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## Research article

### THE INFLUENCE OF PERIPHERAL NEUROPATHY AND PERIPHERAL VASCULAR DISEASE IN THE OUTCOME OF DIABETIC FOOT MANAGEMENT – A PROSPECTIVE STUDY

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## ABSTRACT

**Objective:** Peripheral neuropathy and Peripheral Vascular Disease are the risk factors for the development of diabetic foot. The aim of this study was to evaluate differences and predictors of outcome parameters in patients with diabetic foot by stratifying these subjects according to the severity of these risk factors. **Materials and methods:** This is a prospective study conducted in 70 patients in the age group of 30-90 years diagnosed as Type II Diabetes with foot ulcers. After detailed clinical examination the following tests were conducted in all the patients: Complete blood count (CBC), Haemoglobin (Hb), Random Blood Sugar (RBS), Erythrocyte Sedimentation rate (ESR), Chest X-ray(CXR), Electrocardiography (ECG), foot X-ray, pus culture, Neuropathy testing by Semmes Weinstein Monofilament Test and Vibration Perception Threshold and Peripheral vascularity assessment by Duplex Doppler. Then grading of the ulcers was done using **Wagner's Grade**. The outcome of the patients was assessed by recording the healing time, mode of surgery and amputation rates of the patients. **Results:** A total of 70 patients with diabetic foot were consecutively included into the study (65.7% male, age (31% in 51-60 years), mean diabetes duration (5.2 years), Ulcer Grade (37% in Grade IV), Foot lesions (45.7% in toe), Blood sugar levels (64% in 300-400 mg/dl), Neuropathy (84%), Peripheral vascular disease (67%), major amputation (7%) and mortality (1.4%). **Conclusion:** All diabetic patients should undergo testing for neuropathy and peripheral vascular disease apart from doing other tests.

**Key words:** Diabetic foot, ulcers, neuropathy, peripheral vascular disease.

## INTRODUCTION

Complications affecting diabetes are many with some of the most catastrophic ones affecting the lower extremities. Levin et al<sup>[1]</sup> estimated that 20% of all hospital admissions for diabetes were the result of foot problems. Warren et al<sup>[2]</sup> in their survey of the lower extremities amputations found that 91.8% of amputations were performed secondary to gangrene, necrosis, ulcer, nearly one half of these patients were diabetics. Apelquist J et al<sup>[3]</sup> in their study on

importance of wound classification in the outcome of diabetic foot ulcer stated that the ulcer was classified on the basis of superficial, deep, minor or major gangrene and that the healing rate of superficial ulcer is (88%) and deep ulcers is(78%) 57%. In abscess and osteomyelitis it was (57%) and found that out all there was only marginal difference in primary healing rate between the ulcer sites.

The remarkable pathogenesis of diabetic foot is neuropathy, microvascular and macrovascular diseases. Their process may occur exclusively or they may occur together in varying degrees placing patients at risk for morbidity such as ulceration, gangrene and infection. This is especially true if these pathological changes are combined with a foot deformity, making patients more vulnerable to foot problems. Bauman et al<sup>4</sup> demonstrated that only slight pressure over a fixed bony deformity, such as a prominent metatarsal head or a hammer toe lead to ischemic necrosis and ulceration of skin. For this reason it is necessary to identify the patients at increased risk. Apart from other diabetic complications, one long term complication of diabetes is neuropathy, which causes foot ulceration in diabetic patients, despite considerable research; the pathogenesis of diabetic neuropathy remains undetermined. Current hypothesis regarding the etiology of diabetic neuropathy are centered on a combination of metabolic defects secondary to higher glycaemia and vascular changes that results in nerve hypoxia. Evidence for hypoxia as etiology is considerable and includes reduced endoneurial blood flow, increased vascular resistance, and decreased endothelial production of nitric oxide. Although microvascular dysfunction has been mainly implicated, the role of peripheral vascular disease remains considerable, as it appears likely that a decrease in total limb blood flow would potentiate nerve ischemia. Hence both peripheral neuropathy and peripheral vascular disease are the commonest etiology in diabetic foot ulcer, apart from other risk factors. Tests for neuropathy and peripheral vascular diseases were done and the outcome was assessed.

#### **Aims and Objectives**

1. To study the influence of peripheral neuropathy and peripheral vascular disease in the outcome of diabetic foot management.
2. To ascertain the risk of peripheral neuropathy and peripheral vascular disease in diabetic patients with diabetic foot ulcer.
3. Evaluate all patients with diabetic foot ulcer for both peripheral neuropathy and peripheral vascularity.
4. Assessment of outcome of the diabetic foot ulcers regarding neuropathic/neuroischemic status.

## **MATERIALS AND METHODS**

Prospective study was conducted in 70 patients in the age group of 30 to 90 years diagnosed as Type II diabetes with foot ulcer attending the diabetic OPD and surgical units of MMCH&RI during the period October 2011 to September 2013. Permission was sought from Ethical Committee and Informed consents were obtained from all the patients. All patients in the study group had detailed clinical history of their problem and the foot ulcers were examined in detail.

#### **Inclusion criteria**

Patients attending MMCH&RI surgery OPD and Diabetics clinic diagnosed as diabetic foot ulcers.

Patients above 30 years.

Not previously diagnosed as neuropathy or having peripheral vascular diseases.

#### **Exclusion criteria**

Patients below 30 years of age.

Non-diabetic foot ulcers.

Previously diagnosed to have peripheral neuropathy and peripheral vascular diseases.

All patients had undergone Complete blood count (CBC), Haemoglobin (Hb), Random Blood Sugar (RBS), Erythrocyte Sedimentation rate (ESR), Chest X-ray(CXR), Electrocardiography (ECG). Neuropathy testing was done using Semmes Weinstein Monofilament Test (Fig 1&2) and then they were tested for nerve conduction studies. Peripheral vascularity was assessed clinically and also by Duplex Doppler. After all the tests, grading of the ulcers was done using Wagner's Grade.



**Fig 1: Semmes-Weinstein monofilament**



**Fig 2: Semmes-Weinstein monofilament**

**Wagner Grading System:**

**Grade 1:** Superficial Diabetic Ulcer

**Grade 2:** Ulcer extension

1. Involves ligament, tendon, joint capsule or fascia

2. No abscess or Osteomyelitis

**Grade 3:** Deep ulcer with abscess or Osteomyelitis

**Grade 4:** Gangrene to portion of forefoot

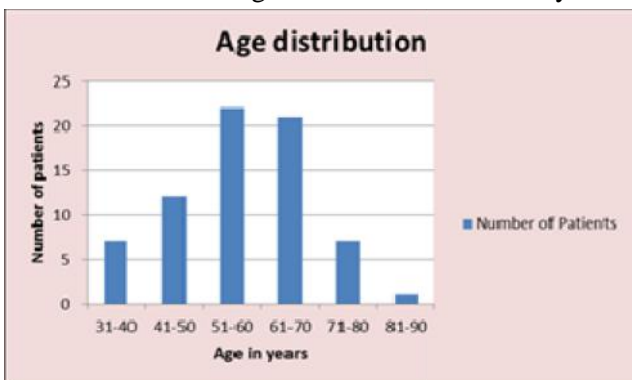
**Grade 5:** Extensive gangrene of foot

The outcome of the patients was assessed by recording the healing time, mode of surgery, pus culture & sensitivity and amputation rates of the patients. All the above data were analyzed.

**Statistical analysis:** All the data were analyzed using Graph Pad Prism Version 6.

**RESULTS AND OBSERVATION**

**Sex distribution** Out of 70 patients enrolled for the study, 46 (65.7%) were males and 24 (34.3%) were females patients. **Age distribution** In our study all the patients above 30 years were included. 30% of the patients were between 51 and 70 years of age. Fig 3 shows the details of age distribution in our study.



**Fig 3: Age distribution**

**Duration of diabetes :** Out of 70 patients enrolled in our study majority of the patients had diabetes for 4-6

years (Table 1). The mean duration of diabetes was 5.2 years.

**Table 1: Duration of diabetes**

Duration (in year)	Number of Patients	(%)
0-2	15	21.4
2-4	14	20.0
4-6	24	34.3
6-8	8	11.4
8-10	5	7.4
10-12	1	1.4
12-14	2	2.8
14-16	1	1.4

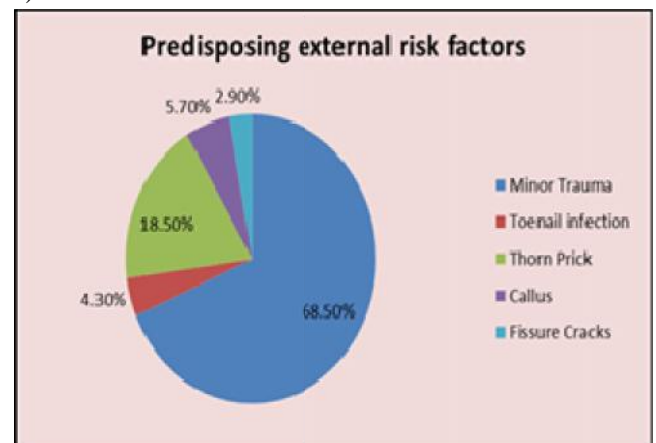
**Distribution of surgeries done previously for foot problems:** Out of 70 patients enrolled in the study, 10 (14.28%) patients had history of previous minor amputations, 2 (2.85%) patients had history of major amputation, 3(4.3%) had undergone other surgeries like Debridement, I & D, Fasiotomies etc (Table 2).

**Table 2: Distribution of surgeries done previously for foot problems**

Foot problems	Number of Patients	(%)
Minor amputation	10	14.2
Major Amputation	2	2.9
Others*	3	4.3
No previous surgeries	55	78.6

\*Debridement, I & D, Fasiotomies, Minor Surgery

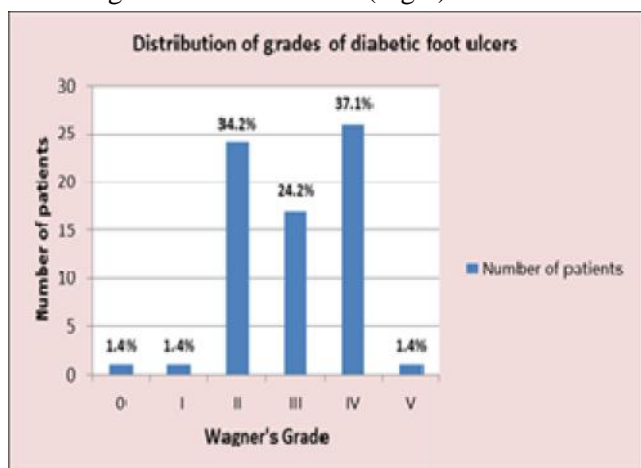
**Predisposing external risk factors :** Out of 70 patients enrolled in our study, 48 (68.5%) patients had history of minor trauma due to bare foot walking and ill-fitting foot wear, 3 (4.3%) had toenail infection, 13 (18.5%) had history of thorn prick (Fig 4).



**Fig 4: Predisposing external risk factors**

**Distribution of grades of diabetic foot ulcers:** Out of 70 patients our study diagnosed with foot

ulceration, grading was done based on Wagner's grading and most of the ulcers were predominantly between grades II to Grave IV (Fig 5).



**Fig 5: Distribution of grades of diabetic foot ulcers**

**Distribution of foot ulcers:** Out of 70 patients in our study, 32 (46%) patients had ulceration in the toes and planter surface of toes, 28 (40%) had ulcers in plantar surface of foot, metatarsal head, mid foot and heel and 10 (14.0%) had ulcers in the dorsum of foot (Table 3).

**Table 3: Distribution of foot ulcers**

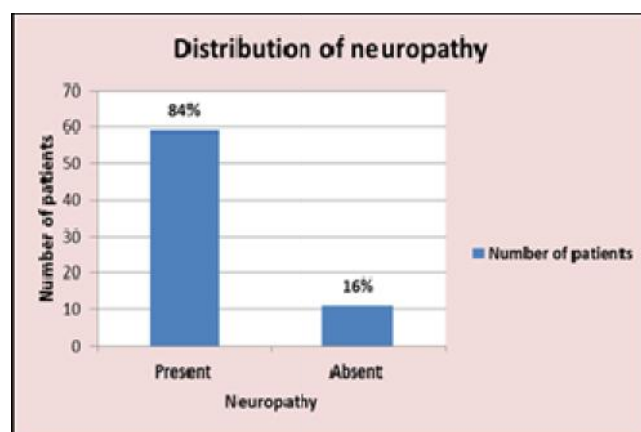
Foot lesions	Number of patients	(%)
Toe (Dorsal and Plantar Surface)	32	45.7
Plantar, Metatarsal Head, Mid Foot, Heel	28	40
Dorsum of Foot	10	14.3
Multiple Ulcers	0	0

**Distribution of scores related to blood sugar values:** Out of 70 patients, 45 (64.3%) had elevated Random Blood Sugar values ranging from 300-400 (Table 4).

**Table 4: Distribution of scores related to blood sugar values**

Blood Sugar Values (RBS)*	Number of patients	(%)
200-300	15	21.4
300-400	45	64.3
400	10	1.4

**Distribution of neuropathy:** Out of 70 patients, all were categorized for neuropathy using Semmes Weinstein monofilament. Graph 4 shows 59 (84%) patients suffered from peripheral neuropathy.



**Fig 6: Distribution of neuropathy**

**Distribution of nerve conduction study scores:** In our study, majority of the patients (89.8%) had both sensory and motor weaknesses (Table 5).

**Table 5: Distribution of nerve conduction study scores**

Neuropathic type	Number of patients	(%)
Sensory	5	8.5
Motor	2	3.4
Sensory (+) Motor	53	89.8

**Distribution of peripheral vascular status scores:** In 70 patients, 23 (33%) had peripheral vascular disease while in 47 (67%) it was not present (Table 6).

**Table 6: Distribution of peripheral vascular status scores**

Peripheral Vascular Disease	Number of patients	(%)
Present	23	33
Absent	47	67

**Distribution of score related to Doppler study:** According to our study, out of 23 patients, 18 (25.7%) had stenosis of peripheral arteries, 3 (4.3%) had occlusion and 2 (2.9%) had both (Table 7).

**Table 7: Distribution of score related to Doppler study**

B. Mode Duplex Doppler	Number of patients	(%)
Normal	47	67.1
Presence of stenosis in peripheral arteries	18	25.7
Complete Occlusion of peripheral arteries	3	4.3
Presence of both stenosis and occlusion of peripheral arteries	2	2.9

### Distribution of score categorized in ulcer groups:

In our study 36 (51.4%) patients had neuropathic foot lesions and 23 (32.8%) had neuro-ischemia (Table 8).

**Table 8: Distribution of score categorized in ulcer groups**

Categories	No. of patients	(%)
Neuropathic	36	51.4
Neuro-ischemia	23	32.8
Infection (Non-ischemic/ non-neuropathic)	11	12.8

**Distribution of patients who had undergone amputations:** In our study majority of the patients who had undergone both minor and major amputations were in patients suffering from both neuropathy and ischemia (Table 9). As per our statistical analysis Chi square test was 21.40, 1 df and the P value was <0.0001. Hence the proportion of amputation cases among neuro-ischaemia patients was significantly higher than the amputation cases in neuropathy cases alone.

**Table 9: Distribution of patients who had undergone amputations**

Categories	Minor amputations (Toe)	Major amputations (Forefoot, BK, AK)
Neuropathic (n=36)	4(11.1%)	-
Neuro-ischemia(n=23)	12 (52.2%)	4 (17.3%)
Infection(Non-ischemic /non-neuropathic (n=9)	4 (44.4%)	1 (11.1%)

**Distribution of outcome of the patients:** Outcome of the patients was calculated according to the healing time. All patients had excellent outcome owing to improvement in treatment modalities as seen in Table 10. Our analysis showed, Chi square 0.2658 and P value <0.6062. Hence the treatment pattern was same in all the cases.

**Table 10: Distribution of outcome of the patients**

Categories	Healed *	Unhealed **	Mortality ***
Neuropathic (n=36)	34 (94%)	2(6%)	-
Neuro-ischemia(n=23)	20 (87%)	2 (9%)	1 (4.3%)
Infection(Non ischemic/Non neuropathic(n=9)	9(82%)	2 (18%)	-

\*with in a period of 6 months either by full primary healing or by SSG,

\*\*healing time more than 6 months period going for further surgeries

\*\*\*patient dead due to complication of the wounds

## DISCUSSION

Aksoy et al<sup>5</sup> in their study in Istanbul (turkey) on diabetic foot ulcerations enrolled 66 patients of which 39 (59%) men and 27 (41%) women. In another study by Unal et al<sup>6</sup> on diabetic foot in 200 patients in Karachi found that the percentages of males were 65 and female were 35. In our study also the results were similar, males 46 (56.7%) and females 24 (34.3%). Hence the complications of diabetic foot ulcers are more common in males. Al Mahroos et al<sup>7</sup> in their study on diabetic patients with foot problems in patients in Bahrain observed that the mean age of the patients were 57.3 + 6.32 years. Ahmed M et al<sup>8</sup> in their study on evaluation of diabetic foot ulcer in 100 subjects observed that the age group of patients was between 40 - 60 years. In our study done on 70 patients with diabetic foot ulcerations majority of the patients fall between 51-60 years of age and mean age of these patients was 55 + 5 years. This is relevant to the above studies and our study proved that the complications of diabetes are more common in the older age group. Nalini Singh et al<sup>9</sup> in their study on prevalence and determinants of foot ulceration in patients with type II diabetes observed that the mean duration of diabetes was 4.3 years. Kumar S et al<sup>10</sup> in their study on prevalence of foot ulceration and its correlation with type II diabetes showed that the mean duration of diabetes among the patients was 7.4 years. In our study the duration of diabetes was for 5.2 years, which signifies that as the duration of diabetes increases, the foot is prone for problems. In comparison to above studies our patients with diabetes tend to develop foot ulceration little earlier. Apelquist J et al<sup>3</sup> in their study on external risk factors for foot ulcerations and the outcome of diabetic foot lesions in 314 patients demonstrated that the external precipitating factors were identified in 264 out of 314. Common factors like ill-fitting shoes, socks, acute mechanical trauma, stress ulcers and paronychia were named. In our study majority of the patients had history of minor trauma, either due to bare foot walking (or) ill-fitting foot wear, leading to minor trauma and ulceration and minor injuries like thorn prick. This signifies the need for education on personal care of foot by self-examinations and general awareness of foot problems and measures to prevent them and stressing the importance of proper footwear in diabetic patients.



Imran S et al<sup>11</sup> in their study on frequency of lower extremity amputations in diabetes with reference to glycaemia control and Wagner's grades in Karachi showed the following results. Grade O, 6 patients, 10 in grade I, 13 in grade II, 14 in grade III, 18 in grade IV and 9 in grade V. Rooh-Ul-Muqim et al<sup>12</sup> in their study on evaluation and management of diabetic foot by Wagner's classification, out of the 100 cases, grade O (6), grade I (14), grade II (25), grade IV 30, grade V (4). In our study the results were Grade O (1), grade I (1), grade II (24), Grade III (17), grade IV (26) and grade V (1). This shows that most of our patients present in later part of the disease. If they were treated in earlier grades the results would have been much better. Apelquist J et al<sup>3</sup> in their study of the long term progress for diabetic patients with foot ulcer observed that the results of patients with lesions in the Toe (dorsal and Plantar surface) was 51%, plantar surface, metatarsal head and foot and heel was 28%, Dorsum of foot 14% and multiple ulcers was 7%, out of 314 subjects. Reiber et al<sup>13</sup> in their study on the burden of diabetic foot ulcers based on severity of lesions found that 52% of patients had lesions in toe (dorsal and plantar surface), 37% had lesions on plantar, metatarsal head, mid foot and heel and 11 % in the dorsum of foot. In our study, 46% of the foot lesions were in the toes (dorsal and plantar surface) and 40% on the plantar and metatarsal head, mid foot and heel. This shows that the toes and sole of feet are vulnerable to ulceration, which signifies that the diabetic foot needs frequent self-evaluations. Oyiboso et al<sup>14</sup> in their study on the outcome of diabetic foot ulcers in 194 subjects observed that 67% of the ulcers were due to neuropathy and 26.3% were neuro-ischemic. Ramani A et al<sup>15</sup> in their study on etiology of diabetic foot ulceration found that peripheral neuropathy was seen in 78 % of the subjects and vascular insufficiency was seen in 49.3%. Kumar S et al<sup>10</sup> in their study on prevalence of foot ulceration in type II diabetic patients showed that the prevalence of neuropathy was 41.6% and prevalence of PVD was 11%. In their study 20 were purely neuropathic 13 were neuroischemic, 5 pure vascular and 5 unclassified. Mohan et al<sup>16</sup> in their study on diabetic foot ulcerations using measures of ABPI and Doppler estimated that 21.3% of the subjects were diagnosed to have PVD. Rooh-Ul-Muqim et al<sup>12</sup> in their study on diabetic neuropathy, foot ulceration, peripheral

vascular disease and their potential risk factors among the patient with diabetes demonstrated that diabetic neuropathy was found in 36.6% of patients and PVD in 11.8% of cases. In our study, 84% of the population had peripheral neuropathy in comparison with other studies. Our patients in the study population had higher incidence of peripheral neuropathy compared to their study. 33% of the patients had presence of PVD in comparison with other studies which is higher. In the ulcer groups the neuropathic ulcer were more common (51.4%), compared to the group neuro-ischemic (32.87%) and others (12.8%). In analyzing the outcome of these patients' in the above three groups the amputation rates were higher in neuro-ischemic group (69.4%) when compared to other two groups and the healing rate was better in the neuropathic group (94%) compared to neuro-ischemic (87%). This signifies that the presence of neuropathy increase the chance of foot ulceration and the presence of ischemia worsen the presentation and which further affects the outcome of the ulcer. Hence both play an important role in the prognosis of the disease apart from other associated risk factors like higher glycaemia, infection, osteomyelitis, and deformity. From our study we confirm that peripheral neuropathy is the predominant factor for foot ulceration, as the insensate foot is prone for undue trauma. The presence of ischemia due to peripheral vascular disease increases the morbidity and mortality of the diabetic foot. PVD also increases the amputation rates and reduces the healing time.

## CONCLUSION

Male population (65.7%) is predominantly affected compared to female (34.3%). The mean age of patients in the study population with foot ulceration was between 55 + 5 years. The mean duration of diabetes was 5.2 years in patients who suffered from foot ulceration. Majority of the patients present with foot problems with G I to G IV (Wagner's Grades). Most of the ulceration occurs in toes, metatarsal head and mid foot. It was more common in deformed foot due to alteration of weight bearing. Most of the patients had blood sugar values more than 200. The duration of diabetics more than the level of sugar is the cause of foot disease.

Neuropathy was present in 84% of the population in the study. Nerve conduction study shows majority of the patients suffer from both sensory and motor neuropathy.

33% of the population in the study had peripheral vascular disease.

51.4% of the ulcer were neuropathic and 32.8% were neuro-ischemic and 12.8% were due to infection alone. Total amputation rate was higher (69.4%) in the neuro-ischemic group, (66.5%) in the infection group and lowest (11.1%) in the neuropathic group.

Healing rates were higher in neuropathic ulcers (94%) when compared with neuro-ischemic (87%) and others (82%).

Control of diabetes with soluble insulin with combination of antibiotics provides a better result.

Hence apart from routine foot examination, both neuropathy and peripheral vascularity should be assessed in all patients with foot ulcerations.

In conclusion "***Prevention is better than Cure***"

Hence the insensitive diabetic foot should be protected by proper patient education, early assessment, which timely management and proper design of foot wear can avoid further (or) recurrent foot ulceration.

**Conflict of Interest:** Nil

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