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Original Research Article

A prospective observational study of role of pedis scoring in predicting complications of diabetic foot in a tertiary centre

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ABSTRACT

Background: Diabetes mellitus is one of the most common non-communicable diseases affecting major population in the world. Diabetic foot ulcer still remains the most common manifestation of diabetes mellitus requiring hospitalisation and invariably resulting in increased risk of morbidity. Our aim is to know the usefulness of PEDIS scoring in identifying the severity of diabetic foot ulcer and its management.
Methods: In this prospective observational study, data of patients with foot ulcer who came to Apollo hospital in Chennai were collected for one year from July 2021 to May 2022. They were followed up for a period of six months. Patients were assessed and classified according to the PEDIS scoring system. All the data were analyzed by IBM SPSS statistics for windows version 25.0 (IBM corp, Armonk, Newyork USA). All p values <0.05 were considered as statistically significant.
Results: Out of one seventy-five patients, one hundred and thirteen were categorized as low risk group with a score between 0-7 and sixty-two as high-risk group with a score between 8-12. Majority of the high-risk groups developed complications like non healing ulcer, osteomyelitis, amputation. It is more prevalent among men with age preponderance for elderly. Whereas management of low-risk groups were limited only to conservative management and debridement. Of twenty-one patients with osteomyelitis, thirteen patients underwent amputation.
Conclusions: Based on our study, we have come to a conclusion that the PEDIS scoring system actually helps in grading the diabetic foot and its management.

Keywords: Diabetic foot ulcer, PEDIS scoring, Osteomyelitis, Non healing, Amputation

INTRODUCTION

Diabetes mellitus is a chronic condition characterized by abnormally increased blood glucose level with raised level of insulin and presence of resistance to the secreted insulin.[1] 15-25% of people with diabetes mellitus are estimated to be at risk to develop foot ulcer in their lifetime.[2] Diabetic foot ulcer is defined as full thickness wound that occurs in the foot just below the level of malleolus.[3] Most commonly affected sites are the pressure points such as plantar aspect of toes, metatarsal heads and heel. It will often progress to non healing ulcer, infection, dry and wet gangrene, ultimately leading to amputation of the involved parts. With early diagnosis and timely intervention, these complications can be prevented. Foot ulcers are very likely to recur in the future with an incidence of 50% after 3 years of occurrence of foot ulcer.[4] PEDIS scoring system helps in predicting the complications of diabetic foot with score of 0-12. This scoring system assess the patients with diabetic foot and grade them into high risk and low risk categories according to the score. This scoring has an excellent accuracy in

grading the diabetic foot ulcer and helps in its management plan.[5] Diabetic foot ulcer is responsible for frequent hospital admissions and impairing quality of life.[6] In order to prevent further complications, the most accurate and globally accepted PEDIS scoring has come into play. This scoring system helps in assessing the wound, by considering its vascularity, infection, depth, extent and the sensation. Causes of diabetic foot ulcer includes modifiable risk factors like diet, lifestyle, occupation, socioeconomic status can be prevented with proper education. Other vital causes are: peripheral polyneuropathy is considered as the most common factor triggering formation of ulcer. Diabetic polyneuropathy is defined as the presence of signs and symptoms due to dysfunction of peripheral nerves after ruling out other causes in patients with diabetes mellitus.[6,7] It can be sensory, motor, autonomic variety.

Vascular insufficiency includes microangiopathy and macroangiopathy.[8] Increased glucose can cause hypercoagulability by altering the endothelial function and impairment of fibrinolysis, platelet aggregation.[9] Increased concentration of glucose in the local tissue precipitates development of infection. It also alters the course of wound healing by impairing neovascularization.[10] Trauma to the foot causing deformity of the foot. Loss of elasticity of tendons and ligaments causes flattening of foot by altering the arches of foot leading to development of ulcer. Complications of diabetic foot are non healing ulcer which is defined as any ulcer which is not showing any signs of healing for more than 3 months of duration, ischemia of foot indicates decreased blood supply to the foot, gangrene of foot which is described as macroscopic death of the tissue with blackish discoloration (Figure 1), Charcots neuroarthropathy a destructive syndrome affecting bones and joints in patients who already have neuropathy. Osteomyelitis infection of bone and bone marrow.[11,12]

Osteomyelitis is one of the most common complications of diabetic foot. It is characterized by infection and inflammation of the bone initially involving the cortex, followed by bone marrow and then the surrounding tissues.[13] It is due to the infection which could be through local or haematogenous spread from the different site of foci. Most common organism responsible for causing osteomyelitis is *Staphylococcus aureus*, which is an aerobic gram positive cocci.[14] Radiological imaging such as X-ray and MRI of the foot helps in confirmation of the diagnosis of osteomyelitis (Figure 2). Clinical signs predictive of osteomyelitis are: foot ulcer-width and depth: Ulcer with width of more than 2 cm^2 shows 56% sensitivity and 92% specificity.[15] Ulcers with depth of more than 3mm are more prone to develop osteomyelitis.[15] Probe-to-bone test (PTB): Probe to bone test is an outpatient test which can be performed by probing the ulcer area with a sterile blunt probe. If the probe can be able to reach the bone surface, then the test is considered as positive.[16] Blood investigations such as hemoglobin, white blood cell count, random blood sugar, HbA1c, urea, creatinine must be done. X ray and MRI of the foot to be carried out to rule out osteomyelitis. Arterial doppler study of the limb to confirm the triphasic blood flow in the limb-poor monophasic flow is an indication of amputation in foot ulcer and nerve conduction study can be done to test for neuropathy.

Diabetic foot ulcer must be kept clean and healthy. Avoiding too much pressure on the foot by using microcellular rubber (MCR) foot wears. Management of the diabetic foot ulcer includes surgical and antibiotic therapy, glycemic control. Antibiotic therapy is the first line of management in diabetic foot ulcer. Wound swab should be taken for culture and sensitivity before starting antibiotics. Prolonged antibiotic therapy is required in severe infections for 3 months.[17] Wound debridement includes medical such as autolytic, enzymatic, biological and surgical methods. Debridement is a procedure which will remove the devitalized tissue from a wound (Figure 3). It removes the necrotic, damaged and infected tissue thereby making the wound healthy and revitalizied.[18] Negative pressure wound therapy is a non-invasive therapy. It reduces the wound discharge, tissue edema and promotes the formation of granulation tissue.[19] Usually, the pressure for the vacuum therapy ranges from 50 to 125 mmHg depending on the size of wound for a period of 5 to 7 days. Split skin graft is a tertiary wound care procedure which is usually done following debridement of wound at a later period when the wound has a good granulation tissue. The final choice of management is amputation. It is commonly done in complicated ulcers with limb ischemia, severely infected wound. There are different types of classification for diabetic foot ulcer such as PEDIS scoring, Meggit-Wagners grading system, University of Texas system mainly concentrating on the depth of the ulcer, SAD system (S-Size including area and depth, Sepsis, A- Arteriopathy, D-Denervation) with a score of 0-3, SINBAD scoring system which is a modification of SAD system with an additional parameter of site consisting a total score of 0-6.[20-22]

PEDIS scoring

Perfusion: 0-no signs of peripheral arterial disease, 1-signs of peripheral arterial disease, but no critical limb ischemia and 2-critical limb ischemia. Extent: 0-skin intact, 1-<1 cm^2, 2-1-3 cm^2, 3-> 3 cm^2. Depth: 0-skin intact, 1-superficial, 2-fascia, muscle, tendon, 3-bone or joint. Infection: 0-none, 1-surface, 2-abscess, fascitis, and/ or septic arthritis, 3-Systemic inflammatory response syndrome (SIRS). Sensation: 0-sensation intact, 1-loss of sensation. PEDIS score interpretation: low:0-7, high:8-12.

Objectives of study

In our study, the main objective was to know about the usefulness of PEDIS scoring in identifying the severity of diabetic foot ulcer and its management by observing patients with diabetic foot. And to know whether early diagnosis of osteomyelitis can prevent amputation.

METHODS

This is a hospital based prospective observational study conducted in Podiatric clinic and inpatients**,** Apollo main hospital in Chennai. Patients who came to Apollo hospitals with Diabetic foot ulcers below the level of malleolus including both outpatients and inpatients were taken into this study after getting consent. This study was conducted for 1 year from June 2021 to May 2022. Totally 175 patients were included in the study and followed up for 6 months. The primary goal of the study is to find the usefulness of PEDIS classification in diabetic foot ulcer, a study (PEDIS scoring and its role in management of diabetic foot ulcer) suggestive of PEDIS score <7 correctly picking up 87.5% of patients who had healed ulcer.[5] This is our background information for calculating the sample size. Using the following formula

$$n = Z2pq / d$$

Where, Z=standard normal variate value, (95% Confidence interval) =1.96, p=proportion of patients correctly identified as healed ulcer by PEDIS classification from the reference study those who had score of <7=87.5%, q=1 - p= 12.5%, d = clinical allowable error = 5%, applying the above, required sample size was 175.

Statistical analysis

Shapiro wilk's test was used to assess the normality pattern of the data. If they are normally distributed, they were expressed as Mean±SD, otherwise median (interquartile range). Categorical variables were expressed by percentage. ROC curve was drawn to find the best cutoff PEDIS score in the prediction of amputation. Comparison of categorical variables was done by either Chi square test or Fischer's extract test. Comparison of continuous variables if any, was done by independent sample t test, if they were normally distributed. Non-normally distributed continuous variables was done by Mann Whitney U test. Data entry was done in Microsoft Excel 2007. Statistical analysis was done by IBM SPSS statistics for windows version 25.0 (IBM corp, Armonk, Newyork USA). All p values <0.05 were considered as statistically significant.

Inclusion criteria

Patients with known DM with foot ulcer below the level of malleolus, more than 18 years of age, with past history of amputation of part of the foot/toes, multiple diabetic ulcer in the same foot, with recurrent diabetic foot ulcer were included in the study.

Exclusion criteria

Patients with diabetes presenting only as soft tissue infections in the foot without any evidence of ulcer, ulcer in the foot following a trauma in a diabetic patient, patients with diabetic foot ulcer presenting with acute limb ischemia were excluded.

All the patients were briefly explained about the study and were included in the study only after ensuring that they were fulfilling the inclusion and exclusion criteria. All the patients presenting with foot ulcers with diabetes mellitus were taken up for survey and classified according to the PEDIS score after a proper assessment. Perfusion i.e. blood supply to the foot was clinically tested by palpating the peripheral pulses of the foot, most importantly the dorsalis paedis pulsation. Hand held doppler study was carried out in patients with feeble pulsation in the foot. In suspected cases of peripheral vascular disease, ultrasound doppler study was done additionally.

CT peripheral angiogram has been carried out for patients only with the features of limb ischemia. The extent of ulcer was determined with the help of measuring tape. Depth of the ulcer was made out by palpating the base of the wound or by inspection of the wound. We can grade the depth according to tissue that is found over the base like muscle, ligaments, tendon, underlying bone. Along with these features and general hemodynamics of the patient being taken into consideration, severity of the infection like sepsis, systemic inflammatory response syndrome, multiorgan dysfunction syndrome can be identified and graded which helps to intervene promptly. Sensation of the foot ulcer was checked by touching the affected foot with cotton, fingertip and giving pain stimuli. Apart from these scores we also tried to validate the reliability of probe to bone test in diagnosing osteomyelitis of diabetic foot. If the test was found to be positive in order to justify its reliability, X-ray of the foot was done for this patients. All of them were managed appropriately with conservative and surgical procedures based on the obtained score. Following the procedure, patients were followed-up for 6 months to find out the healing status of the wound and the approximate time taken by the wound for healing. Both verbal and written informed consent were obtained from the patient before performing procedures.

RESULTS

This study is a prospective observational study with an aim to study the role of PEDIS scoring in predicting the complications of diabetic foot.

Table 1: The distribution of DFU among male and female.

Gender	N	%
Female	49	28.0
Male	126	72.0
Total	175	100.0

Table 2: The mean age of patients with DFU.

Age	N	Min	Max	Mean	SD
	175	35	88	60.06	10.45

Table 3: The elevated white blood cell counts in DFU patients.

WBC	N	%
No	118	67.4
Yes	57	32.6
Total	175	100.0

Table 4: Uncontrolled random blood glucose level in DFU patients.

RBS	N	%
No	58	33.1
Yes	117	66.9
Total	175	100.0

Table 5: Positive probe to bone test in DFU patients.

PTB test	N	%
No	154	88
Yes	21	12
Total	175	100.0

Table 6: Presence of osteomyelitis in DFU.

Osteomyelitis	N	%
Yes	21	12
No	154	88
Total	175	100.0

After a period of regular follow-up and analysis based on the PEDIS scoring, the results of this study are as follows: Out of 175, 126 (72%) were males and 49 (28%) were females. Among them, 34 females had a score of less than 7 and 15 had more than 7. Whereas 79 males had a score of less than 7 and 47 had a score of more than 7 (Table 1).

In this study, males were affected more than the females. Most of the men and women were elderly with mean age (standard deviation) of 60 (±10.45) (Table 2). Most of the patients presented to the outpatient department with complaints of ulcer in the foot commonly over the plantar aspect of the foot near the metatarsal heads. Some of them also had associated pain, discharge from the ulcer and fever. Patients presenting with multiple ulcers were also enrolled in this study. But we have taken only one ulcer which was greatest in dimension. White blood cell counts were found to be elevated in 57 (32.6%) patients (Table 3). The cut-off value for high WBC was considered to be more than 11,000/mm^3. Cut-off value taken for high random blood sugar was 140 mg/dl. About 117 (66.9%) patients were having abnormally elevated random blood sugar as depicted in (Table 4).

Table 7: The treatment of patients with osteomyelitis.

Osteomyelitis	N
Debridement	8
Amputation	7
Both	6

For these patients, in addition to the random blood sugar, HbA1c test were also done. 21 (12%) patients were found to have osteomyelitis and they were tested positive for probe to bone test as mentioned in the (Table 5-6).

Figure 1: 60 years old female with diabetic foot ulcer in the right forefoot with gangrene of the great toe and 2nd toe and impending gangrene of other three toes.

Of 21 patients, 8 patients needed only debridement along with antibiotic therapy. 7 patients directly underwent amputation. In 6 patients debridement was done initially and amputation was done at a later period as the ulcer did not show any progression (Table 7). 3 low risk patients

were managed conservatively. 134 (76.6%) patients apparently had undergone wound debridement.

Figure 2: X- ray of left foot in AP view showing erosion of distal part of the distal phalanx of left great toe with evidence of osteomyelitis.

Figure 3: Wound debridement.

Of 134 patients, 30 (17.1%) patients got their split skin grafting done at a later period of time as a second stage procedure. Around 113 patients were grouped under low risk (0-7) category and 62 were categorised into high risk group (8-12). Out of 134, 103 patients with low PEDIS score and 31 with high PEDIS score underwent wound debridement (Figure 4). Along with wound debridement, 37 patients were managed with additional procedures like bone curettage for 33 (18.9%) patients and vacuum assisted therapy (Figure 5) for 4 (2.3%) patients. 52 (24%) patients had gone through inevitable amputation, because of the extensive wound infection and limb ischemia. Patients with a score of minimum 7 had undergone minor amputation. 98 patients had healed wound without any other additional intervention. 69 patients with past surgical history on the same foot were observed.

Figure 4: Amputation of right great toe and extension of infection with involvement of right second toe too (pointed out with the instrument).

Healing of the wound was seen in 43 patients whereas non healed ulcer noted in 14 patients and amputation in 12 patients. 25 patients had non-healing ulcer which had not showed any signs of healing. In consequence of this, they underwent re-debridement and needed additional procedures despite debridement.

Figure 5: Vacuum therapy-post right great and second toe amputation.

Patients with score of less than 7 managed with debridement showed good results at the end. Patients with score more than 4 with high random blood sugar and white cell count being elevated showed delayed healing process. From (Table 8) we predicted the complications of the diabetic foot based on the PEDIS scoring with factors like uncontrolled blood glucose level, grossly increased white blood cell count, additional co-morbidities and previous history of surgery in the same foot. All of the factors and management of diabetic foot ulcer showed p value of less than 0.05 expect the conservative management. Of the 3 patients who were treated conservatively, 2 had healed ulcer with healing period of less than 3 months.

Table 8: The classification of patients based on PEDIS score and their management.

Parameters	PEDIS score 0-7	PEDIS score 8-12	Total	P value
Male	79	47	126	-
Female	34	15	49	-
RBS	68	49	117	0.001
WBC	24	33	57	0.000
Past surgery	47	22	69	0.009
PTB	4	17	21	0.000
Osteomyelitis	4	17	21	0.000
Conservative	3	0	3	0.196
Debridement	103	31	134	0.000
Healed	95	3	98	0.000
Non healed	8	17	25	0.046
Amputation	10	42	52	0.046

Table 9: The various outcomes of DFU like healed, non-healing ulcers, amputation of involved parts.

Outcome of diabetic foot	Healed	Non healed	Amputation	Total
High RBS	55	17	45	117
High WBC	14	12	31	57
Past surgery	43	14	12	69
Osteomyelitis	2	6	13	21
Conservative	2	1	0	3
Debridement	94	24	16	134

One patient eventually progressed to have non healing ulcer. Apparently, this patient needed wound debridement. According to the study, there is a strong positive association between the risk of developing complicated diabetic foot and high PEDIS score with p value of <0.05 except for conservative treatment with p value of 1.96. Some patients also had complications despite of low PEDIS score. This can be explained due to the other factors which can influence the changes in ulcer like elevated blood glucose level, elevated white blood cell count and low hemoglobin. 73 (41.8%) patients wound healed within a period of 3 months duration. Meanwhile, delayed wound healing more than 3 months was observed in 63 (36%) patients.

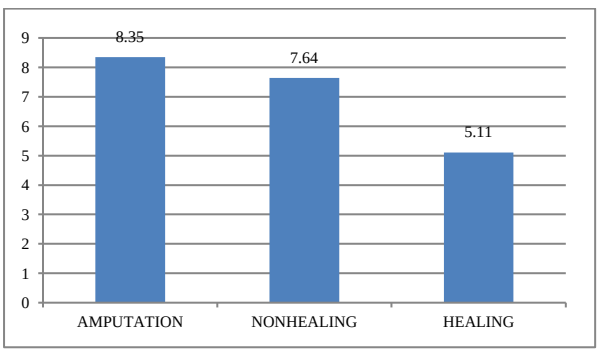

Figure 6: Bar chart shows mean value of amputation, healed, non-healed ulcers.

DISCUSSION

Our study aim was to predict the complications that can occur in a diabetic foot based on the PEDIS scoring. And the primary objective would be assessing the severity of the diabetic foot and prediction of amputation of foot. Moreover, we also tried to find whether the diagnosis of osteomyelitis at an early period at the time of diagnosis will change the intervention like minimising the level of extension of amputation in a diabetic foot. Our patients were clinically assessed thoroughly and were given a score based on the findings. They were classified as low risk group and high risk group. The offered management options would be conservative antibiotic therapy and topical ointment, wound debridement, amputation, split skin grafting, vacuum assisted therapy. Malecki et al recommended some antibiotics used in diabetic foot ulcer like cephalosporins, imepenems, aminoglycosides, tigecycline.[23] We used cefoperozone combined with sulbactam, ciprofloxacin and clindamycin to cover gram negative and gram positive organisms as recommended by Malecki et al. We found that there is a strong association between the PEDIS scoring and the complications of diabetic foot. If the score is very high, most of the patients will develop complications at a later period of time. Most common complications we had encountered are non-healing ulcer and amputation. With suitable effective treatment these complications can be prevented. In our study, males suffered more than the females from foot

ulcer as supported by Dinh et al study, men were having higher risk when compared to women.[24] Ahmad et al, Bijan Iraj et al showed that uncontrolled blood glucose level, abnormally high white blood cell counts can affect the outcome of foot ulcer and also has an impact over the wound healing.[25,26] In our study also, patients with both poor glycemic control and higher WBC count developed infections, non-healing ulcers and delayed healing. Furthermore, patients with co-morbidities like CKD, CAD had high score compared patients with no comorbidities. Osteomyelitis was found in 21 patients who were tested positive for probe to bone test in our study as supported by the study done by Lam et al.[27] Mutluoglu et al used probe to bone test to diagnose osteomyelitis in DFU.[28]

Chuan et al, Gandhi et al studies proved that higher the PEDIS score, more will be the complications of foot ulcer like non healing, amputation.[5,29] In our study 95 patients with low score (0-7) had good outcome of healed ulcer who were managed by debridement. But some patients in spite of low score happened to have poor outcome like non-healing in 8 patients, amputation in 10 patients. These patients were found to have associated uncontrolled blood glucose level. In high risk group (8-12), 17 patients had non healing ulcer requiring re-debridement and /or amputation. 42 patients needed amputation. All the parameters considered in this study showed a p value of less than 0.05 except in conservative management. Conservative management was followed in 3 patients with low score which has got p value of 1.96. 2 patients of them were further managed with wound debridement. Khalid Al-Rubeaan et al suggested that diabetic foot ulcer patients with poorly controlled blood glucose level and the presence of infection affects the prognosis of the diabetic foot.[30] In our study also, patients with low score, high glucose level and elevated WBC count underwent amputation. Armstrong et al observed recurrence of ulcer in DFU patients and they recommended proper counselling of the patient and selfcare to reduce the recurrence rate.[31] Recurrence of ulcer was observed in 69 of our patients. Chinmay Gandhi et al showed the significant association between high PEDIS score and complications like amputation, non-healing ulcers.[5] So as our study also showed association between high score and complications in diabetic foot ulcer. According to Marie Louise Buhl Sorensen [(32)] et al, uncontrolled glucose level and presence of infection affects the healing process of ulcer. In our study patients with high glucose level and WBC count had non-healing and delayed healing of ulcer.

Limitations

In suspected cases of osteomyelitis, we relied more on probe to bone test, X- ray of foot and the inflammatory markers for its diagnosis. But MRI would be a preferable study for the confirmation of osteomyelitis which was not carried out in our study. Categorising the patient according to PEDIS scoring is totally based on the observer's assessment which can vary with different patients.

CONCLUSION

The purpose of this study was to know about the role of PEDIS scoring in predicting complications in diabetic foot which was our study's aim. In our study, PEDIS score helped us in identifying the severity of the diabetic foot ulcer. Patients with higher score needed amputation. Majority of the patients with low score were managed successfully with debridement alone and the outcome was good. Debridement and bone curettage along with long term antibiotic therapy helped in treating DFU patients with early stage of osteomyelitis avoiding the necessity of amputation. From our study we have come to a conclusion that PEDIS scoring helps in predicting complications in diabetic foot ulcer and its management.

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