Turkish Journal of Medical Sciences

Volume 47 | Number 3 Article 17

1-1-2017

Risk factors associated with poor outcome in diabetic foot ulcer patients

SAIRA SALEEM

NAZIM HAYAT

IRSHAD AHMAD

TANVIR AHMAD

ABDULGAFFAR REHAN

TÜBİTAK

Turkish Journal of Medical Sciences

http://journals.tubitak.gov.tr/medical/

Research Article

Turk J Med Sci
(2017) 47: 826-831
© TÜBİTAK
doi:10.3906/sag-1602-119

Risk factors associated with poor outcome in diabetic foot ulcer patients

Saira SALEEM*, Nazim HAYAT, Irshad AHMED, Tanvir AHMED, Abdul Gaffar REHAN
Department of Surgery, Madinah Teaching Hospital, Faisalabad, Punjab, Pakistan

Received: 20.02.2016 • **Accepted/Published Online:** 12.02.2017 • **Final Version:** 12.06.2017

Background/aim: Diabetic foot ulcers and related complications are a major cause of morbidity and hospital admissions. Our aim was to evaluate the risk factors associated with poor outcome in diabetic foot ulcers.

Materials and methods: A prospective study was conducted on patients with diabetic foot ulceration attending the Madinah Teaching Hospital from June 2014 to December 2015. Potential risk factors and laboratory test results at presentation were recorded and their association with outcome (healing vs. amputation) was analyzed using IBM SPSS Statistics for Windows, Version 22.0.

Results: In total, 112 patients were studied during our study period. The majority of the patients were male (60.7%) and aged 50 years and older (62.5%). Regarding the outcome, 68% healed completely, 27.7% underwent amputation, and 4.5% died during this period. Patient age of 50 and older, long duration of diabetes (>10 years), rural origin, and heel ulcers were significantly associated with poor outcome ($P < 0.05$).

Conclusion: Patients with diabetes should have a detailed annual foot examination; those having risk factors for poor outcome require more frequent foot care, patient education, and early referral to tertiary care centers.

Key words: Diabetic foot ulcer, risk factors, poor outcome, amputation

1. Introduction

Among people diagnosed with diabetes mellitus, the lifetime risk of developing a foot ulcer is approximately 15%. The most feared consequence of a foot ulcer is limb amputation, which occurs 10 to 30 times more frequently in diabetics as compared to nondiabetics (1–3). It has been observed that the presence of foot ulceration increases hospitalization duration by 59% in people with diabetes mellitus (4). Worldwide, every year more than 1 million people lose a leg as a consequence of this disease (5). Diabetic foot ulceration is painful, demands increased healthcare utilization, and increases healthcare costs for the patients as well as the healthcare system (6,7).

In diabetic foot patients complications and mortality are closely related to the severity of the disease at presentation. Once an ulcer has developed, there is an increased risk of wound progression ultimately leading to amputation, suggesting that prevention and appropriate management of foot lesions are of paramount importance (8,9). The literature shows several risk factors related to poor outcome in diabetic foot ulcer patients, such as poor glycemic control, peripheral neuropathy, ischemia from peripheral arterial disease, structural foot deformity, and concomitant infection (10,11).

Generally, management of foot ulceration should address glycemic control, pressure relief/offloading, infection control, revascularization when necessary, and local wound care (12). Management is best achieved with a multidisciplinary team approach (13,14). At least 40% of amputations in diabetic patients can be prevented with a team approach to wound care (15). The incidence of diabetic foot ulceration is higher in developing countries like Pakistan because of various sociocultural factors (16). In this study, we evaluated the risk factors related to poor outcome in diabetic patients with foot ulcers.

2. Materials and methods

A prospective study was conducted with diabetic patients with foot ulcers attending the Madinah Teaching Hospital in Faisalabad from June 2014 to December 2015. Patients lost in follow-up and moribund patients were excluded.

Patient age, sex, rural/urban origin, type and duration of diabetes, history of hypertension, duration of ulcer, previous history of ulceration, previous treatment, and site of ulcer were recorded on the first visit. Important laboratory tests like complete blood count, fasting/random blood sugar, HbA1c, blood urea, creatinine, and lipid profile were advised at the first visit.

* Correspondence: dsairaijaz32@yahoo.com

Clinical signs of infection, ischemia, and neuropathy were recorded at presentation. Ulcers were labeled as infected if a purulent discharge was present with two other local signs (warmth, erythema, lymphangitis, lymphadenopathy, edema, pain). Wound depth was evaluated using a sterile blunt probe. The ability to probe to bone along with the presence of local or systemic infection and suggestive radiological features provided a clinical diagnosis of osteomyelitis (17).

Each patient underwent an 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. Patients having clinical signs of ischemia had noninvasive ultrasound (Doppler) vascular studies (18).

Loss of protective sensation (neuropathy) was assessed with a 128-Hz tuning fork for vibration sense and a 10-g monofilament for perception of pressure sense. The monofilament was applied perpendicularly to the plantar surface of the first toe; the first, third, and fifth metatarsal heads; and the plantar surface of the heel and the dorsum of the foot, avoiding any callus, corn, or wound site. It was graded as normal, reduced, or absent sensation (19).

Some patients were managed on an outpatient department (OPD) basis while those having severe local or systemic infection along with tissue necrosis were admitted to the surgical ward. Wound debridement was done to drain the pus and remove necrotic tissue and extensive callus. Broad spectrum antibiotics were advised in the presence of infection. After discharge from the hospital, patients were initially seen in the OPD on a weekly basis, and later as the healing started on a monthly basis.

Outcomes were recorded as complete healing or lower extremity amputation (LEA). LEA is defined as major amputation if there is loss of any part of the lower limb above the ankle and as minor if below this joint (20).

2.1. Statistical analysis

Frequency distributions and percentages were calculated for all the qualitative variables used in the study. The chi-square test was employed to assess the significance of association between the risk factors and outcomes of foot ulcers (amputation/healing without amputation).

If a potential risk factor was dichotomous and the frequency of one of the cells was less than five, Fisher's exact test was used instead of the chi-square test. Odds ratios were calculated in simple binary logistic regression analysis for every potential risk factor.

Variables that were statistically significant risk factors for amputation were later used in multiple binary logistic regression analysis in order to calculate adjusted odds ratios. The 95% confidence interval (CI) was calculated wherever found appropriate. P-values of less than 0.05 were considered significant with two-tailed tests. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., 2013) (21). The results were expressed through frequencies, tables, and graphs.

3. Results

The study population consisted of 112 patients. The majority of the patients were male (60.7%) and aged 50 years and older (62.5%), with a mean age of 54.5 ± 10.2 years. Average follow-up time was 4.3 months (range: 2 weeks to 8 months).

Regarding outcome, 76 patients (68%) healed completely, without amputation. Thirty-one patients (27.7%) underwent amputation and five patients (4.5%) died during our study period. Four patients died due to cardiovascular events and one due to septicemia and multiorgan failure.

Potential risk factors and their association with outcome (healing vs. amputation) are shown in Table 1. Age of 50 and older, longer duration of diabetes (>10 years), and rural origin were significantly associated with poor outcome at $P = 0.001$, $P < 0.001$, and $P = 0.047$, respectively. These factors associated with poor outcome were subjected to multiple binary logistic regression analysis in order to calculate adjusted odds ratios. This showed a strong association of poor outcome with age and rural origin, as shown in Table 2.

Regarding types of amputation, our study showed that 17 patients had minor and 14 patients had major amputations. Because of the smaller number of patients with major amputations in the dorsum of the foot and included in the metatarsal heads group, they were reclassified into the toes ulcer group and a comparison was done with heel ulcers to find an association with major amputations. The chi-square test showed that heel ulcer is significantly associated with major amputation ($P < 0.034$), and according to the odds ratio, patients with heel ulcer have a 3.609 times higher chance of having a major amputation than patients with ulcers on the toes and other sites, as shown in Table 3. Sixty patients had ulcers located on the toes, accounting for 58% of all amputations; however, the majority of amputations in patients with toe ulcers were minor, as shown in the Figure.

Regarding types of ulcers, neuropathic ulcers were the most common type (46.4%), followed by neuroischemic (35.7%) and ischemic (17.9%). No statistically significant association was found between poor outcome and type of ulcer.

4. Discussion

Foot ulcers are a major cause of morbidity and hospitalization in patients with diabetes. The economic burden associated with diabetic foot ulceration is enormous. The estimated cost of treating one foot ulcer

Table 1, Association of potential risk factors and outcome in diabetic foot ulcer patients.

Factors related to foot ulcers n = 112	Outcome* n = 107		Univariate analysis	
	Patients without amputation n = 76 (67.9%)	Patients with amputation n = 31 (27.7%)	Odds ratio (95% CI)	P-value
Age (in years)				
<50 years: 42 (37.5%) >50 years: 70 (62.5%)	38 (35.5%) 38 (35.5%)	4 (3.7%) 27 (25.2%)	6.750 (2.154–21.154)	0.001
Sex				
Female: 44 (39.3%) Male: 68 (60.7%)	33 (30.8%) 43 (40.2%)	10 (9.3%) 21 (19.6%)	1.612 (0.669– 3.882)	0.287
Area				
Rural: 78 (69.6%) Urban: 34 (30.4%)	66 (61.7%) 10 (9.3%)	11 (10.3%) 20 (18.7%)	12.000 (4.451–32.353)	<0.001
Previous H/O foot ulcer				
Yes: 85 (75.9%) No: 27 (24.1%)	57 (53.3%) 19 (17.8%)	24 (22.4%) 7 (6.5%)	0.875 (0.325– 2.353)	0.791
Duration of diabetes				
<10 years: 40 (35.7%) >10 years: 72 (64.3%)	33 (30.8%) 43 (40.2%)	7 (6.5%) 24 (22.4%)	2.631 (1.011–6.847)	0.047
Type of DM				
Type 1: 30 (26.8%) Type 2: 82 (73.2%)	20 (18.7%) 56 (52.3%)	7 (6.5%) 24 (22.4%)	1.224 (0.457–3.278)	0.687
HbA1c				
<7.5: 31 (27.7%) >7.5: 81 (72.3%)	24 (22.4%) 52 (48.6%)	7 (6.5%) 24 (22.4%)	1.582 (0.599–4.178)	0.354
Hypertension				
No: 42 (37.5%) Yes: 70 (62.5%)	29 (27.1%) 47 (43.9%)	12 (11.2%) 19 (17.8%)	0.977 (0.414–2.305)	0.958
LDL cholesterol				
< 130 mg/dL: 79 (70.5%) > 130 mg/dL: 33 (29.5%)	57 (53.3%) 19 (17.8%)	18 (16.8%) 13 (12.1%)	2.167 (0.897–5.236)	0.086
Type of ulcer				
Ischemic: 20 (17.9%) Neuropathic: 52 (46.4%) Neuroischemic: 40 (35.7%)	11 (10.3%) 36 (33.6%) 29 (27.1%)	7 (6.5%) 14 (13.0%) 10 (9.4%)	0.488 (0.146–1.631) 0.745 (0.285–1.946)	0.244 0.548

*Deceased patients (n = 5) are included in the total number of patients (n = 112), but are not mentioned for outcome (n = 107).

Table 2. Multivariate analysis.

Factors	Adjusted odds ratio	95% CI	P-value
Age			
<50 years >50 years	6.910 (1.519–31.432)	0.012	0.012
Duration of diabetes			
<10 years >10 years	0.810 (0.194–3.381)	0.773	0.773
Rural origin			
No Yes	11.215 (3.878–32.430)	<0.001	<0.001

Table 3. Association between site of foot ulcer and major amputations.

Site of foot ulcer (n* = 107)		Major amputations n = 14	CI (95%)	P-value
Heel	22	6	3.609 (1.101–11.836)	0.034
Toes and other sites	85	8		

*Excluding deceased patients.

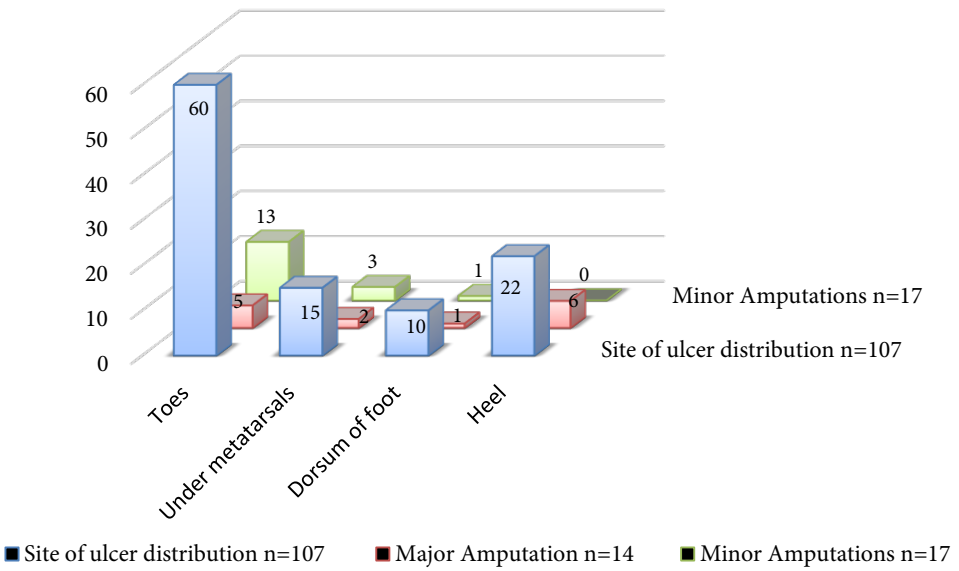

Figure. Ulcer site distribution and its association with type of amputation.

over a 2-year period is $28,000 (9). The prevalence of lower extremity amputation is high in Pakistan, but the underlying risk factors remain to be defined (18). In this study, we assessed various clinical and biochemical factors leading to poor outcome in patients with diabetic foot ulceration. Early detection and proper care of a foot at risk can help prevent complications like amputation.

Our study shows that the majority of patients were male and over 50 years old. Other researchers have also reported the presence of diabetic ulcers mostly in males and middle-aged subjects (22–24). The increase in foot ulcers among diabetic male patients is worrying for individual families, as males are often the sole earning member of the family (22).

In our study 76 patients (68%) healed completely without amputation, while 31 patients (27.7%) underwent lower limb amputation. Similar results were shown by Ali et al. from Karachi (18).

Australian recommendations on the prevention, identification, and management of foot complications in diabetes classify half of lower limb amputations as major (below or above knee) and the other half as minor (distal to the ankle) (25). Our study shows that nearly half of the amputations were major, and 43% of these major amputations occurred for heel ulcers as compared to 35.7%, 14.3%, and 7% for toes, under metatarsal heads, and the dorsum of foot ulcers, respectively. Younes et al. from Jordan also reported heel ulcers to be the most serious of foot ulcers and associated with major amputations. Management of heel ulcers requires a thorough knowledge of risk factors for ulceration in the heel area and a standardized program of ulcer care. Patient education regarding foot hygiene, skin care, and proper footwear can reduce the risk of injury that can lead to heel ulceration. Team management programs using careful foot examination and proper therapeutic measures can significantly reduce the risk of lower-extremity amputations due to heel ulcers (26).

Regarding patient residence, 69.6% of patients came from rural areas, which was significantly associated with poor outcome. This is probably related to poor access to healthcare facilities in rural communities. Similarly, Shahi et al. from India reported that 70.1% of patients were from rural areas, which was associated with poor outcome. As described in this Indian study, people living in rural areas often sleep in farm houses, huts, or outdoors in the villages and they walk bare-footed and commonly get foot damage and chronic ulcers (22). An Australian study also reported diabetes-related foot complications to be more common in Aboriginal and Torres Strait Islanders living in remote areas as compared to those living in central areas. The authors concluded that these populations experience barriers to access or utilization of contemporary diabetes education and require more attention in regards to screening, early intervention, and monitoring to improve clinical outcomes (25).

Regarding types of ulcers, neuropathic ulcers were the most common type (46.4%), followed by neuroischemic (35.7%) and ischemic (17.9%); other studies showed similar findings (10,27). However, in our study no significant association was found between poor outcome and type of ulcer.

We conclude that in people with diabetes foot examination by healthcare providers should be an integral component of diabetes management to identify patients at risk of ulceration and lower-extremity amputation, and this should be performed at least annually. Patients at high risk of foot complications need more frequent monitoring as well as foot care education (including counseling to avoid foot trauma), professionally fitted footwear, and early referrals to a tertiary care center with trained professionals in foot ulcer management. A multidisciplinary healthcare team can help prevent recurrent foot ulcers and amputation in these patients (28).

References

1. O'Rourke I, Heard S, Treacy J, Gruen R, Whitbread C. Risks to feet in the top end: outcomes of diabetic foot complications. ANZ J Surg 2002; 72: 282-286.
2. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. JAMA-J Am Med Assoc 2005; 293: 217-228.
3. Vileikyte L, Peyrot M, Bundy C, Rubin RR, Leventhal H, Mora P, Shaw JE, Baker P, Boulton AJ. The development and validation of a neuropathy and foot ulcer specific quality of life instrument. Diabetes Care 2003; 26: 2549-2555.
4. Van Acker K, De Block C, Abrams P, Bouten A, De Leeuw I, Droste J, Weyler J, Peter-Riesch B. The choice of diabetic foot ulcer classification in relation to the final outcome. Wounds 2002; 14:16-25.
5. Frykberg RG, Banks J. Management of diabetic foot ulcers: a review. Federal Practitioner 2016; 33:16-23.
6. Boulton, AJ, Armstrong DG, Albert SF, Frykberg RG, Hellman R, Kirkman MS, Lavery LA, Lemaster JW, Mills JL Sr, Mueller MJ et al. Comprehensive foot examination and risk assessment: a report of the task force of the foot care interest group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. Diabetes Care 2008; 31: 1679-1685.
7. Davis WA, Norman PE, Bruce DG, Davis TM. Predictors, consequences and costs of diabetes related lower extremity amputations complicating type 2 diabetes: The Freemantle Diabetes Study. Diabetologia 2006; 49: 2634-2641.
8. Larsson J, Apelqvist J. Towards less amputation in diabetic patients: incidence, cause, cost, treatment and prevention: a review. Acta Orthop Scand 1995; 66: 181-192.
9. Boulton AJ, Kirsner RS, Vileikyte L. Clinical practice. Neuropathic diabetic foot ulcers. New Engl J Med 2004; 351: 48-55.
10. Ho TK, Leigh RD, Tsui J. Diabetic foot disease and oedema. British Journal of Diabetes and Vascular Disease 2013; 13: 45-50.

11. Lyons TE. Management of diabetic foot complications. In: Veves A, Malik R, editors. Diabetic Neuropathy, Clinical Management. New York, NY, USA: Humana Press; 2008. pp. 480-482.

12. Margolis DJ, Kantor J, Berlin JA. Healing of diabetic neuropathic foot ulcers receiving standard treatment. A metaanalysis. Diabetes Care 1999; 22: 692-695.

13. Dargis V, Pantelejeva O, Jonushaite A, Vileikyte L, Boulton AJ. Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania: a prospective study. Diabetes Care 1999; 22: 1428-1431.

14. Aydin K, Isildak M, Karakaya J, Gürlek A. Change in amputation predictors in diabetic foot disease: effect of multidisciplinary approach. Endocrine 2010; 38: 87-92.

15. Lavery LA, Armstrong DG, Vela SA, Quebedeaux TL, Fleischli JG. Practical criteria for screening patients at high risk for diabetic foot ulceration. Arch Intern Med 1998; 158: 157-162.

16. Riaz M, Miyan Z, Zaidi SI, Alvi FD, Fawwad A, Ahmadani MY, Zafar AB, Malik RA, Basit A. Characteristics and outcomes of subjects with diabetic foot ulceration. Diabetes Care 2012; 35: e63.

17. Oyibo SO, Jude EB, Tarawneh I, Nguyen HC, Harkless LB, Boulton AJM. A comparison of two diabetic foot ulcer classification systems: the Wagner and the University of Texas wound classification systems. Diabetes Care 2001; 24: 84-88.

18. Ali SM, Basit A, Fawwad A, Ahmedani MY, Miyan Z, Malik RA. Presentation and outcome of diabetic foot at a tertiary care unit. Pak J Med Sci 2008; 24: 651-656.

19. Clayton W Jr, Elasy TA. A review of the pathophysiology, classification, and treatment of foot ulcers in diabetic patients. Clinical Diabetes 2009; 27: 52-55.

20. Ahmad N, Thomas GN, Gill P, Torella F. The prevalence of major lower limb amputation in the diabetic and non-diabetic population of England 2003–2013. Diabetes and Vascular Disease Research 2016; 13: 348-353.

21. IBM Corp. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY, USA: IBM Corp.; 2013.

22. Shahi SK, Kumar A, Kumar S, Singh SK, Gupta SK, Singh TB. Prevalence of diabetic foot ulcer and associated risk factors in diabetic patients from North India. Journal of Diabetic Foot Complications 2012; 3: 83-91.

23. Merza Z, Tesfaye S. The risk factors for diabetic foot ulceration. Foot 2003; 13: 125-129.

24. Unachukwu C, Babatunde S, Ihekwaba EI. Diabetes, hand and/or foot ulcers: a cross-sectional hospital-based study in Port Harcourt, Nigeria. Diabetes Res Clin Pr 2007; 75: 148-152.

25. National Health and Medical Research Council. National Evidence-Based Guideline on Prevention, Identification and Management of Foot Complications in Diabetes (Part of the Guidelines on Management of Type 2 Diabetes Mellitus). Melbourne, Australia: NHMRC; 2010.

26. Younes NA, Albsoul AM, Awad H. Diabetic heel ulcers: a major risk factor for lower extremity amputation. Ostomy Wound Manag 2004; 50: 50-60.

27. Moulik PK, Mtonga R, Gill GV. Amputation and mortality in new-onset diabetic foot ulcers stratified by etiology. Diabetes Care 2003; 26: 491-494.

28. Bowering K, Embil JM. Foot Care. Canadian Diabetes Association 2013. Clinical practice guidelines for the prevention and management of diabetes in Canada: pharmacologic management of type 2 diabetes. Can J Diabetes 2013; 37: 145-149.