Original Research Article

To study the comparative outcome of medical and surgical management of diabetic foot at Tertiary care centre.

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Abstract:

Introduction-Diabetic Foot Ulcer is one of the complications of diabetes Diabetic foot ulcer arises through a complex interplay of 3 major factors: neuropathy and ischemia are the primary cause, with superadded infection often leading to a downward spiral in the condition of the ulcer.

Diabetic foot infections should be handled by a multidisciplinary team approach using appropriate consultations. Patients with a serious infection should usually be hospitalized for possible surgical interventions, fluid resuscitation, and control of metabolic derangement. In every patient, the need for surgery, ranging from minor debridement or drainage to extensive resections or amputation, should be evaluated. In an ischemic foot, antibiotic therapy and drainage should proceed as soon as possible

Methods: This study was conducted on 75 consecutive patients admitted in various surgery units in Department of General Surgery, J.A. Group of Hospitals, G.R. Medical College, Gwalior during period February 2019 – august 2020. Well, and informed consent from the patient was taken before enrolling them in the study.

- **Result:** -The conservative management of diabetes foot osteomyelitis based on early diagnosis, pressure offloading and antibiotic therapy according to culture 56.66% of cases were cured with conservative management with 33.33% recurrence.
- 60% of patients managed surgically and 57.77% patient need debridement and 28.88% needs minor and 13.33% needs major amputation. 66.66% of patients are cured and 20% need further surgery.

Conclusion: 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, use of proper footwear, good diabetes control, and prompt recognition and early professional treatment of newly discovered lesions.

KEY WORDS:- Debridement ,Gangrene ,Necrosis, Amputation

INTRODUCTION

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 .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 & hygiene, and poor access to health care. 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⁽¹⁾.

About 60% of diabetic foot ulcers (DFUs) may get infected.Infection is the forerunner of lower limb amputation in more than two-thirds of the patient with DFU. With the progress of diabetes structural anatomy of the 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 the ulcer remains unnoticed and very soon it develops a septic complication. Osteomyelitis is a common complication of infected diabetic foot ulcers, occurring in 10%-15% of moderate and 50% of severely infected feet⁽²⁾. Osteomyelitis complicated ulcers often require surgical care with prolonged antibiotic therapy.

most commonly the forefoot (90%), followed by the midfoot (5%) and the hindfoot (5%). The forefoot prognosis is better than osteomyelitis of the midfoot and hindfoot. The risk of proximal amputation for the hindfoot (50 percent) is substantially higher than for the midfoot (18.5 percent) and forefoot (0.33 percent)⁽³⁾. To ensure successful care and reduce the risk of minor and major amputations, early and accurate diagnosis is necessary. 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. 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. 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. In India, the diabetic foot is more infectious and neuropathic. The International Diabetes Federation reports that every 30 seconds, at least one leg has lost due to DFU somewhere in the world⁽⁴⁾.

The Infectious Diseases Society of America (IDSA) developed a clinical practice guideline in 2004 for the diagnosis and treatment of diabetic foot infections. The guideline recommends the treatment of diabetic foot ulcers with surgical debridement, redistribution of pressure off the wound, and a selection of dressings that allows a moist wound environment and control excess exudation. Furthermore, it encourages revascularization of the leg if necessary, stimulates the use of antibiotics, and helps active search for osteomyelitis.

Topical therapy could be as effective as an oral therapy for mildly infected diabetic foot ulcers. Silver sulfadiazine, neomycin, polymyxin B, gentamicin, metronidazole, and mupirocin have each been used for soft tissue infections in other sites.

Most initial antibiotic courses will be an empirical regimen. It should aim to cover the most common pathogens including staphylococci and streptococci. Previously treated or severe cases may need extended coverage that also includes commonly isolated gramnegative bacilli, and perhaps enterococcus species.For mild to moderate infection 1 or 2-week

course is effective, for more serious infections- treatment has usually been given for about 2-4 weeks

Early surgical treatment of the affected site is typically necessary as an integral part of infection management. This may include simple debridement of the soft tissues, wide incision and drainage of the pedal compartments, or open amputation to eliminate extensive areas of infection. Several regimens have been recommended as reasonable initial empiric therapy of limb-threatening infections. The choice of agents used empirically should be based on the known polymicrobial nature of these infections with modifications.

The antibiotic therapy of osteomyelitis must be coordinated with the surgical debridement of the involved bone. Several reports have suggested that osteomyelitis of bones in the foot can be cured or at least arrested for extended periods with minimal debridement and prolonged courses of antimicrobial therapy.⁶³

The bacteriology defined by wound cultures can be used to guide therapy, and antibiotic treatment can often be abbreviated, i.e., 2-3 weeks. In contrast, if osteomyelitis involves bones that cannot be resected en bloc without disruption of the functional integrity of the foot, debridement must be done in a piecemeal fashion. Antibiotic impregnated bone cement has been advocated for the treatment of osteomyelitis gentamicin, tobramycin, or vancomycin are typically used in the beads. An alternative to bone cement is absorbable bone graft substitutes mixed with antibiotic powder.

WOUND DRESSING

The appropriate choice of dressing will depend on the characteristic of the ulcer, based on the parameters such as necrosis, infection, slough, granulation, reepithelization, exudate, wound shape, presence of sinuses, and so on.

A wound dressing may be described as passive, active, or interactive.Passive dressing simply has a protective function. Active dressing creates a moist environment of the wound dressing interphase. Interactive dressing creates a moist environment. They are believed to modify the biology of the wound environment in particular modulating and stimulating cell proliferation via the release of growth factor. It includes alginates, foams, hydrocolloids, hydrogels, semipermeable films, cadexomer iodine, hydrofibers.

PRESSURE RELIEF/OFF-LOADING

The reduction of pressure to the diabetic foot ulcer is essential to the treatment. Proper offloading and pressure reduction prevent further trauma and promote healing.

SURGICAL MANAGEMENT

It involves the excision of necrotic and devitalized tissues, the opening of sinuses, and wound pockets, thus allowing drainage of the wound exudate

The central cell responsible for this process is the macrophage, which releases proteolytic enzymes to degrade the devitalized tissue

CHEMICAL DEBRIDEMENT: The substances used are hypochlorite and hydrogen peroxide.

ENZYMATIC DEBRIDEMENT: These include collagenase, sutilans, and papain. The combination of streptokinase and streptodornase (varidase) has been used to debride the ulcer. Other enzyme derivatives like plant-derived urea/papain, fibrinolysin/DNAse, trypsin.

MECHANICAL DEBRIDEMENT: Moistened saline gauze is applied to the wound, allowed to dry and hard, and then removed with the attached devitalized tissue.

BIOSURGICAL DEBRIDEMENT: Maggot (fly larvae) has been used in a wide range of slough and necrotic wounds. Commonly used larvae are green bottle fly (Lucilia sericata).

AMPUTATION

Emergent surgeries are performed to stop the progression of the infection. most often involving amputation, requires removal of all infected and necrotic tissue to the level of viable soft tissue and bone.

Amputation of the foot may be indicated when neuropathy, vascular disease, and ulcerative deformity have led to soft tissue necrosis, osteomyelitis, uncontrollable infection, or intractable pain removal of gangrenous tissue, removal of portions of the foot that frequently ulcerate,

AIMS AND OBJECTIVES-

To study the comparative outcome of medical and surgical management of diabetic foot at Tertiary care centre .

MATERIAL AND METHODS

Sample Size- A minimum of 75 Patients

Type of study: Observational study (Prospective)

Source of data: Patients diagnosed with diabetes foot attending the Outpatient department and getting admitted to Department of surgery, J.A. Group of hospitals, Gwalior during period February 2019 – August 2020

Inclusion Criteria

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

EXCLUSION CRITERIA

- 1) Non-diabetic patients with foot ulcers.
- 2) Presence of peripheral vascular disease (<0.6 ABI)
- 3) Patients who have diabetes with superficial ulcer (width<2cm² and depth<3mm).
- Based on the 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	There is persisting sepsis	
needed		
Infection is confined to a small forefoot	Foot appears to be functionally	
lesion	unsalvageable	
The patient has a strong preference to	Uncorrectable foot ischemia, the patient	
avoid surgery	has a strong preference for surgical	
	treatment	
No hospitalization	Hospitalization	
There are no contraindications to	Major risks of antibiotic problems	
prolonged antibiotic therapy		

STATISTICAL ANALYSIS

All Statistical calculations were done with the help of Chi–Square test with degree of significance <0.5% with SPSS software version 22.0

OBSERVATION & RESULTS

Following observations were made :-

TABLE 1: DISTRIBUTION OF STUDY POPULATION ACCORDING TO		
MANAGEMENT		

MANAGEMENT	FREQUENCY	PERCENTAGE
MEDICAL	30	40
SURGICAL	45	60
TOTAL	75	100

In our study out of 75 patients 45(60%) surgically and 30(40%) medically managed.

TABLE 2. DISTRIBUTION OF SURGICAL TROCEDURE		
PROCEDURE	FREQUENCY	PERCENTAGE
DIBRIDEMENT ALONE	26	57.77
DEBRIDEMENT WITH	13	28.88
MINOR AMPUTATION		
MAJOR AMPUTATION	6	13.33
TOTAL	45	100

TABLE 2 : DISTRIBUTION OF SURGICAL PROCEDURE

In our study 45 (60%) patients managed surgically 0ut of 45,26 (57.77%) patient need debridement and 13(28.88%) minor and 6(13.33%) major amputation.

	STUDY GROUP	
OUTCOME	MEDICALLY MANAGED	SURGICALLY
	GROUP	MANAGED GROUP
HEALED	17(56.66%)	30(66%)
RECURRENCE	10(33.33%)	9(20%)
MORTALITY	1(3.33%)	4(8.88%)
LOST FOLLOWUP	2(6.66%)	2(4.44%)
(LOST FOLLOW UP +		
OTHER CAUSES		
MORTALITY)		
TOTAL CASE	30	45

TABLE 3 : COMPERTIVE OUTCOME AFTER 1 YEAR FOLLOW UP

In our study 40% cases treated medically and 60% case treated surgically. In medical treated group 56.66% healed, 33.33% recurrence and 3.33% mortality and in surgically treated group 66.66% healed, 20% recurrence and 8.88% mortality occurred in one-year period.

TABLE 4: DURATION OF WOUND HEALING			
DURATION	ANTIBIOTIC	SURGERY	
	GROUP	GROUP	
< 3 MONTH	(22)73.33%	(36)80%	
3-6 MONTH		(3)6.67%	
6 MONTH TO 1 YEAR		(1)2.22%	

TABLE 5: FINAL OUTCOME OF STUDY			
OUTCOME	ANTIBIOTIC	SURGERY	
	GROUP	GROUP	
LIMB SALVAGE	(17)56.67%	(32)71.11%	
MAJOR AMPUTATION	(1)3.33%	(9)20%	
DEATH	(1)3.33%	(3)6.67%	
WOUND RECURRENCE	(10)33.33%	(9)20%	

Discussion-

1-MANAGEMENT-

In our study, all patient receives initially broad-spectrum antibiotics as per culture sensitivity and regular dressings of the wound with the pressure offloading.

In our study 17(22.66%) out of 75 patients were benefitted by antibiotic alone and regular dressing of wound. About 30 (40%) patients were benefitted by surgical removal of affected bone at initial presentation of DFO followed by re-epithelization of diabetic foot ulcer. In our setting we used normal saline, betadine, hydrogen peroxide and other antiseptic for dressing.

In the study conducted by Apelquist et al⁽⁵⁾., 63% of diabetic foot ulcers healed by reepithelialization/primary healing.

In a study by **Reiber et al**⁽⁶⁾ foot infection is often the proximate cause leading to the tragic outcome of amputation. In 25-50% of diabetic foot infections end with a minor or partial foot amputation while 10-40% required major amputation. Fiston has suggested using the safest, simplest, and least expensive dressing.

2-OUTCOME IN TERMS OF DURATION OF HEALING, DISCHARGE, **MORTALITY**

In our study out of 75, 30 (40%) cases medically / conservative treated ,17(56.33%) cases of DFO cured and 10 (33%) showed recurrence with need of surgical management. In 45(60%) surgically treated cases 30 (66.66%) patients cured with initial surgery and only 9(20%) need further subsequent surgery. In this study 22(73.33%) cases conservatively treated and 36(80%) surgically treated cases of DFO were cured within 3 months.

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

In **Abubakar et al**⁽⁷⁾. study 42.4% of wounds healed conservatively within 3 months and 12.1% recurrence in 1 year.

In study by **José Luis Lázaro-Martínez et al**⁽⁸⁾. 75% achieved primary healing in the conservative group and 86.3% in the surgical group. The median time to healing was 7 weeks in the conservative group and 6 weeks in the surgical group. The conditions of 16.66 %

patients from the conservative group worsened, and underwent surgery. 15.8% patients from the surgical group required re operation. These results are comparable with our study. However, the results obtained in this study do 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

- Deep tissue culture and bone culture helps to guide appropriate antibiotic therapy.
- The healing duration of the lesion is similar in both groups most lesions healed within 3 months but faster recovery after surgery.
- 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.
- 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, use of proper footwear, good diabetes control, and prompt recognition and early professional treatment of newly discovered lesions.

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