Original Research Article

PEDIS grading and its role in diabetic foot ulcer management

Chinmay Gandhi[1], Prameyratna Kadam[1]*, Venkateswarlu Kamepalli[1], Yugantara Kadam[2]

[1]Department of General Surgery, [2]Department of Community Medicine, BVDUMC and H, Sangli, Maharashtra, India

*Correspondence:
Dr. Prameyratna Kadam,
E-mail: thedocathlete@gmail.com

ABSTRACT

Background: Diabetic foot ulcer is the commonest cause of hospitalization in diabetic patients. Amputation is one of its dreaded complications, which deteriorates quality of life and increases mortality. Most of amputations are preventable and it is essential to define standard and efficient approach to treat diabetic foot ulcer in a timely manner. The first step is to define correct grade of diabetic foot ulcer and its risk of developing complications. Aim was to assess the outcome of treatment of diabetic foot ulcer with the given PEDIS score and to find the role of PEDIS score in predicting the outcome.

Methods: This is a prospective cohort study. PEDIS score was calculated after all variables were categorized for a give patient and documented. PEDIS score was recorded for each patient. Patients followed up for 6 months and outcome was categorized as healed, unhealed, amputed, or death. Study was carried out till adequate sample size was achieved.

Results: High PEDIS score in diabetic foot ulcer was associated with peripheral neuropathy. Adverse outcome like amputation and unhealed ulcer were more seen with high PEDIS score. All amputed patients were having high PEDIS score.

Conclusions: PEDIS score is more useful in clinical practice for diabetic foot ulcer grading and can be uniformly applied to compare outcome all over the world.

Keywords: Diabetes, Diabetic foot ulcer, PEDIS grading

INTRODUCTION

Diabetes is a major public health problem. 2 to 3% diabetic patients will develop diabetic foot ulcers every year.[1,2] 15% of diabetic population will ulcerate during their lifetime.[3-5] Diabetic foot ulcer leads to 15-20% of amputations.[3-5] Hence diabetic foot ulceration in a patient had a major medical, economical and social consequences. In India 75% amputations are preventable caused by neuropathy and secondary infection. Pendsey detected risk factors like barefoot walking, illiteracy, low socioeconomic status, late presentation, ignorance of primary health care physician and belief in alternative systems of medicine which are contributing to high prevalence of diabetic foot ulcer in India.[6]

Diabetic foot ulcer is a full thickness wound, skin necrosis or gangrene below ankle induced by peripheral neuropathy, arteriopathy and reduced immunity to infection in diabetic patients. It is most common, severe and costly complication of diabetes. It is most common cause of hospitalization worldwide.[7,8] Diabetic foot ulceration leads to amputation, deteriorates quality of life and increases mortality.[9-11] Because of all these negative impacts, it is essential to define standard and efficient approach to treat diabetic foot ulcer in a timely manner. The first step should be to define correct grade of diabetic foot ulcer and its risk of developing complication.

Diabetic foot ulcer lesions are graded in various scales like Wagner, Sinbad, Amit Jain etc. For this study PEDIS

grading was selected as recommended by international working group of the diabetic foot (IWGDF). PEDIS grading includes all relevant variables that are etiological factors of diabetic foot ulcers. These variables include perfusion, extent, depth, infection and sensation of foot. Hence PEDIS grading will be more helpful for predicting ulcer outcome with acceptable accuracy.[12]

The aim of this study was to assess the outcome of treatment of Diabetic foot ulcer with given PEDIS score and to find the role of PEDIS score in predicting the outcome.

METHODS

This is a prospective cohort study. IEC (institutional ethical committee) approval was taken. All patients of Type 2 Diabetes with diabetic foot ulcer attending department of general surgery (Bharati vidyapeeth deemed to be university medical college and hospital) either in O.P.D. or I.P.D. were included in study. If more than two foot ulcers were present, most recent and largest ulcer identified will be selected as index ulcer.[13] Diabetic foot ulcer related with autoimmune disease, malignancy and acute limb ischemia were excluded.[14] Study was started on 1st April 2017 and finished on 30th September 2018.

Sample size was determined by statistical method $p=z^2pq/d^2$ Where p=2.05% (diabetic foot ulcer complications over all in population), q=100-p=97.95%, d=error=5%, alpha=level of significance=1%, hence z=2.58.[15] Minimal sample size n= z^2pq/d^2=53.46=55 pts. We had 61 patients in the study.

Data was collected for each patient of diabetic foot ulcer with the help of proforma. Proforma included demographic details like age, sex, diabetic type, diabetic duration, co-morbid factors, diabetic complications, end point of treatment along with PEDIS grading.

PEDIS score was calculated after all variables were categorized for a given patient and documented.

- Perfusion was determined after combination of physical examination, non invasive vascular studies like transcutaneous oxygen saturation measurement and color Doppler for arterial system of limb.
- Extent of ulcer was estimated in cm^2 was allocated in three groups.
a) <1 cm^2, b)1- 3 cm^2, c) > 3 cm^2.
- Depth of ulcer evaluated using sterile blunt probe
- Diagnosis of infection was based principle on the presence or absence of symptoms and signs infection and the presence of pus, laboratory results of culture and sensitivity and imaging tests like x ray and MRI.
- Sensation was evaluated with 10 gram. Monofilament and 10 sites on planter and dorsum surface were selected for each patient and results recorded.

PEDIS score was recorded for each patient. Pedis score ranges from 1 to 12 for each patient.

All patients were followed for 6 months or until death, whichever is earlier.

Outcome was categorized as healed, unhealed, amputed or death. Study was carried out till adequate sample size is achieved.

Statistical analysis

Statistical analysis was done using SPSS version 22 software (IBM Corp, Armonk, New York, USA). Initially ROC curve was obtained and cut off value was fixed. Chi square and fisher's exact test were used to come to conclusion.

RESULTS

61 patients were included in study and prospectively observed for PEDIS score and its association with the outcome of treatment of diabetic foot ulcer. PEDIS score of 7.5 was obtained as a cut-off from receiver operating characteristics (ROC) curve (Figure 1). PEDIS score of 7.5 can predict outcome for diabetic foot ulcer with 100% sensitivity and 18.5% false-positivity. For analytical purpose we have rounded off the PEDIS score of 7.5 to 8.

ROC Curve

Diagonal segments are produced by ties.
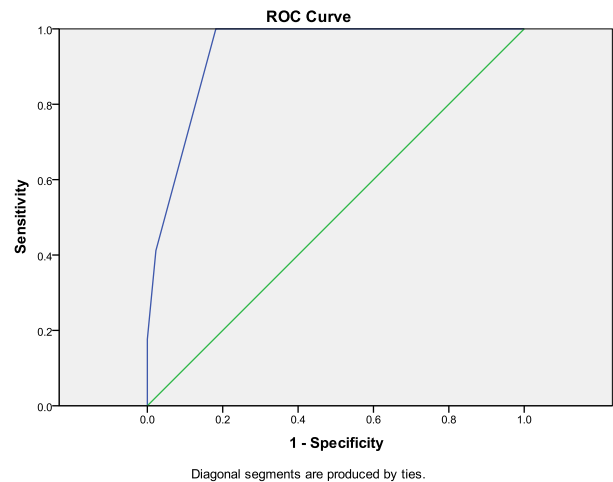
Figure 1: ROC curve.

The Figure 1 shows receiver operating characteristics (ROC) curve. This curve can be considered as an 'excellent' curve. Area under the ROC curve is the measure of accuracy. The area under curve for PEDIS score is 0.937 and can be considered as having an excellent accuracy for predicting the outcome for diabetic foot ulcer. Since p=0.000, PEDIS score is useful in predicting the outcome for diabetic foot ulcer.

Hence patients were grouped into high and low PEDIS score. Low PEDIS score is between 0 to 7 and High

PEDIS score is between 8 to 12. 59% of our patients were in low score and 41% were in high PEDIS score group.

Total 47 (77%) were male and 14 (23%) were female patients with diabetic foot ulcer. It was found that there was no relationship of gender with low or high PEDIS score (chi square=1.16 and p=0.22).

17 (27%) of the patients of diabetic foot ulcer were in age group 32 to 50 years. Maximum 30 (50%) patients of diabetic foot ulcers were in age group 51 to 65 years of age, rest 14 (23%) were above 65 years. As age advances more than 65 years more patients were with high PEDIS score (chi Square=0.71 and p=0.41).

Table 1: Peripheral neuropathy and PEDIS score group.

Peripheral neuropathy	PEDIS score group		Total	Significance
	0-7	8-12		
	N (%)	N (%)	N (%)	
No	27 (75.00)	9 (25.00)	36 (100.00)	Chi square=9.28 P=0.003
Yes	9 (36.00)	16 (64.00)	25 (100.00)	
Total	36 (59.02)	25 (40.98)	61 (100.00)	

Table 2: Peripheral arterial disease and PEDIS score group.

Peripheral arterial disease	PEDIS score group		Total
	0-7	8-12	
	N (%)	N (%)	N (%)
No	36 (70.59)	15 (29.41)	51 (100.00)
Yes	0 (0.00)	10 (100.00)	10 (100.00)
Total	36 (59.02)	25 (40.98)	61 (100.00)

Table 3: Endpoint and PEDIS score group.

Endpoint	PEDIS score group		Total
	0-7	8-12	
	N (%)	N (%)	N (%)
Amputed	0 (0.00)	17 (100.00)	17 (100.00)
Healed	35 (87.50)	5 (12.50)	40 (100.00)
Unhealed	1 (25.00)	3 (75.00)	4 (100.00)
Total	36 (59.02)	25 (40.98)	61 (100.00)

There were 25 (41%) patients with hypertension. (chi square=0.16 and p=0.45). Cardiac disease was found in 6 (10%) patients and 66.67% were having high PEDIS score (chi square=1.81 and p=0.18). Stroke was seen in 1 (2%) patient. (chi square=0.71 and p=0.59). It was found that there is no statistically significant correlation of co-morbid factors like hypertension, cardiac disease and stoke with high or low PEDIS score.

There were 4 (7%) patients with nephropathy and 75% of them had high PEDIS score. (chi square=2.05 and p value=0.18). There were 17 (28%) patients with retinopathy and 52.94% were with high PEDIS score. (chi square=1.39 and p=0.19).

There was significant association of high PEDIS score with peripheral neuropathy. 25 (40.98%) patients were with peripheral neuropathy (chi square=9.28 and p=0.003) (Table 1).

Peripheral arteriopathy was seen in 10 (16%) patients and all were having high PEDIS score (chi square=17.22 and p=0.00) (Table 2).

Autonomic neuropathy was seen in 2 (3%) patients both had high PEDIS score (chi square=2.98 and p=0.16).

Out of 25 patients with high PEDIS score, 17 required amputation and 3 had unhealed ulcer at 3 months of admission and treatment. Adverse outcome like amputation and unhealed ulcers were seen more in high PEDIS score than in low PEDIS score group (Table 3).

All patients who required amputation were having high PEDIS score (chi square=33.93 and p=0.000) (Table 3).

DISCUSSION

Many scoring systems have been proposed with the purpose of facilitating quick and accurate clinical decisions. PEDIS grading of diabetic foot ulcer is a new classification system which may help clinicians in everyday assessment and management of patients of diabetic foot ulcer. It will also help researchers in the development and assessment of new therapies for diabetic foot ulcers.

Our study of 61 patients is an attempt to know whether PEDIS classifications can asses severity of diabetic foot ulcer and outcome of its treatment. Diabetic foot ulcer is a heterogeneous pathological entity caused by various etiological factors. Lawrence demonstrated relationship between depth of infection and necessity of amputation.[16] Blood supply, presence of infection, depth of ulcers and area of ulcers, were studied by Oyibo and others for confirmation for their effect on diabetic foot ulcer healing.[17-20]

PEDIS classification contains five factors like perfusion, extent, depth, infection and sensation. Increased severity of each subcategory correlated with adverse outcome of diabetic foot ulcer.

Monterio found that total PEDIS score of 7 or more was associated with significant greater probability of difficulties in healing of diabetic foot ulcers.[21-23] In our studies 7.5 PEDIS score and above was associated with significantly greater probability of difficulties in healing of diabetic foot ulcer.

PEDIS classification includes strict definitions and categorization based on objective techniques which are all applicable worldwide.

Loss of protective sensation plays a crucial role in the pathogenesis of most of diabetic foot ulcer. In our patients loss of sensation was significantly associated with higher PEDIS score and adverse outcome after treatment (p=0.003). Neuropathy can have motor, sensory or autonomic component.[24] Motor neuropathy causes damage to intrinsic foot muscle, which can lead to foot deformities. Foot deformities create abnormal bony prominences and pressure points, which cause skin breakdown and ulceration. Autonomic neuropathy leads to hypohidrotic, dry fissured skin susceptible to infection with bone demineralization. callosities, bulla and prominent vein, nail lesion are also result of neuropathy. Loss of sensation due to sensory neuropathy causes undetected insults to foot, resulting in to wounds going unnoticed and getting infected. It also leads to joint and muscle laxity, leading to changes in the arches of feet. Charcot's arthropathy is a consequence of peripheral neuropathy.[25]

Peripheral vascular disease in diabetic patient occurs prematurely and progresses at accelerated rate, in lower limb more distal vessels such as peroneal, anterior and posterior tibial are commonly involved. It leads to loss of hairs on the foot and rubor. In our studies peripheral vascular disease was seen in 10(16%) patients. All patients with peripheral vascular disease were having high PEDIS score.

Foot infection is a limb threatening condition, because the consequences of deep infection are more disastrous than elsewhere, because of certain anatomical peculiarities. Foot has several compartments, which are inter communicating and the infection can spread from one into another and lack of pain allows the patient to continue ambulating and facilitates spread. Combination of neuropathy, ischemia and hyperglycemia reduces defense mechanism.[4] Osteomylitis generally results from continuous spread of deep soft tissue infection through the cortex to bone marrow. X ray may show focal osteoporosis, cortical erosion or periosteal reaction in early stage and later sequestration. In chronic sinus or ulcer if sterile metal probe penetrates bone it confirms osteomylitis.4 Foot infections can be superficial and deep. Superficial infections are caused by gram positive bacteria and deep infection are polymicrobial. All deep infections involving deep tissue, bone and muscle (tender) should be hospitalized and started on broad spectrum antibiotics. Antibiotics changed after culture sensitivity results. These patients may require surgical debridement, off loading or amputations.

CONCLUSION

Diabetic foot ulcer patients with diabetic neuropathy were associated with high PEDIS score. Adverse outcomes like amputation and unhealed ulcers were more seen in patients with high PEDIS score than in low PEDIS score group. All amputed patients were having high PEDIS score. PEDIS score is more useful in clinical practice and can be uniformly applied to compare outcome all over world.

ACKNOWLEDGEMENTS

REFERENCES

1. Moss SE, Klein R, Klein BE. The prevalence and incidence of lower extremity amputation in a diabetic population. Arch Intern Med. 1992;152(3):610-6.
2. Borssen B, Bergenheim T, Lithner F. The Epidemiology of foot lesions in diabetic patients aged 15-50 years. Diabet Med. 1990;7(5):438-44.
3. Palumbo PJ, Melton LJ. Peripheral vascular disease and diabetes. In: Harris MI, Hamman RF, Editors. Diabetes in America. Washington: US Government printing office; 1985: 16-21.
4. Pendsey S. Diabetic Foot: A Clinical Atlas. Jaypee Brothers Medical Publishers; 2003.
5. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation: Basis for prevention. Diabetic Care. 1990;13:513-21.

6. Pendsey S, Abbas ZG. The Step-by-Step program for reducing diabetic foot problem: A model for the developing world. Curr Diab Rep. 2007;7:425-8.
7. Alavi A, Sibbald RG, Mayer D, Goodman L, Boutros M, Armstrong DG, et al. Diabetic foot ulcers: Part I. Pathophysiology and prevention. J Am Accad Dermatology. 2014;70:1 e1-18.
8. Wang AH, Xu ZR, Ji LN. Clinical characteristics and medical costs of diabetics with amputation at central urban hospitals in China. Zhonghua Yi Xue Za Zhi. 2012;92:224-7.
9. Lipsky BA, Weigelt JA, Sun X, Johannes RS, Derby KG, Tabak YP. Developing and validating a risk score for lower-extremity amputation in patients hospitalized for a diabetic foot infection. Diabetes Care. 2011;34:1695-700.
10. Martinsmendes D, Monteirosoares M, Boyko EJ, Ribeiro M, Barata P, Lima J, et al. The independent contribution of diabetic foot ulcer on lower extremity amputation and mortality risk. J Diabetes Complicat. 2014;28:632-8.
11. Monteirosoares M, Boyko EJ, Ribeiro J, Ribeiro I, Dinisribeiro M. Risk stratification systems for diabetic foot ulcers: a systematic review. Diabetologia. 2011;54:1190-9.
12. Chuan F, Tang K, Jiang P, Zhou B, He X. Reliability and validity of the perfusion, extent, depth, infection and sensation (PEDIS) classification system and score in patients with diabetic foot ulcer. PLoS One. 2015;10(4):e0124739.
13. Treece KA, Macfarlane RM, Pound N, Game FL, Jeffcoate WJ. Validation of a system of foot ulcer classification in diabetes mellitus. Diabet Med. 2004;21:987-91.
14. Shahbazian H, Yazdanpanah L, Latifi SM. Risk assessment of patients with diabetes for foot ulcers according to risk classification consensus of International Working Group on Diabetic Foot (IWGDF). Pak J Med Sci. 2013;29:730-4.
15. Al-Rubeaan K, Al Derwish M, Ouizi S, Youssef AM, Subhani SN, Ibrahim HM, et al. Diabetic foot complications and their risk factors from a large retrospective cohort study. PLoS One. 2015;10(5):1-5.
16. Lavery LA, Armstrong DG, Murdoch DP, Peters EJ, Lipsky BA. Validation of the Infectious Diseases Society of America's diabetic foot infection classification system. Clin Infect Dis. 2007;44:562-5.
17. Oyibo SO, Jude EB, Tarawneh I, Nguyen HC, Armstrong DG, Harkless LB, et al. The effects of ulcer size and site, patient's age, sex and type and duration of diabetes on the outcome of diabetic foot ulcers. Diabet Med. 2001;18:133-8.
18. Oyibo SO, Jude EB, Tarawneh I, Nguyen HC, Harkless LB, Boulton AJ. A comparison of two diabetic foot ulcer classification systems: the Wagner and the University of Texas wound classification systems. Diabetes Care. 2001;24:84-8.
19. Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system. The contribution of depth, infection, and ischemia to risk of amputation. Diabetes Care. 1998;21:855-9.
20. Younes NA, Albsoul AM. The DEPA scoring system and its correlation with the healing rate of diabetic foot ulcers. J Foot Ankle Surg. 2004;43:209-13.
21. Monteirosoares M, Vazcarneiro A, Sampaio S, Dinisribeiro M. Validation and comparison of currently available stratification systems for patients with diabetes by risk of foot ulcer development. Eur J Endocrinol. 2012;167:401-7.
22. Reynolds T. Disease prediction models aim to guide medical decision making. Ann Intern Med. 2001;135:637-40.
23. Lee JA, Halpern EM, Lovblom LE, Yeung E, Bril V, Perkins BA. Reliability and validity of a point-of-care surely nerve conduction device for identification of diabetic neuropathy. Plops One. 2014;9:e86515.
24. Bowering CK. Diabetic foot ulcers: Pathophysiology, assessment, and therapy. Can Fame Physician. 2001;47:1007-16.
25. Clayton W, Easy TA. A review of pathophysiology, classification and treatment of foot ulcers in diabetic patients. Clin Diabetes. 2009;27:52-8.