International Journal of Research and Review
DOI: https://doi.org/10.52403/ijrr.20210629
Vol.8; Issue: 6; June 2021
Website: www.ijrrjournal.com
Original Research Article *E-ISSN: 2349-9788; P-ISSN: 2454-2237*

Clinical Profile of Patients with Diabetic Foot Ulcer Treated Conservatively or Surgically and Effect of Risk Factors on Ulcer Healing

Ved Prakash

Associate Professor, Department of Endocrinology, Indira Gandhi Institute of Medical Science, Patna, Bihar.

ABSTRACT

Objective: The aim of this study was to assess the clinical profile of patients with diabetic foot ulcer treated conservatively or surgically and effect of risk factors on ulcer healing.

Methods: This was a retrospective observational study conducted in tertiary medical teaching hospital where medical records of diabetic patients who were admitted with foot problem were evaluated. All diabetic patients who were aged >18 years and admitted with DFU were included in this study. A structured proforma was used to collect data from the medical record. SPSS version 20.0 was used to perform the statistical analysis.

Result: 280 subjects with diabetic foot ulcer (DFU) were evaluated in this study. 71% ulcers were healed where as 11% were persisted unhealed. Patients who were undergone for amputation 12% were minor (Foot only) and 4% were major (above the ankle). A statistically significant association between age, duration of diabetes, glycemic control peripheral neuropathy, and ulcer size were found with diabetic foot ulcer healing.

Conclusion: Modifiable factors like good glycemic control, early management of ulcers and early treatment of peripheral neuropathy can influence Diabetic foot ulcer outcomes. Special care should be provided to diabetic subjects who are aged and have longer duration of diabetes.

Keyword: Diabetic foot ulcers, ulcer severity, clinical profile, Wagner's Classification, outcome

INTRODUCTION

In India 4%-11.6% in urban and 2.4% in rural dwellers were affected with a common disease called diabetes [1]. Foot complications from simple calluses to major abscesses and osteomyelitis were developed in approximately 10%-25% of all diabetics subjects. As compare to non diabetic subjects had 40 times higher chance of leg amputation and 50% of the diabetic subjects who had 1st leg amputation were undergo second leg too within 5 years [2]. Heavy expenses, loss of productive time and often unbearable suffering pain are associated with diabetic foot ulcer (DFU) [3] and accompanying neuropathy further worsen the situation and can led to limb amputation [4].

In India poverty, poor sanitation, poor hygiene, lack of basic medical infrastructure, lack of knowledge regarding diabetic foot and habits like walking barefooted have further worsened the problem. In most of the diabetic care centre in India still diabetic foot care still used to avoid amputation thus from the very beginning the proper foot care and the awareness were generally missing which lead to increase in more frequent presentation of the cases in referring hospitals.

Thus despite a life threatening complication still foot care has received the same level of attention as other diabetes complications [5]. Still the initiation of current research clinical characteristic in foot ulcers among diabetic patients and its healing outcome were not properly studies in highly dense eastern Indian diabetic populations. The aim of this study was to

assess (1) the clinical profile of patients with diabetic foot ulcer treated conservatively or surgically and (2) effect of risk factors on ulcer healing and also for further improvement in diabetic foot management which may become a reference.

METHODS

Study design: This was a retrospective observational study conducted in tertiary medical teaching hospital where medical records of diabetic patients who were admitted with foot problem were evaluated. The study was conducted among patients who were admitted over a 3 years periods from January 2017 to December 2019 and were mostly referred from the rural hospitals. As this retrospective study evaluated de-identified data and involved no potential risk to patients, requirement to obtain written informed consent was waived off. Ethical clearance was obtained from the Institutional Review Board. For the sake of privacy and confidentiality no personal identifiers (names, address and any private information) was not collected. Data was anonyms and handled confidentially during all phases of research activities. This study was conducted in accordance with the Declaration of Helsinki.

Population: The final sample size of the population was calculated to be 280 considering 95% confidence level and a 4% margin of error and almost 13-15% prevalence of diabetic foot ulcer in India [6,7].

Eligibility Criteria: All diabetic patients who were aged >18 years and admitted with DFU were included in this study. Any patient clinically suspected with incidental ulcers, having Charcot foot and traumatic amputations were excluded along with gestational diabetic and patients who were seriously ill.

Treatment settings: All patients were individually monitored during their hospital stay regarding hypoglycemia and medical dose adjustment was done as per requirement and decoration of treating physician. When there were clinical signs of infection, antibiotic was instituted. Diabetic people who were presented with nontraumatic lesions of the skin on the foot distal to malleoli were considered as diabetic foot ulcer. For evaluation of ulcers, Wagner's classification for diabetic foot was used. At discharge when previously open wound were covered by continuous viable epithelial were defined as healed. In other hand incomplete re-epithelialization of the wound were defined as persisting unhealed. Amputations restricted to the foot were defined as minor amputation where as any other amputation took place above the levels of the ankle were defined as major amputation.

Data Analysis: A structured proforma was used to collect data from the medical record. SPSS version 20.0 was used to perform the statistical analysis. As counts and percentages, the data were reported, and the level of significance is set at $p < 0.05$. To test for correlations between variables, the χ^2 test and Fisher's exact test were used. Multiple logistic regression model were used to assess the effect of risk factors on ulcer healing.

RESULTS

Clinical and demographic features of the participating patients were summaries in table 1. 46.3 ± 16.4 years were the mean age of the patients and 96% were having type 2 diabetes and 61% of the population were either obese or overweight. 68% of the population were having long duration of diabetes (> 5 years of duration). Almost all patients were in medication. 39% of patients were also having co-morbid hypertension and peripheral neuropathies were documented with 63% patients. Different type of foot ulcers were observed at presentation among which in 120 (43%) patients it were pure neuropathic, 31(11%)

patients it were ischemic-type, while 84 (30%) it were neuro-ischemic origin.

Table 1: Basic characteristics of the participants

Variables	Category	N(%)
Sex	Male	171 (61%)
	Female	109 (39%)
Age	<30	32 (11%)
	30-50	140 (50%)
	>50	108 (39%)
BMI	Normal	110 (39%)
	Overweight	93 (33%)
	Obese	77 (28%)
Type of DM	Type 1	12 (4%)
	Type 2	268 (96%)
Duration of DM	<5 years	89 (32%)
	5 to 10 years	99 (35%)
	≥10 years	92 (33%)
HbA1c (%)	<7 (good control)	11 (4%)
	7.1–8% (fair control), *n* (%)	35 (12%)
	8.1–10% (poor control), *n* (%)	67 (24%)
	>10% (very poor control), *n* (%)	167 (60%)
Treatment of DM	Oral Antidiabetic	98 (35%)
	Insulin	104 (37%)
	Combined	76 (27%)
	No Treatment	2 (1%)
Comorbid hypertension	Yes	108 (39%)
	No	172 (61%)
Periphral Neuropathy	Present	176 (63%)
	Absent	104 (37%)
Type of ulcer	Pure neuropathic,	120 (43%)
	Pure ischemic,	31 (11%)
	Neuroischemic,	84 (30%)
	Non-classified,	45 (16%)
Ulcer Size	< 1 cm	132 (47%)
	1-5 cm	128 (46%)
	> 5 cm	20 (7%)

Distributions of foot lesion in accordance with Wagner grading system at presentation were summaries in table 2. In this retrospective study, it were observed that majority of patients were in grade 2 (38%) and grade 3 (22%).

Disarticulation (23%) and Debridement (21%) were the most common procedure to treat DFU in this study. Treatment modalities were summarise in table 3.

Table 2: Distribution of foot lesion in accordance with Wagner grading system at presentation.

Wagner grade	Signs	N (%)
0	No ulcer in a high-risk foot	0
1	Superficial ulcer involving the full skin thickness	51 (18%)
2	Deep ulcer penetrating to ligaments/muscle, but no bone involvement or abscess formation	106 (38%)
3	Deep ulcer with cellulitis or abscess formation, often with osteomyelitis	62 (22%)
4	Localized gangrene	40 (14%)
5	Extensive gangrene involving the whole foot	16 (6%)
Missing data not stated		5 (2%)
Total		280

Table 3: Treatment modalities in the present study.

Treatment Type	No of Patients (N%)
Conservative	46 (16%)
Debridement	60 (21%)
Disarticulation	63 (23%)
Fasciotomy	34 (12%)
Debridement + Fasciotomy	8 (3%)
Debridment + SSG	38 (14%)
I and D	16 (6%)
Minor Amputation	14 (5%)
Major Amputation	1 (0%)

Association between HbA1c and outcome of diabetic foot ulcers after discharge were summarises in table 4. Regarding the relation between DFU an HbA1c , patients who were achieved good glycemic control, i.e. HbA1c ≤ 7%, had a 100% healing rate (table 4). Whereas the healing rate was only 52% among subjects whose HbA1c were still in higher grade (i.e., >7%) and the difference were statistically significant (p=0.007)(table 4).

Table 4: Association between Age, duration of diabetes, HbA1c, peripheral neuropathy, ulcer size and outcome of diabetic foot ulcers after discharge.

Category	Age				Duration of Diabetes				HbA1c (%)			Peripheral Neuropathy			Ulcer Size			
	<30 (N= 32)	30-50 (N= 140)	>50 (N= 108)	P value	<5 years (N= 89)	5 to 10 years (N= 99)	≥10 years (N= 92)	P value	≤ 7 % (N-25)	> 7 % (N=255)	P value	Present (N= 176)	Absent (N=104)	P value	< 1 cm (N= 132)	1-5 cm (N= 128)	5 cm (N= 20)	P value
Healed	32 (10o%)	118 (84%)	50 (28%)	0.006	89 (100%)	83 (84%)	28 (30%)	0.0001	25 (100%)	175 (69%)	0.007	96 (54%)	104 (100%)		132 (100%)	68 (53%)	-	0.001
Persisting unhealed		14 (10%)	18 (17%)	0.06	-	11 (11%)	21 (23%)	0.001	-	32 (12%)	-	32 (18%)	-			32 (25%)	-	-
Minor amputation		8 (6%)	28 (26%)	0.008	-	2 (2%)	34 (37%)	0.02	-	36 (14%)	-	36 (20%)	-		-	28 (22%)	8 (40%)	0.02
Major amputation			12 (11%)	-	-	3 (3%)	9 (10%)	-	-	12 (5%)	-	12 (7%)	-		-	-	12 (60%)	-

After applying multiple logistic regression he univariate statistical significance was maintained and the same were summarises in table 5

Table 5: Multiple logistic regression model of the effect of risk factors on ulcer healing

Risk Factor	Odds ratio	95% CI	P Value
Age	1.01	0.98-1.02	0.19
Diabetes Mellitus duration	0.93	0.76-1.06	0.23
HbA1c	0.96	0.82-1.1	0.51
Peripheral neuropathy	1.13	0.82-1.48	0.62
Ulcer Size	1.00	0.83-1.21	0.94

DISCUSSION

Majority of the patients were having type 2 diabetes, and belongs to middle age group (50%). 37% of the patients were on insulin and 27% were on both oral and insulin combined treatment. High percentage of insulin was also correlated with heavy weight as 61% of the population were either obese or overweight. Similar high BMI were also noticed in few earlier studies among subjects who developed DFU [8]. It was already established by Klaphake et al [9] that amputation rate in diabetes subjects increase with age. Similarly in current study treatment outcome was poorest in >50 years age group.

For evaluation and management of diabetic foot ulcers best known method is consider as Wagner's classification mainly because of its simplicity in use. In current study 38% patients had Wagner classification grade II and occupied highest frequency. 42% of total subjects in current study were presented with higher Wagner classification grade (i.e., with grade 3,4 and 5) which clearly shows that subjects were presented at late stage with deep ulcer, with cellulitis or abscess formation, with osteomyelitis and even with frank gangrene of the foot. Thus the higher chance of sepsis may influence their poor treatment outcomes.

It has also documented that both Macrovascular and microvascular complications of diabetes are linked directly with duration of the disease [10]. In current observation 68% of the population were having long duration of diabetes (> 5 years of duration) at presentation. This findings were correlated with few previous studies [11,12], where healing was very limited and maximum patients were ended up with minor or major amputation.

The current finding demonstrated that participants who had uncontrolled blood sugar having lesser success rate in treating DFU. Thus degree of glycemic control not only acts as a major risk factor for developing DFU but also plays a major role for its treatment success rate. Similar findings also documented in few previous studies [13,14]. Current study clearly shows that progression of major complications like DFU can be controlled if patients achieve optimal plasma glucose level.

In similar to the current observation few earlier studies [15,16] also documented the strong relation of peripheral neuropathy with diabetic foot complications. If diabetic tic subjects were having peripheral neuropathy it further increase the duration of pressure and therefore produce repetitive trauma to the feet. Perhaps lack of awareness regarding foot care and presence of neuropathy were the the main cause of higher incidence of wound severity at presentation. As per few earlier studies the most common cause of foot ulceration were spontaneous blisters [17,18] and use of inadequate footwear [19-21]. In current study at presentation 43% had pure neuropathic ulcer, where as 30% were neuroischemic. Similar findings were also documented by Thewjitcharoen et al. [21] where they found that neuropathy was approximately 56.8% among diabetic subjects with diabetic foot ulcer and neuroischemic ulcers were present in another 29.3%.

Fife et al, [22] already demonstrate that ulcer size, wound age (duration in days), Wagner grade and number of concurrent wounds of any etiology please a crucial role for the wound healing of the patients. Even in current study 46% of the patients were having ulcer size of 1-5 cm and 75 were haven having ulcer of >5 cm.

Limitation of the study: Retrospective studies always have few limitations like review of medical records [23] and several missing variables. Apart of this hospital facilities or the physicians or surgeons decision may influence the treatment outcome. Single centre study was

another limitation which warned the necessity for multicenter study in future towards further clarity. Author suggest a further research to address the important issues like level of awareness regarding foot ulcer and patients attitude to use preventive measure like use of proper footwear.

CONCLUSION

Modifiable factors like good glycemic control, early management of ulcers and early treatment of peripheral neuropathy can influence Diabetic foot ulcer outcomes. Special care should be provided to diabetic subjects who are aged and have longer duration of diabetes. During follow-up of patients with a history of peripheral neuropathy and ulceration, physician should thoroughly emphasis to prevent further severity of diabetic foot ulcer. There is an urgent need that right from the beginning of diabetes detection health care professionals should prioritised proper patients education regarding awareness and preventive measures.

Acknowledgement: None

Conflict of Interest: None.

Source of Funding: No funding was received from any organization.

Ethical Approval: Approved

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How to cite this article: Prakash V. Clinical profile of patients with diabetic foot ulcer treated conservatively or surgically and effect of risk factors on ulcer healing. *International Journal of Research and Review*. 2021; 8(6): 238-244. DOI: *https://doi.org/10.52403/ijrr.20210629*

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