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Research Article

STUDY TO EVALUATE CLINICAL PROFILE AND OUTCOME OF PATIENTS IN DIABETIC FOOT IN A TEACHING HOSPITAL

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ABSTRACT

Objective: The objective is to investigate the clinical characteristics and results of individuals who present with diabetic foot infections (DFI).

Methods: This was a prospective study conducted in collaboration with the DFID Department of General Surgery at the Arundhati Institute of Medical Sciences and Hospital in Gandhimaisamma, Hyderabad, involving patients aged 20–80 years.

Results: There were 55 patients in the current investigation, with a mean age of 61.78±11.75 years and a preference for males (n=45, 81.8%) over girls (n=10, 18.2%). The study's largest number of patients (n=27, 49.1%) were observed in the 61–80 year age range. The average hemoglobin A1c (HBA1c) was 10.74±1.60 years, while the mean duration of diabetes mellitus was 10.87±2.681 years. Our patients' microbiological profiles revealed that 32.7% of them were Gram positive and 67.3% were Gram negative. Gram-negative bacillus *Escherichia coli* was the most often found bacterium in our investigation (67.3%), followed by *Pseudomonas* (29.1%), *Klebsiella* (18.2%), and *Staphylococcus aureus* (5.5%).

Conclusion: Since DFIs are the most prevalent consequence of diabetes mellitus that surgeons are notified about, managing them needs a multidisciplinary approach. It is crucial to do extensive, repeated examinations, as well as any required investigations to determine the infection severity at the time of presentation.

Keywords: Amputation, Diabetic foot infection, Diabetic foot ulcer, Diabetic foot.

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INTRODUCTION

Diabetic foot as defined by the World Health Organization is, "The foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes in the lower limb" [1,2].

With an estimated 109 million diabetics by 2035, India is poised to become the global center for diabetes [3]. India comes in second place (after China) with around 66.8 million people in the 20–70 age range suffering from diabetes. In India, 8.6% of people have diabetes [4] and, as of 2013, diabetes-related causes of death claimed the lives of over a million Indians annually [5].

One of the most frequent admittance problems, diabetic foot (DF) places a significant financial and medical strain on our health-care system [6,7]. Foot ulcers are the most prevalent cause of hospitalization for diabetic patients (30%) and account for roughly 20% of all health care costs, more than all other diabetic complications [8,9]. The lifetime risk of developing a foot ulcer is as high as 25% [10].

In India, 3% of diabetics attending centers for DF care – both indoor and outdoor – have foot ulcers [11,12].

10.4% of diabetic patients, both inpatient and outpatient, who visited hospitals in rural India had foot ulcers [13]. About 3.2% of diabetics under 50 have PVD, while the percentage climbs to 55% in those over 80 [14]. After 10 years, DF affects 15% of those with diabetes; after another 10 years, the number rises to nearly 50% [15].

A history of DF ulcers is present in about 85% of non-traumatic lower limb amputation cases [6,16]. DF causes more than a million diabetics to lose at least a portion of their leg annually. It illustrates how a limb is lost in the world someplace every 20 s [17].

An estimated 45,000 legs are amputated annually in India, despite the lack of contemporary population-based data available. Because an infected neuropathic foot frequently leads to amputation, the great majority (75%) of these cases are likely avoidable [18].

Twenty percentages of infections result in amputation, and over half of all foot ulcers become infected and necessitate hospitalization [19].

Fifty percentages of patients who suffer a major amputation will have their other limb amputated within 2 years. The 10-year mortality rate is 40% higher in those having a history of DF ulcers than in those with diabetes alone.

Aim of the study

The aim of this study was to evaluate clinical profile and outcome of patients in DF.

METHODS

Study subjects

This prospective observational study was carried out from September 2022 to February 2023 (6 months) at the General Surgery Department of the Arundhati Institute of Medical Sciences and Hospital in Gandhimaisamma, Hyderabad. The study involved 55 diabetic patients who were receiving treatment for DF ulcers in a tertiary care hospital at the general surgery ward. Enrollment of patients who agreed to take part in the trial took place.

Data gathering patients provided sociodemographic and anthropological information about their age, marital status, level of literacy, occupation, lifestyle (sedentary vs. active), family history (parents vs. siblings), causes of stress, length and severity of illness, etc.

Sample collection

Using a needle aspirate, samples were taken from diabetic patients who had ulcers, surgical sites that were infected, and other wounds. When dealing with closed wounds, the skin or mucosal area was first cleaned with 70% alcohol or 2% chlorhexidine, then an iodine solution (1–2% tincture iodine or 10% povidone-iodine solution). Iodine was eliminated with alcohol before specimen collection.

Inclusion criteria

The following criteria were included in the study:

Age 20–80 years.

Wagner's foot ulcers in Grades 1 and 2 in diabetic patients.

Those with duration of foot ulcers more than 4–6 weeks; and with good glycemic control and neuropathic ulcers.

Exclusion criteria

The following criteria were excluded from the study:

Age <10 and more than 80 years.

Uncontrolled DM, Wagner's grade 3, 4, 5 ulcers, severely infected wounds and gangrene, neuroischemic ulcers, traumatic ulcers, PVD, coronary artery disease, and varicose veins.

Wagner–Meggitt classification of DF

- Grade 0 – Foot symptoms like pain, only
- Grade 1 – Ulcerations on the skin and subcutaneous tissue that are superficial
- Grade 2 – Deep ulcers involving ligaments, muscles, tendons, etc.
- Grade 3 – An ulcer involving the bone
- Grade 4 – Forefoot gangrene
- Grade 5 – Full-foot gangrene.

Statistical analysis data were analyzed using student paired t-test $p<0.05$ which was considered statistically significant. Statistical software SPSS version 22.0 was used for analysis.

RESULTS

There were 55 patients in the current investigation, with a mean age of 61.78±11.75 years and a preference for males (n=45, 81.8%) over girls (n=10, 18.2%). Table 1 displays the largest number of study patients (n=27, 49.1%) who were seen in the 61–80 year age range.

In the present study, left foot (58.2%) was involved more than right foot (41.8%).

Diabetes profile

Mean duration of diabetes mellitus was 10.87±2.681 years with mean hemoglobin A1c (HBA1c) of 10.74±1.60.

In the present study, grade 2 in 34.5% cases and grade 3 seen in 25.5% cases.

Table 1: Age sex distribution

Age	Frequency	Percentage
20–40	04	7.3
41–60	24	43.6
61–80	27	49.1
Total	55	100

In our study, the most common comorbidities were hypertension, kidney disease, heart disease, and anemia. Most of the study patients had and were currently on medication.

For 55 individuals (100%), the most frequent presenting complaint was an ulcer. Graph 1 shows the other presenting aspects.

Clinical characteristics arteries palpable

Every limb's femoral artery was felt. Palpable in 20%, 25%, and 5% of the limbs were the dorsalis pedis artery, the popliteal artery (55%) and the anterior, posterior, and dorsalis tibial arteries.

Brachial ankle index

ABI on average was 0.48±0.99.

The average ulcer area at baseline was 16.75 cm±19.1 cm; after a month, it was 9.75 cm±12.59 cm; after 2 months, it was 7.24 cm±11.05 cm; and after 3 months, it was 6.18 cm±11.19 cm Table 2.

Our patients' microbiological profiles revealed that 32.7% of them were Gram positive and 67.3% were Gram negative. Gram-negative bacillus *Escherichia coli* was the most often found bacterium in our investigation (67.3%), followed by *Pseudomonas* (29.1%), *Klebsiella* (18.2%), and *Staphylococcus aureus* (5.5%).The number of amputation (7) significantly associated with anterior tibial artery Table 3.

It showed statistical significance with p=0.013 Table 4.

There was a statistically significant correlation between the severity of DF infections (DFI) and the clinical outcome (p=0.003) Table 5.

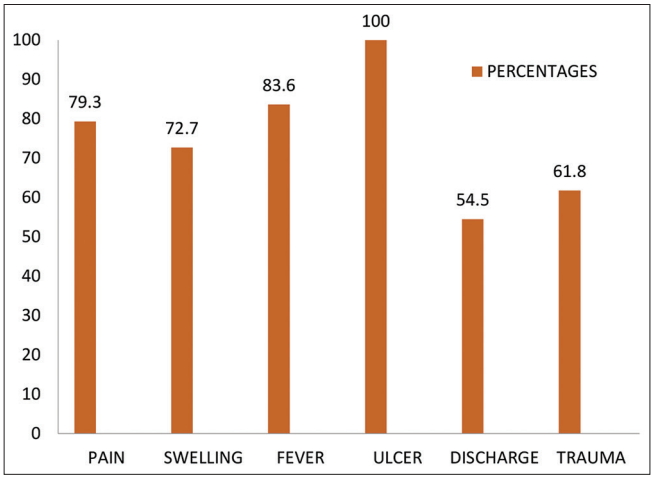
Palpable anterior tibial artery (p=0.01 and <0.01, respectively), palpable posterior tibial artery (p=0.05 and 0.01, respectively), and palpable dorsalis pedis artery (p=0.01 and 0.04, respectively) were significantly correlated with the number of both major and minor amputations, while the palpable popliteal artery was significantly correlated with the number of minor amputations only (p=0.003) Table 6.

DISCUSSION

Comparative studies related to age distribution

There were 55 patients in the current investigation, with a mean age of 61.78±11.75 years and a preference for males (n=45, 81.8%) over girls (n=10, 18.2%). There was a maximum number of study patients (n=27, 49.1%) who were observed in the 61–80 year age range.

In Seth *et al*. [20] study, the mean age of the 65 patients was 58.49±11.04 years, and there was a preference for males (n=54, 83.08%) over females (n=11, 16.92%).



Graph 1: Bar diagram showing distribution of complaints of patients

Table 2: Distribution of ulcer healing during follow-up

Ulcer area (cm2)	Baseline	1st month	2nd month	3rd month
Mean±SD	40.79±11.99	36.27±11.54	33.07±11.54	30.67±11.54
p-value		<0.001	<0.001	<0.001

Table 3: Wagner –Meggitt classification of diabetic foot

Grade	Frequency (n)	Percentage
0	4	7.3
1	9	16.4
2	19	34.5
3	14	25.5
4	9	16.4
Total	55	100

Table 4: Microbiological distribution

Spectrum	No. of patients	Percentage
Gram positive	18	32.7
Gram negative	37	67.3
Escherichia coli	26	47.3
Klebsiella pneumoniae	10	18.2
Pseudomonas	16	29.1
Staphylococcus aureus	3	5.5

Table 5: Distribution of amputation and anterior tibial artery

Amputation	Anterior tibial artery		Total
	Not palpable		
Yes	5	2	7
No	12	36	48
Total	17	38	55

Chi-square=6.167, *P*=0.013*

Table 6: Association of severity of diabetic foot infections with clinical outcome

Amputation	Severity			Total
	Mild (%)	Moderate (%)	Severe (%)	
Major	1 (11.1)	2 (22.2)	6 (66.7)	9
Minor	8 (47.1)	6 (35.3)	3 (17.6)	17
No amputation	18 (62.1)	9 (31.0)	2 (6.9)	29
Total	27	17	11	55

Chi-square=16.31, *P*=0.003*

In Abhishek *et al*. [21] study, DF was identified in 49 individuals. Patients with DF ranged in age from 22 to 86. Not a single patient was younger than 20. Ten patients (20.4%) were aged between 21 and 40, 20 patients (40.8%) were aged between 41 and 60, and 19 patients (387.7%) were older than 60. The majority of DF patients were older than 40; Ahmad Sahy *et al*. [22] in his study, 60 patients in all. There were thirty-five men (58.33%). The age range was 30–87, with a mean of 60.06±11.33 years.

In Bhoopathy *et al*. [23] study of the 120 cases, 48 were women and 72 were men. The age group with the highest number of affected patients was 51–60 years old (43 individuals), followed by 30–40 years old (29 patients), 41–50 years old (25 patients), and 61–70 years old (23 patients).

Comparative studies related to diabetes profile

In our study, the average HBA1c was 10.74±1.60 years, while the mean duration of diabetes mellitus was 10.87±2.681 years.

In Seth *et al*. [20] study, the average HBA1c was 7.23±1.57 years, while the mean duration of diabetes mellitus was 12.03±6.96 years.

In Abhishek *et al*. [21] study of the 49 patients diagnosed with DF, 33 had a HbA1c>8.5, and 16 had a HbA1c of 10.24 days or higher.

In Bhoopathy *et al.* [23] study, the majority of patients (49 patients) with diabetes had been diagnosed for 6–10 years, then for <5 years (36 patients), 11–15 years (18 patients), and 16–20 years (17 patients). The ulcers lasted for 2–3 months in 63 individuals, 1 month in 25, 3 to 5 months in 20, and more than 5 months in 12 patients.

In Ahmad Sahy *et al*. [23] study for patients having major limb amputation, the mean hemoglobin level was 10.20±2.73 and 9.84±2.69 g/dl, respectively. For amputees, the mean random blood glucose was 14.16±6.10 mmol/L and 13.18±6.17 mmol/L. 34 people, or nearly two-thirds (56.67%), had had diabetes for longer than 5 years.

In the present study, left foot (58.2%) was involved more than right foot (41.8%).

In Mutonga *et al*. [24] study, the majority of patients (88.10%) only had one foot affected by ulcers. Forty-nine ulcers (53.26%) on the right foot and 43 ulcers (46.74%) on the left foot were found. The forefoot and hindfoot were the sites of the majority of ulcers.

Comparative studies related to presenting complaints

For 55 (100%) of the patients in our study, the ulcer was the most frequent presenting ailment. About 61.8% of cases had trauma, 54.5% had discharge, 83.6% had fever, 72.7% had edema, and 79.3% had discomfort.

In Seth *et al*. [20] study among the 60 patients (92.31%), the ulcer was the most frequent presenting complaint encountered. The second most frequent presenting feature, which was found in 47 (72.31%) patients, was discharge from the foot wound.

Comparative studies related to microbiological profile

Gram-positive and Gram-negative microbiological profiles were found in 32.7% and 67.3% of the individuals in the current investigation. Gram-negative bacilli *E. coli* were the most often found organism in our study (67.3%), followed by *Pseudomonas* (29.1%), *Klebsiella* (18.2%), and *S. aureus* (5.5%).

In Seth *et al*. [20] according to our patients' microbiological profiles, 36 patients (55.38%) had monomicrobial growth, while six patients (9.23%) had polymicrobial growth. Of the total patients, 23 patients (35.39%) had a sterile culture. Gram-negative isolates made up the majority of the isolates (n=35, 71.43%), while Gram-positive isolates were found in (n=14, 28.57%). Acinetobacter (12.24%) and *S. aureus* (28.57% each) were the most frequently isolated microorganisms.

In Abhishek *et al*. [21] study of the 59 patients with DF, 14 (29%) had *Pseudomonas*, 12 (25%) had *E. Coli*, 11 (22%) had *Klebsiella*, 10 (20%) had staphylococci, and 2 (4%) showed no growth on aerobic culture media.

In Bhoopathy *et al*. [23] study, 84 of the 120 patients have the isolated pathogens visible. This was primarily found in *Pseudomonas aerugionsa* (54.8%), *Klebisella* (28.6%), and *E. coli* (16.7%).

Comparative studies related to Wagner classification

In the present study, grade 2 in 34.5% cases and grade 3 seen in 25.5% cases.

In Bhoopathy *et al.* [23] 120 patients total according to Wagner's classification, there were 46 patients in type 2 and 74 patients in type I.

In our study anemia, heart disease, kidney disease, and hypertension were the most prevalent comorbidities. Similar results were seen in the Mutonga *et al.* [24] investigation, where the majority of the study participants had type 2 diabetes mellitus and were taking medication at the time.

Comparative studies related to ulcer

The average initial ulcer area in our investigation was 16.75 cm±19.1 cm; after a month, it was 9.75 cm±12.59 cm; after 2 months, it was 7.24 cm±11.05 cm; and after 3 months, it was 6.18 cm±11.19 cm.

In Seth *et al.* [20] study, the average ulcer area at baseline was 14.85 cm±23.12 cm; after 1 month, it was 11.75 cm±22.68 cm; after 2 months, it was 8.44 cm±22.05 cm; and after 3 months, it was 6.38 cm±21.19 cm.

The number of major and minor amputations was found to be significantly correlated with the palpable anterior tibial artery (p=0.01 and <0.01), posterior tibial artery (p=0.05 and 0.01), and dorsalis pedis artery (p=0.01 and 0.04) in our study. On the other hand, the number of minor amputations was found to be significantly correlated with the palpable popliteal artery (p=0.0003). Similar results were noted in the study of Seth *et al.* [20].

CONCLUSION

Since DFIs are the most prevalent consequence of diabetes mellitus that surgeons are notified about, managing them needs a multidisciplinary approach. It is crucial to do extensive, repeated examinations, as well as any required investigations to determine the infection severity at the time of presentation.

REFERENCES

1. Frykberg RG, Zgonis T, Armstrong DG, Driver VR, Giurini JM, Kravitz SR, *et al*. Diabetic foot disorders: A clinical practice guideline (2006 Revision). J Foot Ankle Surg 2006;45:S1-66.
2. International Working Group on the Diabetic Foot. International Consensus on the Diabetic Foot. In: The Netherlands: International Working Group on the Diabetic Foot; 2015. p. 20-96. Available from: https://iwgdf.org/guidelines/definitionscriteria-2015
3. Zaman MJS, Philipson P, Chen R, South Asians and coronary disease: is there discordance between effects on incidence and prognosis? Heart 2013;99:729-736.
4. International Diabetes Federation. IDF Diabetes Atlas, 10th edn. Brussels, Belgium: International Diabetes Federation, 2021.
5. Vardell E. Global Health Observatory Data Repository. Med Ref Serv Q. 2020 Jan-Mar;39(1):67-74. doi: 10.1080/02763869.2019.1693231. PMID: 32069199.
6. Reiber GE, Lipsky BA, Gibbons GW. The burden of diabetic foot ulcers. Am J Surg 1998;176:5S-10. doi: 10.1016/S0002-9610(98)00181-0, PMID 9777967
7. Wu SC, Driver VR, Wrobel JS, Armstrong DG. Foot ulcers in the diabetic patient, prevention and treatment. Vasc Health Risk Manag 2007;3:65-76. PMID 17583176
8. Thomson FJ, Veves A, Ashe H, Knowles EA, Gem J, Walker MG, *et al*. A team approach to diabetic foot care: The Manchester experience. Foot 1991;1:75-82. doi: 10.1016/0958-2592(91)90034-9
9. Williams R, Airey M. The size of the problem: economic aspects of foot problems in diabetes. In: Boulton AJ, Connor H, Cavanagh PR, editors. The Foot in Diabetes. 3rd ed. Chichester: Wiley; 2000. p. 3-17.
10. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA 2005;293:217-28. doi: 10.1001/jama.293.2.217, PMID 15644549
11. Pendsey SP. Epidemiological aspects of diabetic foot. Int J Diab Dev Ctries 1994;14:37-8.
12. Apelqvist J, Bakker K, van Houtum WH, Nabuurs-Franssen MH, Schaper NC. International consensus and practical guidelines on the management and the prevention of the diabetic foot. International Working Group on the Diabetic Foot. Diabetes Metab Res Rev. 2000 Sep-Oct;16 Suppl 1:S84-92. doi: 10.1002/1520-7560(200009/10)16.
13. Mehra BR, Thawait AP, Karandikar SS, Gupta DO, Narang RR. Evaluation of foot problems among diabetics in rural population. Indian J Surg 2008;70:175-80. doi: 10.1007/s12262-008-0048-2, PMID 23133052
14. Palumbo PJ, Melton LJ. Peripheral vascular disease and diabetes. In: Harris MI, Hamman RF, editors. Diabetes in America, NIH 1985; Publication no. 85. Washington, D.C: US Government Printing Office; 1985. p. XVI-21.
15. Janka HU, Stand IE, Mehnert H. Peripheral vascular disease in diabetes mellitus and its relation to cardiovascular risk factor: Screening with Doppler ultrasonic technique. Diabetes Care 1980;3:207-13.
16. Larsson J, Apelqvist J. Towards Less Amputations in Diabetic Patients: Incidence, Causes, Cost, Treatment, and Prevention-a Review. UK: Informa UK Ltd.; 2009. Available from: https://informahealthcare.com/doi/abs/10.3109/17453679508995520 [Last accessed on 2015 Aug 31].
17. Boulton AJ, Vileikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. Lancet 2005;366:1719-24. doi: 10.1016/S0140-6736(05)67698-2, PMID 16291066
18. Pendsey S. Clinical profile of diabetic foot in India. Int J Low Extrem Wounds 2010;9:180-4. doi: 10.1177/1534734610380025, PMID 21134956
19. Pendsey S. Reducing diabetic foot problems and limb amputation: An experience from India. In: Dinh T, editor. Global Perspective on Diabetic Foot Ulcerations. Croatia: InTech; 2011. p. 15-24.
20. Seth A, Attri AK, Kataria H, Kochhar S, Seth SA, Gautam N. Clinical profile and outcome in patients of diabetic foot infection. Int J Appl Basic Med Res 2019;9:14-9.
21. Abhishek Gupta, Subash Chandra Sharma , Janmejai Prasad Sharma: Original Research Article Clinical Profile and Outcome of Diabetic Foot in a Tertiary Care Centre: International Journal of Contemporary Surgery, July-December 2019, Vol.7, No. 2
22. Ahmed Shabhay, Pius Horumpende, Zarina Shabhay, Andrew Mganga, Jef Van Baal, David Msuya, Kondo Chilonga and Samwel Chugulu, Clinical profles of diabetic foot ulcer patients undergoing major limb amputation at a tertiary care center in North-eastern Tanzania BMC Surg (2021) 21:34.
23. Bhoopathy, D. Boopathy, P. K. Asokan , T. R. Yeshwanth: Clinical profile and outcome of diabetic foot ulcers: International Journal of Research in Medical Sciences Boopathy D et al. Int J Res Med Sci. 2023 May;11(5):1553-1557
24. Mutonga DM, Mureithi MW, Ngugi NN, et al. Diabetic foot ulcers in a Kenyan referral and teaching hospital: risk factors, patient characteristics and clinical outcomes. Series Endo Diab Met. 2019;1(2):41-51