

Clinical Profile and Management Outcome of Diabetic Foot Ulcers in a Tertiary Care Hospital

Khalid Mahmood, S. Tehseen Akhtar, Abu Talib, Badar Abbasi, Siraj-ul-Salekeen and Iftikhar Haider Naqvi

ABSTRACT

Objective: To determine major risk factors and management outcome of diabetic foot ulcers in order to prevent amputation.

Study Design: Cross-sectional descriptive study.

Place and Duration of Study: Study was conducted at the Department of Medicine, Civil Hospital Karachi, from January 2005 to December 2006.

Patients and Methods: One-hundred and sixteen consecutive diabetic patients, with foot ulcers of Wagner's grade 1 to 4 were assessed at baseline for demographic information, detailed history, neuropathy, peripheral pulses and frequency of diabetic complication. Glycemic control was determined on the basis of HbA1c levels. Appropriate medical and surgical treatments were carried out and patients were followed-up until healing or for 6 months as end point of study. Outcome was recorded as healed, incomplete healing and amputated.

Results: A majority of subjects had type 2 diabetes (95.7%) with male predominance (66%). The mean age was 54.29 ± 7.71 years. Most of the patients were overweight, hyperglycemic and had diabetes > 10 years duration. Neuropathic ulcers were found in 91 (78.4%) patients, while rest of the 25 (22.6%) had neuroischemic ulcers. Wound cultures revealed polymicrobial organisms. Foot ulcers of 89 (77.7%) patients healed without amputation and 17 (14.7%) patients had minor or major amputations. Long-duration of diabetes, poor glycemic control and type of foot ulcers had effect on prognosis ($p < 0.05$).

Conclusion: Effective glycemic control, optimal wound care, aggressive medical management and timely surgical intervention may decrease disabling morbidity with better outcome of diabetic foot ulcer.

Key words: Diabetic foot ulcers. Risk factors. Foot care protocol. Amputation.

INTRODUCTION

Diabetic foot ulcer, a major problem that can impair the quality of life, require prolong hospitalization and entails high cost to the patient. Diabetic foot disease affects about 15% of diabetic patients.¹ People with diabetes are 15 times more likely to undergo a lower-extremity amputation than their non-diabetic counterparts.²

In Pakistan, with an approximate population of 160 million, incidence of foot ulcer is 10% as per studies done by Basit *et al.*³ The prevalence of diabetes in Pakistan in the age group 20-79 years is 6.2 million,⁴ which indicates that over 11% of the adult population is suffering from DM. A similar proportion of the population has Impaired Glucose Tolerance (IGT) test,⁵ which is expected to rise more rapidly in the future. Therefore, the magnitude of diabetic foot ulcers is enormous in Pakistan. In order to control this problem, risk factors of diabetic foot disease should be addressed. The risk of

foot ulcers or amputations is increased in people who have had diabetes for more than 10 years, are male; have poor glycemic control, or have cardiovascular, retinal, or renal complications.⁶ Foot related risk conditions are: peripheral neuropathy, peripheral vascular disease, history of ulcer or amputation, bony deformity and severe nail pathology.⁶ In subcontinent, diabetic foot disease is exacerbated by sociocultural factors such as the habit of walking bare foot, lack of knowledge regarding diabetic foot complications and socio-economic status of patients.⁷

The diabetic foot clinics exist in very few hospitals. Furthermore, foot-care protocol is not followed. There is a need to establish diabetic foot clinics in public sector hospitals that would follow the footcare protocol properly for early identification and treatment of diabetic foot ulcers and provide standard foot care by a multidisciplinary team to prevent amputation.

The objective of this study was to determine the risk factors associated with diabetic foot ulcer, its early diagnosis and prompt treatment to prevent amputation.

PATIENTS AND METHODS

This was a cross-sectional descriptive study conducted at Diabetic Clinic and Department of Medicine at Civil

Department of Medicine, Dow University of Health Sciences and Civil Hospital, Karachi.

Correspondence: Dr. S. Tehseen Akhtar, R-26, Sector Z-II, Gulshan-e-Maymar, Karachi.

E-mail: drstakhtar@yahoo.com

Received November 12, 2007; accepted April 25, 2008.

Hospital, Karachi, from January 2005 to December 2006. All consecutive adults diagnosed with type 1 and type 2 diabetes (according to WHO criteria) with diabetic foot ulcers of Wagner's⁸ grade 1 to grade 4 were included in this study after taking informed consent. A foot ulcer was defined as a full thickness skin break corresponding to at least Wagner's stage⁸ located distal to the malleoli's. Patients with previous major amputations due to diabetic foot disease and Wagner's grade 5 diabetic foot ulcer i.e. gangrene of whole foot, were excluded from the study because of a predictable outcome.

At baseline, detailed history was taken from each patient to obtain information regarding general biodata of patients, type and duration of diabetes, previous control and treatment, history of foot disease and awareness about its care, history of complications of diabetes and other comorbid illnesses. General and physical examinations, along with the detailed examination of the involved foot to determine the nature of lesion, sensory and motor system, vascularity of the limb were recorded on a pre-designed proforma.

Peripheral neuropathy was assessed using the modified neuropathy disability score⁹ derived from inability to detect pinprick sensation, vibration sensation (using 128 Hz tuning fork) and difference in temperature sensation (using warm and cold rods) plus Achilles reflex (using tendon hammer). For each foot, sensory test scored 0 for normal sensation and 1 for abnormal sensation; ankle reflex scored 0 if present, 1 if elicitable on reinforcement or 2 if absent. The maximum score was 10 for both feet. A score of ≥ 6 indicated moderate to severe neuropathy.

A six-point foot deformity score assessed small muscle wasting, hammer or claw toes, bony prominences, prominent metatarsal heads, charcot arthropathy, and limited joint mobility; an overall score of ≥ 3 indicated significant foot deformity.²

Femoral, popliteal, dorsalis pedis and posterior tibial pulses on both sides were palpated to assess peripheral arterial status. Presence of 2 or fewer of the 4 pedal pulses either with or without the presence of edema indicated peripheral arterial disease, which was further assessed by Ankle-Brachial Index and values < 1.0 were considered peripheral vascular disease. Fundal changes were assessed for retinopathies after dilating the pupil with 1% mydriacil (Tropicamide 1%) and examined by the physician using Keeler fundoscope (vista 20). Retinopathy was taken as positive if there was evidence of microdots, hard exudates, soft exudates, new vessels or maculopathy. Microalbuminuria was detected by using semiquantitative dry immunochemical screening strips. Microalbuminuria was defined as an urinary albumin > 30 mg/day. Test was repeated if required to exclude false positives.

Presence of associated hypertension was noted, if the patients was on anti-hypertensive treatment or had blood pressure $>135/85$ (mean of two readings while sitting, at 5 minutes interval). Ischemic heart disease was considered positive if the patients had previous history or positive symptoms or ECG findings like ST segment depression or T-wave inversion.

For diagnosis of infection tissue specimens from ulcers, after wound debridement, were cultured using optimal aerobic and anaerobic microbiologic techniques. Other investigations including complete blood count, fasting and random blood sugar, glycosylated hemoglobin (HbA1c), renal function test and radiograph of foot were recorded.

Patients were managed according to the recommended protocol by International Diabetic Federation. Both medical and surgical methods of treatment were used in collaboration with orthopedic department. Optimal wound care like proper wound cleansing, debridement of callus and necrotic tissues, aseptic wound dressing and pressure off-loading devices, where indicated, were used. Proper insulin dosage was used for optimal blood glucose levels. Appropriate antibiotic regimens were used according to tissue C/S reports. Patients were followed-up for 6 months as endpoint of study. Ulcer healing was defined as a total closure of the skin with a normal appearance of the skin without callus. The date at which this stage was reached was used as an endpoint. Healing time was expressed in days. The disease outcome in each patient was determined in terms of healed, incomplete healing and amputation.

Data were analyzed on statistical software package SPSS version 13. Continuous variables were expressed as mean \pm SD and analyzed with t-test. Discrete variables were expressed as percentages and analyzed by Chi-square test. A p-value < 0.05 was considered as statistically significant.

RESULTS

A total of 116 consecutive diabetic patients with foot ulcers were studied. Male were predominant (66%) with male to female ratio 2:1. Most of the patients belonged to 5th decade of life with a mean age of 54.29 ± 7.71 years (ranging 29-71 years). The majority of subjects had type 2 diabetes (95.7%). Most of the patients were overweight with a mean body mass index 28.35 ± 2.93 (Table I). Seventy-seven (66.4%) patients had diabetes of more than 10 years duration with a mean duration of 12.29 ± 3.55 , and most of them had poor glycemic control with a mean HbA1c level of 9.6 ± 1.4 . Awareness about risk factors regarding foot care was lacking and only 35 (30.2%) patients were aware about foot care. There were 79 (68.1%) patients taking oral hypoglycemic agents, while 26 (22.4%) were on insulin and rest of the 11 (9.5%) were on a combined treatment.

Table I: Clinical characteristics of DFU (n = 116).

Characteristics	Number (%)	X ± SD
Gender		
Male	77 (66.4 %)	
Female	39 (33.6 %)	
Age		
		54.29 ± 7.71
Type of DM		
T1DM	5 (4.3 %)	
T2DM	111 (95.7 %)	
BMI		
		28.35 ± 2.93
Treatment of DM*		
OHA	79 (68.1 %)	
INSULIN	26 (22.4 %)	
COMBINED	11 (9.5 %)	
Awareness of foot care		
NO	81 (69.8 %)	
YES	35 (30.2 %)	
Duration of diabetes		
< 5 years	2 (1.7 %)	
5-10 years	37 (31.9 %)	
> 10 years	77 (66.4 %)	
H/O previous ulcer		
YES	43 (37.06 %)	
NO	73 (62.94 %)	
Glycemic control (HbA1c)*		
< 7%	1 (0.86 %)	
7-8%	10 (8.62 %)	
> 8%	105 (90.52 %)	
Type of DFU		
Neuropathic	91 (78.4 %)	
Ischemic	0	
Neuroischemic	25 (21.6 %)	
Duration of Healing (days)		
		80.5 ± 26.87

*At the time of admission, Key: DFU= Diabetic foot ulcer

Forty-three (37.1%) patients had history of previous ulcer. Ninety-one (78.4%) had neuropathic ulcers, while rest of the 25 (21.6%) had neuroischemic ulcers. There was no patient with Ischemic ulcer in this study. Sixty-seven (58.6%) patients had significant foot deformity and majority of them had hammer or claw toes and prominent metatarsal heads.

All diabetic foot ulcers were classified and grouped according to Wagner’s grading. The commonest among all in this study was grade 3 ulcers. Common sites of ulcers were toes and soles. The organisms isolated from the ulcers were mixed in nature. *Staph. aureus* was the commonest isolate being recovered in 71 (61.2%) patients. Other organisms predominantly isolated were *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Klebsella*, *E.coli*, and *Bacterioids fragilis*. Regarding complications, 98 (84.4%) patients had moderate to severe neuropathy, 67 (58.6%) nephropathy, 41 (35.3%) retinopathy, 25 (21.5%) peripheral vascular disease, 13 (11.2%) ischemic heart disease, and 53 (45.7%) hypertension. Foot ulcers of 89 (76.7%) patients healed without amputation with mean duration of 80.5 ± 26.87 days of healing. Seventeen (14.7%) patients had minor or major amputations, 5 (4.3%) patients were lost to follow-up, while in 4 (3.4%) patients, ulcers did not heal upto 6 months and one patient died due to septicemia. (Table II).

On comparison between healed and amputated patients, variables such as long duration of diabetes, poor glycemic control and type of foot ulcers were found to effect the outcome in terms of amputation (p <0.05). (Table III).

Table II: DFU outcome with reference to Wagner’s grading.

Wagner’s Grade	No of patient	Healed	Unhealed	Lost follow-up	Died	Minor amputation	Major amputation
1	3 (2.6%)	3	-	-	-	-	-
2	25 (21.6%)	23	1	1	-	-	-
3	62 (53.4%)	52	2	2	-	4	2
4	26 (22.5%)	11	1	2	1	6	5
Total	116	89 (76.72 %)	4 (3.45 %)	5 (4.3 %)	1 (0.86%)	10 (8.62%)	7 (6 %)

Table III: Relation of healed and amputated patients among variables.

Variable		Outcome		p - value	
		Healed (n = 89)	Amputation (n = 17)		
Age of patient (years)	Mean ± SD	53.7 + 7	56.9 + 10	0.112	
Gender	Male	56 (63%)	14 (82.4%)	0.121	
	Female	33 (37%)	3 (17.6%)		
Duration of DM (years)	Mean ± SD	11.8 + 3.5	14 + 3.1	0.018*	
BMI	Mean ± SD	28.4 + 3	28.2 + 3.1	0.844	
Glycemic control	Mean ± SD	9.3 + 1	11.3 + 2	< 0.001 *	
	Diabetes	Type 1	4 (4.5%)	1 (6%)	0.805
	Type 2	85 (95.5%)	16 (94%)		
Treatment of diabetes	OHA	61 (68.6%)	13 (76.5%)	0.514	
	INS	18 (20.2%)	4 (23.5%)	0.758	
	COMB	10(11.2%)	0	0.146	
Awareness of foot care	Yes	27 (30.3%)	4 (23.5%)	0.572	
	No	62 (69.7%)	13 (76.5%)		
Type of DFU	Neuropathic	75 (84.3%)	8 (47%)	0.002*	
	Neuroischemic	14(15.7%)	9 (53%)		
Wagner’s classification	1	3 (3.4%)	0	0.443	
	2	24 (27%)	0	0.015*	
	3	47 (52.8%)	6 (35.3%)	0.186	
	4	15 (16.8%)	11 (64.7%)	< 0.001 *	

Key: OHA=Oral Hypoglycemic Agent, INS=Insulin, COMB= Combination of OHA and Insulin.

DISCUSSION

This study shows that poor glycemic control, long duration of diabetes, unawareness regarding foot care, micro and macro vascular complications are risk factors for foot ulcers, but adherence to foot care advice and prompt optimum treatment reduces the overall rate of amputations.¹⁰

In this study, males were predominant simulating to several other studies.¹¹⁻¹⁷ There is increased prevalence of diabetic foot ulceration in males ¹⁰⁻¹³ and male gender is associated with 1.6 times increased risk of ulcers and 2.8 - 6.5-fold high risk of amputation.¹⁰

Poor glycemic control and long duration of diabetes were significant risk factors in relation to foot ulceration. One-hundred and five (90.52%) patients had HbA1c level > 8% and 77 patients had diabetes of > 10 years duration. This has been shown in other studies as well.^{6,10,12} Poor glycemic control and over 10 years history of diabetes are significant risk factors for foot ulceration.¹² The risk of amputation increases 2 - 4 folds with both age and duration of diabetes.¹⁰

Furthermore, poor glycemic control and high HbA1c levels are associated with an increased incidence and progression of diabetic complications.^{18,19} In this study, 67 patients had significant foot deformity. Several studies,²⁰⁻²² have reported that foot deformities are important contributory risk factors by predisposing skin to high pressure at the site of the foot deformity. Ninety-eight (84.4%) patients of this cohort had peripheral neuropathy similar to studies by Pecoraro,²³ Edmonds,²⁴ and Boulton.²⁵ Neuropathy predisposes to unrecognized injury due to loss of sensations. It is, therefore, important that physician must have thorough foot examination of patients on every visit and educate patients regarding preventive measures of foot care.

Ninety-one (78.4%) of patients had neuropathic ulcers and 25 (21.6%) had neuroischemic ulcers. No pure ischemic ulcer was seen during this study. This fact is supported by other studies.^{7,10,15} This finding still needs further evaluation of vasculopathy through Doppler and Angiography, which were beyond the scope of this study.

Sixty-seven patients in this study had nephropathy while 41 had retinopathy. Other studies have shown this association of foot disease with other micro and macro vascular complications of diabetes.^{6,10,15}

Forty-three patients had a past history of foot ulcerations. It is known that a previous history increases the risk for further lesions.^{6,10,12,15} Most of the patients had grade 3 ulcers similar to the study by Rooh-ul-Muqem,¹⁴ while Llanes¹⁷ and Balderas¹⁶ have reported grade 2/3 and grade 2 ulcers, respectively, in their studies.

In this study, wound culture revealed a mixed culture of gram (-ve) and gram (+ve) organisms and *Staph. aureus* was the commonest isolate being recovered in 67 (58%) patients almost similar to other studies.^{14,15} Other organisms predominantly isolated were *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Klebsiella*, *E.colli* and *Bacterioides fragilis*. In diabetic population, wound and foot have often mixed infection and may contain 3 - 6 organisms creating a significant problem regarding the choice of antibiotics,²⁶ so more detailed microbiological studies are required regarding the prevalence of diabetic foot infection in this region of the world.

Debridement of callus and necrotic tissue, incision and drainage of puss were the surgical interventions

instituted where indicated. Appropriate antibiotics therapy and effective blood sugar control with proper insulin dosage were the mainstay of medical treatment. Aseptic dressing of wounds and some pressure off-load methods were used where needed. Fifty percent of grade 4 lesions needed amputation while all grade 1 lesions healed with conservative management. The rate of amputations is low in this study because of exclusion of grade 5 ulcers. Seventeen patients had minor or major amputations and the rate of amputation was 14.7% while it was 21%, 48% and 30.5% in studies by Ali¹⁵, Rooh-ul-Muqem¹⁴ and Llanes¹⁷, respectively.

The present study shows that by adherence to foot care advice and intensive management by multidisciplinary diabetic foot team, overall healing rate has increased and the rate of amputations decreased. By adopting foot care management program, incidence of ulcers and amputations can be reduced by upto 44-85%.¹⁰

In an amputation prevention study by Patout *et al.*²⁷ conducted in an African-American population, intensive management of foot ulcerations resulted in a 79% decrease in incidence of lower-extremity amputation. In a longitudinal study of Chippewa Indians²⁸ it was shown that management of foot problem was effective in reducing lower-extremity amputation by 50%.

CONCLUSION

Lack of awareness, poor glycemic control, long duration of diabetes, and neuropathy were the main risk factors in the causation of diabetic foot ulcers. Effective glycemic control, optimal wound care, aggressive medical management and timely surgical intervention may decrease disabling morbidity with better outcome. This all need to develop a multidisciplinary team in all medical institutions for better care of diabetic foot disease.

We used Wagner's classification of diabetic foot ulcer instead of detailed classification because of its simplicity so that adequate population based powered prospective studies with detailed classification like Van Acker/Peter or University of Texas system be undertaken to elucidate and validate systems for diabetic foot care in the region.

Acknowledgement: The authors acknowledge the contribution of orthopedic department of this hospital for the study.

REFERENCES

1. Zafar A. Management of diabetic foot: two years experience. *J Ayub Med Coll* 2001; **13** (1):14-6.
2. Abbott CA, Carrington AL, Ashe H, Bath S, Every LC, Griffiths J, *et al.* The north-west diabetes foot care study: incidence of, and risk factor for new diabetic foot ulceration in community-based patient cohort. *Diabet Med* 2002; **19**: 377-84.

3. Basit A. Economic burden of diabetic foot at a tertiary care hospital of Karachi, Pakistan. Proceedings: Royal College of Physicians, London, Regional conference at FJMC Lahore. *Pulse Intern* 2006; **7**: 6.
4. International Diabetes Federation. Diabetes atlas. Executive summary. 2nd ed. Belgium *IDF*; 2003.
5. Heartfile. The gateway health indicators. Islamabad: Heartfile, the Statistics Division and the Ministry of Health, Government of Pakistan; 2006.
6. American Diabetes Association. Standard of medical care in diabetes - 2007. *Diabetes Care* 2007; **30** (Suppl 1):S4-41.
7. Vijay V, Snehalatha C, Ramachandran A. Sociocultural practice that may affect the development of the diabetic foot. *IDF Bull* 1997; **42**:10-2.
8. Wagner FW Jr. The dysvascular foot: a system for diagnosis and treatment. *Foot Ankle* 1981; **2**: 64-122.
9. Young MJ, Boulton AJ, MacLeod AF, Williams DR, Sonksen PH. A multicentre study of the prevalence of diabetic peripheral neuropathy in the United Kingdom hospital clinic population. *Diabetologia* 1993; **36**:150-4.
10. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. *Diabetes Care* 1998; **21**: 2161-77.
11. Boulton AJ. End-stage complications of diabetic neuropathy: foot ulceration. *Can J Neurol Sci* 1994; **21** (Suppl 4): S18-22.
12. Levin ME. Classification of diabetic foot wounds. *Diabetes Care* 1998; **21**:681.
13. Tan JS, Friedman NM, Hazelton-Miller C, Flanagan JP, File TM Jr. Can aggressive treatment of diabetic foot infections reduce the need for above ankle amputation? *Clin Infect Dis* 1996; **23**: 286-91.
14. Rooh-ul-Muqem, Ahmed M, Griffen S. Evaluation and management of diabetic foot according to Wagner's classification: a study of 100 cases. *J Ayub Med Coll* 2003; **15**: 39-42.
15. Ali S, Basit A, Sheikh T, Mumtaz S, Hydrie M. Diabetic foot ulcer- a prospective study. *J Pak Med Assoc* 2001; **51**:78-81.
16. Balderas JA, Oribio RU, Racho V, Lim-Abraham MA. Diabetic extremity management by a multidisciplinary care team: the Philippine General Hospital experience. *Philipp J Intern Med* 1999; **37**: 246-52.
17. Llanes LR, Peng AC, Cauton-Valera R. Clinical, microbiological profile and outcome of diabetic patients with foot ulcers admitted at the Quirino Memorial Medical Center 2000-May 2001. *Philipp J Microbial Infect Dis* 2001; **30**:101-7.
18. Intensive blood glucose with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS33). UK Prospective Diabetes Study (UKPDS) groups. *Lancet* 1998; **352**: 837-53.
19. Boehm BD, Home PD, Behrend C, Kamp NM, Lindholm A. Premixed insulin aspart 30 vs. premixed human insulin 30/70 twice daily: a randomized trial in type 1 type 2 diabetic patients. *Diabet Med* 2002; **19**:393-9.
20. Boyko EJ, Ahroni JH, Stensel V, Forsberg RC, Davignon DR, Smith DG. A prospective study of risk factors for diabetic foot ulcer. The Seattle diabetic foot study. *Diabetes Care* 1999; **22**: 1036-42.
21. Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, et al. Causal pathways for incident lower-extremity ulcers in patients with diabetes from two settings. *Diabetes Care* 1999; **22**:157-62.
22. de Sonnaville JJ, Colly LP, Wijkkel D, Heine RJ. The prevalence and determinants of foot ulceration in type II diabetic patients in a primary health care setting. *Diabetes Res Clin Pract* 1997; **35**: 149-56.
23. Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation. Basis for prevention. *Diabetes Care* 1990; **13**: 513-21.
24. Edmonds ME. Experience in a multidisciplinary diabetic foot clinic. In: Connor H, Boulton AJ, Ward JD, (edi). The foot in diabetes: proceedings of the First National Conference on the diabetic foot, Malvern, England, May 1986. Chichester, England: John Wiley; 1987: p. 121-34.
25. Boulton A. Lawrence lecture. The diabetic foot: neuropathic in aetiology? *Diabet Med* 1990; **7**:852-8.
26. Snyder RJ, Cohen MM, Sun C, Livingston J. Osteomyelitis in the diabetic patient: diagnosis and treatment. Part 2: medical, surgical, and alternative treatments. *Ostomy Wound Manage* 2001; **47** : 24-30, 32-41, quiz 42- 3.
27. Patout CA Jr, Birke JA, Horswell R, Williams D, Cerise FP. Effectiveness of a comprehensive diabetes lower-extremity amputation prevention program in a predominantly low-income African-American population. *Diabetes Care* 2000; **23**:1339-42.
28. Rith-Najarian S, Branchaud C, Beaulieu O, Gohdes D, Simonson G, Mazze R. Reducing lower-extremity amputations due to diabetes. Application of the staged diabetes management approach in a primary care setting. *J Fam Pract* 1998; **47**:127-32.

