

Clinical Outcomes of Below Knee Amputations in Diabetic Foot Patients

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Abstract

Introduction: This study aims to evaluate the predictive factors affecting the clinical outcome of Below Knee Amputations (BKA) performed in diabetic foot patients admitted to National University Hospital (NUH) Multi-Disciplinary Diabetic Foot Team. **Materials and Methods:** This is a prospective cohort study of 151 patients admitted to the Department of Orthopaedic Surgery, NUH, for Diabetic Foot Problems (DFP) from January 2006 to January 2010. All had undergone BKA performed by NUH Multi-Disciplinary Diabetic Foot Team. Statistical analyses (univariate and multivariate analysis with logistic regression) were carried out using SPSS version 18.0, for factors such as demographic data, diabetic duration and control, clinical findings and investigations, indications for surgery, preoperative investigations and evaluation, microbiological cultures, and these were compared to the clinical outcome of the patient. A good clinical outcome is defined as one not requiring proximal re-amputation and whose stump healed well within 6 months. The ability to ambulate with successful use of a prosthesis after 1 year was documented. Statistical significance was set at $P < 0.050$. **Results:** Mean age of study population was 55.2 years with a male to female ratio of about 3:2. Mean follow up duration was 36 months. Of BKAs, 73.5% gave a good outcome. Univariate analysis showed that smoking, previous limb surgery secondary to diabetes, high Total White Count (TW), Erythrocyte Sedimentation Rate (ESR), C-Reactive Protein (CRP), Urea, Creatinine (Cr), Neutrophils, absence of posterior tibial and popliteal pulses, low Ankle Brachial Index (ABI) and Toe Brachial Index (TBI) were associated with poor clinical outcome. Multivariate analysis showed that high CRP, ESR, Neutrophils, absence of popliteal pulse and low ABI were associated with poor clinical outcome. Of patients, 50.3% attained mobility with prosthesis after 1 year. Mortality rate was 21.2% within 6 months of operation, with sepsis being the most significant cause of death. **Conclusion:** Success rate of BKA was 73.5%, with mortality rate being 21.2% within 6 months. In this cohort, 50.3% were able to attain eventual mobility with prosthesis after 1 year. Sepsis was the most significant cause of death. Markers of infection such as high CRP, ESR, neutrophils; and indicators of poor vascularity such as absence of popliteal pulse and low ABI were significantly associated with poor clinical outcome.

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Key words: Amputation, Diabetic foot, Epidemiology, Outcome assessment

Introduction

Diabetes currently affects 366 million people worldwide or 8.3% of the world's adult population. This figure is expected to increase to 9.9% by 2030, owing to environmental factors such as sedentary lifestyles and changing dietary patterns.¹ Every year, more than 1 million people undergo a lower-limb amputation as a consequence of diabetes, which calculates to a limb lost to diabetes in the world every 30 seconds.² Singapore has one of the highest prevalence of diabetes in the developed world, with 11.3% of residents aged between 18 and 69 years old living with diabetes in 2010.³ It is one of the top 10 causes of death locally.³ Diabetic foot complications accounts for almost

700 amputations annually in Singapore.⁴

A Below Knee Amputation (BKA) has a 30-day postoperative mortality rate of 7.0%, and the morbidity rate is 30.4%.⁵ Moreover, the psychological trauma of patients who had undergone a lower extremity amputation is significant, with more expressed sensitivity, anxiety, hostility and paranoia post lower extremity amputation.⁶

In a diabetic patient who had undergone a BKA, the healing process poses a challenge due to intrinsic factors such as neuropathy, vascular problems, as well as extrinsic factors such as wound infection and excessive pressure to the wound site.⁷ Complications from BKA such as wound

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breakdown and infections incur high healthcare costs due to multiple and extended hospitalisations.⁸ Boulton et al have estimated that 77% of the cost of a major lower extremity amputation was utilised after the actual amputation, with a substantial part being spent in rehabilitation, managing post surgery wound infections and also in nursing homes.⁹

Benefits of a good outcome in a diabetic patient who had undergone a BKA include early mobilisation and rehabilitation to avoid deleterious effects of immobility especially in the geriatric population, as well as to enhance the quality of life of the remaining years.¹⁰ A well healed prosthesis fitted BKA stump which allows the patient to ambulate would also provide a better psychological status compared to one who has limited mobility due to a debilitating foot ulcer.¹¹ A shorter stay in hospital following an uneventful surgery would also decrease healthcare costs.¹²

With the high prevalence of diabetic foot patients in our institution, along with high incidences of BKA performed in this patient group, our institution has been working with the aim of preventing a BKA in our patients.^{13,14} Our institution has adopted a team approach to managing diabetic foot infections, with the major amputation rate being significantly reduced from 31.15% to 11.01%.¹²

The aim of this study is to evaluate the predictive factors affecting the clinical outcome of BKA performed in diabetic foot patients admitted to National University Hospital (NUH) Multi-Disciplinary Diabetic Foot Team. The results of this study would allow clinicians to identify significant preoperative factors and thus be able to optimise these significant factors in patients going for BKA to achieve a favourable outcome.

Materials and Methods

This is a prospective cohort study of 151 patients admitted to the Department of Orthopaedic Surgery, NUH, for Diabetic Foot Problems (DFP) from January 2006 to January 2010. All had undergone BKA performed by NUH Multi-Disciplinary Diabetic Foot Team. The indication for BKA was severe progressive diabetic foot infection with sepsis, which cannot be controlled by debridement and optimal conservative treatment, including antibiotics. Informed consent was obtained from all subjects studied in this cohort. Data on all patients were documented using a carefully designed study protocol.

Documentation included age, sex, race, smoking status, premorbid status, comorbidities, history of previous limb surgery (such as Ray amputation) attributable to diabetes, indication for surgery, physical examination such as presence of neuropathy, presence of foot and popliteal pulses, capillary filling and measurement of Ankle Brachial Index (ABI) and Toe Brachial Index

(TBI). Neuropathy was assessed using the 5.07 Semmes-Weinstein Monofilament Test (SWMT). Ability to detect 7 or less sites out of a total of 10 sites indicated the presence of neuropathy. Preoperative laboratory investigations, including glycosylated hemoglobin (HbA1c), erythrocyte sedimentation rate (ESR), haemoglobin level (Hb), total white blood cell (WBC) count, creatinine (Cr) and C-reactive protein (CRP) levels were also collected. Blood cultures were performed for all patients and deep tissue cultures were taken from the infection sites for culture of aerobic and anaerobic organisms. In patients undergoing debridement or amputation, intraoperative infected tissue was sent for culture. The American Society of Anesthesiologists (ASA) status was also recorded prior to operation.

A good clinical outcome is defined as one not requiring proximal re-amputation and whose stump healed well within 6 months. A poor clinical outcome is defined as death within 6 months of BKA, poor stump healing and another operation was needed within 6 months. The cohort was followed up for a minimum of 12 months. We documented whether the patient was able to achieve mobility with the successful use of prosthesis at the end of 12 months.

In this cohort, the following factors were evaluated for significant predictive factors of clinical outcome of BKA: age, sex, ethnicity, smoking status, premorbid functional status, previous limb surgery attributable to diabetes, comorbidities such as renal impairment, diabetic control, ASA status, type of pathogen(s) encountered, presence of neuropathy, presence of vasculopathy (ABI, pulses), WBC, Neutrophils, ESR, CRP, Hb, HbA1c and Cr. The ability to ambulate with a successful use of prosthesis after 1 year was also compared to the clinical outcome.

Statistical Analysis

All statistical analyses were performed using SPSS 18.0 with statistical significance set at $P < 0.050$. Predictive factors for clinical outcome were determined using univariate and stepwise logistic regression analysis. Mann-Whitney U test was used for numerical prognostic factors, and chi-square test was used for categorical factors.

Results

The patient profile of our study population is shown in Table 1. Table 2 shows the results of our study, evaluating various factors as predictive factors of poor outcome.

Our patients aged between 31 and 95 years with a mean of 55.2 years. The majority was in their 5th and 6th decades of life (32.5%). Those above 60 years old in our study population were 52.3%. The ratio of male to female patients was approximately 3:2, with 62.3% of patients being males and 37.7% being female. Racial distribution in our study

Table 1. Patient Profile

Factors	Value (%)
Age distribution (years)	
≤40	7 (4.6%)
41 – 50	16 (10.6%)
51 – 60	49 (32.5%)
61 – 70	37 (24.5%)
>70	42 (27.8%)
Gender distribution	
Male	94 (62.3%)
Female	57 (37.7%)
Race	
Chinese	68 (45.0%)
Malay	58 (38.5%)
Indian	21 (13.9%)
Others	4 (2.6%)
Premorbid Activities of Daily Living (ADL)	
Independent	100 (66.2%)
Walking with Aid	11 (7.3%)
Wheelchair Bound	31 (20.5%)
Bed Bound	9 (6.0%)
Comorbidities	
Hypertension	109 (72.2%)
Ischaemic Heart Disease (IHD)	68 (45.0%)
Stroke	32 (21.2%)
Hyperlipidemia	80 (53.0%)

population was 45% Chinese, 38.5% Malays and 13.9% Indians, with 2.6% of other races. In comparison with the national racial composition of Singapore,¹³ which reported 74.1% Chinese, 13.4% Malays, 9.2% Indians and 3.3% others, there was a significant increased representation in Malays ($P < 0.001$) and a significant decreased representation in Chinese ($P < 0.001$). The mean follow-up duration was 36 months.

About 74% of BKAs gave a good outcome. Univariate analysis showed that smoking, previous limb surgery secondary to diabetes, high Total White Count (TWC), Erythrocyte Sedimentation Rate (ESR), C-Reactive Protein (CRP), Urea, Creatinine (Cr), Neutrophils, absence of pulses, low Ankle Brachial Index (ABI) and Toe Brachial Index (TBI) were significantly associated with poor clinical outcome. Our analysis found that age, race, gender, premorbid Activities of Daily Living (ADL), hypertension, hyperlipidemia, previous stroke (CVA), ischaemic heart disease, previous acute myocardial infarction (AMI), type and duration of diabetes mellitus, ASA score, End Stage Renal Failure (ESRF) and types of micro-organisms causing infection were not significant in the affecting the outcome of BKAs. Multivariate analysis showed that smoking ($P \leq 0.001$), high ESR ($P = 0.008$), CRP ($P = 0.018$), Neutrophils ($P = 0.005$), absence of popliteal pulse ($P = 0.016$) and low ABI ($P = 0.010$) were associated with poor clinical outcome. These results demonstrated that the severity of infection and the severity of vasculopathy of diabetic foot patients

Table 2. Results of Evaluation of Factors as Predictives of Outcome

Risk Factors	Outcome		Unadjusted	Adjusted
	Good	Poor	<i>P</i> value	OR (95% CI) <i>P</i> value
Gender				
Male	67 (71.3)	27 (28.7)	0.273	
Female	44 (77.2)	13 (22.8)		
Race				
Chinese	48 (70.6)	20 (29.4)	0.823	
Malay	43 (74.1)	15 (25.9)		
Indian	17 (81.0)	4 (19.0)		
Others	3 (75.0)	1 (25.0)		
Age (years)				
<40	5 (71.4)	2 (28.6)	0.324	
41 – 50	9 (56.3)	7 (43.7)		
51 – 60	35 (71.4)	14 (28.6)		
61 – 70	27 (73.0)	10 (27.0)		
>70	35 (83.3)	7 (16.7)		
Premorbid Activities of Daily Living (ADL)				
Independent	73 (73.0)	27 (27.0)	0.991	
Walking with Aid	8 (72.7)	3 (27.3)		
Wheelchair	23 (74.2)	8 (25.8)		
Bedbound	7 (77.8)	2 (22.2)		

Table 2. Results of Evaluation of Factors as Predictives of Outcome (Con't)

Risk Factors	Outcome		Unadjusted	Adjusted		
	Good	Poor	P value	OR (95% CI)	P value	
Smoking						
	Yes	31 (46.3)	36 (53.7)	<0.001	42.1	<0.001
	No	80 (95.2)	4 (4.8)		1.0	
Comorbidities						
Hypertension	Yes	80 (73.4)	29 (26.6)	0.567		
	No	31 (73.8)	11 (26.2)			
Hyperlipidaemia	Yes	58 (72.5)	22 (27.5)	0.455		
	No	53 (74.6)	18 (25.4)			
Cerebral vascular accident	Yes	23 (71.9)	9 (28.1)	0.488		
	No	88 (73.9)	31 (26.1)			
Intermittent haemodialysis	Yes	51 (75.0)	17 (25.0)	0.426		
	No	60 (72.3)	23 (27.7)			
Previous acute myocardial infarction	Yes	62 (77.5)	18 (22.5)	0.160		
	No	49 (69.0)	22 (31.0)			
Sensory neuropathy	Yes	95 (73.1)	35 (26.9)	0.499		
	No	16 (76.2)	5 (23.8)			
End stage renal failure						
	Yes	25 (65.8)	13 (34.2)	0.288		
	No	86 (76.1)	27 (23.9)			
Diabetes mellitus type						
Type 1		1 (50.0)	1 (50.0)	0.461		
Type 2		110 (73.8)	39 (26.2)			
Duration of diabetes						
< 1 year		0 (0.0)	1 (100.0)	0.060		
1 – 5 years		8 (72.7)	3 (27.3)			
5 – 10 years		22 (91.7)	2 (8.3)			
>10 years		81 (70.4)	34 (29.6)			
Previous limb surgery 2* diabetes						
	Yes	43 (62.3)	26 (37.7)	0.005		
	No	68 (82.9)	14 (17.1)			
ASA Score						
2		25 (73.5)	9 (26.5)	0.813		
3		76 (74.5)	26 (25.5)			
4		10 (66.7)	5 (33.3)			
Vasculopathy						
Pulses	0	61 (68.5)	28 (31.5)	0.252		
	1	13 (81.3)	3 (18.8)			
	2	37 (80.4)	9 (19.6)			
Dorsalis Pedis Pulse	Yes	42 (80.8)	10 (19.2)	0.101		
	No	69 (69.7)	30 (30.3)			
Posterior Tibial Pulse	Yes	45 (83.3)	9 (16.7)	0.030		
	No	66 (68.0)	31 (32.0)			
Popliteal Pulse	Yes	80 (80.0)	20 (20.0)	0.011	0.256 (0.085 – 0.773)	0.016
	No	31 (60.8)	20 (39.2)			
Abnormal Capillary Filling	Yes	68 (71.6)	27 (28.4)	0.307		
	No	43 (76.8)	13 (23.2)			

Table 2. Results of Evaluation of Factors as Predictives of Outcome (Con't)

Risk Factors	Outcome		Unadjusted	Adjusted		
	Good	Poor	P value	OR (95% CI)	P value	
ABI	< 0.4	20 (55.6)	16 (44.4)	0.018	1.0	0.030
	0.4 – 0.8	44 (77.2)				
	133	13 (22.8)		0.401 (0.154 – 1.046)	0.062	
TBI	> 0.8	47 (81.0)	11 (19.0)	0.049	0.270 (0.100 – 0.730)	0.010
	< 0.4	27 (60.0)	18 (40.0)			
	0.4 – 0.7	48 (80.0)	12 (20.0)			
Preoperative Parameters: Median (range)	> 0.7	36 (78.3)	10 (21.7)			
Hb (g/dL)		9.8 (6.5 – 14.5)	9.4 (6.7 – 12.9)	0.179		
TWC (x10 ⁹ /L)		15.3 (5.9 – 40.7)	18.8 (6.4 – 42)	0.018		
CRP (mg/L)		121 (5 – 606)	189 (7 – 546)	0.014	1.007 (1.001 – 1.012)	0.018
ESR (mm/hr)		100 (12 – 150)	111.5 (50 – 150)	0.018	1.029 (1.009 – 1.049)	0.004
Urea (mmol/L)		7.1 (1.8 – 34.5)	10.7 (2.2 – 43)	0.029		
Creatinine (umol/L)		95 (33 – 830)	167.5 (29 – 903)	0.024		
Neutrophils (x10 ⁹ /L)		12.8 (4.3 – 38.5)	16.2 (5.5 – 39.1)	0.015	1.088 (1.004 – 1.179)	0.040
HbA1c (%)		7.8 (4.1 – 16.8)	8.4 (5 – 16)	0.150		
Ability to successfully ambulate with prosthesis after 1 year	Yes	66 (60.0)	10 (40.0)	<0.001		
	No	45 (86.8)	30 (13.2)			
Micro-organisms						
Methicillin-resistant <i>Staphylococcus aureus</i>		34 (69.4)	15 (30.6)	0.474		
<i>Bacteroides fragilis</i>		17 (73.9)	6 (26.1)			
<i>Staphylococcus aureus</i>		24 (85.7)	4 (14.3)			
<i>Pseudomonas aeruginosa</i>		17 (70.8)	7 (29.2)			
<i>Streptococcus agalactiae</i> (Group B)		4 (100.0)	0 (0.0)			
<i>Enterococcus faecalis</i>		1 (100.0)	0 (0.0)			
Others		14 (63.6)	8 (36.4)			

ASA: American Society of Anesthesiologists; ABI: Ankle Brachial Index; TBI: Toe Brachial Index; TWC: Total White Count; CRP: C-Reactive Protein; ESR: Erythrocytes Sedimentation Rate

Note: Mann-Whitney U test used for numerical prognostic factors, chi-square test used for categorical factors

influence the clinical outcome of BKAs. In our cohort, 76 patients (50.3%) were able to attain eventual mobility with a successful use of a prosthesis at the end of 12 months after surgery. Univariate analysis showed that this was significantly associated with a good outcome ($P = 0.005$).

Methicillin-resistant *Staphylococcus aureus* (MRSA) was the most common pathogen identified, with 49 (32.5%) patients infected, followed by methicillin-susceptible *Staphylococcus aureus* (MSSA) with 28 (18.5%) patients and *Bacteroides Fragilis* with 23 (15.2%) patients. Majority of the patients were of ASA status 3 (67.5%), followed by ASA 2 (22.5%) and ASA 4 (10.0%).

Forty patients (26.5%) had a poor outcome. Of these patients, 32 patients (21.2%) died within 6 months, 4 (2.6%) patients underwent stump revision, 3 (2.0%) patients underwent above knee amputation and 1 (0.7%) patient underwent through-knee amputation.

Mortality rate was 21.2% within 6 months post BKA, with sepsis being the most significant cause of death (Fig. 1).

Discussion

There is substantial literature on lower extremity amputations in a mixed cohort which includes both diabetic and non-diabetic patients.^{15,16} Other studies involving diabetic patients combined both above and below knee amputations.¹⁷ There is currently no documented study on the outcome of below knee amputations in diabetic patients only. This paper studies the outcome of BKA in a diabetic population.

Our study showed 73.5% good outcome for diabetic patients undergoing a BKA, which is defined as one not requiring proximal re-amputation and whose stump healed well within 6 months. This is similar to a previous local

study performed by Low et al with a smaller sample size of 54 patients, who reported a 78.3% good outcome.¹⁸ This outcome was similar to that previously published by Lepantalo et al¹⁵ with a cohort of 69 cases, including both diabetic and non-diabetic patients, who reported a 72.9% success rate. Taylor et al¹⁶ with a much larger cohort of 627 patients including both diabetic and non-diabetic patients reported good outcome in only 51.1%. However, it must be borne in mind that a good outcome was concluded to be one whose stump had healed and who was also ambulating within 1 year. Viswanathan et al¹⁷ studied the re-amputation rate of major amputations (above and below knee amputations) of 405 diabetic foot patients in 3 developing countries. They reported a re-amputation rate of 3% and a recurrence of ulceration from 9% to 30%.¹⁷

Markers of infection such as high CRP, ESR and neutrophils were found to be significant predictive factors of outcome from our multivariate analysis of our study. These findings concurred with Johnston et al, who demonstrated that the severity of infection to be a predictive factor for outcome in BKA.¹⁹

Patients who had previous limb surgery attributable to diabetes were associated with a poor outcome in our univariate analysis. We postulate that in these cases, the control of sepsis may be inadequate in the initial distal level amputation performed on these patients, and hence they are subjected to a longer duration of sepsis along with the physical impact of a second surgical stress, which may have contributed to their poor outcome.

Patients with ESRF demonstrated a poorer outcome, however this was not found to be significant in our study. All our ESRF patients were co-managed by the renal physicians in our hospital, and these patients were optimised preoperatively and postoperatively in terms of dialysis

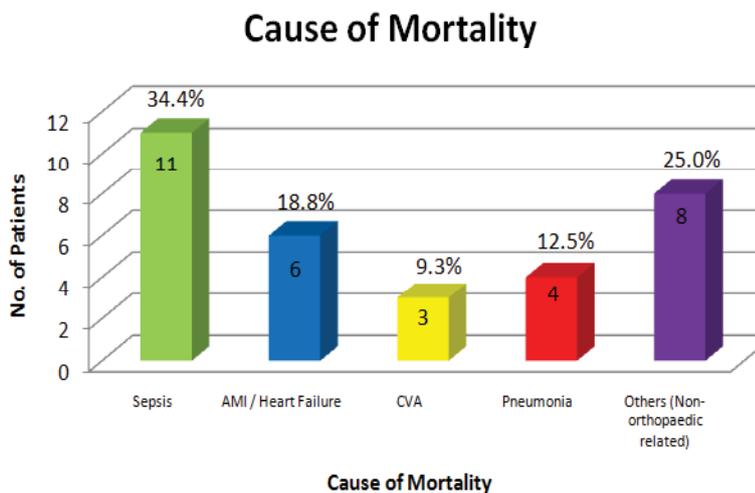


Fig. 1. Breakdown of mortality causes.

support, perioperative nutrition and electrolyte balance. We believe that these are some of the many factors that have contributed to the results as shown.

Indicators of poor vascularity such as low ABI and absence of popliteal pulses were found to be significant as a predictive factor for outcome from our multivariate analysis. Faglia et al²⁰ have shown that in diabetic patients with critical limb ischaemia, revascularisation is feasible in most cases and allows a low rate of early major amputation.

Conclusion

The success rate of BKA was 73.5%, with mortality rate being 21.2% within 6 months. Among our patients, 50.3% were able to attain eventual mobility with prosthesis after 1 year. Sepsis was the most significant cause of death. Markers of infection such as high CRP, ESR, high neutrophils; and indicators of poor vascularity such as absence of popliteal pulse and low ABI were significantly associated with poor clinical outcome.

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