

## PRESENTATION AND OUTCOME OF DIABETIC FOOT AT A TERTIARY CARE UNIT

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### ABSTRACT

**Objectives:** The prevalence of lower extremity amputation (LEA) is high in Pakistan, but the underlying risk factors remain to be defined. The purpose of this study was to define the presentation and risk factors determining outcome of diabetic foot ulceration leading to LEA in a tertiary care hospital in Karachi, Pakistan.

**Methodology:** We have characterized the presenting features, grade of foot ulceration and risk factors for ulceration and LEA in 214 diabetic patients presenting with foot ulceration between January 1997 and December 2003 to a tertiary care unit in Karachi, Pakistan.

**Results:** Seventeen (7.9%) patients had grade one, one hundred thirty three (62.1%) grade two and sixty four (29.9%) grade three ulceration. One hundred fifty five (72.43%) patients completely healed without LEA, while fifty nine (27.5%) patients underwent LEA. The risk of LEA was significantly associated with the grade of ulceration at presentation ( $p$  value=0.001), increasing age, and UT staging. Females presenting with foot ulceration had a higher BMI ( $P=0.0001$ ), systolic ( $P=0.002$ ) and diastolic ( $P=0.03$ ) blood pressure and total cholesterol ( $P=0.03$ ).

**Conclusion:** The outcome of ulceration was determined by the severity and grade of foot ulceration at presentation. Despite a significant proportion of patients having an underlying neuroischaemic aetiology for foot ulceration, the majority healed. There was significant gender difference for risk factors for neuropathic ulceration.

**KEY WORDS:** Diabetic foot, Lower Extremity Amputation (LEA).

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### INTRODUCTION

Diabetic foot ulceration may affect approximately 15% of patients with diabetes and is the most common precursor of lower limb amputation.<sup>1-5</sup> The outcome of diabetic foot ulceration is closely related to the severity of disease at presentation.<sup>2</sup> Common risk factors for amputation following ulceration include the presence of peripheral vascular disease, severity of neuropathy, structural foot deformity and concomitant infection.<sup>6,7</sup> Lower Extremity Amputation (LEA) occurs 10-30 times more frequently in diabetic patients compared to non diabetic patients<sup>8</sup> and 70% of lower limb amputations occur in people with diabetes,

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85% of which follow foot ulceration.<sup>8-11</sup> The incidence of lower extremity amputation is 25.8/1000/ year in diabetic patients compared to 1.1/1000/year in non-diabetic patients.<sup>12,13</sup> The prevalence of LEA however varies greatly across the world.<sup>5,12-15</sup> In the USA a lower extremity amputation occurs at a rate of 8.6/1000 (0.86%) diabetic subjects per year.<sup>16</sup> However, in Pakistan despite a comparable prevalence of diabetic foot ulceration,<sup>17</sup> the amputation rate was 21%<sup>17</sup> but has also been reported to be as high as 48%.<sup>18</sup> Many factors have been suggested to contribute to this unacceptably high rate of LEA and include lack of diabetes education, unhygienic conditions, poor social status and late referral to secondary and tertiary care.<sup>19</sup> We are not aware of any studies which have systematically analyzed factors contributing to LEA in Pakistan. The purpose of this study was to define the presentation and risk factors determining outcome of diabetic foot ulceration leading to LEA in a tertiary care hospital in Karachi, Pakistan.

## METHODOLOGY

All diabetic patients with foot ulceration attending the Baqai Institute of Diabetology and Endocrinology (a tertiary care center) from January 1997 to December 2003 were included in the study. Patients lost to follow up or who were unable to complete the treatment were excluded. The diabetic foot clinic is run by a consultant diabetologists, associate diabetologists trained especially in the diabetic foot, a surgeon with an interest in the diabetic foot, chiropodist and an orthotist.

Age, sex, type/duration of diabetes, cause of ulceration, duration of ulcer, previous history of ulceration, presenting signs & symptoms of ulceration and previous treatment and socio-economic status were recorded on the first visit. Proteinuria was detected by using the combur 10 test strip & was confirmed by using the micral test (for microalbuminuria) or 24 hours urinary protein estimation. Glycaemic control was assessed by measuring glycosylated haemoglobin (HbA1c) and a HbA1c <6.5% was regarded as good glycaemic control, 6.6-7.5%

fair control and >7.5% poor. Where HbA1c was not available, glycaemic control was assessed on the basis of the fasting (FPG) & random (RPG) plasma glucose levels (F.P.G <120mg/dl good, 121-140 mg/dl, fair and >140mg/dl, poor. For RPG values <160mg/dl, good, 160-180mg/dl, fair >180mg/dl, poor.<sup>17</sup> Each patient underwent assessment of the vascular status by manual palpation of femoral, popliteal, dorsalis pedis and posterior tibial arteries to define patency and grade: (a) good volume (b) diminished volume or (c) absent. Neuropathy was quantified assessing vibration sensation using a 128 HTZ tuning fork and a 10g monofilament applied perpendicularly to the plantar aspect of the first toe, the first, third and fifth metatarsal heads, the plantar surface of the heel and dorsum of the foot<sup>14</sup> avoiding any callus, corn or wound site and graded as normal, diminished or absent.<sup>7</sup> Ankle and knee reflexes were assessed as normal reinforced or absent. Osteomyelitis was determined by probing to bone and radiological examination. The University of Texas Classification System was used to classify the severity of ulceration at presentation. All foot ulcers were photographed at the initial presentation and at each stage of review through the study. Outcomes were recorded as: No amputation or LEA defined as loss of any part of the lower limb as major if proximal to tarso-metatarsal joint and minor if distal to this joint.<sup>20,21</sup>

*Statistical Analysis:* The data was analyzed using SPSS version 10.0. The independent sample T test was used to assess the gender differences between various physical and biochemical parameters. Chi square and Exact Fisher tests were used to assess the association between different variables. Odds ratios and 95% confidence interval (CI) were reported for independent variables associated with each outcome variable. Independent variables having p-value <0.05 were used in a multivariate model. Multivariate analysis was done by using logistic regression analysis. Adjusted odds ratios with 95% confidence interval were reported for each factor associated with the outcome variable.

Table-I: Mean and standard deviation of physical and biochemical parameters by gender.

Parameters	Male Mean $\pm$ SD (n=136)	Female Mean $\pm$ SD (n=76)	P value
Age (years)	53.64 $\pm$ 10.38	51.29 $\pm$ 9.77	0.108
Body Mass Index (kg/m <sup>2</sup> )	25.01 $\pm$ 4.41	28.48 $\pm$ 5.44	0.000
Duration of diabetes (years)	16.26 $\pm$ 6.91	16.30 $\pm$ 6.65	0.963
Systolic Blood Pressure (mmHg)	128.39 $\pm$ 20.84	138.14 $\pm$ 23.24	0.002
Diastolic Blood Pressure (mmHg)	78.86 $\pm$ 10.94	82.47 $\pm$ 12.80	0.032
Serum Creatinine (mg/dl)	1.17 $\pm$ 0.38	1.09 $\pm$ 0.59	0.220
Fasting plasma glucose (mg/dl)	193.42 $\pm$ 86.43	182.18 $\pm$ 76.65	0.409
Random plasma glucose (mg/dl)	247.08 $\pm$ 86.63	234.18 $\pm$ 78.87	0.314
HbA1c (%)	10.13 $\pm$ 2.67	9.77 $\pm$ 2.47	0.451
Serum Cholesterol (mg/dl)	183.67 $\pm$ 38.36	198.65 $\pm$ 42.34	0.034
Serum Triglycerides (mg/dl)	145.55 $\pm$ 80.07	168.15 $\pm$ 73.52	0.099
Serum LDL (mg/dl)	116.01 $\pm$ 34.39	123.76 $\pm$ 34.00	0.241
Serum HDL (mg/dl)	39.18 $\pm$ 7.70	39.28 $\pm$ 7.46	0.942

## RESULTS

Two hundred fourteen patients were studied 63.5% (n=136) were males and the average duration of diabetes was 16.27 $\pm$ 6.80 years. All physical and biochemical parameters are shown in Table-I. Most of the subjects had poor glycaemic control at presentation with a mean HbA1c of 10.03 $\pm$ 2.69. Six (2.8%) patients died due to cardiovascular events. Gender differences existed for patients presenting with foot ulceration. Females had a higher BMI (P=0.0001), systolic (P=0.002) and diastolic

(P=0.03) blood pressure and total cholesterol (P=0.03).

In accordance with the UT grading system seventeen (7.9%) patients were classified as grade one, one hundred thirty three (62.1%) as grade two and sixty four (29.9%) as grade three ulceration. Regarding type of foot ulcer 44% had neuropathic ulcer while 55.6% patients had non-ischaemic ulceration and <1% patient had pure ischaemic ulceration. Ulcers healed completely in 155 (72.43%) of patients and 59 (27.5%) underwent LEA. Table-II shows

Table-II: Foot ulcers and amputations according to University of Texas grades and stages\*

Grade 1	Stages	Superficial wound not involving tendon, capsule or bone					P-value
		No. of Patients (n)	No. amputation	(%)	Amputation (%)		
None	Stage A	1	1	100.0	0	0	0.001
Infection	Stage B	9	8	88.8	1	11.1	
Ischemia	Stage C	1	1	100.0	0	0	
Both	Stage D	6	5	83.3	1	16.6	
Grade 2		Wound penetrating to tendon					0.001
None	Stage A	0	0	0	0	0	
Infection	Stage B	60	52	86.6	8	13.3	
Ischemia	Stage C	1	0	0	1	100.0	
Both	Stage D	72	54	75.0	18	25.0	
Grade 3		Wound penetrating to bone or joint					0.001
None	Stage A	0	0	0	0	0	
Infection	Stage B	21	15	71.4	6	28.5	
Ischemia	Stage C	1	0	0	1	100.0	
Both	Stage D	42	19	45.2	23	54.7	

\*Lavery LA, Armstrong DG, Harkless LB. Classification of diabetic foot wounds. Journal of Foot Ankle Surgery 1996;35:528-31.

Table-III: Outcome of patients (n=214)

Outcome	n= 214 (%)
No LEA	155(72.43)
Toe amputation	35(16.35)
Transmetatarsal amputation	2 (0.93)
Below knee amputation	13(6.07)
Above knee amputation	9(4.20)

there is a significant increase in the amputation rate from grade one to grade three (P =0.001) with the majority of amputations being performed in patients with grade three ulceration (50.8%) followed by 45.7% in grade two and only 3.3% in grade one. There was a

significant increase in LEA in stage D as compared to stage A of UT ulceration severity for grade one, grade two and grade three ulceration (P=0.001). Table-III shows the distribution of the site of amputation. Most of the patients underwent toe amputations (n=35, 16.3%).

Table-IV shows univariate factors associated with LEA for diabetic foot ulceration include age, gender and history of foot ulceration, hospital admission, and grade of ulcer. In the multivariate logistic regression model increasing age, hospital admission and higher UT

Table-IV: Univariate analysis of the factors associated with LEA

Variables	No LEA(n=155) n(%)	LEA(n=59) n(%)	Odds Ratio (95% Confidence Interval)
Age (years)*	51.69±10.0	55.81±10.20	1.04(1.01-1.08)
Gender			
Female	62 (28.97)	16 (7.47)	1.79(0.9281-3.46)
Male	93 (43.45)	43 (20.09)	
Duration of Diabetes (years)			
<10	30 (14.21)	10 (4.73)	
10-15	44 (20.85)	10 (4.73)	0.68(0.25 -1.84)
16-20	47 (22.27)	14 (6.63)	0.89(0.35 -2.27)
>20	34 (16.11)	22 (10.42)	1.94(0.79 - 4.75)
LDL (mg/dl)			
<130	58 (50.87)	21 (18.42)	
≥130	25 (21.92)	10 (8.77)	1.11(0.46-2.68)
Fasting Blood Sugar (mg/dl)			
<126	37 (22.83)	9 (5.55)	
≥126	84 (51.85)	32 (19.75)	1.57(0.68-3.61)
Random Blood Sugar (mg/dl)			
<200	47 (25)	18 (9.57)	
≥200	91 (48.40)	32 (17.02)	0.92(0.47- 1.81)
HBA1c (%)			
≤7.5	17 (12.59)	4 (2.96)	
>7.5	80 (59.25)	34 (25.18)	1.80(0.56-5.76)
HTN			
No	57 (27.27)	21 (10.04)	
Yes	95 (45.45)	36 (17.22)	1.03 (0.55- 1.93)
Protienurea			
No	147 (69.33)	50 (23.58)	
Yes	8 (3.77)	7 (3.30)	2.57(0.88 – 7.45)
History of foot ulcer			
No	87 (42.43)	21(10.24)	
Yes	64 (31.21)	33 (16.09)	2.14(1.13 – 4.03)
Hospital Admission			
No	76 (35.84)	8 (3.77)	
Yes	79 (37.26)	49 (23.11)	5.89(2.62-13.26)
Type of Ulcer			
Neuropathic	77 (37.74)	16 (7.84)	
Neuro-ischemic/ischemic	75 (36.76)	36 (17.64)	2.31(1.18 – 4.51)

\*Mean ±SD was reported

Table-V: Multivariate model for factors associated with amputation in those with diabetic foot ulceration.

Factor	Adjusted Odds ratio	95% Confidence Interval
Age	1.04	1.01-1.07
Hospital Admission		
No		
Yes	5.89	2.57 -13.49
UT Stage		
Stage B		
Stage C&D	2.35	1.15 – 4.79

staging were independently associated with amputation (Table-V). For each one year increase in age the odds of amputation increased by 1.04 (95% CI for AOR: 1.01 - 1.07). The odds of hospital admission among amputees were 5.9 times as compared to non amputees (95% CI for AOR: 2.57 – 13.49). The odds of patients being classified in the higher UT stage amongst those who had amputations were 2.35 times as compared to those who had no amputation (95% CI for AOR: 1.15 – 4.79). The goodness of fit demonstrated good fit (p value =0.56).

## DISCUSSION

Diabetic foot ulceration is the most frequent cause of hospitalization among diabetic patients.<sup>22</sup> LEA, is the most feared and costly consequence of foot ulceration.<sup>15,23</sup> In this study the majority of patients presented at an advanced stage of foot ulceration with a resultant high amputation rate in agreement with several other studies.<sup>2,15</sup> Furthermore, male subjects had a greater chance of undergoing LEA than female subjects as shown in other studies.<sup>2,24</sup> Patients with neuropathy and ischemia were more likely to undergo LEA but neuropathy alone was not independently associated with LEA, as shown in a number of other studies.<sup>5,10,14,21</sup> Multivariate logistic regression analysis showed that beside age, hospital admission was independently associated with LEA. Clearly this is related to more advanced grade and stage of ulceration requiring hospitalization for intravenous antibiotics and surgical intervention leading to LEA.

The majority of patients presented with advanced stage and grade of ulceration

reflecting a lack of structure in the health care delivery system of Pakistan between primary, secondary and tertiary care units. Attempted home surgery, trust in faith healers and undetected diabetes further aggravates the problems.<sup>25</sup> Moreover inadequate antibiotic treatment and the use of non sterile instruments for dressing results in the growth of multi resistant organisms necessitating hospital admission and surgical intervention.<sup>26</sup> These poor outcomes also reflect the low priority in terms of health spending with the average monthly household expenditure being Rs. 8965 (US\$ 149.41) of which only Rs. 260 (2.9%) (US\$ 4.33) is spent on health.<sup>27</sup> The same is reported in an analysis for eight countries where 2% to 5% of the total household expenditure is spent on health but the amount for expenditure is much higher.<sup>28</sup>

We do not find an association between LEA and poor glycaemic control as shown in a study where patients with neuropathy underwent LEA independent of poor glucose control.<sup>15</sup> It also reflects the fact that all these patients had poor glycaemic control. The current study confirms a high amputation rate as a consequence of diabetic foot ulceration in Pakistan.<sup>17,18</sup> The major deficiency in this study is that it is not population based and represents patients referred to a tertiary care centre. However, it has the advantage of accurate characterization of the stage and severity of foot ulceration with a high follow up rate. Earlier presentation with aggressive and appropriate medical and surgical treatment according to the severity of ulceration can improve morbidity and mortality.<sup>18</sup> This can be achieved by educating health care professionals and patients<sup>5,10,12</sup> through education programs and instituting comprehensive multi disciplinary foot care programs.<sup>12,15,29</sup> At the patient level effective foot care advice should be propagated to reduce the burden imposed by diabetic foot complication, particularly in developing countries.<sup>30,31</sup>

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