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Key Words

DFU-diabetic foot ulcer,
IDF-international diabetes
federation, DFO-diabetic foot
osteomyelitis, PTB-probe to bone
test, ABI-ankle brachial index

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A Prospective Observational Study of Different Modalities of Diagnosis, Medical Versus Surgical Treatment and Outcome of Diabetic Foot Patients with Osteomyelitis

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ABSTRACT

Diabetes is one of the most prevalent diseases in society in which no medical specialty should be exempted from understanding the disease and its complications. Since diabetic foot complications are very prevalent and affect all diabetics, causing significant burden in their lifestyle and loss of limb or life, making it is important to study. Peripheral vascular changes and neurological changes are induced by long-standing untreated diabetes, which worsens the path of the disease by ulceration, infections, deformities and other systemic complications. There is a need to review clinical presentation, patho-physiology and categorize the lesion and classify for best management to minimize morbidity in diabetic patients who were most often present with uncontrolled infection and ulcerations leading to compromise of part of the foot or entire foot. The present research proposes a systematic research on clinical presentation and diagnosis and diabetic foot management in G.R. Medical College, Gwalior, so that more could be learned about clinical presentation, pathophysiology and management of DFO in this geographic area. An accrual study was conducted in patients who presented with infected foot ulcer with history of diabetes mellitus or with raised blood sugar levels. A population of 75 patients with diabetic foot was enrolled for study. Detailed history, clinical examination, chemical and biochemical evaluation was done. Assessment of peripheral neuropathy, lower limb pulsation and ABI was done followed by wound assessment for number, location, dimension, presence and nature of discharge, granulation tissue extent of necrosis extent and type of gangrene scar of previous surgeries and deformities etc. Based on above parameters foot ulcers were classified according to university of texas wound classification system and patients were henceforth treated medically or surgically and observations were made. There was more risk of developing DFO with increasing duration of diabetes and more among in uncontrolled diabetic patient and family history of diabetes mellitus. Maximum DFO patient present with non-healing foot ulcer with underlying infected bone. Most common microorganisms grown from culture taken from the lesion was staphylococcus aureus followed by streptococcus. Slightly higher healing with less recurrence found in surgically managed DFO. Healing duration of lesions is similar in both groups most lesions healed within 3 month. It can be concluded that Maximum DFO patient present with non-healing foot ulcer with underlying infected bone. Deep tissue culture and bone culture helps to guide appropriate antibiotic therapy. Slightly higher healing with less recurrence found in surgically managed DFO. Healing duration of lesion are similar in both groups most lesion healed within 3 months.

INTRODUCTION

According to the International Diabetes Federation (IDF), diabetes is a major global health issue, with 463 million people currently are living with diabetes across the globe and of which 88 million people in the area of Southeast Asia. In 2020, India accounted for 77 million of those 88 million inhabitants. According to the IDF, the prevalence of diabetes in the population is 8.9 percent. 80% of people with diabetes live in low- to middle-income countries including India, a country with the second largest number of diabetic patients in the world after China^[1]. According to the World Health Organization and the International Diabetic Foot Working Group on diabetic foot, diabetic foot is described as "The foot of diabetic patients with deep tissue ulceration, inflammation and/or destruction associated with neurological dysfunction and varying degrees of peripheral vascular disease of the lower limb^[2]. DFU is one of the complications of diabetes associated with severe morbidity, mortality and reduced quality of life and socioeconomic implication^[3-4]. Incidence of DFU continues to rise^[5]. Diabetic Foot ulcer is characterized as a full-thickness wound below the ankle in a diabetic individual, irrespective of the period, as per the international consensus on diabetic foot 6. Foot ulceration is a very common complication among diabetics in the Indian population and can be due to various social and cultural activities such as barefoot walking, lack of awareness, poverty, poor foot care and hygiene and poor access to health care^[7]. It has been predicted that at least 19-34% of diabetic patients are likely to be infected throughout their lifetime with a diabetic foot ulcer with a recurrence rate of 50% within the next 5 years^[8-9]. The International Diabetes Federation estimates that DFUs will be developed by 9.1 -26.1 million people annually. The annual incidence of foot ulcer amongst Medicare beneficiaries with diabetes is 6 percent, according to recent data from the United States^[10]. About 60% of diabetic foot ulcers (DFUs) may get infected^[11]. Infection is the forerunner of lower limb amputation in more than two thirds of patient with DFU^[12]. With progress of diabetes structural anatomy of foot undergoes alteration and gait pattern to change due to vasculopathy and neuropathy. The insensate foot is very prone to trauma which may be unperceived and hence neglected and ulcer remain unnoticed and very soon it develops septic complication. Osteomyelitis is a common complication of infected diabetic foot ulcer, occurring in 10%-15% of moderate and 50% of severely infected feet^[13]. Osteomyelitis complicated ulcers often require surgical care with prolonged antibiotic therapy^[14]. Diabetic foot osteomyelitis (DFO) is the consequence of a soft tissue infection that extends into the bone in diabetic individual, affecting the cortex first followed by marrow. In all DFUs chronic wound, recurrent ulcers with clinical findings of inflammation,

bone involvement should be suspected. Any bone can be affected by osteomyelitis, but most commonly the forefoot (90%), followed by the mid foot (5%) and the hind foot (5%). The forefoot prognosis is better than osteomyelitis of the mid foot and hind foot. The risk of proximal amputation for the hind foot (50 percent) is substantially higher than for the mid foot (18.5 percent) and forefoot (0.33 percent)^[15]. To ensure successful care and reduce risk of minor and major amputations, early and accurate diagnosis is necessary^[16]. As the Vascular Society of India (2010) reports, the number of amputations in India is 80,000 to 100,000 annually. The initial presentation of about 85 percent of lower extremity amputations appears to be DFUs. Diabetic foot ulcers, 15 times higher than in the non-diabetic population, remain a significant cause of non-traumatic lower extremity amputations worldwide. The length of hospital stay for patients with diabetic foot ulcers is approximately 60 percent longer compared to those without diabetic foot ulcers^[17]. Diabetic foot surgical procedures include debridement, minor amputation (including ray, transmetatarsal and Pirogoff amputation), major amputation (including below-knee, through-knee and above-knee amputation), split skin grafting and vascular bypass surgery^[18-19]. Usually, debridement is left to on duty resident to do. This practice, however, is not good. A skilled surgeon who would be able to excise devitalized tissue properly needs good debridement. The resident can often not measure the degree of debridement required. Repeated debridement is often needed. If it is carried out by an experienced surgeon, the result would be better for the patient. The secret to success in the treatment of diabetic foot ulcers is adequate debridement^[20]. Compared to western countries; there is a small variation in a diabetic foot appearance in Indian patients. Necrotizing fasciitis, for example, is common in India, although it is uncommon in western countries^[21]. In addition, peripheral vascular disease is more prevalent in western countries, although it accounts for less than 10 percent in India^[22]. In India, the diabetic foot is more infectious and neuropathic in nature^[23]. The International Diabetes Federation reports that every 30 seconds, at least one leg has lost due to DFU somewhere in the world^[24].

MATERIALS AND METHODS

Patients and Methods: A total of 75 patients were included on accrual in this study.

Inclusion Criteria:

- All diabetic foot patients admitted in department of general surgery of G.R. Medical College in the above mention time period.
- Duration of ulcer \geq 2 weeks
- Ulcer width $>$ 2 cm and depth $>$ 3 mm with or without gangrene.

- Patients who are willing to participate.

Exclusion Criteria:

- Non diabetic patients with foot ulcers.
- Presence of peripheral vascular disease(<0.6 ABI)
- Patients who have diabetes with superficial ulcer (width<2cm² and depth<3mm).
- Very sick patient with presence of severe life-threatening complications.
- Patients receiving corticosteroid, immunosuppressive agents, radiation, or chemotherapy within one year.
- Patient Not willing to participate in the study.

MATERIALS AND METHODS

- The patients selected for this study were those who presented with infected foot ulcer with history of diabetes mellitus or with raised blood sugar level.
- After obtaining informed consent from patient for enrolling in study, demographic profile, data was taken which included name, age, sex and duration of diabetes history of presenting complaints, family history of diabetes, associated co-morbidities, history of surgical intervention and treatment history.
- Assessment of diabetic foot osteomyelitis by using probe to bone test in open wound if probe to bone test negative or not possible we used xray and inflammatory marker.
- A detailed clinical and biochemical evaluation of patients were carried out upon admission. In clinical evaluation Assessment of peripheral neuropathy, lower limb pulsation and ABI was done followed by wound assessment for number, location, dimension, presence and nature of discharge, granulation tissue extent of necrosis extent and type of gangrene scar of previous surgeries and deformities etc.
- Based on detailed history and clinical examination the foot ulcer classified according to University of Texas Wound Classification System [table]

Study population defined as conservative group if surgery was not carried out in the first 5 days following admissions, if surgery done categorized as surgical group.

- Dressings were done every day or as per wound status in both groups. Wound was assessed for the need for surgical intervention by local and general examination.
- Glycemic control of patient was carried out as per instruction of medicine department.
- Antibiotic selection primarily empirical till culture and sensitivity. after Culture sensitivity antibiotic use up to 3 months in conservative group and up to 10 days in surgical group.

Increasing depth of wounds and complications of ischemia or infections in this classification have been associated with increased likelihood of amputation.

RESULTS AND DISCUSSIONS

- This study was conducted on admitted patients in different units of department of general surgery in G.R. Medical College; Gwalior during the period of

Fig.1: Bacterial Distribution in Culture

Fig.2: Comparison of Different Procedures Needed in Surgical Group

Fig.3: Duration of Wound Healing

Fig.4: Outcome of Study

Table 1 :-Based on following criteria patient wound treated medically and surgically

MEDICAL	SURGICAL
Patient too unstable for surgery	Foot infection is associated with substantial bone necrosis or exposed joint
No other surgical procedures on foot are needed	There is persisting sepsis
Infection is confined to small forefoot lesion	Foot appears to be functionally unsalvageable
Patient has a strong preference to avoid surgery	Uncorrectable foot ischemia, patient has a strong preference for surgical treatment
No hospitalization	Hospitalization
There are no contraindications to prolonged antibiotic therapy	Major risks of antibiotic problems

Table 2: University of texas wound classification system

Stage	Grade 0	Grade 1	Grade 2	Grade 3
A	Preulcer or postulcer lesion No skin break	Superficial ulcer	Deep ulcer to tendon or capsule	Wound penetrating bone or joint
B	+Infection	+Infection	+Infection	+Infection
C	+Ischemia	+Ischemia	+Ischemia	+Ischemia
D	+Infection and ischemia	+Infection and ischemia	+Infection and ischemia	+Infection and ischemia

Table 3 :-Male and female ratio

Ratio	Abubaker et al.	Didier pittet et al.	Present study
Male: female	3:1	0.9:1	1.6:1

Table 4: History of trauma

History of trauma	Jennifer. A., may field et al,119	Present study
Yes	44%	63%
No	66%	37

Table 5: Clinical diagnosis

Diagnosis	Present study	Didier pittet et al.
non healing ulcer	54.67%	28%
Osteomyelitis and deep tissue infection	22.66%	54.95%
Gangrene	17%	16.5%

Table 6: Site of lesions

Site	Didier pittet et al.	Present study
Forefoot	91%	54.67%
Mid foot	5.2%	20%
Hind foot	8.7%	35.34%

Table 7: Culture and sensitivity comparison

Percentage of patients	Gibbons et al 124 .ai.,	Wheat et al.,125	Hughes et al.,126	Present Study
Staph aureus	22	20	25	47.14
Streptococcus species	13	23	20	30
Pseudomonas species	3	4	0	20
E. Coli	7	5	3	12.86
Klebsiella	4	6	7	11.43
Proteus	11	9	11	10
No growth				14.29

1st January 2019-31st August 2019 over a period of 20-months, 75 cases of diabetic foot osteomyelitis were observed and analyzed. The results observed in the study are as follows:-

- Most of DFO cases observed are of 51-60 years age group with mean age±standard deviation 58.95±10.87.
- Out of 75 patients, 46 (61.33%) were males and 29(38.66%) were females. male and female ratio is 1.6:1.
- Out of 75 DFO patients 57(76%) presented with <10 years history of DM-II at the time of admission and 24% had >10 years duration.
- 39(52%) patients out of 75 gave a positive family history of diabetes.
- Out of 75 patients 29(38.66%) presented with severe form of foot complications.
- Out of 75, 17 (22.66%) patients presented with deep soft tissue infections with osteomyelitis, 41 (54.66%) with non-healing ulcers, 17(22.66%) with gangrenous foot.

- Out of 75, 41(54.67%) patient present with fore foot involvement, 15(20%) had mid foot and 19(35.34%) hind foot involvement.
- Patients presented with some kind of trauma .i.e. injury to foot and leg before the development of symptoms was reported in 62.67% of case in present study.
- Out of 75, 42(56%) patients presented with history of some kind of alcohol, smoking and tobacco addiction.
- 55(73.33) % patients had neuropathic symptoms.
- Out of 75, 52(69.33%) patients present with mild arterial obstruction.
- Out of 75 patients test done in 60 patients and 49(81.66%) patients showed positive result.
- Out of 75 patients x-ray foot done in 35 patient, out of 34 patient 30 x-ray showed osteomyelitic changes and 3 patients had normal x-ray foot.
- Out of 75 patients test done in 70 patient, out of 70, 60(85.71%) samples were positive and 10(14.29%) showed negative result. Out of 60,

38(54.29%) were mono-microbial and 22(31.43%) poly-microbial.

- 47.14% were culture positive for staph aureus , 30% for streptococcus , 20% for pseudomonas 12.86% for e. coli, 11.43% for klebsiella,10% for proteus and 14.29% sample show no bacterial growth.
- In this study out of 75 patients, 45(60%) were surgically and 30(40%) were medically managed.
- 45 (60%) patients were managed surgically and out of 45 ,26 (57.77%)patients needed debridement and 13(28.88%) underwent minor and 6(13.33%) major amputation.
- In this study in medically treated patients 56.66% healed and 33.33% patients had recurrence.
- 3.33% mortality related to diabetic foot complications and 6.66% patients lost follow-up including death unrelated to diabetic foot complications in the study period.
- 60% patients were treated surgically and 66.66% healed and 20% recurrence occurred.
- 8.88% mortality related to diabetic foot complications and 4.44% patient lost follow up including death unrelated to diabetic foot complications in the study period.

Most of diabetic foot osteomyelitis patients were in 51-60 age group with mean age 58.95±10.87 Abubaker^[25]. In their study also found commonest age group 51-60 with mean age 56.6±11.6 comparable to our study.

The Present Study had Ratio of Male: Female as 1.6:1. The incidence is more among males probably as they are mostly working out door, which makes them more vulnerable for trauma and sequel.

Duration of Diabetes: In study by Didier pittet^[26].had diabetes osteomyelitis most case having history of 10-20 years DM duration. In our study 76% patients present with DFO with history of diabetes<10 years of duration, because In our study most of patients belong to rural area were having diabetic foot complication in earlier phase of diabetes because of bare foot walking common in rural and poor health care awareness so patient present in our scenario with infected foot with short duration of dm.

Status of Diabetes: In diabetics with controlled blood sugar level and regularly taking antidiabetic drug patient present with less severe form of disease and cure with conservative treatment with less relapse as compared to uncontrolled diabetics with poor drug compliance.

Family History of Diabetes: In our study 39(52%) patients present with family history of DM. M. Vishwanath *et al* and Monhan^[27].found that a series of

familial aggregation of disease in India and in other Asian population. In India nearly 75% of type II patients have 1st degree family history of diabetes. Familial aggregate of diabetics highly prevailed in I degree relative than II generation is commonly seen in Asian Indian. The risk of offspring developing diabetic foot complication higher in with parenteral history of dm.

Addiction and Personal Habits: Tobacco increases local hypoxia and is detrimental to wound healing as nicotine is a potent vasoconstrictor agent smoke also contains high level of carbon mono-oxide which binds to hemoglobin forming carboxy-hemoglobin. It has a higher affinity for O₂ and decreases O₂delivery to hypoxic tissue. Alcohol is known to cause atherosclerosis which further aggravates, ischemia thereby delaying wound healing. In a study by Nicolucci *et al*^[28]. 60% patients were nonsmokers (of which 14% continued smoking till presentation of ulcer while 26% had stopped smoking).

In our study 75 out of 42(56%) patients were addicted to one of alcohol, tobacco or smoking. These patients showed delayed healing. It clearly indicates that in patients who are using either mode of addiction, prognosis is poor.

47(63%) out of 75 cases in this study had a history of foot trauma before the onset of the lesion. In Jannifer. A. May Field *et al.*, there was no significant percentage of cases: with respect to history of trauma prior to occurrence of diabetic foot lesion.

Study conducted by Mac Fadane, RM and Jeffocoats WT. Showed that the most common cause of ulceration and infection was friction inside from foot wear which was responsible for 20.6% cases.

Incidence of non-healing ulcer in the present study is comparatively high as compare to Didier pittet *et al* but gangrene is nearly equal.

75 cases studied in this series, Out of these, 41(54.67%) cases common site of DFO was on forefoot. In Didier pittet *et al* study also much higher incidence of forefoot osteomyelitis because in our study most of patient present in severe form of foot complication.

Complications:

Neuropathy: Dr Mohan reported foot ulcers in 69.85% as purely neuropathic ulcers and 23.3% having Neuro-ischaemic ulcers.

In our study 73.33% of patients (55 out of 75 were diagnosed to have neuropathy) emphasizing the fact that the diabetic foot infection is developed against the background of neuropathy. These neuropathic feet are more vulnerable to trauma which results in breakdown of skin barrier to infection.

When monofilament is applied patient should be able to identified area being touched and should also be able to detect the presence of monofilament at the time it buccal. Mc Neely *et al* also stressed that in a

clinical setting the insensitivity to the 10 gram 5.07 monofilament was the single most practical measurement of risk assessment.

Vasculopathy: Dr Pendsey^[29] has reported 23.21% patients who underwent amputations had vasculopathy causing ischemia. It is generally believed that 75-90% of patients with foot lesions will have neuropathy in India and 10-15% will have vasculopathy. There would be some who have neuroischemic foot as well.

In our study 69.33% of patients having mild vasculopathy but severe vasculopathic patient not included in my study. This suggests that severe peripheral arterial disease is found in very few cases with DFO.

In the present study the commonest organism cultured was staphylococcus aureus 33 (47.14%) which was similar to study conducted by Gibbons et al. and Wheat et al., Hughes^[30], 126 studies.

Diagnosis of DFO: In present study maximum cases were diagnosed with simple plain radiograph and PTB, 91.42% patient x ray and 81.66% PTB finding suggestive of DFO.

Grayson^[31] have shown that in a high percentage of cases simply probing to bone can make the diagnosis of osteomyelitis in 85% of cases which can be difficult to diagnose even on bone culture or plain x-rays.

Management:

(Antibiotic, Dressing, Pressure off Loading Debridement and Amputation with Debridement, Amputation): In our study all patients received initially broad-spectrum antibiotics, then as per culture sensitivity and regular dressings of wound with pressure off loading.

In our study 17(22.66%) out of 75 patients, benefited exclusively by antibiotics with regular dressing of wound and 30 (40%) patients benefited exclusively by surgery at initial presentation of DFO leading to re-epithelialization of diabetic foot ulcer and cure of osteomyelitis.

We used normal saline, betadine and hydrogen peroxide and other local antibiotics ointment for dressing.

In the study conducted by Apelquist^[32], 63% of the diabetic foot ulcers healed by re-epithelialization/primary healing. Similar studies by Reiber GE showed that 81% of diabetic foot ulcers healed by re-epithelialization of primary healing.

In study by Pecoraro^[33] and Reiber et al foot infection is often the proximate cause leading to tragic outcome of amputation in 25-50% of diabetic foot infections and lead to a minor (i.e. foot sparing amputation) while 10-40% require major amputation. Fiston has suggested to use safest, simplest and least expensive dressing.

Outcome:

Duration of Healing, Discharge, Mortality: In our study 30(40%) medically treated patient 17(56.33%) DFO healed and 10(33%) recurrence and need further surgical management and in 45(60%) surgically treated 30 (66.66%) patient cured with initial surgery and 9(20%) need further subsequent surgery. DFO cured <3 month in medically treated and 22(73.33) and surgically treated 36(80%).

In our study, mortality was 3.33% in medically treated and 8.88% surgically treated. Mortality higher in surgically treated because in surgical patient having more severe disease at initial presentation.

In Abu-Bakr *et al.* study 42.4% wound healed conservatively within 3 months and 12.1% recurrence in 1 year.

However, the results obtained in this study does not match with the opinion. This may be attributed to the geographical differences, differences in post-operative care set up and small sample size.

CONCLUSION

DFO is more common in men due to their increased susceptibility to trauma. Diabetic patients at risk for foot complication must be educated about risk factors and the importance of foot care, including the need for self-inspection and surveillance, monitoring foot temperatures, daily foot hygiene and use of proper footwear, good diabetes control and prompt recognition and early professional treatment of newly discovered lesions.

Not all diabetic foot complications can be prevented, but it is possible to reduce their incidence through appropriate management. The multidisciplinary team approach of diabetic foot disorders has been demonstrated as the optimal method to achieve favorable rates of limb salvage in high-risk diabetic patients.

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