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Treatment of Diabetic Foot Osteomyelitis; Antibiotics Versus Conservative Surgery

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ABSTRACT

Objective: To assess the outcome in patients with diabetic foot osteomyelitis being treated with antibiotics alone with those being treated with antibiotics coupled with conservative surgery.
Study Design: Quasi-experimental study.
Place and Duration of Study: Combined Military Hospital, Rawalpindi from Feb to Aug 2016.
Methodology: Sixty patients with diabetic foot osteomyelitis, fulfilling inclusion criteria, were included in this study. They were divided into two groups of 30 each. The "Antibiotic-Group" received only antibiotics while, the "Surgical-Group" underwent surgery in addition to antibiotics.
Results: There were 37 males (61.66%) and 23 females (38.33%). The average age of patients was 59.72±9.79 years. 20 patients (66.67%) had full recovery in the Surgical-Group, and in the Antibiotics-Group, 18 patients (60%) had healed wounds (*p*-value=0.599)
Conclusion: The outcome of antibiotics only and conservative surgery plus antibiotics is similar.

Keywords: Antibiotics, Conservative surgery, Diabetic foot, Osteomyelitis.

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INTRODUCTION

Diabetic foot is one of the most troublesome complications affecting patients with diabetes with prolonged treatment. Patients with diabetes develop foot ulcers because of multiple causes.[1] The most important is the neuropathy causing loss of sense to neglect, followed by immunosuppression primarily due to neutrophil dysfunction and clogging of minute arterioles resulting in ischemia and delayed healing. Moreover, higher sugar in the blood provides the ideal bacterial medium for growth.[2,3]

The diabetic foot has a very grave sequel. The International Diabetic Federation has predicted that the Pakistani population will have progressively more patients of diabetes by 2050, which currently stands at 6.4%.[4] Various studies have found that the prevalence of diabetes ranges between 4-10% in Pakistan.[5] 15% patients of diabetes will develop foot ulcerations in their lifetime. Treatment of diabetic foot involves a multi-disciplinary approach that requires close monitoring, however, there is a 21-22% chance of minor and a 10% risk of major amputations.[6] This is further exacerbated by poor education about the disease, poor mental health and ritual treatments in rural areas which often mislead the patients causing delay and ultimately result in loss of limb and even life.[7] It was found out that 85% of diabetic foot amputation had prior ulceration of some sort.[8]

It is considered that osteomyelitis of foot bones is very difficult to treat and often ends up in amputation.[9] However, there are some studies which show that judicious and right dose of antibiotics for the correct time duration has comparable results to conservative surgery.[10] We are planning to study two different treatment plans, i.e., antibiotics alone and antibiotics along with conservative surgery for the treatment of diabetic foot osteomyelitis. The outcome of this study will help us understand the outcome of various management modalities. It may also help the general practitioner to manage the disease, which is more accessible.

METHODOLOGY

The quasi-experimental study conducted at the Department of General Surgery Combined Military Hospital, Rawalpindi Pakistan, from February 2016 to August 2016. The Hospital Ethical Committee (AMC /Q/12) granted permission to undertake the study. The WHO calculator was used to ascertain the sample size for this study, keeping anticipated popu-lation proportion in Surgery Group as 86.3%, and in Antibiotics Group as 52.9%.[11]

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Inclusion Criteria: All patients aged 18-80 years, with diabetes mellitus, who had complicated foot ulcers with osteomyelitis, and those who could attend the appointments during the follow-up period were included in the study.

Exclusion Criteria: Patients with gangrenous limbs, spreading sepsis, severe arterial insufficiency, Charcot foot, uncontrolled diabetes, antibiotic allergies, patients requiring dialysis, hepatic insufficiency, and patients unwilling to participate were excluded from the study.

Informed consent was taken before recruiting. The whole procedure was explained to the patient. Patients were randomly allotted to groups, Surgery-Group (SG) and Antibiotics-Group (SG). The AG patients were given only antibiotics, whereas the SG patient was administered antibiotics and conservative surgery. There was a total of 60 patients who had diabetic foot osteomyelitis. The treatment was given inwards, and glycemic control was sorted by putting patients on a sliding scale and oral hypoglycaemics. The patients were given I.V Amikacin 500mg 12 hourly and Co-Amoxiclav 1.2gm eight hourly empi-rically at the start, which was then changed after the culture-sensitivity report. The wound toilet was done daily with saline washing and dressing and removing necrotic debris. The SG patients underwent minor amputation for the removal of infected bone. In the Antibiotic-Group, antibiotic therapy was continued for at least 90-days. The same surgeon performed all surgeries, and X-rays and blood culture sensitivity test reports were reported from the same departments. Patients were examined after 1-2 weeks, and the outcome was considered complete healing of the ulcer.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Quantitative variables were expressed as mean±SD and qualitative variables were expressed as frequency and percentages. Chi-square test was applied to find out the association. The *p*-value lower than or up to 0.05 was considered as significant.

RESULTS

The study population comprised 60 cases of diabetic foot osteomyelitis, divided into two groups "SG", who underwent conservative surgery while being given antibiotics and "AG" were given antibiotics alone. No subjects dropped out at any point in the study. The overall mean age was 59.72±9.79 years. There were 37 males (61.7%) and 23 females (38.3%). The mean duration of Diabetes Mellitus was 10.68± 0.469 years. Over 38 wounds (63.3%) healed in both groups. The demographic distribution in both groups is shown in Table-I.

Table-I: Demographic Distribution of Study Groups (n=60)

Group	No of Participants	Age in Years (Mean±SD)	Duration of Diabetes Mellitus (Years) (Mean±SD)
Antibiotic Group	30	60.87±9.871	10.67±0.479
Surgery Group	30	58.57±9.747	10.70±0.466

In AG, 18 Patients (60%) had a full recovery, whereas, in SG, the frequency of Healing wounds was in 20 Patients (66.67%). The chi-Square test showed no statistical significance in terms of healing (*p*-value= 0.599) as shown in Table-II.

Table-II: Wound Healing Comparison between Antibiotics-Group and Surgery-Group (n=60)

Variables	Groups	Wound Healing		*p*-value
		Not-Healed n(%)	Healed n(%)	
Gender				
Female	Antibiotics Group	3(27.2%)	8(72.8%)	0.901
	Surgery Group	3(25%)	9(75%)	
Males	Antibiotics Group	9(47.3%)	10(52.7%)	0.603
	Surgery Group	7(38.8%)	11(61.2%)	
Duration of Diabetes Mellitus				
<5 years	Antibiotics Group	2(22.2%)	7(77.8%)	0.466
	Surgery Group	1(10%)	9(90%)	
>5 years	Antibiotics Group	10(47.6%)	11(52.4%)	0.867
	Surgery Group	9(45%)	11(55%)	
Age				
40-60 years	Antibiotics Group	4(25%)	12(75%)	0.720
	Surgery Group	4(20%)	16(80%)	
61-80 years	Antibiotics Group	8(57.1%)	6(42.9%)	0.889
	Surgery Group	6(60%)	4(40%)	

DISCUSSION

Treatment of Diabetes is expensive and prolonged. With the advent of insulin and antibiotics and advancements in vascular surgical techniques, fewer people are dying or losing limbs to diabetic feet. It is not easy to diagnose diabetic foot osteomyelitis. The probe-to-bone test and plain radiographs of the foot have a 97% sensitivity.[11] Still, the most sensitive tests are either via tissue diagnosis or culturing of bacteria from the bone which sadly is not always possible.[12] The most effective management strategy for this disease includes controlling the blood sugar, regular debridement of the wound, off-loading, appropriate vascular intervention and lastly appropriate antibiotics which may or may not be coupled with conservative surgery. the most common organisms to have been cultured from diabetic feet are *Staphylococci* or *E.coli*.[13] The empirical therapy with antibiotics is thus always directed against these organisms. Conservative surgery removes all infectious and necrotic tissue, improves mortality and morbidity, and lessens admission time. Drawbacks of conservative surgery, however, include improper orientation of the pressure points, making the foot prone to re-ulceration. On the other side, Antibiotics alone have made their mark in diabetic foot treatment with results com-parable to conservative surgery but with the benefit of keeping the foot intact.[14] This form of treatment can be given only to patients who are not septic, do not have pus or necrotic tissue in the foot, have well-perfused limbs, and respond to it.[11,15] 66.9% of patients were treated successfully with antibiotics alone in one study.[16] Lázaro-Martínez *et al.* documented a healing rate of 75% and an admission time of 7 weeks in patients undergoing treatment with antibiotics alone.[10] Another study found conservative surgery coupled with antibiotics to have a better healing rate of 78% compared to a healing rate of 57% on treatment with antibiotics alone.[17] Another previous study completely opposed the idea of forgoing aggressive surgery in case of diseases limited to the toes.[18] We conducted this study to explore further the results of treating diabetic foot osteomyelitis. We had a sample size comparable to that of Lazaro *et al*. and Bamberger *et al.*[10,11] We achieved a healing rate of 63.33%, comparable to Lazaro *et al.* and Bamberger *et al.* but less than one study conducted in Pakistan.

We excluded patients with severe infections, necrotizing soft tissue infections with osteomyelitis, peripheral arterial diseases and seriously ill patients. 60% of patients in the Antibiotic Group and 66.7% in the surgical group achieved healing in our study. These are comparable to the results of Lazaro *et al.* (75% vs 86.3%, respectively),[10] other studies have also shown no difference between the two treatment modalities.[9,10,11]

One study claimed to have prevented major amputations in 87.25% of cases by performing minor amputations instead.[18] In contrast, our definition of conservative surgery is the removal of involved bone only means that we consider all types of amputations a failure. Other than documentation of healing, we also did a risk assessment of age, sex and duration of diabetes. Like Game *et al*. we found age and time of diabetes to be significant confounding factors, unlike gender.[13] 77.78% healing rate was observed in patients aged 40-60 years and 41.67% in patients aged 61-80 years. This is probably because the elderly have more pronounced co-morbidities and a weaker immune system and healing power. However, this did not affect the healing in the two groups significantly. In our study, we found the duration of diabetes to be an important confounding factor. In patients who had diabetes for less than five years, the healing rate was 84.21%, and those who had diabetes for a longer duration than that had a healing rate of 57.89%. We have also found that diabetic foot is more prevalent in patients with diabetes for longer durations. This is probably because atherosclerosis causes reduced perfusion of tissues which in turn causes reduced healing.

CONCLUSION

If appropriately treated, all diabetic ulcers of the feet with osteomyelitis not complicated by ischemia or necrotizing infections can heal. However, if regular debridement is undertaken, appropriate culture-specific antibiotics are given, and the blood sugar is kept in check, the involved bone will not be excreted.

Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

AUA & ABS: Data acquisition, data analysis, data interpretation, approval of the final version to be published.

AAK & KK: Conception, study design, , approval of the final version to be published.

SAA & MT: Critical review, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated & resolved.

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