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Outcomes of diabetic patients with Wagner grade 3 foot lesions admitted to Port Moresby general hospital: A prospective cohort study

***Corresponding Author: Yakea E Jimmy**
University of Papua New Guinea, Kiunga Hospital, North Fly District of Western Province, Papua New Guinea.
Email: essaujames17@gmail.com

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Abstract

Background: Diabetic foot lesions are associated with an increased morbidity and a high use of resources. Although early amputation is indicated for the Wagner Grade 3 diabetic foot ulcer, conservative treatment is a more attractive option.

Objective: To determine the outcomes of patients with diabetic foot ulcers admitted for inpatient treatment.

Method: I conducted a 1 year prospective cohort study from June 2019 to June 2020 of 26 diabetic patients with foot lesions that were admitted to the surgical unit of Port Moresby General Hospital. The Wagner Diabetic Foot Ulcer Grade Classification System was used for the diagnosis and classification of diabetic foot lesions. Study variables include patient demography and clinical parameters related to diabetes and the foot infection. Independent predictors for a good outcome were selected by logistic regression analysis. The primary outcome of the study was the outcome of treatment of Wagner Grade 3 (Wagner 3) lesions.

Results: Of the 26 patients studied, 5 patients (19%) had amputation while conservative treatment was successful in 19 patients (90%). Two patients died (10%). Independent predictive factors for good outcome are the partial pressure of oxygen (SpO_2) at the affected foot (p=0.042) (OR=1.02; 95% CI, 1.02– 1.021), a normal ankle brachial index (p = 0.05) (OR = 1.1; 95% CI, 1.0 – 1.2), a normal Doppler study (p = 0.043) (OR = 1.4, 95% [CI], 1.2-1.6), sensitivity of the bacteria isolated from ulcer.

Conclusion: Diabetic patients with the Wagner Grade 3 diabetic foot lesions can be successfully managed conservatively.

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Introduction

Diabetic foot ulcers (DFU) are the principal cause of severe complications and hospitalizations among patients with diabetes; this substantially increases the costs of treating it [1-4]. In the United States, the annual cost of foot ulcers is estimated at US$ 11 billion [5]. In Papua New Guinea (PNG), it costs PGK12, 950.20 (approximately US$ 3113) per annum to care for one diabetic patient with DFU [6]. DFU necessitates more hospital admissions than other diabetic complications [7,8]. Diabetic patients have 10-15 times greater risk of lower extremity amputation compared to non-diabetic patients; fifteen percent of diabetic patients will develop DFU during their lifetime and five to eight percent of DFU will require major amputations [9]. The quality of life is poor for patients with chronic foot ulcer but is worsened after an amputation [10]. Patients with diabetes and amputations caused by infectious foot gangrene have a limited 5 year survival rate of 40% [11].

In PNG, diabetic foot is an increasing burden, with the incidence increasing from

1.4-2.2% over a period of 5 years, and the female population slowly over taking the male [12]. However, only 3% are seen at a health facility [13]. Nuli et al (2016) reported 3 diabetic amputations per month with 36 amputations per year [14] and 40,000 registered type 2 diabetes in one province alone [15]. The European association of diabetes is aiming to reduce the rate of diabetic amputation for the next decade [16]. Efficient diagnostic, prognostic and therapeutic strategies are needed to minimise the ever-increasing cost of looking after diabetic patients.

I conducted a one year prospective cohort study of diabetic foot patients admitted to the surgical ward in Port Moresby General Hospital (PMGH) in PNG from June 2019 to June 2020. The aim of this study was to determine the outcome of conservative management of diabetic patients with Wagner Grade 3 foot lesions, and to identify criteria predictive of good outcome in diabetic patients with Wagner Grade 3 foot lesions.

Study method

During the study period, 70 patients with diabetic foot lesions were admitted to the surgical unit of PMGH. The patients were all locals. All patients were evaluated by recording a detailed history, clinical examination, and other necessary investigations. The end point of the evaluation was the outcome of the foot lesion – whether it was successfully managed conservatively, or the patient underwent amputation.

The surgical department of PMGH has 5 subspecialty units - Cardiothoracic, Orthopedic, Pediatric Surgery, Neurosurgical and Urology. Each unit is headed by a senior consultant with a minimum of 10 years of working experience. The subspecialty units rotate in taking on calls. As there is no dedicated unit caring for patients with diabetic foot lesions, management decisions regarding the patients were approved by the respective Unit's Head under which they were admitted. All members of each unit, including the Head, were blind to the study. The primary investigator's role was purely observational.

Inclusion criteria

1. All patients with a lower limb ulcer and a known history of diabetes mellitus.
2. All patients with a lower limb ulcer and no history of diabetes who were found to have underlying diabetes post-admission.

Exclusion criteria

1. All patients who died prior to intervention.
2. All patients who withdrew during the course of their treatment.
3. All patients who were lost to follow-up prior to reaching the end-points of evaluation.
4. All patients who were classed as having Wagner class 1, 2, 4 and 5 lesions.

Variables of interest and measurement

Variables this study was interested in were:

- The patient's age and gender,
- Diabetic-specific information:

o The medication the patient is on and whether patient is compliant to it

o How long the patient has been living with diabetes

o The patient's hemoglobin A1c (HBA1c) level on admission

o The patient's creatinine level on admission

o The patient's albumin level on admission

o The presence of peripheral artery disease (PAD) – determined by measuring the Ankle brachial index (ABI), pulse oximetry, and Doppler studies to establish the site of occlusion.

o Signs of systemic infections such as neutrophilic leucocytosis

- Ulcer-related information

o Location of the ulcer

o Type of bacteria growing in the ulcer and its microbial sensitivity –determined by culture of samples obtained by deep needle aspiration, bone biopsy or curettage of the ulcer

o The presence or absence of osteomyelitis – determined by plain roentgenogram

o Type of therapy patient underwent whilst admitted to the ward

o Ulcer evolution.

Definitions

Foot lesion: evidence of ulceration on clinical examination, inflammation with purulent discharge or necrosis and wound gram stain cultures demonstrating presence of leukocytes and pathogenic micro-organisms. The location of the ulcer was basically left or right foot.

Foot lesions were classified according to the Wagner Diabetic Foot Ulcer Grade Classification System, which is a classification of diabetic, neuropathic and dysvascular foot problems.

The Wagner classification is as follows [17]:

Grade 0: No skin lesion, hyper-keratosis below and above bony prominence.

Grade 1: Skin and immediate subcutaneous tissue are ulcerated and base may be gangrenous, infected or clean.

Grade 2: Lesions are deeper and may penetrate the tendon, bone or joint capsule.

Grade 3: Deep tissues are involved, progression along tendon sheath to mid-space. Abscess is frequent and osteomyelitis may be present but may not be visible on x¬ray for several weeks

Grade 4: Gangrene of some portion of the toes or forefoot is present.

Grade 5: The entire foot is involved with gangrene or there is sufficient gangrene and infection that no local procedure is possible.

Conservative treatment: Treatment was defined as conservative if surgery was not carried out in the first five days of admission.

Surgical treatment: Treatment was defined as surgical when bone amputation, either limited or extensive, was necessary.

Successful conservative treatment: The lesion responsible for hospitalisation completely heals up, and there are no signs of relapse at the same site or at a contagious site during the 14 weeks of follow up.

Failure of conservative treatment: If the patient subsequently requires amputation, or if the lesion had not completely healed, or a new lesion develops contagious to the original one during follow up, or the patient dies during hospitalisation and the cause of death is directly or indirectly attributed to the foot lesion.

Treatment and outcome

Conservative treatment was commenced on all patients once they were admitted. It consisted of daily wound care, debridement when indicated, bed rests, special casts, crutches or wheel chairs to avoid putting pressure on affected area when ambulating, and appropriate parenteral antibiotics. Before commencing empirical antibiotics, samples for culture were obtained; all specimens were cultured for aerobic microorganisms; anaerobic cultures are not performed routinely by the lab. Antibiotics were adjusted once culture results became available. Antibiotics were initially administered parenterally and then changed to oral; treatment duration was at least six weeks. Plain x rays were done to look for the presence of osteomyelitis; osteomyelitis was established by evidence of osteopenia, cortical lysis, periostitis, bone sequester, bone erosion or intra-articular bone fragment.

All patients on whom conservative treatment failed underwent surgical treatment.

After the patients' foot infection was treated and good wound granulation was achieved, they were educated on how to care for their foot and were discharged from the ward. After discharge, they were followed up for a maximum of 14 weeks. During each follow up visit, the foot was inspected for ulcer recurrence and/or development of new ulcer at a contiguous site. Education on foot care was also given on each follow up visit.

Statistical analysis

Analysis was conducted using SPSS software. The strength of the association between single prognostic variables of conservative treatment was evaluated by calculating the odds ratio (OR) and their corresponding 95% confidence intervals (CI). Continuous variables were compared using the Mann-Whitney U test, with correction for ties when appropriate. For selected continuous variables, mean values were compared using two sample tests for independent samples after correction for equality of variances using the F test. Differences in proportions were compared using Fisher exact test. Logistic regression was used to estimate the independent effect of each selected variable on the outcome. All tests of significance were 2 tailed. Mean values were given to 1 standard deviation (SD). P values <0.05 were considered significant.

Results

Of the 70 patients admitted between June 2019 and June 2020 with diabetic foot lesions, 26 were recruited for the study. Figure one outlines the flow of the study participants. Twenty patients were excluded from the study as their charts were unavailable (n=10) or follow up was impossible (n=10). Twenty four patients had foot ulcers of other Wagner grades and so were excluded.

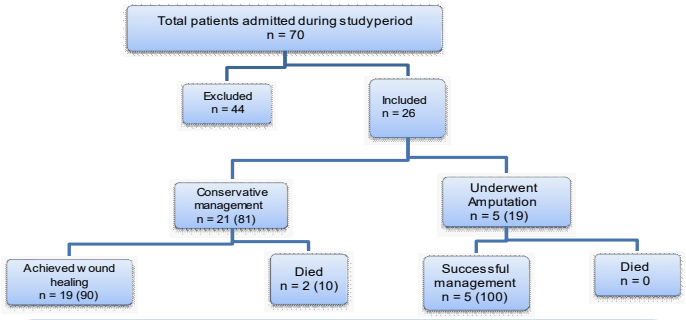

Figure 1: Summary of patient recruitment and treatment modalities they underwent.

Table 1 shows the basic characteristics of the study participants.

Table 1: Baseline characteristics of the study participants.

Baseline characteristics of study participants		
	No	**(%)**
Sex		
Male Female	15 11	58 42
Age		
Age range Mean age Median Age	24 – 77 years 53 years 55 years	
BMI		
Normal Overweight Obese	18 7 1	69 27 4
Diagnosis category Newly diagnosed Known diabetic Mean years of suffering from DM Median years of suffering from DM Range	14 12 13 ± 8.6 years 6 ± 9.3 years 1 – 40 years	54 46
Family history of DM		
Positive Negative	17 9	65 35
Compliance to treatment		
Compliant Non-compliant	3 23	12 88
Site of lesion		
Right foot Left foot	16 10	62 38
Presence of other complications		
Osteomyelitis Hypertension Neuropathy Retinopathy Sepsis Nephropathy	17 14 7 6 7 4	65 54 27 23 27 15
Smoking status		
Active smokers	17	65
Presence of sepsis on admission		
Septic Non-septic	7 19	27 73
Non-smokers	9	35

Pulse oximetry was used to determine peripheral perfusion; only 7 patients (27%) had SpO_2 readings <96%, indicating the presence of vasculopathy (p=0.042) (OR=1.02; 95% CI, 1.02 – 1.021).

Ankle brachial index (ABI) was used to determine the presence of vasculopathy. None of the patients had severe occlusion; only 7 patients (17%) had mild or moderate occlusion (p= 0.05) (OR = 1.1; 95% CI, 1.0 – 1.2).

Dorsalis pedis was the most commonly occluded artery (n=4; 15%), followed by posterior tibialis (n =3; 12%). There was no occlusion of the popliteal artery in all cases, and 73% (n=19) had normal findings in all three vessels (p= 0.043) (OR=1.4, 95% [CI], 1.2 -1.6).

The baseline blood results of the study participants are shown in the table below.

Table 2: Baseline blood results of the study participants.

Baseline laboratory results of the study participants			
Parameter	**Mean**	**Range**	**Normal**
Hemoglobin A1c	7.9	7 - 10	3 - 6 %
Fasting blood glucose level	13.6	8 – 20	4.4 – 7.2 mmol/L
Hemoglobin (male patients)	9.3	3 – 12.8	13 – 18 g/dL (M)
Hemoglobin (female patients)	9.5	8 - 11	11.5 – 16 g/dL (F)
White cell count	13 400	6000 - 42 000	4000 – 10 000 x 10^3/µL
Creatinine	227.8	40 – 970	< 115 µmol/L
Urea	9.9	4 – 33	3.2 – 7.1 mmol/L
Albumin	26.7	18 - 35	35 – 50 g/L
	no		(%)
Leucocytosis	15		58
Normal leucocyte count	11		42
Neutrophilia	8		31
Normal neutrophil count	18		69
High creatinine	12		46
Normal creatinine	14		54
High urea	2		8
Normal urea	8		31
Urea result unavailable	16		61
Hypoalbuminemia	24		92
Normoalbuminemia	2		8
Albuminuria	22		85
No albuminuria	4		15
Dyslipidaemia	10		39
No dyslipidaemia	5		19
Lipid profile unavailable	**11**		42

Table 3 below gives the baseline ankle brachial index (ABI), SpO_2 and sites of arterial occlusion in the study participants.

Table 3: Baseline ankle-brachial index (ABI), pulse oximetry and sites of arterial occlusion of the lower limb.

Baseline ABI, SpO_2 and sites of arterial occlusion.				
ABI	**Range**	**n**	**%**	**p Value**
Normal	0.9 – 1.3	19	73	
Mild occlusion Moderate occlusion Severe occlusion	0.7 – 0.8 0.4 – 0.6 <0.4	5 2 0	9 8 0	0.05
SpO_2				
Normal	≥ 95 %	19	73	
Mild occlusion Moderate occlusion	91 – 95 % 85 – 90 %	3 4	12 15	0.042
Severe occlusion	< 85 %	0	0	
Sites of occlusion (artery)				
No occlusion		19	73	
Popliteal		0	0	
Dorsalis pedis		4	15	
Posterior tibial		**3**	**12**	

Table 4 below shows the types of bacteria isolated from the sample and their frequency of isolation. Methicillin-resistant Staphylococcus aureus (MRSA) was the most commonly isolated bacteria.

Table 4: Frequency of the different bacteria isolated from the ulcers.

Bacterial isolates from the ulcers and their frequency of occurrence		
Bacteria	n	**(%)**
MRSA	17	**53**
Klebsiella pneumoniae	7	**22**
Proteus mirabilis	4	**13**
Proteus rettgeri	3	**9**
Proteus vulgaris	**1**	**3**

Table 5 below presents the antibiotic sensitivity of the isolated bacteria.

Table 5: Antibiotic sensitivities of the isolated bacteria (S=sensitive; R=resistant).

Antibiotic sensitivities of the isolated bacteria					
	MRSA	**K. pneumoniae**	**P. mirabilis**	**P. rettgeri**	**P. vulgaris**
Amoxycillin-clavulanic acid			R	S	
Ampicillin		R	R		
Ceftriaxone			R		
Chloramphenicol				R	
Ciprofloxacin	S	S	S	S	
Co-trimoxazole	S			S	
Flucloxacillin	R	R			R
Gentamicin				R	
Meropenem			S		S
Tetracycline	R	S			R
Vancomycin	**S**	**S**	**S**		

Outcome was measured against significant predictors to assess their effect. The amputation risk was 26% higher for patients who were less compliant with diabetes treatment. High fasting blood sugar levels increases the risk of dying from diabetic complications by 55% (odd ratio [OR] = 1.5 mmol/L; 95% [CI] = 1.0 – 2.3).

Of the 5 patients that underwent amputation, the reasons were:

- Expected low compliance with conservative treatment (n=3), and
- Advanced peripheral vascular disease (n=2).

The cause of death for the 2 patients that died was sepsis.

Discussion

In this study, 81% of the patients were successfully treated conservatively. None of them relapsed or developed a new ulcer contiguous to the site of the previous one during the follow up period.

In this study, 73% of the patients had good tissue perfusion as demonstrated by the ABI, SpO_2 readings on the affected foot and Doppler studies. Thus, the success rate for conservative management was very high. Independent positive predictors of adequate wound healing include good haemoglobin, good albumin levels, good tissue perfusion and low contamination [18]. Knowledge of these factors will help clinicians determine whether or not to conservatively manage the patient.

The most common organism isolated from the wounds was MRSA (53%); it was highly sensitive to ciprofloxacin, co-trimoxazole and vancomycin, and resistant to flucloxacillin and tetracycline. Other bacteria isolated were K. pneumoniae, P. mirabilis, P. vulgaris and P. rettgeri. All the bacteria isolated were resistant to the readily-available flucloxacillin. Jan et al and Ramani et al found that Staphylococcus aureus was the most common bacteria isolated from diabetic foot patients [19,20].

Thirty one percent of the patients were overweight or obese; 39% had dyslipidaemia; 54% were hypertensive; 27% had neuropathy; 23% had retinopathy; 15 % had nephropathy and 27% had sepsis. However, not all demonstrated indications for amputations. This is supported by Wagner Jr and Wysser et al who noted that a multidisciplinary management is beneficial for good outcome despite the established complications on presentation [21,22].

All patients were advised on foot care, as well as compliance to their medication and living a healthy lifestyle. It has been shown that improved foot care and diabetic education reduces the rate of diabetes-related amputations by 50-75% [23].

Sixty five percent (n=17) of the patients had osteomyelitis on admission; five of them (29%) underwent amputation. This further supports the finding that some cases of diabetic foot osteomyelitis can be conservatively treated for 6 weeks or less, via culture-guided antibiotic therapy [24,25].

This study identified that simple clinical and laboratory parameters such as HbA1c, white cell count, hemoglobin, fasting blood glucose level, creatinine, urea, albumin ABI, SpO_2 and severity of arterial occlusion as determined by Doppler studies predict which patients are at a higher risk of failure of conservative treatment. Independent factors predictive of outcome of therapy were the ABI, SpO_2 level of the affected foot, severity of arterial occlusion of the affected foot and the microbial sensitivity of the microorganism isolated from the foot lesion. This finding supports what previous studies have noted [26,27].

This study only looked at hospitalised patients. Its findings need further evaluation in ambulatory patients in whom the defined predictors have not been examined. Moreover, the findings noted by this study needs to be validated with a bigger sample size, followed up over a longer time period. Validating these findings would help physicians decide on treatment approaches – conservative or surgical, as well as comparing it with results of early amputation or novel therapeutic strategies.

A limitation of this study is the small sample size and the duration of follow up.

Conclusion

This study shows that Wagner 3 diabetic foot lesions can be successfully managed conservatively. Readily available, safe, cost-effective and non-invasive investigative tools such as the Doppler and x-ray, together with a good microbiology laboratory, can assist with diagnosing and managing DFU cases. Knowledge of these factors and their influence on amputation outcomes is critical to allow multidisciplinary teams to develop

management protocols for patients with diabetic foot ulcers.

Declarations

Conflict of interests: There is no conflict of interests or financial support to be disclosed by the author.

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