# **ORIGINAL ARTICLE**

# A Comparative Study of Antibiotic Therapy with and without Bone Debridement in Diabetic Foot Osteomyelitis

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## ABSTRACT

**Objective:** To compare the outcomes of antibiotic therapy with and without bone debridement in diabetic foot osteomyelitis (DFO) patients.

**Methods:** The surgical and orthopaedics Units of Islam Medical College conducted a prospective randomized comparison study on 100 diabetic individuals with DFO between January 1, 2020, and June-2021. Patients were separated into two groups: those who got just antibiotic therapy and those who had debridement and/or contemporaneous minor amputation. Three outcome indicators were evaluated between treatment groups: hospitalization time, antibiotic therapy time, and wound healing time.

**Results:** Patient's demographics e.g., age, BMI and gender were almost similar among groups. The hospital stay duration was 39.7±18.4 days in antibiotic versus 43.4±23.9 days in the combination group. Duration of antibiotics was 42.8±15.6 days in the antibiotic group versus 45.3±18.0 days in the combination group (p-value 0.45). Mean duration of wound healing was 230.8±120.8 days in antibiotic group versus 217.1±95.3 days in combination group (p-value 0.53).

**Conclusion:** Our study has demonstrated comparable outcomes amongst individuals who got antibiotic treatment alone and those who had debridement and/or contemporaneous minor amputations.

Keywords: diabetic foot osteomyelitis (DFO), Antibiotics, amputation.

#### INTRODUCTION

Patients with diabetes are at risk of developing osteomyelitis in their feet, which is one of the most contentious aspects of the diabetic foot syndrome.<sup>1</sup> Majority of experts agree that bacteria enter through soft tissue before moving on to cortical bone and /or bone marrow. Some patients need sophisticated imaging investigations to help in making diagnosis. However, extracting bone samples for microbiological and histological examinations is necessary for a conclusive diagnosis.<sup>2</sup>

The treatment option is determined on the basis of location and amount of soft tissue involvement, bone deterioration and necrosis, systemic infection indicators and preferences of patient and doctor.<sup>3</sup> Surgery and antibiotic therapy are now under controversy in deciding their proper roles in a patient's treatment plan.

In a number of retrospective studies, treatment of diabetic foot osteomyelitis (DFO) with antibiotics for a period of 5 to 8 weeks has been shown to be effective for this condition. Using antibiotics to treat DFO has the primary benefit of reducing biomechanical changes in the feet following surgery and avoiding the financial costs and potential medical/surgical complications of surgery, although it has yet to be proven that using largely nonsurgical therapy is a more cost-effective method.<sup>4, 5</sup>

Surgery has been employed in treatment of DFO. Surgical therapy of osteomyelitis has been found to be an effective modality. Also considering conservative surgery to treat bone infection without amputation is an appealing option.<sup>6,7</sup> In this study we compared the outcomes of antibiotic therapy with and without bone debridement in diabetic foot osteomyelitis (DFO) patients.

## **METHODS**

The surgical and orthopaedics units of Islam Medical College conducted a prospective randomized comparison study on 100 diabetic individuals with DFO between January 1, 2020, and June-2021. Diagnosis of DFO was made using X-rays and probing-to-bone tests. Osteomyelitis was diagnosed when plain X-rays discovered cortical disruptions, periosteal elevation, a sequestrum or involucrum, or severe bone loss.

Patients were more than18 years of age; neuropathic ulcers aggravated by osteomyelitis; capacity to attend follow-up sessions; and written agreement for participation in the trial were the inclusion criteria. Patients with deep infections, necrotizing infections, and peripheral arterial disease (PAD) were all excluded. The Institutional Review Board gave its clearance for the study's ethical considerations.

Patients were separated into two groups: those who got just antibiotic therapy and those who had debridement and/or contemporaneous minor amputation. Antibiotic therapy was administered to all patients. All small amputations were conducted distal to metatarsal bones and consisted of surgical operations performed at the patient's bedside. When it came to minor amputation, the amount of gangrene in the overlying tissue was the most important factor to determine level of amputation i.e. if just the distal phalanx was gangrenous, only the distal phalanx was cut. The groups were then compared based on demographics, wound characteristics, and laboratory marker levels. Three outcome indicators were evaluated between treatment groups: hospitalization time, antibiotics therapy time, and wound healing time. At the end of the study's monitoring period, complete epithelialization and absence of clinical indicators of wound infection was termed as wound healing.

The statistical studies were carried out with the help of the SPSS program (SPSS Inc., version 11.0, Chicago, IL, USA). When dealing with discrete data, the chi-square calculation was performed, and when dealing with continuous data, the student t-test was used. The threshold for statistical significance was fixed at p 0.05. alone and 66.0% patients in combination group were hypertensive as well. Mean DM duration was  $13.9\pm8.4$ years in the antibiotics group, and  $16.9\pm9.7$  years in the combination group. The commonest location of DFO was great toe, followed by little toe and heel. The commonest etiology of DFO was neuro-ischemic, followed by neuropathy (Table 1).

There was no difference in study outcomes in antibiotic and combination groups. The hospital stay duration was  $39.7\pm18.4$  days in antibiotic versus  $43.4\pm23.9$  days in the combination group. Duration of antibiotics was  $42.8\pm15.6$  days in the antibiotic group versus  $45.3\pm18.0$  days in the combination group (p-value 0.45). Mean duration of wound healing was  $230.8\pm120.8$  days in antibiotic group versus  $217.1\pm95.3$  days in combination group (p-value 0.53) [Table 2].

## RESULTS

Patient's demographics e.g., age, BMI and gender were almost similar among groups. 62% patients in antibiotics

	Antibiotic group (N=50)	Antibiotic plus amputation group (N=50)	P-value
Age	63.20±11.4	62.9±9.8	0.89
Male Gender	36 (72%)	38 (76%)	0.64
Diabetes duration (Y)	13.9±8.4	16.9±9.7	0.11
Hypertension (%)	31 (62%)	33 (66.0%)	0.17
BMI	26.5±2.7	27.1±2.1	0.10
Previous Amputation	12 (24%)	14 (28%)	
DFO Location	· · · ·	· · ·	
Great Toes	20 (40%)	23 (46%)	0.71
Little Toe	13 (26%)	12 (24%)	
Heel	13 (26%)	09 (18%)	
Foot middle area	4 (08%)	06 (12%)	
Etiology			
Ischemic	03 (06%%)	04 (08%)	0.24
Neuropathic	20 (40%)	21 (42%)	
Neuro-Ischemic	27 (54%)	25 (50%)	

Table 2. Comparison of Study Outcomes.

Table 1. Demographic Characteristics.

	Antibiotic group (N=50)	Antibiotic plus amputation group (N=50)	P-value
Hospital Stay Duration (Days)	39.7±18.4	43.4±23.9	0.38
Antibiotics Therapy Duration (Days)	42.8±15.6	45.3±18.0	0.45
Duration of Healing (Days)	230.8±120.8	217.1±95.3	0.53

#### DISCUSSION

DFO is a difficult condition to deal with. Because of impaired perfusion of the foot in diabetic patients, the underlying bones become more vulnerable to infection, and the effectiveness of antibiotics therapy is reduced.<sup>8</sup> Among this specific category of diabetic patients, recurrence is quite prevalent, and chronicity presents a significant difficulty. According to the conventional view, which is widely held among surgeons, early surgical removal of all contaminated bone, whether necrotic or not, is necessary to remove osteomyelitis more effectively and permanently.<sup>9</sup> Today, however, a growing amount of evidence demonstrates that the use of antibiotics therapy alone may result in good treatment results in certain cases.<sup>10</sup>

It is up to the doctor to decide whether or not to perform surgery or prescribe antibiotics for diabetic foot infections.<sup>11</sup> The effectiveness of surgical removal of the whole infection with clean non-infected margins makes surgery the first line therapy for DFO. When compared to antibiotic therapy alone, surgical treatment for diabetic foot osteomyelitis has been shown to be more effective.<sup>12, 13</sup> It was shown that conservative surgery consisting of simply removal of the contaminated bone was preferable to antibiotic treatment alone. Van et al. reported that conservative surgery is a better option in comparison to antibiotics treatment in DFO, the authors reported primary healing in 78% patients in surgery group versus only 57% patients in anti-biotics group, and shorter healing time in surgery group; 181 days versus 462 days in anti-biotics group, and longer duration of antibiotics in anti-biotics alone group; 246 days versus 111 days in surgery group. However, this study was limited to only 67 patients so the results can be influenced by this limited sample size.<sup>14</sup>

Patients with diabetic foot osteomyelitis who did not have limb-threatening osteomyelitis were followed for five years by Game et al in a retrospective case study published in 2008. Only 147 patients were included in this research, so the results are rather restricted. However, of the 113 patients who got only antibiotics, 93 of them recovered completely (82.8 percent).<sup>15</sup> This research found that antibiotics may be given to individuals who are otherwise stable and do not have a limb-threatening illness.

Similar to our study, Ulcay et al. in their study reported that antibiotics therapy alone has similar outcomes as antibiotics plus bone debridement in treating DFO. The authors reported wound healing duration of  $265.2\pm132.7$  days in antibiotic and  $222.6\pm85.9$  days in combination group.<sup>16</sup>

Lazaro-Martinez et al. in another trial on antibiotics versus surgical management of DFO, also concluded that both of these management options are equally effective.<sup>17</sup>

#### CONCLUSION

Our study has demonstrated comparable outcomes amongst individuals who got antibiotic treatment alone and those who had debridement and/or contemporaneous minor amputations.

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