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ORIGINAL ARTICLE

Risk Factors for Amputation Among Patients with Diabetic Foot Disease in a Tertiary Hospital: A Retrospective Case-control Study

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ABSTRACT

Background. Amputation is commonly indicated to control infection in patients with diabetic foot disease. There were over 3.7 million diabetic adults in the Philippines in 2017. Around 4 of 1000 patients with diabetes underwent lower extremity amputations.

Objective. This study aimed to evaluate patients with diabetic foot disease who underwent lower extremity amputation at a tertiary hospital and analyze possible risk factors for their amputations.

Methodology. Records of patients treated for diabetic foot disease from 2017 to 2021 were reviewed. We identified risk factors such as sex, renal disease, arterial duplex scan, white blood cell count, HbA1c level, Wagner classification, and history of cigarette smoking, and correlated these with amputation.

Result. In 260 patients, older age, arterial occlusion (i.e., monophasic results on arterial duplex scan), poorer soft tissue status (i..e, higher Wagner classification), and higher WBC levels increased the likelihood of amputation. Renal disease, sex, smoking, and hemoglobin A1c (HbA1c) were not significantly related.

Conclusion. The factors associated with amputation in patients with diabetic foot disease were similar to those in literature, including age, soft tissue compromise, elevated white blood cell levels, and monophasic arterial duplex scans. Renal disease, sex, smoking, and HbA1c were not found to be statistically significant factors in this study.

Keywords. risk factors, type 2 diabetes, major amputation, diabetic foot, Wagner, renal disease, arterial duplex, smoking

INTRODUCTION

Amputation is commonly indicated as a means of controlling infection in patients with diabetic foot disease when debridement has failed or is not a viable option. Over 3.7 million cases of diabetes in adults were reported in the Philippines in 2017. Around 4 of 1000 patients with diabetes mellitus underwent lower extremity amputations.[1]

There are numerous risk factors associated with amputation like advanced age, smoking history, sex, peripheral neuropathy, renal impairment, peripheral arterial occlusive disease, soft tissue status, and glycemic control, among others.[2]

Clinical assessment and diagnostic procedures help determine whether amputation is necessary, and the appropriate level to ensure optimal healing and function. Peripheral pulses, hair growth, sensation, and skin color are examined.[3] Infection parameters, such as white blood cell (WBC) counts, C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), have predicted amputation in diabetic foot ulcer patients.[4]

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Arteriograms, by contrast, are rarely indicated unless revascularization is. Peripheral arterial occlusion is quantified using the ankle-brachial index (ABI) and color and pulsed-wave Doppler ultrasound.[5] ABI, however, may be falsely elevated in people with diabetes due to calcification of the tibial and peroneal arteries.

The primary aim of the study was to determine the risk factors for amputation among patients with diabetic foot disease treated at a tertiary hospital in the Philippines (Baguio General Hospital and Medical Center), specifically in terms of age, sex, arterial duplex scan results, soft tissue status, presence or absence of renal disease, Hba1c level, WBC level, and smoking history.

The researchers found several international articles, but few regional and local studies on the risk factors of amputation among diabetes mellitus patients. The study aimed to paint a picture of patients with diabetes and diabetic foot disease in the local setting.

METHODOLOGY

We conducted a retrospective case-control study, including all admitted patients with diabetic foot disease from January 2017 to December 2021. All patients with diabetic foot ulcers or infections were referred to the Orthopedics Department at the Baguio General Hospital and Medical Center. Excluded were patients with lost medical records, traumatic amputations, patients with gestational diabetes, diabetic infants born to diabetic mothers, and diabetic patients without foot wounds (Wagner 0). All available data sources were exhausted, including charts from hospital records, patient census, and electronic medical records. Age, sex, presence or absence of renal disease, results of arterial duplex scans, white blood cell count, HbA1c level, Wagner classification of soft tissue status, and smoking history were identified and correlated with the risk of amputation. The predictability of the risk factors were computed using Odds ratio, logistics regression analysis and Fisher exact test. Odds ratio is the odds of the event in the exposure group divided by the odds of the event in the control or non-exposure group. Logistics regression analysis is a statistical method used to predict the probability of a binary outcome (like yes/no, success/failure, or amputated/not amputated) based on one or more independent variables, while the Fisher exact test is used to determine whether there is a significant association between two categorical variables.

Wagner grading was done as follows: Grade 0: Pre-ulcerative lesion, healed ulcers, presence of bony deformity. Grade 1: Superficial ulcer without subcutaneous tissue involvement; Grade 2: Penetration through the subcutaneous tissue (exposed bone, tendon, ligament, or joint capsule); Grade 3: Osteitis, abscess, or osteomyelitis; Grade 4: Gangrene of the forefoot; Grade 5: Gangrene of the entire foot. Minor amputations were defined in this study as amputations distal to the tarsal joints, including ray amputations and disarticulations. Major amputations were defined at or proximal to the tarsal joints.

The sample size was determined by using the formula:

$$n = \frac{[(Z\alpha)/2 + Z\beta]^2 \times [P1(1-P1) + P2(1-P2)]}{(P1 - P2)^2}$$

Where:
$(Z\alpha)/2 = 1.96$ (for 95% confidence)
$Z\beta = 0.84$ (for 80% power)
P1 = proportion of exposure in cases (0.5 assumed value)
P2 = proportion of exposure in controls (0.3 assumed value)
505: mean population

Computation:

$$n = \frac{(1.96 + 0.84)^2 \times [(0.5 \times 0.5) + (0.3 \times 0.7)]}{(0.5 - 0.3)^2}$$

$$= \frac{(2.8)^2 \times [(0.25) + (0.21)]}{(0.2)^2}$$

$$= (7.84 \times 0.46) / 0.04$$
$$= 3.6064 / 0.04$$
$$= 90.16 \text{ (91 per group)}$$

The study was a retrospective case control study using the purposive sampling technique total enumeration to provide a full picture of the population while minimizing sampling error. Descriptive and inferential statistics were used. Frequencies and percentages were used to describe demographic data set while the Chi Square test was used to determine association between the risk factors and amputation. The level of significance was set at 0.05. Data were analyzed using IBM-SPSS ver.20.

RESULTS

A total of 260 patients with diabetic foot disease were included. All patients included had unilateral disease only. One hundred fifty-three patients underwent amputations, while 107 did not. Among the amputations performed, 97 were major and 56 were minor amputations.

The mean age for all patients was 62 years. Patients were analyzed per age group. Age groups 46–60, 61–75, and >75 were more likely than not to receive amputation (p <0.05) (Table 1).

Sex was not found to be a significant risk factor for amputation (Odds ratio = 1.00, Table 2). Most (n = 86) of the amputees were male, and 67 were female. Smoking history was associated with an odds ratio of 1.086 of amputation compared to non-smokers (p = 0.152, Table 3).

The presence of renal disease was associated with a 1.27 times higher likelihood of amputation, however, this association was not statistically significant (p = 0.152, Table 4). Of the 52 diabetics with concomitant renal disease, 33 underwent amputation.

Table 1. Age

Age (in years)	Amputated	Not amputated	Total	*P*-value	Odds ratio
1-15	0	1	**1**	insufficient data – cannot be computed	zero value (not computed)
16-30	1	2	**3**	0.52	Reference
31-45	6	17	**23**	0.066	0.71
46-60	62	44	**106**	<0.001*	2.82
61-75	68	38	**106**	<0.001*	3.58
>75	16	5	**21**	0.010*	6.40
Total	**153**	**107**	**260**		

*p <0.05, significant

Reference – this was used as a baseline for standard of comparison

The odds of amputation increased accordingly as one went up the Wagner Classification. None of the 11 Wagner I patients underwent amputation, while all 10 Wagner V patients underwent amputation. All Wagner grades from II to V showed statistically significant increases in the odds of amputation. Wagner V had the highest coefficient indicating the strongest effect (Table 5).

Arterial duplex scans were not available for all patients. Among the 125 patients that had data, Monophasic flow (indicating stenosis or occlusion) showed the strongest and most significant association with amputation (p <0.001) (Table 6).

High WBC values (10.01 x 10^9/L and higher) were associated with higher odds of amputation. WBC levels above 10 show statistically significant increase in amputation risk. WBC levels higher than 15.01 x 10^9/L had the most significant impact (Table 7).

Although patients with higher hemoglobin A1c levels had greater odds of amputation, this difference was not statistically significant (Table 8).

Table 2. Sex

Sex	Amputated	Not amputated	Total
Male	86	60	**146**
Female	67	47	**114**
Total	**153**	**107**	**260**

p = 0.152 (NS)

Odds Ratio: 1

Table 3. Smoking

Smoking	Amputated	Not amputated	Total
Smoker	44	29	**73**
Non-Smoker	109	78	**187**
Total	**153**	**107**	**260**

p = 0.441 (NS)

Odds Ratio: 1.086

Table 4. Renal disease

Renal disease	Amputated	Not amputated	Total
Present	33	19	**52**
Absent	120	88	**208**
Total	**153**	**107**	**260**

p = 0.276 (NS)

Odds Ratio: 1.27

DISCUSSION

Diabetic foot ulcers are frequent causes of hospitalization in diabetic patients. This condition represents a significant and preventable health issue among adults living with diabetes. These ulcers can lead to serious complications such as reduced mobility, infections, hospital admissions, lower limb amputations, and even death. Over a lifetime, the risk of developing a foot ulcer ranges from 19% to 34%, and this figure continues to grow due to increased life expectancy and the rising medical complexity of individuals with diabetes.[6]

Diabetic foot ulcers develop from a combination of peripheral vascular dysfunction, peripheral neuropathy, and infection. Several risk factors for major amputation in diabetic patients have been identified, including age, sex, ulcer size, hypertension, neuropathy, nephropathy, inadequate glycemic control, white blood cell count, and abnormal lipid levels.[7-13] There are various causes of diabetic foot ulceration, but micro- and macrovascular diseases greatly influence severity.

We investigated different risk factors and their association with odds of amputation in patients with diabetic foot ulcers. In this study, increasing age was found to be a significant risk factor, aligning with previous studies. A retrospective study by Farine et al., revealed a significant negative correlation between older age at the time of initial surgical amputation and three-year survival post-amputation.[14] Older age is also accompanied by more pathologies of the bone and joint associated with diabetes mellitus.[15] Diabetic foot ulcers were more prevalent in the 50- to 59-year-old age group, as reported by Yao et al.[16]

Ulcer severity often dictates treatment. Conservative treatment of foot ulcers can be demanding, requiring daily foot hygiene, effective offloading, and glycemic control. Infection is common, being a common cause of hospitalization. Most (60 to 80%) of diabetic foot ulcers will heal, but 10 to 15% will not, and up to 24% will require amputation.[17]

Patients with higher Wagner grades were more likely to need amputation and multimodal management, as seen in our study and in the literature.[18]

In a prospective study by Musa et al., older age and elevated WBC were associated with amputation, consistent with this study.[19] Elevated neutrophil-to-lymphocyte ratio and platelet-to-lymphocyte ratio were markers of systemic inflammation, indicating ongoing tissue damage, microangiopathy, and microvascular complications among diabetic patients. Increased neutrophils may lead to endothelial damage. Lymphocytes dwindle in number due to apoptosis of these cells during a heightened inflammatory process.[20]

Popliteal artery stenosis or occlusion, indicated by a monophasic arterial duplex scan was a statistically significant risk factor for amputation in our study and in the literature.[21] This monophasic Doppler waveform is typically seen in multilevel obstructive arterial disease.[22]

The researchers did not find either sex to be at higher risk for amputations. However, in a meta-analysis and systematic review by Fan et al., the male sex was mildly more predictive of an amputation following a diabetic foot ulcer.[23]

Table 5. Wagner

Wagner	Amputated	Not Amputated	Total	*P*-Value	Odds Ratio
I	0	11	**11**	Cannot be computed	Zero value (not computed)
II	10	62	**72**	0.026	*Reference*
III	53	29	**82**	<0.001	*11.33*
IV	80	5	**85**	<0.001	99.2
V	10	0	**10**	<0.001	*Undefined***
Total	**153**	**107**	**260**		

**p* <0.05, significant

Reference – this was used as a baseline for standard of comparison

**Undefined or infinite Odds ratio suggests perfect association

Table 6. Arterial duplex scan

Arterial duplex	Amputated	Not amputated	Total	*P*-value	Odds ratio
No record	55	70	**125**		0.30
Monophasic	25	3	**28**	<0.001	*6.77*
Biphasic	15	5	**20**	0.016	*2.22*
Triphasic	58	29	**87**	0.049	*1.64*
Total	**153**	**107**	**260**		

**p* <0.05, significant

Table 7. WBC

WBC Level x 10^9/L	Amputated	Not amputated	Total	*P*-value	Odds ratio
0 to 5	1	4	**5**	Reference	0.25
5.01 to 10	20	30	**50**	0.298	0.67
10.01 to 15	45	38	**83**	0.049	1.18
15.01 to 20	33	18	**51**	0.013	1.83
20.01 to 25	21	7	**28**	0.005	3
25.01 to 30	21	7	**28**	0.005	3
30.01 above	12	3	**15**	0.010	4
Total	**153**	**107**	**260**		

**p* <0.05, significant

Reference – this was used as a baseline for standard of comparison

Table 8. HbA1c

Hemoglobin A1c	Amputated	Not amputated	Total	*P*-value	Odds ratio
0 to 6	27	22	**49**	Reference	1.23
6.1 to 12	92	63	**155**	0.204	1.46
12.1 to 18	33	22	**55**	0.121	1.50
18.1 to 24	1	0	**1**	Cannot be computed	Undefined**
Total	**Z**	**107**	**260**		

**p* <0.05, significant

**Undefined or infinite Odds ratio suggests perfect association

Reference – this was used as a baseline for standard of comparison

Despite the widely acknowledged link between poorly controlled diabetes and various microvascular and macrovascular complications, we found that elevated HbA1c levels, often considered a primary marker of glycemic control, did not directly correlate with an increased risk of lower extremity amputation. Previous studies have found that HBA1c ≥6.5% was strongly associated with major and minor amputations.[24] Zhou et al., concluded in their meta-analysis that a high level of HbA1c was a significant risk factor for lower extremity amputation in patients with diabetes. The odds ratio for a lower extremity amputation was 1.229 for every 1% increase in HbA1c.[25] However, HbA1c level has limited utility as a sole predictor.[26] While poor glycemic control is generally associated with microvascular and macrovascular complications, evidence has not consistently shown a linear relationship between HbA1c and risk of amputation.[27] Despite this lack of evidence, glucose level control is still recommended to reduce the risk of amputation in patients with diabetes.[25]

A holistic approach to risk assessment and prevention may be more critical than solely focusing on HbA1c levels.[28,29] HbA1c acts more as an indicator of systemic diabetic burden and metabolic dysregulation rather than a singular predictive variable for limb loss.[30,31] Ulceration, rather than chronic hyperglycemia alone, is a major precursor to amputation.[32] Specifically, the pathogenesis of lower extremity amputation in diabetic patients is multifactorial, primarily driven by microvascular and macrovascular complications, coupled with neurological deficits that lead to impaired sensation and structural deformities.[33] Focusing solely on HbA1c as a risk factor might distract from the critical interventions targeting vascular health, neurological integrity and aggressive wound care in diabetic foot management.[34]

Our study did not find an association between renal impairment and risk of amputation, in contrast with other studies.[35] Renal disease reflects vascular health in diabetic patients. In a retrospective study, lower glomerular filtration rate (GFR) and end-stage kidney disease were identified as risk factors for major amputations.[36]

This paper did not find smoking history as a statistically significant risk factor for amputation, unlike a retrospective study by Anderson et al., which showed that amputation was more likely to occur in diabetic patients who smoked. There were also more proximal amputations among smokers.[37]

In the local setting, where healthcare resources are limited, identified risk factors can guide appropriate screenings, educational programs, and preventive measures. This study, however, was limited by incomplete charts and the absence of EMR records during earlier years and may not be applicable to the larger population. We also had a decrease in cases from 2020 to 2021 due to the COVID-19 pandemic.

Based on the recognized risk factors in this and other studies, we recommend the following for clinical practice. Since the decision for amputation is mainly based on soft tissue status (i.e., Wagner classification), routine foot examinations help identify those at high risk. Physicians must emphasize patient education, instructing patients on proper foot care, daily inspection, selecting suitable footwear, avoiding injuries, and seeking early consultation when necessary.

We recommend further study of risk factors, and methods to reduce the incidence of diabetic foot amputations, particularly in local settings.

CONCLUSION

Age, soft tissue status (i.e., Wagner classification), elevated WBC levels, and arterial occlusion (i.e., arterial duplex scan) were found to be statistically significantly associated with amputation in patients with diabetic foot disease. On the other hand, sex, Hba1c levels, smoking, and the presence of renal disease were not statistically significant risk factors. With multiple risk factors present in diabetic patients undergoing amputation, clinical examination and available ancillary procedures should be exhausted.

Future studies should use stronger study designs for stronger evidence regarding risk factors for lower extremity amputations in patients with diabetes mellitus.

STATEMENT OF AUTHORSHIP

All authors certified fulfillment of ICMJE authorship criteria.

CREDIT AUTHOR STATEMENT

ACDR: Software, Validation, Formal analysis, Investigation, Resources, Data Curation, Writing – original draft preparation, Visualization, Funding acquisition; **FPMS:** Validation, Investigation, Data Curation, Funding acquisition; **IEG:** Conceptualization, Methodology, Writing – review and editing, Supervision, Project administration.

DATA AVAILABILITY STATEMENT

Datasets generated and analyzed are included in the published article.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

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