Original Article

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Predictors of Major Lower Limb Amputation among Type II Diabetic Patients

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Abstract

Diabetes mellitus (DM) is the most common cause of amputations. This study aimed toidentify the predictive factors for major lower limb amputation among patients with type 2 DM (T2DM) who were admitted to our hospital, in order to reduce its likelihood. *Methods:* This study involved 218 patients with T2DM who were admitted for diabetic foot problems from January 2015 to July 2016. A form was developed to document the patients' profiles, comorbidities, complications, investigations, treatment and clinical outcomes. The predictors for major lower limb amputations were determined using univariate and stepwise analysis. *Results:* A total of 31 patients underwent major lower limb amputations (25 transtibial, 6 transfemoral). The followingfactors were found to be associated with the incidence of major lower limb amputations: T2DM duration ≥ 10 years, diabetic neuropathy, diabetic nephropathy, presentation with gangrene, diabetic foot conditions of Wagner grade 4 or 5, and necrotising fasciitis. Patients who underwent major amputations had significantly lower haemoglobin and albumin levels, and higher total white blood cell counts, erythrocyte sedimentation rates, and C-reactive protein, urea and creatinine levels. However, only T2DM duration ≥ 10 years, positive bacterial culture and albumin levels were significant on stepwise analysis. *Conclusion:* T2DM duration ≥ 10 years, positive bacterial culture and low albumin levels were found to be significantpredictive factors for major lower limb amputation among patients with T2DM admitted for diabetic foot problems.

Keywords*:* Diabetes Mellitus; Amputation; T2DM; Diabetic Foot.

Introduction

Diabetes is fast gaining the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease. In 2000, India (31.7 million) topped the world with the highest number of people with diabetes mellitus followed by China (20.8 million) with the United States (17.7 million) in second and third place respectively. According to Wild et al, the prevalence of diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India. It is predicted that by 2030 diabetes mellitus may afflict up to 79.4 million individuals in India, while China (42.3 million) and the United States (30.3 million) will also see significant increases in those affected by the disease.

The Average amputations performed were related to Patients with diabetic foot problems were also found to have a poorer health-related quality of life, especially in terms of physicality Given the abundant problems related to amputations and prostheses, it would be beneficial to reduce the amputation rate due to DM. The present study sought to determine predictive factors for major lower limb amputations

Methods

This study involving 218 patients who were

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admitted PSH IMSR and Hospitals from January 2015 to 2016 with type 2 DM (T2DM) were included in the study. A case record form was developed for the documentation of data prior to the commencement of this study. The following predictive factors were analysed: age, gender, marital status, duration of T2DM, smoking habits, alcohol consumption, hypertension, ischaemic heart disease, neuropathy, peripheral vascular disease, hyperlipidaemia, glycated haemoglobin level, renal profile, total white blood cell count, and erythrocyte sedimentation rate (ESR).

Peripheral Vascular Assessment was Done Using a Doppler Ultrasound

Other information that was documented included the type of diabetic foot problems (i.e. abscess, osteomyelitis, gangrene, ulcers, cellulitis, necrotising fasciitis and/or charcotosteoarthropathy). Foot conditions were graded according to the Wagner classification (grade 0: high-risk foot; grade 1: superficial ulcer; grade 2: deep ulcer, penetrating tendon, bone or joint; grade 3: deep ulcer with abscess or osteomyelitis; grade 4: localised toe, forefoot or heel gangrene; grade 5: hindfoot gangrene). Patients who underwent below- or above-knee (i.e. transtibial or transfemoral, respectively) amputations were considered to have had a major lower limb amputation.

Minor lower limb amputation was defined as an amputation distal to the ankle joint. The decision to amputate was made by the general surgeons.

Duration of ten years and above was chosen as it yielded about 80% sensitivity and specificity for having a major lower limb amputation. Demographics as well as clinical and laboratory variables of the minor and major amputation groups were compared. Unless stated otherwise, numerical data was described using mean ± standard deviation, while categorical data was described using percentages. The statistical differences of the variables for minor and major amputations were tested using independent sample *t*-tests for numerical variables and chi-square tests for categorical variables. Important variables were modelled with logistic regression to determine significant predictors.

Results

Of the 218 patients included in the present study, 147 were male and 71 were female. Their mean age was 60.97 (range 36–98) years About half (n = 131, 60.1%) of the patients had hyperlipidaemia and 183 (83.9%) had hypertension; 79 (36.2%) patients were obese and 86 (39.4%) were smokers.

Nearly 60% of the patients (n = 130) were on oral hypoglycaemic agents and 88 (40.4%) patients were on insulin therapy. In terms of follow-up location, 143 (65.6%) patients were followed up at government health clinics, 57 (26.1%) at tertiary government hospitals and 18 (8.3%) at general practitioner. Retinopathy was observed in 62 (28.4%) patients, neuropathy in 94 (43.1%) patients, nephropathy in 65 (29.8%) patients, and peripheral vascular disease in 80 (36.7%) patients. 15 (6.9%) patients had a history of cerebrovascular accidents and 55 (25.2%) had underlying coronary heart disease. The most common presentation was abscesses (n = 68, 31.2%), followed by osteomyelitis (n = 56, 25.7%), cellulitis (n = 45, 20.6%), gangrene (n = 30, 13.8%), necrotising fasciitis (n = 19, 8.7%), charcotosteoarthropathy (n = 2, 0.9%) and ulcers (n = 1, 0.5%). When the foot conditions were categorised according to the Wagner classification (n = 203), 27 (13.3%) were grade 1, 19 (9.4%) were grade 2, 114 (56.2%) were grade 3, 19 (9.4%) were grade 4 and 24 (11.8%) were grade 5. Among the 218 patients, 31 (14.2%) underwent major lower limb amputation – 6 (2.8%) were transfemoral amputations, while 25 (11.5%) were transtibial amputations.

We found that age, gender, ethnicity, monthly income, dependency on family, smoking status, obesity, hyperlipidaemia, hypertension and history of ischaemic heart disease were not associated with major lower limb amputation (Table 1). The factors associated with major lower limb amputations included T2DM duration of ≥ 10 years, higher or tertiary education level, diabetic neuropathy, presentation with gangrene, diabetic foot condition of Wagner grade 4 or 5, and necrotising fasciitis (Table 2). Coronary heart disease, abscesses, osteomyelitis, ulcers and cellulitis were not significant factors for major lower limb amputation. Gangrene was a significant factor because 12 (40%) patients with gangrene underwent major lower limb amputation compared to 19 (10.1%) patients without gangrene.

Compared to those who underwent minor lower limb amputations, the patients who underwent major lower limb amputations were found to have significantly lower haemoglobin and albumin levels, higher white blood cell count, ESR, and, urea and creatinine levels. A significantly higher number of patients who underwent major amputations also had a positive bacterial culture result, compared to those who underwent minor amputations (Table 3).

To determine the significant predictors for major

lower limb amputation, we included those variables that we considered to be clinically important. The variables were duration of T2DM(< 10 years vs. ≥ 10 years), Wagner classification (grade 1–3 vs. grade 4–5), positive bacterial culture (regardless of type of bacterial specimen cultured) and plasma albumin level.

A stepwise logistic regression was performed and the final model consisted of: duration of T2DM, positive bacterial culture and. Based on a 95% confidence interval level, the independent significant predictive factors for major lower limb amputations among our patients were duration of T2DM of ≥10 years, positive bacterial culture and low albumin levels).

Table 1: Characteristics of the patients with type 2 diabetes mellitus

Gender	Minor lower limb amputation (n = 187)	No. (%)	Major lower limb amputation (n = 31)
Female (n = 71)	60 (84.5)	11	(15.5)
Male (n = 147)	127 (86.4)	20	(13.6)
Age (yr)			
< 60 (n = 96)	84 (87.5)	12	(12.5)
≥ 60 (n = 122)	103 (84.4)	19	(15.6)
Comorbidity			
Smoker			
Yes (n = 86)	76 (88.4)	10	(11.6)
No (n = 132)	111 (84.1)	21	(15.9)
Obesity			
Yes (n = 79)	67 (84.8)	12	(15.2)
No (n = 139)	120 (86.3)	19	(13.7)
Hyperlipidaemia			
Yes (n = 131)	109 (83.2)	22	(16.8)
No (n = 87)	78 (89.7)	9	(10.3)
Hypertension			
Yes (n = 183)	158 (86.3)	25	(13.7)
No (n = 35)	29 (82.9)	6	(17.1)
History of ischaemic heart disease			
Yes (n = 53)	49 (92.5)		4 (7.5)
No (n = 165)	138 (83.6)		27 (16.4)

Table 2: Characteristics of type 2 diabetes mellitus (T2DM) in the patients (n = 218), according to whether they underwent major or minor lower limb amputation

Characteristic	Minor lower limb amputation (n = 187)		No. (%)	Major lower limb amputation (n = 31)
Duration of T2DM (yr)				
< 10 (n = 145)	141	(97.2)	4	(2.8)
≥ 10 (n = 73)	46	(63.0)	27	(37.0)
Medication				
Oral hypoglycaemic agents (n = 130)	116	(89.2)	14	(10.8)
Insulin (n = 88)	71	(80.7)	17	(19.3)
Follow-up location				
Government health clinics (n = 143)	124	(86.7)	19	(13.3)
General practitioner clinics (n = 18)	17	(94.4)	1	(5.6)
Tertiary government hospitals (n = 57)	46	(80.7)	11	(19.3)
T2DM complication				
Diabetic retinopathy				
Yes (n = 62)	55	(88.7)	7	(11.3)
No (n = 156)	132	(84.6)	24	(15.4)
Diabetic neuropathy				
Yes (n = 94)	63	(67.0)	31	(33.0)
No (n = 124)	124	(100.0)		0
Diabetic nephropathy				
Yes (n = 65)	61	(93.8)	4	(6.2)
No (n = 153)	126	(82.4)	27	(17.6)
Cerebrovascular accident				
Yes (n = 15)	15	(100.0)		0

No (n = 203)	172	(84.7)	31	(15.3)
Coronary heart disease				
Yes (n = 55)	54	(98.2)	1	(1.8)
No (n = 163)	133	(81.6)	30	(18.4)
Peripheral vascular disease				
Yes (n = 80)	70	(87.5)	10	(12.5)
No (n = 138)	117	(84.8)	21	(15.2)
Type of diabetic foot problem				
Abscesses				
Yes (n = 68)	68	(100.0)		0
No (n = 150)	119	(79.3)	31	(20.7)
Osteomyelitis				
Yes (n = 56)	56	(100.0)		0
No (n = 162)	131	(80.9)	31	(19.1)
Gangrene				
Yes (n = 30)	18	(60.0)	12	(40.0)
No (n = 188)	169	(89.9)	19	(10.1)
Necrotising fasciitis				
Yes (n = 19)	1	(5.3)	18	(94.7)
No (n = 199)	186	(93.5)	13	(6.5)
Charcot osteoarthropathy				
Yes (n = 2)	1	(50.0)	1	(50.0)
No (n = 216)	186	(86.1)	30	(13.9)
Ulcers				
Yes (n = 1)	1	(100.0)		0
No (n = 217)	186	(85.7)	31	(14.3)
Cellulitis				
Yes (n = 45)	45	(100.0)		0
No (n = 173)	142	(82.1)	31	(17.9)
Wagner grade of diabetic foot†				
1–3 (n = 160)	154	(96.3)	6	(3.8%)
4–5 (n = 43)	19	(44.2)	24	(55.8)

Table 3: Vital signs and investigation results of the patients during admission (n = 218)

Vital sign/investigation result	Mean ± standard deviation			
	Minor lower limb amputation (n = 187)		Major lower limb amputation (n = 31)	
Systolic blood pressure (mmHg)	151	± 23	110	± 25
Diastolic blood pressure (mmHg)	91	± 13	62	± 13
Pulse (bpm)	84	± 13	112	± 13
Temperature (°C)	37.7	± 1.1	38.5	± 0.6
Haemoglobin level (g/dL)	10.7	± 1.7	9.3	± 1.7
Total white blood cell count (× 10^9/L)	13.4	± 3.1	18.4	± 4.3
Erythrocyte sedimentation rate (mm/hr)	68.9	± 25.8	84.8	± 21.0
C-reactive protein level (mg/dL)	35.8	± 36.2	105.5	± 23.4
Glycated haemoglobin level (%)	8.0	± 1.4	8.1	± 0.4
Urea level (mmol/L)	8.4	± 2.8	14.7	± 4.3
Creatinine level (mmol/L)	111.2	± 36.2	231.9	± 104.5
Albumin level (g/L)	35.3	± 5.7	23.2	± 4.4
Positive bacterial culture*	88 (80.7)		21 (19.3)	
Negative bacterial culture*	99 (90.8)		10 (9.2)	

Discussion & Conclusion

The rate of major lower limb amputations for diabetic foot problems in the present study (14.2%) is lower than the ratesreported by other studies.These differences in the rates of major lower limb amputation could be due to poor acceptance of amputations as a means of diabetic foot management among our study population. In the present study, duration of T2DM of ≥ 10 years was found to be a significant independent predictive factor for major lower limb amputation and age was not found to be a significant predictive factor for major lower limb amputation. While neuropathy was found to be associated with major lower limb amputation in the present study, it was not a significant independent predictive factor. Necrotising fasciitis was found to be associated with major lower limb amputation, following stepwise logistic regression, only a positive bacterial culture result was

found to be a significant independent predictive factor for major lower limb amputation. Abscess, osteomyelitis, ulcers and cellulitis were not significant factors for major lower limb amputation, suggesting that they could be treated with minor limb amputation. In the present study, total white blood cell count, ESR and Albumin were dependent factors for major lower limb amputation. While major lower limb amputation was not significantly associated with peripheral vascular disease. It was significantly associated with gangrene at presentation anddiabetic foot conditions. Albumin level was found to be an independent predictive factor for major lower limb amputation. Nephropathy and high levels of urea and creatinine were also found to be associated with major lower limb amputation. A low albumin level indicates poor nutritional and renal function. Low albumin levels were also found to be associated with poor wound healing after Syme amputations, leading to major lower limb amputation in patients with DM. In conclusion, the present study showed that a duration of T2DM ≥ 10 years, positive bacterial culture and low serum albumin levels were predictors for major lower limb amputation in patients admitted with diabetic foot problems. Hence, we recommend early aggressive treatment for infections in patients with a long history of T2DM who are admitted for diabetic foot problems, without neglecting their clinical management and nutritional support.

Conflict of Interest

None

Source of Funding

None

References

1. Sargen MR, Hoffstad O, Margolis DJ. Geographic variation in Medicare spending and mortality for dia-betic patients with foot ulcers and amputations. J Diabetes Complicat. 2013; 27: 128–133. doi: 10. 1016/ j.jdiacomp.2012.09.003PMID: 23062327.
2. Gordois A, Scuffham P, Shearer A, Oglesby A, Tobian JA. The health care costs of diabetic peripheral neuropathy in the US. Diabetes Care. 2003; 26: 1790–1795. PMID: 12766111.
3. Gordois A, Scuffham P, Shearer A, Oglesby A. The healthcare costs of diabetic peripheral neuropathy in the UK. The Diabetic Foot. 2003; 6: 62–73.
4. Katsilambros N, Tentolouris N, Tsapogas P, Dounis E. Atlas of Diabetic Foot. Chichester, UK: Wiley-Blackwell; 2003.
5. International Working Group on the Diabetic Foot. Epidemiology of Diabetic Foot Infections in a Popula-tion Based Cohort. Noordwijkerhout, The Netherlands; 2003.
6. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJM. Diabetic foot syndrome: evaluat-ing the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. Diabetes Care. 2003; 26: 1435–1438. PMID: 12716801.
7. Boulton AJM, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. Lancet. 2005; 366: 1719–1724. doi: 10.1016/S0140-6736(05)67698-2 PMID: 16291066.
8. Krishnan S, Nash F, Baker N, Fowler D, Rayman G. Reduction in diabetic amputations over 11 years in a defined U.K. population: benefits of multi-disciplinary team work and continuous prospective audit. Di-abetes Care. 2008; 31: 99–101. doi: 10.2337/ dc07-1178 PMID: 17934144.
9. Carstensen B, Kristensen JK, Ottosen P, Borch-Johnsen K, Steering Group of the National Diabetes Register. The Danish National Diabetes Register: trends in incidence, prevalence and mortality. Diabetologia. 2008; 51: 2187–2196. doi: 10.1007/s00125-008-1156-z PMID: 18815769.
10. Gudbjörnsdottir S, Cederholm J, Nilsson PM, Eliasson B, Steering Committee of the Swedish National Diabetes Register. The National Diabetes Register in Sweden: an implementation of the St. Vincent Declaration for Quality Improvement in Diabetes Care. Diabetes Care. 2003; 26: 1270–1276. PMID: 12663609.