ORIGINAL RESEARCH

Validity of PEDIS Scoring in Predicting Outcome Among Diabetic Foot Patients Admitted at Visayas Community Medical Center from April 2014 to April 2016*

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Background: Infections in persons with diabetes are increasingly common problem and are associated with potentially serious sequelae. Diabetic foot infection (DFIs) is one of the dreaded complication of diabetes. Many diabetic foot classification schemes have been formulated, however not all of them offered an extensive scoring system. The International Working Group on Diabetic Foot has developed, PEDIS (Perfusion, Extent, Depth, Infection, Sensation,) classification. However, it has not yet been extensively studied in predicting outcomes among diabetic foot patients. Thus, this study is to test the validity of PEDIS in predicting surgical management among patients with Diabetic foot infection (DFIs)

Objective: This study aimed to establish the validity of PEDIS classification as a prognosticating tool in determining the outcome for Diabetic Foot patients admitted at the Visayas Community Medical Center

Design: Prospective cross sectional validity study of PEDIS Risk Classification tool using actual surgical management as gold standard

Subjects: All diabetic foot patients admitted at the Visayas Community Medical Center

Data collection procedure: The data were purposively collected as follows. Identified patient was enlightened about the study, its aims, and the maneuvers to be done. After which, informed consent was signed by the patient. Thorough history and physical examination were done to the candidate patient. Guided by the checklist, appropriate data was collected. All data gathered will be encoded in MSEXCEL 2013. Chi square test was performed to establish the associations among PEDIS risk classifications and actual surgical management. 2x2 Fisher Exact test was also performed to test the associations between variables with 2x2 categories.

Results: Accuracy of PEDIS Classifications revealed that a score of 2 yielded higher sensitivity of 100% and specificity of 66.7% in predictive debridement, while a score of 3 was accurate in predicting BKA (sensitivity of 100% and specificity of 64.3%), and a score of 4 generated higher accuracy in predicting BKA (sensitivity of 100% and specificity of 60%) and AKA (sensitivity of 100% and specificity of 46.2%).

Conclusion: The PEDIS Classifications demonstrated clinically acceptable accuracy in predicting surgical management of patients with Diabetic foot infection (DFIs). The classification also indicated that the higher the PEDIS score, the more complex the surgical procedure.

Key words: diabetic foot infection

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Introduction

Globally, the International Diabetes Foundation, estimated that for the year 2010, 285 million people have diabetes, and it is expected to rise to 438 million by the year 2030.[1] The incidence of diabetes is also rising in the Philippines. It has been reported in November 2008 that one out of every 10 Filipinos living in the Philippines had diabetes.[2] A survey conducted showed that 20.6% of Filipinos aged 30 years and above were diabetic compared to 3.9% in 1998. By 2030, the Philippines is projected to be number 9 globally.[3]

Infections in persons with diabetes are increasingly common problem and are associated with potentially serious sequelae. Diabetic foot infection (DFIs) is one of the dreaded complications of diabetes.[1] DFIs usually arise either as a skin ulceration that occurs as a consequence of peripheral sensory and motor neuropathy or in a wound caused by some form of trauma which causes a major morbidity, including physical and emotional distress.[1]

Various systems have been developed to classify diabetic foot infections, however, in most published classification schemes, assessing infection is a subsection of a broader wound classification. Each classification system has some what different purposes, and there is no consensus on which to use. Some universally-accepted classifications include the Meggit-Wagner which assesses ulcer depth and the presence of infection and gangrene. Another classification is the S (AD)/SAD which is an acronym for 5 key points of foot ulcers: size, (area, depth), sepsis (infection), arteriopathy, and denervation.[14]

In 2003, the International Working Group on Diabetic Foot introduced PEDIS classification for research purposes. This system aims to categorize the different population of diabetic foot patients.[15] PEDIS stands for perfusion, extent (size), depth (tissue loss), infection, sensation (neuropathy). While originally developed as a research tool, it offers a semi-quantitative gradation for the severity of each category. Another advantage of this classification is a clear definition and a relatively small number of categories making them more user-friendly for clinicians having less experience with diabetic foot management. However, this type of classification has not been compared in a large prospective trial. [14]

This study aimed to establish the validity of PEDIS Classification as a prognosticating tool in determining the outcome for diabetic foot patients admitted in Visayas Community Medical Center.

Materials and Methods

Study Design

Prospective cross sectional validity study of PEDIS Risk Classification tool using actual surgical management as gold standard.

Study Setting

The study was conducted at the Visayas Community Medical Center, Cebu City, from April 2014 to April 2016.

Sample Population

Inclusion Criteria

a. All admitted patients at Visayas Community Medical Center diagnosed with diabetic foot.
b. All diabetic foot patients male and female, 18 years old and above.
c. All diabetic foot patients who will undergo surgical intervention
    i. Debridement
    ii. Ray amputation
    iii. Below knee amputation
    iv. Above knee amputation
d. All Diabetic foot patients who had previous surgical intervention and will undergo another surgical procedure.

e. All diabetic foot patients with both laboratory results of cbc and lipid profile, as ordered by the attending physician.

Exclusion Criteria

a. All diagnosed diabetic patients admitted at the Visayas Community Medical Center with no concurrent diabetic foot infection
b. All diabetic foot patients, male and female, and below 18 years old .
c. All diabetic foot patients both without cbc and lipid profile as part of the laboratory workup.

The identified candidate patient was enlightened about the study, its aims, and the maneuvers to be done during data gathering. After which, a secured consent was signed by the patient. Thorough history and physical examination were done to the candidate patient. Guided by the checklist, appropriate data were collected. Perfusion was measured by physically examining the color of the affected foot whether it was cyanotic. Extent of the damage of the affected foot was measured in cm by a ruler. Depth of the wound on the affected foot was estimated by visually examining the ulcer of the affected foot. The extent of the damage can now be estimated whether it has penetrated beyond the subcutaneous, muscle or has reached the bone. The degree of infection was assessed by looking at the patient's complete blood count and vital signs. Lastly, the sensation was tested for pain by gently rubbing the tip of the reflex hammer and light touch by touching a brush on the surroundings of the affected foot. Dyslipidemia was assessed by looking at the lipid profile of the patient, whether there was an elevation of cholesterol, triglyceride or both, or a low high density lipoprotein. After which, data collected were then analyzed and interpreted.

Research Instrument

PEDIS scoring system that uses the acronym P= perfusion, E= extent, D= depth, I= infection, S= sensation was used.

Data Processing and Analysis Plan

All data gathered were encoded in MSEXCEL 2013. Categorical patient profiles were expressed in frequency and percentage distribution while continuous data were presented in mean and standard deviation.

To establish associations among PEDIS risk classifications and actual surgical management, Chi square test was performed. Also, 2x2 Fisher Exact test was performed in testing associations between variables with 2x2 categories. After testing associations, validity of PEDIS risk classifications was estimated using sensitivity, specificity, negative, and positive predictive values.

Any associated p-values lesser than 0.05alpha was considered significant. IBMSPSS version 21 was used as statistical software.

Ethical Considerations

Selected patients were asked to sign an informed consent after the study was thoroughly explained to them and confidentiality was strictly observed all throughout the study period.

Results

Majority of patients with PEDIS scores of females dominate those 1 and 2, were males [66.7% and 56.1%] while those with scores of 3 and 4, [52.6% and 52.9%], [p=0.644]. Moreover, cigarette smoking was not associated with any PEDIS scores [p=0.187] as well as hypertension [p=0.530]. On the other hand, dyslipidemia was associated with higher PEDIS score [p=0.002]. (Table 1)

No one among, those with PEDIS score of 1, had surgery, in those with PEDIS score of 2, 78% had debridement and 22% had RAY management. Also, 73.3% those with PEDIS score of 3 had BKA and 26.3% had AKA. Those with PEDIS 4, 61.8% had BKA and 38.2% had AKA. As shown in the analysis, PEDIS 3 and 4 were associated with BKA and AKA while PEDIS 2 with debridement.

Table 1. Patients' profiles with diagnosed diabetic foot infection at Visayas Community Medical Center.

	PEDIS				
Patients' Profiles	1 n=18	2 n=41	3 n=38	4 n=34	p-value
Sex					
females	8 [44.4%]	18[43.9%]	20[52.6%]	18[52.9%]	0.644
males	12[66.7%]	23[56.1%]	18[47.4%]	15[44.1%]	
Co-morbidities					
cigarette smokers	11[61.1%]	21[51.2%]	22[57.9%]	12[35.3%]	0.187
dyslipidemia	18[100%]	36[87.8%]	37[97.4%]	24[70.6%]	0.002
hypertension	18[100%]	38[92.7%]	35[92.11%]	33[97.1%]	0.530

Table 2. PEDIS classifications and surgical management of patients with diabetic foot.

	PEDIS				
Patients' Profiles	1 n=18	2 n=41	3 n=38	4 n=34	p-value
None	18[100%]	0[0%]	0[0%]	0[0%]	<0.001
Debridement	0[0%]	32[78%]	0[0%]	0[0%]	<0.001
Ray	0[0%]	9[22%]	0[0%]	0[0%]	<0.001
BKA	0[0%]	0[0%]	28[73.7%]	21[61.8%]	<0.001
AKA	0[0%]	0[0%]	10[26.3%]	13[38.2%]	<0.001

Accuracy of PEDIS classifications revealed [Table 3] that a score of 2 yielded sensitivity of 100%, specificity of 66.7%, likelihood ratio + of 3, predictive positive value of 78%, and negative predictive value of 100% in predicting debridement surgical management. Meanwhile, in predicting ray management, the score of 2 generated the following, sensitivity of 100%, specificity of 36%, likelihood ratio + of 1.56, predictive positive value of 22%, and negative predictive value of 100%. A score of 3 showed the following, sensitivity of 100%, specificity of 64.3%, likelihood ratio + of 2.8, predictive positive value of 73.7%, and negative predictive value of 100% in predicting BKA management while the score of 3 reported to have sensitivity of 100%, specificity of 39.1%, likelihood ratio + of 1.64, predictive positive value of 26.3%, and negative predictive value of 100% in predicting AKA management. Lastly, a score of 4 reported the following accuracy, sensitivity of 100%, specificity of 60%, likelihood ratio + of 2.50, predictive positive value of 63.6%, and negative predictive value of 100% in predicting BKA management while the score of 4 reported to have sensitivity of 100%, specificity of 46.2%, likelihood ratio + of 1.86, predictive positive value of 38.2%, and negative predictive value of 100% in predicting AKA management.

Discussion

This study involved 131 purposively selected patients with diabetic foot infection. Upon admission they were

Table 3. Accuracy of PEDIS classifications in predicting surgical management of patients with diabetic foot.

PEDIS SCORE	Predicted Outcome	Sensitivity	Specificity	Likelihood Ratio +	Predictive value positive	Predictive value negative
2	DEBRIDEMENT	100.0%	66.7%	3.00	78.0%	100.0%
	RAY	100.0%	36.0%	1.56	22.0%	100.0%
3	BKA	100.0%	64.3%	2.80	73.7%	100.0%
	AKA	100.0%	39.1%	1.64	26.3%	100.0%
4	BKA	100.0%	60.0%	2.50	63.6%	100.0%
	AKA	100.0%	46.2%	1.86	38.2%	100.0%

assessed using the PEDIS classification. Majority of those with PEDIS scores 1 and 2, were males [66.7% and 56.1%] while those with scores 3 and 4, most of them were females [52.6% and 52.9%], [p=0.644]. Moreover, cigarette smoking was not associated with any PEDIS scores [p=0.187] as well as hypertension [p=0.530]. On the other hand, dyslipidemia was associated with higher PEDIS score.

According to literatures, relative risk of major amputation in people with diabetes mellitus is 15 times higher compared with the population without diabetes.[15,16] In the study by F, Chuan, et al. on 364 patients with diabetic foot, 219 were males while 145 were female[35] which was also the case in the present study. Similar to the present study, previous study pointed out that hypertension, smoking, and dyslipidemia were the risk factors among diabetic patients. It would lead to macrovascular disease which impairs and affects blood vessels resulting to impaired perfusion.[29] Grundy described dyslipidemia as one of the risk factors for diabetes. It is characterized by 3 lipoprotein abnormalities; increased VLDL, increased LDL and decreased HDL.[28] The impaired ability of the insulin to inhibit free fatty acids leads to enhance hepatic VLDL and cholesterol production.[31]

This study found out that after the assessment, 100% of those with PEDIS score of 1, had no surgery, while those with PEDIS score of 2, 78% had debridement and 22% had RAY management. Those with PEDIS score of 3, 73.3% had BKA and 26.3% had AKA. Those with PEDIS 4, 61.8% had BKA and 38.2% had AKA. As shown in the analysis, PEDIS 3 and 4 were associated with BKA and AKA while PEDIS 2 with debridement. Consistent with Imran, et al. study in which the frequency of minor and major amputation increases with higher grades of foot pathology.[17]

As noted in previous study, PEDIS 1 involved wound without inflammation or purulence. Patients were treated with antibiotics.[34] In this group no surgical intervention was done during the study period.

Purulence/erythema, pain, tenderness, and warmth characterized PEDIS 2.[34] Cellulites were less than 2cm around the ulcer and infection was limited to the skin and usually not limb threatening.[34] In this stage, ulcers were treated with debridement and excision of necrotic tissues and amputation of digits.[34] In this study, the likelihood of undergoing debridement was three times over ray amputation with this classification. This was maybe due to the fact that one in five patients having any version of partial ray amputation would eventually require more proximal re-amputation.[36]

Armstrong, et al. (2004) stated that in a non-severe infection, careful observation of the effectiveness of medical therapy following debridement is prudent.[24] If there is a tendency that surgical intervention is needed, adequacy of the blood supply to the apparent viable tissue must be considered.[25]

PEDIS 3 was characterized with the presence of infection, cellulites greater than 2cm deep tissue abscess, gangrene, muscle, tendon and bone may be involved.[34] In a study by Larsson J, et al., patients with abscess, gangrene of the entire foot involving the bones underwent major amputation such as below the knee amputation (BKA) and above the knee amputation (AKA).[18] All of the patients under this classification went through amputation, with almost 3 times the likelihood of undergoing below the knee over above the knee amputation.

Diabetic patients are susceptible to bacteremia and can be considered immunocompromised. Neutrophil dysfunction in phagocytosis and chemotaxis may allow a localized infection to progress to a serious form of sepsis.[19] In PEDIS 4, the infection is with systemic toxicity, chills fever, tachycardia, vomiting, acidosis, hypotension, hyperglycemia, and confusion which are usually life threatening as infection is severe. Patients in this classification were treated with below the knee amputation.[34] Jones reported that an urgent amputation is required when there is extensive sepsis or any life threatening infection, as higher level amputation that results in a more functional residual stump may be a better choice than preserving a foot that is mechanically unsound with a life threatening tendency to the patient.[27]

This was true in this study. Majority of the patients in this classification were three times more likely to undergo a BKA than AKA.

The functional advantage of BKA over AKA is well established.[37] Although AKA has the advantage of a high incidence of wound healing, the procedure carries a functional disadvantage as it requires more energy expenditure[38] upon ambulation as it no longer has the knee joint as compared to the BKA. Thus consequently, more surgeons would offer a BKA and make it a candidate for rehabilitation[38] as noted also in patients in the present study.

Diabetic foot infection management becomes more complex when the PEDIS score increases. This study further proved the validity of such scoring system. It is revealed in this study that a PEDIS score of 2 yielded sensitivity of 100%, specificity of 66.7%, likelihood ratio + of 3, predictive positive value of 78%, and negative predictive value of 100% in predicting debridement surgical management. Meanwhile, in predicting ray management, the score of 2 generated the following, sensitivity of 100%, specificity of 36%, likelihood ratio + of 1.56, predictive positive value of 22%, and negative predictive value of 100%.

Furthermore, a score of 3 showed the following, sensitivity of 100%, specificity of 64.3%, likelihood ratio + of 2.8, predictive positive value of 73.7%, and negative predictive value of 100% in predicting BKA management while the score of 3 reported to have sensitivity of 100%, specificity of 39.1%, likelihood ratio + of 1.64, predictive positive value of 26.3%, and negative predictive value of 100% in predicting AKA management.

Lastly, a score of 4 reported the following accuracy, sensitivity of 100%, specificity of 60%, likelihood ratio + of 2.50, predictive positive value of 63.6%, and negative predictive value of 100% in predicting BKA management while the score of 4 reported to have sensitivity of 100%, specificity of 46.2%, likelihood ratio + of 1.86, predictive positive value of 38.2%, and negative predictive value of 100% in predicting AKA management.

Conclusion and Recommendation

In conclusion, the PEDIS Classification demonstrated clinically acceptable accuracy in predicting surgical management of diabetic foot patients wherein higher score implies prediction of a more complicated surgical management.

Based on the outcome of this study, the authors recommend the use of PEDIS scoring as a tool in the examination of diabetic foot patients.

However due to the limited diabetic foot patients admitted at the Visayas Community Medical Center, the researchers would recommend to have a follow up study regarding the validity of PEDIS scoring in a large scale population to further evaluate its predictability.

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