

## Comparison Between Conservative and Operative Management of Diabetic Foot Having Bone Involvement

Hammad Qayyum, Imran Ashraf, Waqas Farooq Ali, Muhammad Shahzad, Sultan Ahmed Minhas, Abdul Rehman Rashid

Department of Surgery, Combined Military Hospital/National University of Medical Sciences (NUMS) Rawalpindi Pakistan

### ABSTRACT

**Objective:** To compare the efficacy of conservative and operative management of diabetic foot having bone involvement.

**Study Design:** Quasi-experimental study.

**Place and Duration of study:** Combined Military Hospital, Rawalpindi Pakistan, from May to Dec 2022.

**Methodology:** The study included all the patients with neuropathic diabetic foot ulcers worsened by bone involvement/osteomyelitis. All the included patients were divided randomly into two equal groups, A and B (Conservative and Operative Management Groups, respectively). They were followed up for the study period to assess the healing of the wound. All the participants of the study were given antibiotics. Outcome measures were the proportion of patients achieving primary wound healing, hospitalization time, and wound healing time.

**Results:** In our study, we included 302 patients, amongst which 206(68.20%) were male subjects and 96(31.80%) were female subjects. The mean age was  $33.89 \pm 7.57$  years. The proportion of patients achieving primary wound healing in the Conservative Management-Group was 121(80.13%), and in the Operative Management-Group, it was 132(87.42%) ( $p=0.086$ ). However, the difference between the duration of hospitalization and the time of wound healing was statistically insignificant ( $p$ -values of 0.199 and 0.538, respectively).

**Conclusion:** Conservative management with antibiotics alone may be a good alternative to operative management, avoiding surgical complications and costs.

**Keywords:** Diabetes complications, Diabetic neuropathies Conservative management, Primary wound healing, Anti-bacterial agents

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### INTRODUCTION

Diabetic foot ulcers are one of the most common consequences of diabetes mellitus. They are more likely to occur in patients whose diabetes is poorly managed, which complicates the disease course significantly.<sup>1</sup> Along with the yearly growth in the number of persons receiving a diabetes diagnosis for the first time, it is anticipated that the prevalence of diabetic foot ulcers will increase as well.<sup>2</sup> There might be somewhere between 9.1 million and 26.1 million instances of diabetic foot ulcers worldwide each year.<sup>3,4</sup>

Patients who have diabetes incur an increased risk of developing osteomyelitis in their feet, which is one of the aspects of the "diabetic foot syndrome" that has been a topic of extensive research when it comes to its management.<sup>5</sup> The location and amount of the involvement of the soft tissue, deterioration and necrosis of the bone underneath, patient preferences, symptoms of systemic infection and the preferences of the treating physician all play a part in selecting the best course of action to take.<sup>6,7</sup> The appropriate role

that surgery and antibiotic treatment play in the overall healing process of a patient is now the subject of much discussion. The primary benefit of using antibiotics to treat "diabetic foot osteomyelitis" is that it reduces the biomechanical changes that occur in the feet as a result of surgery, which in turn helps patients to reduce the costs of the treatment as well as possible complications that patient may develop as an aftermath of surgery.<sup>8</sup> On the other hand, it has been observed that surgical therapy for osteomyelitis is also a highly useful treatment option, especially conservative surgery to treat bone infection instead of amputation.<sup>9,10</sup>

Based on this variability in the results of previous studies, it is imperative to conduct a study to compare these two different modalities, i.e., conservative and operative, used for treating diabetic foot with bone involvement.

### METHODOLOGY

The quasi-experimental study was conducted at Combined Military Hospital, Rawalpindi Pakistan, from May to December 2022 after obtaining approval from the Ethical Committee. The sample size was

**Correspondence:** Dr Hammad Qayyum, Department of Surgery, Combined Military Hospital, Rawalpindi Pakistan  
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calculated using WHO sample size calculator 2.2b by taking the anticipated proportion of patients achieving primary wound healing in conservative (antibiotics only) group at 75% and anticipated proportion of patients achieving primary wound healing in operative (antibiotics + surgery) group at 86.3%.<sup>11</sup>

**Inclusion Criteria:** Patients of either gender, aged 18 to 50 years, having diabetes (HbA1C%  $\geq 6.5\%$ ,<sup>12</sup> for six months or more and have neuropathic diabetic foot ulcers worsened by bone involvement/osteomyelitis, who provided written consent to participate in the study, were included.

**Exclusion criteria:** Patients suffering from profound infections, necrotizing infections or peripheral arterial disease were not included.

In our study, diagnosis of osteomyelitis or diabetic foot with bone involvement was made when plain X-rays revealed substantial bone loss, cortical erosions, thickening of periosteum and formation of new bone.<sup>12</sup> A paper lottery method was used for randomization of the patients into two equal groups of 151 patients each (Figure-1).

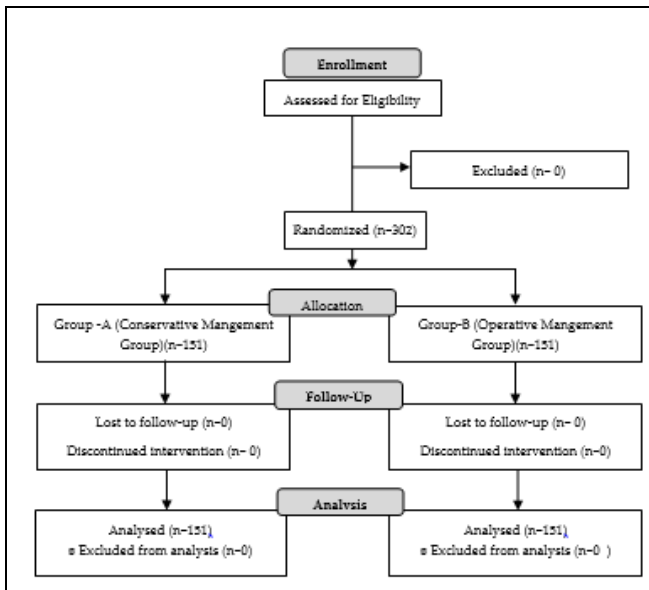


Figure-1: Patient Flow Diagram (n=302)

Patients in the Conservative-Group (Group-A) received only antibiotic therapy which was a combination of injection Piperacillin+Tazobactam (a Penicillin antibiotic),<sup>4,5</sup> grams thrice daily and tablet linezolid (Oxazolidinones) 600mg twice daily, while those in the Operative-Group (Group-B) underwent debridement and/or concurrent minor amputation

along with the antibiotic treatment [combination of injection Piperacillin+Tazobactam 4.5 grams thrice daily and tablet Linezolid 600mg twice daily].

Every single minor amputation involved a surgical procedure done right by the bedside of the patient, distal to the metatarsal bones. The quantity of gangrene in the surrounding tissue was the key element in determining the level of amputation in minor amputations. Baseline demographics characteristics, body mass index (BMI), duration of diabetes, presence of hypertension, smoking and wound location (big toe, little toe, mid-part of foot or heel), were compared between the groups. The proportion of patients achieving primary wound healing, defined as “complete epithelialization of the ulcer and/or the surgical wound created while treating the infection”, hospitalization time and wound healing time (time from the date of osteomyelitis diagnosis to the date of healing) were outcome indicators compared between treatment groups.

Statistical Package for Social Sciences (SPSS) version 21 software was used for the statistical analysis of the data. Normality of test will be checked using Shapiro-Wilk test. For qualitative variables frequency and percentages were used, whereas for quantitative data mean with standard deviation. Chi-square test and Independent sample t-test were applied to explore the inferential statistics. The  $p$ -value of  $\leq 0.05$  was set as the cut-off value for significance.

## RESULTS

In our study, a total of 302 patients who had neuropathic diabetic foot ulcers worsened by bone involvement/osteomyelitis were included. In our study, the mean age of the patients was  $33.89 \pm 7.57$  years. In our study, 206(68.20%) of the patients were male, while the remaining 96(31.80%) of the study participants were female. In our study, the patients' mean body mass index (BMI) was  $32.32 \pm 2.88$  kg/m<sup>2</sup>.

Comparison of demographic features of the study participants, including age (in years), gender, body mass index (BMI), duration of diabetes (in months), presence of hypertension and smoking, are shown in the Table-I. The most common part of the foot that was involved in our study was the big toe (151,50.00%), followed by the little toe (92, 30.50%), heel (36 ,11.90% and mid-foot (23,7.60%), demonstrated in Figure-2.

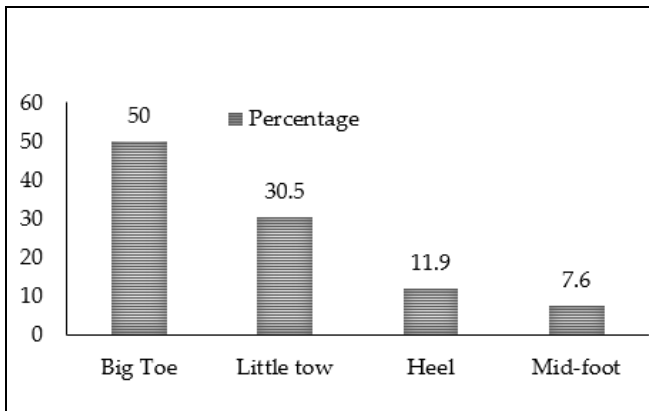
It was found that the proportion of patients who achieved primary wound healing in the Conservative Management-Group (Group-A) was 121(80.13%),

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while the proportion of patients who achieved primary wound healing in operative Management Group (Group-B) was 132(87.42%). Hospitalization time (in weeks) was almost similar in both groups. In the conservative Management-Group (Group-A), it was 6.58±1.17 weeks; in the Operative Management-Group (Group-B), it was 6.75±1.15 weeks. Similarly, the wound healing time was also quite similar in both groups. In the Conservative Management Group (Group-A), it was 32.49±2.52 weeks; in the Operative Management Group (Group-B), it was 32.31±2.52 weeks (Table- II).

**Table-I: Comparison of Demographic Features (n=302)**

Demographic Features	Conservative Management-Group (A) (n = 151)	Operative Management-Group (B) (n = 151)	p-value
Age (years)	34.07±7.56	33.72±7.57	0.688
Male Gender	102(67.54%)	104(68.87%)	0.805
Female Gender	49(32.46%)	47 (31.13%)	
Body Mass Index (kg/m <sup>2</sup> )	32.63±2.56	32.01±3.15	0.064
Duration of Diabetes (years)	10.69±2.52	9.99±2.25	0.011
Hypertension	85(56.29%)	89(58.94%)	0.641
Smoking	74(49.01%)	67(44.37%)	0.419



**Figure-2: Wound Location(n=302)**

**Table II: Comparison of Outcome Measures (n=302)**

Outcome Measures	Conservative Management-Group (A) (n = 151)	Operative Management-Group (B) (n = 151)	p-value
Primary Wound Healing (%)	121 (80.13%)	132(87.42%)	0.086
Hospitalization Time (weeks)	6.58 ± 1.17	6.75±1.15	0.199
Time of Wound Healing (weeks)	32.49 ± 2.52	32.31±2.52	0.538

## DISCUSSION

Diabetic foot ulcers complicated by bone involvement are notoriously difficult to treat. Inadequate blood flow to the feet of diabetics increases the risk of infection in the underlying bones and reduces the effectiveness of antibiotic treatment.<sup>13</sup> People in this subset of the diabetic population tend to experience recurrences, and the chronic nature of the disease presents a significant obstacle. Surgeons generally agree that early surgical removal of all infected bone, whether necrotic or not, is the most effective and durable treatment for osteomyelitis.<sup>14,15</sup> Growing evidence demonstrates that antibiotic treatment alone can achieve desirable therapeutic effects in various situations.<sup>16-17</sup> We, therefore, compared the two modalities of treating diabetic foot ulcers with bony involvement, including conservative management with antibiotics alone as compared to operative management.

In our study, we found out that when it comes to the proportion of patients who achieved primary wound healing. However, there was a numerical superiority in the proportion of patients who achieved primary wound healing inoperative management over conservative management. However, there was no statistically significant difference between conservative and operative management regarding the proportion of patients achieving primary wound healing. This was similar to a study conducted by Lázaro-Martínez *et al.*<sup>11</sup> They reported that the proportion of patients who achieved primary wound healing in the operative management group was higher than in the conservative management group. However, there was no statistically significant difference between the two groups. However, these results were inconsistent with the findings of Ha Van *et al.*<sup>18</sup> in which the proportion of patients achieving primary wound healing operative management group was much better than that of the conservative management group. The difference in the proportion of patients who achieved primary wound healing by conservative management versus operative management was also statistically significant.

Similarly, when it comes to hospitalization time as well as the time of wound healing, we found that there was no statistically significant difference between the Conservative Management Group and the Operative Management Group. These findings were similar to the results of a study conducted by Ahmad *et al.*<sup>19</sup> and Ulcay *et al.*<sup>20</sup> in which it was found that the hospitalization time was shorter in the

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Conservative Management Group. The wound healing time was lesser in the Operative Management Group.

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## CONCLUSION

Conservative management of diabetic foot ulcers with bone involvement is almost equally effective as the operative management of diabetic foot ulcers with bone involvement. In conclusion, conservative management with antibiotics alone may be a good alternative to operative management, avoiding surgical complications and costs.

**Conflict of Interest:** None.

## Authors' Contribution

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

HQ & IA: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

WFA & MS: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SAM & ARR: Conception, data acquisition, 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 and resolved.

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