

Usefulness of PEDIS Scoring in Identifying the Severity of Diabetic Foot Ulcer and its Management: An Observational StudyPraveen Kishore¹, Mukesh Kumar², Sunil Kumar Ranjan³, Ashok Kumar⁴¹Senior Resident, Department of General Surgery, Government Medical College, Bettiah, Bihar, India²Senior Resident, Department of General Surgery, Government Medical College, Bettiah, Bihar, India³Assistant Professor, Department of General Surgery, Government Medical College, Bettiah, Bihar, India⁴Assistant Professor, Department of General Surgery, Government Medical College, Bettiah, Bihar, India

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Abstract**Aim:** The aim of the present study was to evaluate the usefulness of PEDIS scoring in identifying the severity of diabetic foot ulcer and its management.**Methods:** This was a hospital based prospective observational study conducted in Department of General Surgery. Patients who came to Hospital 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. Totally 200 patients were included in the study and followed up for 6 months.**Results:** Out of 200, 140 (70%) were males and 60 (30%) were females. White blood cell counts were found to be elevated in 64 (32%) patients. The cut-off value for high WBC was considered to be more than 11,000/mm³. Cut-off value taken for high random blood sugar was 140 mg/dl. About 132 (66%) patients were having abnormally elevated random blood sugar. 20 (10%) patients were found to have osteomyelitis and they were tested positive for probe to bone test. 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 elevated white cell count being showed delayed healing. 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 comorbidities 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.**Conclusion:** From our study we have come to a conclusion that PEDIS scoring helps in predicting complications in diabetic foot ulcer and its management.**Keywords:** Diabetic foot ulcer, PEDIS scoring, Osteomyelitis, Non healing, Amputation

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Introduction

With a prevalence rate of between 15% and 34% in persons with diabetes, [1,2] diabetic foot ulcer (DFU) is the main cause of non-traumatic lower limb amputation worldwide.1 Approximately 50% of diabetic ulcers become infected [3] and 20% of moderate or severe diabetic foot infections lead to amputation. [4,5] The presence of DFU in patient increase the risk of death at 5 years by 2.5 times. [6] While the clinical presentation of diabetic lesions in Tanzanian populations was previously reported, [7] to decrease the socioeconomic cost associated with diabetic foot complications, a population-based DFU risk assessment tool needs to be developed that can identify patients vulnerable to future DFU occurrence. There has been an abundance of studies focusing on the predictive factors for diabetic foot ulceration with the majority indicating the multifactorial nature of

DFUs and their link to a number of different parameters. Systematic reviews of the literature indicated that impaired sensation, peripheral vascular disease indicated by ankle brachial index (ABI), vibration perception threshold (VPT), peak plantar pressure, foot deformities, and fasting blood sugar level were identified as risk factors for DFU. Furthermore, other easily identifiable parameters like age, duration of diabetes, height, body weight, and body mass index (BMI) have been associated with the risk of DFU occurrence. [8,9]

The International Working Group of the Diabetic Foot (IWGDF) has published an evidence-based guideline concerning the classification of DFU and the use of classification systems in routine clinical practice. Three types of classifications have been defined: patient-related (morbidity of the patient,

e.g., presence of chronic kidney disease), limb-related (peripheral artery disease and loss of protective sensation), and ulcer-related (area, depth, localization, number, and infection). The IWGDF [10] recommends these classifications to facilitate communication among health professionals, for treatment guidance, and for audits of clinical outcomes in healthcare units and populations, but does not recommend their use for prognostic purposes in patients with DM foot ulcers. Indeed, there is a lack of information on the applicability of the different DFU classifications and their prognostic value in primary care.

Peripheral arterial disease is an independent risk factor for subsequent ulceration and limb loss in diabetes. It is present in 50% of patients with diabetic foot ulceration (DFU), a proportion which may be increasing. [11,12]

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 cm², 2-1-3 cm², 3-> 3 cm². Depth: 0-skin intact, 1- superficial, 2-fascia, muscle, tendon, 3-bone or joint. Infection: 0-none, 1-surface, 2-abscess, fasciitis, 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.

The aim of the present study was to evaluate the usefulness of PEDIS scoring in identifying the severity of diabetic foot ulcer and its management.

Materials and Methods

This was a hospital based prospective observational study conducted in department of General Surgery, Government Medical College, Bettiah, Bihar, India. Patients who came to 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. Totally 200 patients were included in the study and followed up for 6 months.

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 pedis 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.

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 exact 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.

Results

Table 1: Gender distribution

Gender	N	%
Female	60	30
Male	140	70
Total	200	100.0

Out of 200, 140 (70%) were males and 60 (30%) were females.

Table 2: White blood cell counts, blood glucose level, Positive probe to bone test and presence of osteomyelitis in DFU patients

WBC	N	%
No	136	68
Yes	64	32
Total	200	100.0
RBS		
No	68	34
Yes	132	66
Total	200	100.0
PTB test		
No	180	90
Yes	20	10
Total	200	100.0
Osteomyelitis		
No	180	90
Yes	20	10
Total	200	100.0

White blood cell counts were found to be elevated in 64 (32%) patients. The cut-off value for high WBC was considered to be more than 11,000/mm³. Cut-off value taken for high random blood sugar was 140 mg/dl. About 132 (66%) patients were having abnormally elevated random blood sugar. 20 (10%) patients were found to have osteomyelitis and they were tested positive for probe to bone test.

Table 3: The classification of patients based on PEDIS score and their management

Parameters	PEDIS score 0-7	PEDIS score 8-12	Total	P value
Male	81	51	132	-
Female	36	18	54	-
RBS	70	52	122	0.001
WBC	27	37	64	0.000
Past surgery	50	25	75	0.007
PTB	5	20	25	0.000
Osteomyelitis	5	20	25	0.000
Conservative	5	0	5	0.182
Debridement	105	35	140	0.000
Healed	98	4	102	0.000
Non healed	8	20	28	0.048
Amputation	15	40	55	0.048

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 elevated white cell count being showed delayed healing.

Table 4: 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	57	18	47	122
High WBC	16	14	34	64
Past surgery	46	16	13	75
Osteomyelitis	4	8	13	25
Conservative	3	2	0	5
Debridement	96	26	18	140

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.

Discussion

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. [13] 15-25% of people with diabetes mellitus are estimated to be at risk to develop foot ulcer in their lifetime. [14] Diabetic foot ulcer is defined as full thickness wound that occurs in the foot just below the level of malleolus. [15] 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. [16]

Vascular insufficiency includes microangiopathy and macroangiopathy.8 Increased glucose can cause hypercoagulability by altering the endothelial function and impairment of fibrinolysis, platelet aggregation. [17] Increased concentration of glucose in the local tissue precipitates development of infection. It also alters the course of wound healing by impairing neovascularization. [18] 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, Charcots neuroarthropathy a destructive syndrome affecting bones and joints in patients who already have neuropathy. Osteomyelitis infection of bone and bone marrow. [19,20]

Out of 200, 140 (70%) were males and 60 (30%) were females. White blood cell counts were found to be elevated in 64 (32%) patients. The cut-off value for high WBC was considered to be more than 11,000/mm³. Cut-off value taken for high random blood sugar was 140 mg/dl. About 132 (66%) patients were having abnormally elevated random blood sugar. 20 (10%) patients were found to have osteomyelitis and they were tested positive for probe to bone test. 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 elevated white cell count being showed delayed healing. 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. [21,22]

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. 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. [23] 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. [24] So as our study also showed association between high score and complications in diabetic foot ulcer.

Conclusion

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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