessment of diabetic foot patients as the treatment protocol of each type of foot varies depending upon the underlying etiology.PDN (Painful Diabetic Neuropathy) detected in 70.8% of patients which is a significant cause of morbidity in diabetic foot patients. 31.8% of patients without clinical neuropathy (NDS $\leq$2) had painful symptoms(NSS$\geq$5). It emphasizes the need to ask all patients about the occurrence of painful neuropathic symptoms, not just those who have clinical neuropathy. Our study showed worsening clinical neuropathy scores associated with an increasing proportion of patients with more severe painful neuropathic symptoms which challenge the dogma that painful neuropathic symptoms improves as the severity of neuropathy worsens.These findings emphasizes the need for large community based future studies in our subcontinent addressing the risk factors and much morbid painful neuropathy in diabetic foot .It will also help in making the patients aware of the importance of foot care habits, glycaemic control, podiatric review, and appropriate footwear. It also warrants for future researches to find newer modalities of treatments to optimally manage the issue of painful diabetic neuropathy.

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ISSN:0975-3583,0976-2833 VOL12,ISSUE 01,2021

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