

Evaluation of different surgical modalities in management of diabetic foot.

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Abstract

Background: Foot ulcerations, infections and peripheral arterial disease are major complications of diabetes leading to serious consequences like gangrene and/or amputation.

Objectives: To analyse different target interventions to predict wound healing and major amputation for salvation of limb in patients with diabetic foot ulceration.

Methodology: In this prospective study, patients showing clinical signs of diabetes foot ulcers were studied for their demographic variables, clinical parameters, haematological and radiological investigations and different treatment modalities used for management and analysed statistically.

Results:The mean patient age was 54.58 ± 9.04 years with male predominance (62%). Most common presentation was ulcer in 25(50%) patients followed by gangrene in 7(14%) patients. Majority (28%) of patients had diabetes duration of 6-10 years and 18 (36%) had peripheral neuropathy. Most common organism identified in the wounds was *Staphylococcus aureus* (48%) sensitive to ampicillin. Hospital stay ranged from 3-90 days. 22 (44%) cases were managed by wound debridement, 4 (8%) by incision and drainage and rest 24 (48%) undergone amputation. Out of total 24, 17 (34%) cases were treated with toe amputation, 2 (4%) patient needed transmetatarsal amputation, 3 (6%) needed below knee amputation and above knee amputation required in 2 (4%) patients.

Conclusion: Early detection and management of the diabetes foot ulcer is most important parameter for limb salvation. Poor glycaemic control and duration of diabetes along with peripheral neuropathy are risk factors for diabetes foot complications. Foot care education would be the most important way of dealing with this major problem.

Key words: Diabetes foot, complications of diabetes, gangrene, amputation, management of diabetes complications.

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I. Introduction

Diabetes mellitus is a global issue as declared by International Diabetes Federation with more than 426 million population globally affected with India enduring the highest global burden of diabetes. (1) One of the major devastating complication of diabetes is diabetic foot disease (DFD) which is associated with highest rate of morbidity, mortality, and reduced quality of life. It has been estimated by International Diabetes Federation that globally in every 30 seconds a patient loses at least one limb due to diabetic foot disease which is one of the most common cause of hospitalization with significant socioeconomic impact. It has been also estimated that patients with diabetes are at 25% higher risk of developing diabetic foot ulcers with two fold increase in rate of mortality compared to non-ulcerated diabetic patients. (1) Peripheral neuropathy, trauma, peripheral vascular disease, cellulitis, increased age and renal disease predispose development and aggravation of foot ulceration. Diabetic foot ulcers have been grouped into two major segments including soft tissue and bone infections. Soft tissue infections are diffuse skin inflammation which are not too deep but are confined to epidermis and subcutaneous tissue. Soft tissue when untreated further penetrates to periosteum, cortical region and bone marrow increasing the risk of limb amputation, with its substantial associated morbidity and mortality. (2)

Major pathophysiology of DFD involves high blood sugar levels. Hyperglycemia impairs host immune system by impairing leukocyte function and macrophages morphology. Reduced levels of cytokines and chemotaxis impairs normal wound healing and promotes inflammatory reactions. High blood glucose levels causes diabetic peripheral arterial disease damaging nerves and blood vessels. It also impairs collagen synthesis which in turn resists wound healing leading to deteriorated conditions ranging from extensive infection to gangrene. Once ulceration or gangrene has affected the tissue, the objective of the treatments confines to preservation of viable tissue and prevention of its spread. (3) Appropriate treatment strategy and its implementation depends upon evaluating the extent of infection, its depth and blood supply in the infected area with presence or absence of sensation. Mild to moderate infection requires empiric wide spectrum antibiotics therapy while severe infection requires surgical interventions which ranges from minor debridement to major amputations. Surgical treatment is based on evacuation of pus and removal of necrotic tissue for minimization of spread and salvaging the limb. (4, 5)

There has been a wide disparity in various treatment guidelines laid down by international health bodies and scientific associations for selection of the appropriate and precise treatment modality for infected diabetic foot ulcers/wounds. There are also few areas which lack understanding on the infected diabetic wound management guidelines. Hence there is a need to analyse various treatment practices and assessment of evidences for selection of appropriate treatment modality. This study is planned with the objectives of analysing different clinical presentations and consequences of diabetic foot and various surgical modalities in management of diabetic foot.

II. Material and Methods

A prospective study was conducted on diabetic patients with foot lesions presented in the Department of General Surgery at a tertiary care teaching hospital in western India. The study protocol was approved by the institutional ethics committee and written informed consent was obtained from all patients. All the adult patients upto 80 years of age and presented to the surgical outpatient department with diabetes foot lesion as per treating surgeons' clinical judgement either for primary or secondary treatment during September to February 2018 were enrolled for the study. Patients with foot lesions other than diabetes foot and not willing to give written informed consent were excluded from the study. A pre designed questionnaire- proforma was prepared and filled up for individual patient. The questionnaire- proforma included demographic details of the patient, past diabetic and other comorbid history including personal lifestyle details. It includes clinical parameters like, duration of diabetes, sign and symptoms, cause of ulcer, duration of ulcer, any previous treatment taken for the ulcer, previous history of foot ulcer and addiction including smoking. Results of haematological investigation, biochemical and microbiological analysis were also recorded in the proforma. The proforma also included information about clinical examination of the wounds including relevant diagnosis, results of instrumental examination with details of primary and secondary treatment. Precise details of the antibiotics with other treatment modalities were also recorded. Detailed analysis of the pre-designed questionnaire- proforma of all patients was carried out and its final outcome was assessed based on complete healing, toe amputation; below knee amputation or whether they were still on treatment.

Wagner's classification (6) was used for grading DFUs by measuring the lesions and both the feet were closely examined to describe the type of foot ulcers. A Doppler study was performed to determine presence or absence of peripheral sensation or reduced pulses. Low grade and superficial DFUs were treated with initial debridement of lesions followed by elimination of surrounding hyperkeratosis regular dressing with saline moistened gauze every 24 hours and medications. Patients with deep ulcers with affected bone or joint were preoperatively evaluated by taking ECG, chest x-ray, blood cell count and plasma chemistry following for scheduled surgery. On the day of surgery patient had their capillary glucose monitored with IV infusion of 5% glucose and insulin throughout the procedure of surgery. The glucose levels were maintained between 5.5 and 11.1 mmol/l. The Surgery involved removal of the ulcer through conic ulcerectomy in which both the walls and the bottom part of the lesion was removed. In case of visible bone segments under the ulcers, or in cases where bone segments are found interfering with the closure of the margins of wound, scalpels were used for the debridement. Resected bone fragments were subjected to culture test for evaluation of microbial or fungal infection to verify the possibility of presence of osteomyelitis. The surgical wound was closed with single stitches and a drain, which was removed after 48 h. The closed wound was covered with sterile gauze and the limb was positioned in slight anti-orthostatic position for 48 h. Then the wounds were treated with antiseptic solution (povidone iodine 50 % + saline 50 %) twice a week. Stitches were removed after 3 weeks.

Statistical analysis: Data were presented as actual frequencies, percentage, mean, standard deviation as appropriate. Microsoft excel 2016 was used for the analysis. Chi-square test was used for association analysis and p value less than 0.05 was considered significant.

III. Results:

Total of 50 patients meeting inclusion-exclusion criteria were enrolled for the study. The demographic details of the patients are shown in Table 1. The youngest patient was 30 years and oldest was 80 years of age. The highest number of cases was found in the age group 51-60 years (32%) followed by 61-70 years (28%). Out of the total 50 cases studied here, 31 (62%) cases were male and 19 (38%) cases were female.

Table 2 shows mode of presentation of diabetic foot ulcers in 50 cases, out of which 25 (50%) cases presented with ulcer, 7 (14%) cases with gangrene of toe or foot, 12 (24%) cases with cellulitis and 6 (12%) with abscess. X-ray of 4 cases showed Osteomyelitis. Doppler studied in one patient showed arteriosclerotic changes with low volume flow in anterior and posterior tibial arteries. The exact duration is not accurately known, as few patients were unaware of being diabetics and were diagnosed as suffering from diabetes on admission with complaints of non-healing ulcers. There is significant difference in presentation of disease between the patients as most of patients were suffering from ulceritis. (P value < 0.008)

Table 3 gives detail about history of patient regarding duration of diabetes. In our study 07 (14%) patients presented with duration less than or equal to one year. Only seven (14%) patients had diabetes of more than 20 years of duration. Maximum patients in our study were diabetics of 6-10 years duration (28%).

Majority of the septic lesions (48%) yielded Staphylococcus aureus on culture of pus as shown in Table no: 4. Other organisms that were isolated are, Pseudomonas, Klebsiella, E. Coli, and Proteus. Most of them were sensitive to Ampicillin, Gentamycin, and Amikacin. Some cultures yielded more than one type of bacteria.

In the present study 18 (36%) cases were found to have neuropathy. Patients with neuropathy varied from 35-80 years. Majority had history of diabetes of more than 5 years. This shows that peripheral neuropathy is common in long standing diabetic patients. 8 (16%) patients had Gangrene. The minimum stay in hospital was 3 days and maximum was 90 days. This long duration of hospitalization can be explained by the refractory to treatment of the lesions owing to the diminished resistance of the body, hyperglycemia, impaired hormonal defense mechanisms and resistance of the organisms to antibiotic therapy.

Table 5 gives details about treatment given to patients. In this series 22 (44%) cases were managed by daily dressing and repeated wound debridement, and slough excision. Total 9 out of 50 patients were treated with vacuum dressing in post-operative period which was changed within every 2-3 days. 4 (8%) patients were treated with I & D and fasciotomy, Total 24 (48%) patients needed amputation to prevent further spreading of which 17 (34%) cases were treated with toe amputation, 2 (4%) patient needed TMT amputation and 3 (6%) patient needed Below knee amputation and above knee amputation in 2 (4%) cases. In most of the cases, limb was salvaged by conservative treatment and minor amputations.

Table 1: Age and Gender wise distribution of Patients with Diabetic foot (n=50)

Parameter	No. of Patients (%) N (%)	P value
Age in years		
21-30	01 (02)	0.1 (NS)
31-40	07 (14)	
41-50	10 (20)	
51-60	16 (32)	
61-70	14 (28)	
71-80	02 (04)	
Total	50 (100)	
Gender		
Male	31 (62)	0.08 (NS)
Female	19 (38)	

Table 2: Mode of Presentation of Patients with diabetic foot (n=50)

Mode of Presentation	No of cases (%)	P Value
Ulcer	25 (50)	0.008 (Significant)
Gangrene	07 (14)	
Abscess	06 (12)	
Cellulitis	12 (24)	

Table 3: Total duration of diabetes in patients suffering from DFD

Duration of Diabetes In Years	No of Patients	P Value
0-1	07 (14)	0.35 (NS)
2-5	06 (12)	
6-10	14 (28)	
11-15	07 (14)	
16-20	09 (18)	
>20	07 (14)	

Table 4: Distribution of microbial isolates from different diabetic foot ulcer patients

Bacteria	No of Cases	P Value
Staphylococcus aureus	24 (48)	0.0003 (Significant)
Pseudomonas	05 (10)	
Klebsiella	10 (20)	
Coliform	06 (12)	
Proteus	03 (06)	
Non-Haemolytic Streptococci	02 (04)	

Table 5: Treatment modes of Diabetic foot ulcer

Treatment	No of cases	P Value
Debridment	22 (44)	0.0001 (Significant)
Incision - drainage and Fasciotomy	04 (08)	
Toe amputation	17 (34)	
Transmetatarsal (TMT) amputation	02 (04)	
Below Knee amputation	03 (06)	
Above Knee amputation	02 (04)	

IV. Discussion

Diabetic Foot ulcers and its consequential infections are a complex disease conditions and a serious cause of morbidity in patients with hyperglycemia and diabetes mellitus. These Foot ulcers begin superficially and are often accompanied by infection in muscle, tendon, bone, and joints in later stages. They progress to deeper spaces and tissues which if not treated immediately would lead to gangrene like devastating condition that eventually requires foot amputation. It also affects the quality of life of the patients adversely and require treatment by team of doctors involving physician, surgeon, dietitian etc.

Data obtained from our study suggest that diabetic foot complications were more prevalent in males compared to females. More prevalence in males can be explained by the social structure in India where males are the breadwinners of the family and are mostly working out door, which makes them more vulnerable for trauma and squeale. Habit of smoking and alcohol also makes males more prone for diabetic foot lesions. Also middle age is the most common age group affected by the diabetes foot. Findings are similar with the earlier studies. (7) Also findings similar to this results were observed in previous studies in patients with diabetic foot complications due to associated comorbidities. (8, 9)

Most common presentation of the diabetes foot disease is ulcer followed by gangrene which is similar to earlier studies (7). Control of the blood sugar is very important aspect for development of complications of diabetes. Achieving the good control of blood glucose by drug and life style modifications is essential for delaying in development of complications for the diabetes patients. Studies have shown that complications of diabetes like diabetes foot ulcer occur more frequently in patients with poor control of blood sugar. (10, 11)

Diabetic foot ulcers are commonly diagnosed through symbiotic clinical and bacteriological approach which is based on assessment of purulent discharge from an ulcer or the classic signs of inflammation. Prominent ulcer formation with presence of necrosis and failure of wound healing were the most prevalent symptoms presented by patients with diabetic foot ulcer. It was also observed that development of suppurative cellulitis from infected diabetic foot ulcer due to colonization of *S. aureus* was another important risk factor which demands immediate control to avoid complications. (12, 13)

An important clinical observation during this study was that people with diabetes are commonly associated with peripheral neuropathy which plays a major role as an initiating factor for development of foot ulcer. Prominent manifestation of peripheral neuropathy is peripheral nerve dysfunction which contributes to 45% to 60% of all ulcerations in patients with diabetes. Similar clinical observations were reported by other diabetic foot ulcer study as well. (14-16)Osteomyelitis was most critical condition found in patients with moderate to severe soft tissue infections that spreads into the bone, involving the cortex and marrow. Ulcers with depth greater than 3mm and manifested through changes in width and depth of the foot are commonly associated with osteomyelitis. Osteomyelitis commonly involves *S. aureus* a gram positive bacteria in majority of the cases followed by *Escherichia coli*, *Klebsiella pneumoniae* and *Proteus* among Gram negative bacteria. (17)

It predominantly requires resection of infected bone accompanied by four to six weeks of culture-directed antibiotic therapy. Similar treatment modality was followed in previous study. (18)Advanced age, longer duration of diabetes, uncontrolled hyperglycemia and associated diabetic peripheral neuropathy are responsible for development of Peripheral arterial disease (PAD) which is also a major cause of diabetic foot disease. PAD progresses infection deteriorating the damaged tissue due to oxygen insufficiency and nutrition which contribute to a potential foot amputation. (19)

Early diagnosis and assessment of the area of involved tissue helps in proper management and prevention of progression of foot ulcer. Determining the etiology of the ulcer to ascertain whether the lesion is neuropathic, ischemic, or neuro-ischemic is the foremost step in treatment. Cleaning and debridement of the wound for removal of foreign bodies or necrotic material properly prevents the progression of the disease. (20) A Probe-to-bone test (PTB) by using sterile blunt probe with X-ray improves sensitivity, specificity and positive predictive value in diagnosis of diabetic foot osteomyelitis. (21) Radiological examinations using X-ray to determine osteopenia, erosion of cortical bone, cortical lysis, osteolysis are most common approaches to detect bone involvement in case of suspect osteomyelitis without clinical signs of infection. (22) Ultrasonography and computed tomography techniques helps in assessing abnormalities in the soft tissue (e.g., abscess, sinus tract, cortical bone involvement) which may provide guidance for diagnostic and therapeutic aspiration, drainage, or tissue biopsy. (23)

Overall, this study has highlighted the presentation and management of diabetes foot ulcers in western India. This study has been conducted in a single centre with no long term follow up. Further larger multicentric studies involving different ethnic and genetic population and long term follow-up can be helpful in better understanding of the complexities of the diagnosis and management of diabetes foot ulcer for better patient management.

V. Conclusion:

Multimodality treatment including antibiotic therapy, surgical drainage, debridement and resection of dead tissue and appropriate wound care are most suitable approach for the effective management of diabetic foot ulcer. Early prevention through repeated foot examination for anatomical deformities, strict glycemic control and proper foot care would help in reducing infection and amputation rates thereby improving the quality of life of patients.

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