

A Clinical Evaluation of Diabetic Foot Ulcer: Prospective Study

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Abstract

Background: Diabetic foot ulcer (DFU) is the most common complication among all diabetics. With progressing age and duration of diabetes the risk of developing DFU increases. This study was conducted to understand the course of DFU and its association.

Objectives: To study the risk factors and clinical course among DFU subjects and assesses the association between clinical course and outcome.

Methodology: This prospective study was conducted among 40 subjects who reported to S.V.S medical college and hospital surgery department with wound/s on the foot. The study period was for a year. The data was collected using a pretested questionnaire, analyzed, and presented.

Results: The study consisted of 18 males and 22 females. About 52.7% of the subjects were barefooted. The most common precipitating factor was trauma, abscess, and ulceration. Wagner classification system was used to grade the lesion in which 50% of the subjects belonged to grade 3 and the remaining grade 1 and 4. Most of the subjects had lesions at the toes, plantar and dorsum aspect of the foot, web-spaces, and lateral/medial borders of the foot. Culture and sensitivity were done to isolate various organisms and accordingly antibiotics were started. Surgery was done for 28 subjects and wound debridement was commonest. Wound healed and wound showed signs of healing in 90% of subjects were seen. The association between all the variables was significant ($P < 0.05$)

Key words: Diabetes mellitus, Diabetic foot ulcer, Precipitating factors, Lesions and antibiotics

INTRODUCTION

The most common precursor for lower extremity amputations among diabetics is foot ulceration.^[1,2] About a quarter of all diabetic hospital admission is for the treatment of infected wounds.^[3,4] Diabetic foot is multifactorial in nature which has been described in number of observational studies.^[5-7] Risk factors identified include peripheral neuropathy, vascular diseases, foot deformity, minor and major trauma, ulceration, and amputation.^[8-10] In the face of unobserved trauma peripheral sensory neuropathy is the primary factor leading to diabetic foot.^[11,12] Nearly 45–60% ulcerations are neuropathic and

up to 45% neuropathic and ischemic constituents.^[11,13] Trauma of foot in the presence of sensory neuropathy is an important component cause of ulceration.^[11] Dry skin with fissuring and cracking is a portal for bacteria entry resulting from autonomic neuropathy.^[14] These variations can later embroil in the pathogenesis of ulceration.^[14,15] Elevated plantar foot pressures are associated with amputations and neuropathic ulceration in a large population based study.^[16] In this study the cause of ulceration, site of ulceration, most common organism found, treatment and outcome patterns are described.

METHODOLOGY

The present prospective study of 40 cases of diabetic foot disease was carried out in the department of General surgery, SVS medical college over a period of 1 year from July 2015 to June 2016. All patients admitted with foot infection found to have elevated blood sugar level or having previous history of diabetes mellitus. Patients

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having specific infections of the foot (Mycetoma, actinomycosis, hansen’s disease). After obtaining informed consent of the concerned patients data was collected using a pretested questionnaire. General assessment and systemic examination was done for all the patients are done. A detailed local examination of the diabetic foot lesion was also done. Complete blood investigations including Random blood sugar, Fasting blood sugar, Post-prandial blood sugar was done. Urine is examined for the presence of sugar, albumin, ketone, and any deposits. A plain X-Ray (both antero-posterior and lateral views) of the affected limb is done to find out the presence of any osteomyelitic changes and calcification of arteries. The discharge obtained from the site of diabetic foot lesion was sent for culture and sensitivity to find out the organism(s) responsible and to determine further therapeutic management with antibiotics. The data were compiled and analyzed and presented as tables and percentages. Keeping the significance level at $P = 0.05$ the association was assessed and tabulated.

RESULTS

Table 1 shows the distribution of subjects, this study consisted of 18 males and 22 females. The mean age among the subjects was 51.8 + 3.42. 50% of the subjects were above 60 years. Footwear is an important variable were 52.7% of subjects were barefooted and 47.5% wore footwear. Among the 40 subjects, the precipitating factor leading to foot ulcer was taken into consideration. Six subjects each had history of trauma, thorn prick, and previous surgeries respectively. Thirteen of the 40 subjects had a history of previous ulceration. Trauma with previous surgeries and thorn prick with previous ulcer were seen in five and four subjects respectively. Majority of the subjects, 32.5% presented with gangrene. The other presentations were in the form of abscess, ulcer with abscess and gangrene, cellulitis, and ulcer.

Wagner ulcer classification was used to classify subjects were half of the subjects belonged to Grade 3. Ten subjects each had Grade 1 and Grade 4, respectively. Grade 2 and 5 were not seen in this study as seen in Table 2.

Site of lesion was enlisted as shown in Table 3 were eight subjects each had lesion in the toes +lateral/medial borders of foot, plantar aspect of foot +toes and dorsum of foot +lateral/medial borders of the foot. Four subjects each had lesion on the lateral/medial borders of the foot, web spaces, and plantar aspect of foot + lateral/medial borders of the foot respectively.

Culture and sensitivity were done for all the subjects. The organisms isolated are as follows, 16 (40%) subjects had

Escherichia coli and *Klebsiella+Enterococcus*. Seven (17.5%) subjects had no growth. Five (12.5%) had *Pseudomonas aeruginosa*. *Staphylococcus aureus* was seen in four subjects and only two subjects had *Klebsiella* and *Staphylococcus* together [Table 4].

Table 5 shows the usage of antibiotics based on the C and S report. In the present, 17 various antibiotics were used. In majority of the subjects, all the antibiotics were used.

Table 6 presents the surgical procedure done for the subjects. Twelve subjects did not need any surgical intervention. The remaining 28 subjects underwent surgical procedures as enumerated.

Table 1: Distribution of subjects according to age, sex, and clinical presentations

| Characteristics | Number (%) | |
|---|------------|-----------|
| Age | | Mean |
| 30–39 years | 06 (15) | 51.8+3.42 |
| 40–49 years | 08 (20) | |
| 50–59 years | 06 (15) | |
| >60 years | 20 (50) | |
| Sex | | Ratio |
| Males | 18 (45) | 0.81:1 |
| Females | 22 (55) | |
| Footwear | | |
| Barefooted patients | 21 (52.7) | |
| Patients wearing footwear | 19 (47.5) | |
| Precipitating factors | | |
| No history of trauma/prick/previous lesion | 0 | |
| Positive history of trauma | 06 (15) | |
| Positive history of thorn prick | 06 (15) | |
| Positive history of trauma+previous surgeries/amputations for DFU | 06 (15) | |
| Positive history of previous abscess/ulceration | 13 (32.5) | |
| Positive history of trauma+previous abscess/ulceration | 05 (12.5) | |
| Positive history of thorn prick+previous abscess/ulceration | 04 (10) | |
| Presentation | | |
| Ulcer | 04 (10) | |
| Cellulitis | 06 (15) | |
| Abscess | 07 (17.5) | |
| Gangrene | 13 (32.5) | |
| Ulcer+abscess | 06 (15) | |
| Ulcer+gangrene | 04 (10) | |

DFU: Diabetic foot ulcer

Table 2: Distribution of subjects according to staging using WAGNER ulcer classification system

| WAGNER classification | Grade | Number (%) |
|--|-------|------------|
| No open lesion; may have deformity or callus | 0 | |
| Superficial diabetic ulcer | 1 | 10 (25) |
| Ulcer extension to ligament, tendon, joint capsule or Deep fascia without abscess or osteomyelitis | 2 | 0 |
| Deep ulcer without abscess, osteomyelitis, or joint sepsis | 3 | 20 (50) |
| Gangrene localized to portion of forefoot/heel | 4 | 10 (25) |
| Extensive gangrenous involvement of the whole foot | 5 | 0 |

With regard to outcome post-surgery the subjects were evaluated after 4 weeks. Table 7 shows 67.5% showed signs of healing and 32.5% of subjects wound healed by the end of the 4th week.

The association between clinical onset, site of ulcer, and course of the disease with outcome was assessed. Taking the value of significance ($P < 0.05$) as significance high significance was seen between precipitating factor and site of lesion, subjects presentation, site of lesion, precipitating factors, antibiotics, and surgery with outcome was also significant [Table 8].

Table 3: Distribution of subjects according to site of lesion

| Site of lesion | Number (%) |
|---|------------|
| Plantar aspect of foot | 2 (5) |
| Dorsum of foot | 1 (2.5) |
| Toes | 1 (2.5) |
| Lateral/medial borders of foot | 4 (10) |
| Web spaces | 4 (10) |
| Toes+web spaces | 0 |
| Plantar aspect of foot+web spaces | 0 |
| Plantar aspect of foot+lateral/medial borders of foot | 4 (10) |
| Toes+lateral/medial borders of foot | 8 (20) |
| Plantar aspect of foot+toes | 8 (20) |
| Dorsum of foot+lateral/medial borders of foot | 8 (20) |

Table 4: Various organisms isolated from C and S

| Organism | Number (%) |
|---|------------|
| No growth | 07 (17.5) |
| <i>Staphylococcus aureus</i> | 04 (10) |
| <i>Escherichia coli</i> | 08 (20) |
| <i>Pseudomonas aeruginosa</i> | 05 (12.5) |
| <i>Klebsiella+Staphylococcus aureus</i> | 02 (5) |
| <i>Klebsiella+Enterococcus</i> | 08 (20) |
| <i>Streptococcus species</i> | 06 (15) |

Table 5: Antibiotics used based on the C and S report

| Antibiotics | Number |
|-----------------------------|--------|
| Amoxicillin_clavulanic acid | 27/40 |
| Ampicillin cloxacillin | 27/40 |
| Cefoperazone sulbactam | 27/40 |
| Piperacillin tazobactam | 33/40 |
| Co trimoxazole | 27/40 |
| Tetracycline | 27/40 |
| Ciprofloxacin | 30/40 |
| Ofloxacin | 37/40 |
| Levofloxacin | 33/40 |
| Ceftriaxone | 27/40 |
| Amikacin | 27/40 |
| Gentamycin | 30/40 |
| Imipenam cilastin | 37/40 |
| Linezolid | 26/40 |
| Azithromycin | 30/40 |
| Clidamycin | 32/40 |
| Chloramphenicol | 31/40 |

DISCUSSION

In our study of 40 subjects of Diabetic foot, maximum rate of 50% was seen in above 60 years age group, while it was 15% and 20% in the 50–59 and 40–49 years age- groups respectively. This study is similar to that reported by Hasburn *et al.*^[17] from Mexico Hospital (Mean age 60 ± 4 years).

A study done in the USA in 2004 by Reed^[18] suggested that elderly Diabetics had twice the risk of developing a foot ulcer, 3 times the risk of developing a foot abscess, and 4 times the risk of developing Osteomyelitis.

Sinnock^[19] estimated that the amputation rates in diabetic subjects are higher for males than females which were evident in our study.

Footwear being a vital part for diabetics this study had 52.7% barefooted and 47.5% who used footwear. Ashry

Table 6: Surgical procedure among the subjects

| Surgical procedure | Number (%) |
|---|------------|
| Incision and drainage | 07 (17.5) |
| Wound debridement | 24 (60) |
| Toe amputation | 13 (32.5) |
| Forefoot amputation | 1 (2.5) |
| Below knee amputation | 04 (10) |
| Above knee amputation | 03 (7.5) |
| Split skin grafting | 03 (7.5) |
| Incision and drainage+wound debridement | 03 (7.5) |
| Wound debridement+toe amputation | 03 (7.5) |
| No surgical procedure done | 12 (30) |

Table 7: Distribution of subjects according to progress of wound healing

| Wound healing | Number (%) |
|--------------------------------|------------|
| Wound healed | 11 (27.5) |
| Wound showing signs of healing | 25 (62.5) |
| Non- healing wound | 4 (10) |
| Total | 40 (100) |

Table 8: Association between clinical onset and course of disease with outcome among the subjects

| Clinical onset and course | Mean | SD | 95% CI | | P-value |
|---------------------------------------|-------|-------|--------|-------|---------|
| | | | Lower | Upper | |
| Precipitating factors *site of lesion | 3.050 | 2.605 | 3.897 | 2.202 | <0.001 |
| Presentation * outcome | 1.900 | 1.481 | 1.426 | 2.373 | <0.001 |
| Site of lesion * outcome | 4.80 | 2.028 | 4.151 | 5.448 | <0.001 |
| Precipitating factor * outcome | 1.750 | 1.597 | 1.239 | 2.260 | <0.001 |
| Antibiotics * outcome | 2.488 | 1.051 | 2.182 | 3.179 | <0.001 |
| Surgery * outcome | 2.724 | 3.356 | 0.675 | 2.724 | <0.001 |

et al.^[20] in their study noted that patients at high risk of diabetic foot ulceration benefit greatly from the use of footwear that corrects or least mitigates the biomechanical defects. Knowles and Boulton^[21] found that patients suffering from diabetic foot problems often look for footwear that is presentable and fashionable as well as protective. They also observed that only 22% of their subjects wore their prescribed footwear all the day.

In our study, the most common cause of diabetic foot was trauma and a history of previous abscess or ulcer. There was high level of significance ($P < 0.001$) when compared with progress and outcome. In Nigeria study by Muhammad^[22] variously suggested that trauma or complications of traditional bone setting and complications from Diabetes Mellitus are the most common causes

With regard to presentation our study showed various presentations such as gangrene, abscess, cellulitis, and ulceration. Linklater and Potter^[23] noted that soft tissue abnormalities associated with the diabetic foot include soft-tissue edema, cellulitis, abscess, ulcers, sinus tracts, tenosynovitis, joint effusions, and arthritis. Our study showed strong significance ($P < 0.001$) when compared with progress of the ulcer.

In a study conducted by Treece *et al.*^[24] in the UK among 389 diabetic ulcer patients, 78.4% were of Grade 2 type, 10.8% had Grade 3 type and rest Grade 4 which nearby to the present study findings based on Wagner ulcer classification system.

In the present study, diabetic foot lesions were found at multiple sites. Toes with web spaces and plantar and dorsum aspects of the foot were the most common sites found in 70% of the patients. Lesion and progress were assessed for association and noted highly significant ($P < 0.001$). Reiber *et al.*^[25] noted that ulcer sites are predominantly under the plantar surface of the toes, forefoot, and midfoot followed by the dorsal surface of the toes and heel. Apelqvist *et al.*^[26] cautioned that ulcer severity is more important than the ulcer site in determining the final outcome.

Chahne *et al.*^[27] found that *S. aureus* and beta-hemolytic streptococci were the most common infecting organisms in patients with mild-to-moderate diabetic foot infections. They also noted that *P. aeruginosa* was associated with exposure to water and warm climate; obligate anaerobes were associated with necrotic, gangrenous, or ischemic tissue in chronic and severe infections. Patients who had recent antibiotic therapy or having chronic ulcers tend to develop mixed infection with Gram-positive cocci and Gram-negative bacilli with or without the presence of anaerobic organisms.

Lee *et al.*^[28] in 2003 in a study of 13,271 patients with diabetes have shown 78.4% have fungal infection of the feet. Among these infections, 70.8% are Tinea pedis. The investigators, therefore, consider fungal infection a risk factor for foot ulcers.

In the treatment aspect, various antibiotics were used, cefoperazone-sulbactam was the most common used antibiotic in patients to combat both Gram-positive and Gram-negative organisms followed by clindamycin and ampicillin-cloxacillin and the third common antibiotic used was ciprofloxacin. Many patients required treatment with more than one antibiotic drug. Antibiotics play a major role and combination of a couple of them yielded good progress ($P < 0.001$).

Twenty-four patients had undergone wound debridement (60%), 13 patients underwent toe amputation (32.5%), seven patients underwent incision and drainage (17.5%), four patients underwent below-knee amputation (10%), three patients underwent above-knee amputation (7.5%), only one patient underwent forefoot amputation (2.5%), 3 patients have split skin grafting out of which two had undergone wound debridement and one had undergone below-knee amputation. 12 patients had no surgical intervention. Surgical procedures on follow-up with regard to progress was fair and good and of high significance ($P < 0.001$). Hawkins and Brike^[29] in their study of diabetic outpatients predicted that 6% to 43% (depending on ulcer severity) of patients with foot ulcers have the most severe diabetic foot outcome, amputation.

Garbalosa *et al.*^[30] stated that despite everyone's best efforts in performing diabetic foot care, an amputation is occasionally the treatment of choice.

Eneroth^[31] observed that debridement is also necessary in case of sepsis secondary to acute osteomyelitis, progression of infection despite antibiotics, and recurrent foot infections secondary to chronic osteomyelitis.

Pitei *et al.*^[32] observed that the callus needs to be removed frequently, as it can build up quickly, with some patients needing debridement as often as every 3–4 weeks or sometimes even more frequently.

A study by Abbott *et al.*^[33] involving 9700 patients showed that the presence of diabetic foot ulceration incurred an 80 to 85% risk of amputation.

Wrobel *et al.*^[34] suggested that only four surgical procedures exhibit higher variation than major amputation in diabetes: lower extremity revascularization, carotid endarterectomy, back surgery, and radical prostatectomy.

It is seen that after 4 weeks of treatment 25 patients showed signs of wound healing (62.5%), wound had healed completely in 11 patients (27.5%) and only 4 patients had a non-healing wound (10%). Thus, 90% of patients in the study group had wound healing by the end of the 4th week.

Peter Sheehan *et al.*^[35] predicted that the percentage of wound healing after 4 weeks of treatment was a significant predictor of wound healing after 12 weeks.

CONCLUSION

This study was conducted among 40 diabetic subjects. The study consisted of 18 males and 22 females. The mean age was 51.8 + 3.42. Footwear, precipitating factors, and presentation were taken into consideration. The lesions were graded using the Wagner ulcer classification system. The various site of lesion was elucidated. Culture and sensitivity were done for all the subjects and the most common organisms were identified and the treatment was given accordingly. Surgical procedures were carried out in 28 subjects. Healing and healed was 90% after 4 weeks at follow-up. There was a strong association observed in the study with regard to precipitating factors, presentation, site of lesion, role of antibiotics, and surgical procedures with outcome.

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