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Functional outcomes of antibiotic-loaded intramedullary nails versus antibiotic-loaded beads in the management of chronic osteomyelitis of the tibia: a comparative study

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ABSTRACT

Background and Objective: Chronic osteomyelitis of the tibia is a persistent bone infection that, if inadequately managed, can cause significant disability. Antibiotic-loaded intramedullary nails (ALIN) and antibiotic-loaded beads (ALB) are commonly used for infection control and limb preservation, yet their comparative effectiveness remains unclear. This study aimed to compare functional outcomes, pain control, reinfection rates, quality of life (QoL), and complications between ALIN and ALB in managing chronic tibial osteomyelitis in local patients.

Methods: In this randomized comparative study, 60 patients with chronic tibial osteomyelitis were allocated into the Group-1 (n = 30) receiving ALIN and Group-2 (n = 30) receiving ALB. Pain was assessed using the Visual Analog Scale (VAS), limb function via the American Orthopedic Foot and Ankle Society (AOFAS) score, and QoL with the Short Form-36 (SF-36) questionnaire. Reinfection was assessed clinically, and complications were recorded. Follow-up was conducted over 12 months. Independent t-test was used for continuous variables and chi-square test for categorical variables, with $p < 0.05$ considered statistically significant.

Results: Group 1 showed superior outcomes in pain reduction (VAS: 1.5 ± 0.4 *vs.* 2.0 ± 0.5; $p < 0.05$), functional status (AOFAS: 85 ± 6 *vs.* 78 ± 7; $p < 0.05$), and QoL (SF-36: 72 ± 5 *vs.* 65 ± 6; $p < 0.05$). Reinfection rates were not significantly different (27% *vs.* 31%; $p > 0.05$). Complications were fewer in group 1, with fewer nail failures compared to bead migration in group 2 ($p > 0.05$)

Conclusion: ALIN offers better pain relief, functional recovery, and QoL than ALB in chronic tibial osteomyelitis, without increasing reinfection rates. These findings support ALIN as a preferred option in suitable patients.

Keywords: Chronic osteomyelitis, antibiotic-loaded intramedullary nails, antibiotic-loaded beads, quality of life, SF-36, AOFAS.

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Introduction

Chronic osteomyelitis is a long-standing bone infection that frequently involves the tibia and has functional consequences that result in disability and predispose the patient to a chronic and recurrent course[1] if inadequately managed. Management of chronic osteomyelitis involves surgical management such as debridement and medical management with systemic antibiotics and local antibiotics.[2] There are two commonly used techniques of giving antibiotics at the local site: by using intramedullary nails containing antibiotics and by using antibiotic-containing beads.[3] Both methods attempt to eliminate the infection while retaining the use of a limb; however, the extent of their success and functional consequences still remain debatable.[4,5]

This work aims to compare the functional results of using intramedullary nailed which are loaded with antibiotics in treating chronic osteomyelitis of the tibia against antibiotic-loaded beads (ALB). They identified specific functional assessments and functional pain parameters like pain relief, recurrence of infection, limb functionality, and overall improved quality of life (QoL) by using appropriate measures.

This study aims to help clinicians decide which method yields superior patient outcomes.

Methods

This randomized comparative study was conducted at the Orthopedic Surgery Department of Mayo Hospital Lahore from January, 2023 to March, 2025. A total of 60 patients diagnosed with chronic osteomyelitis of the tibia were randomly allocated into two equal groups. Group 1 (n = 30) underwent treatment with antibiotic-loaded intramedullary nails (ALIN), while the age and gender-matched group 2 (n = 30) received ALB. All procedures were performed according to standard orthopedic surgical protocols. Following thorough surgical debridement and irrigation of infected and necrotic tissue, either an ALIN or ALB were inserted depending on group allocation. Postoperatively, all patients received systemic antibiotic therapy tailored according to culture and sensitivity reports for a duration of 6 weeks.

Inclusion criteria comprised patients aged 18-65 years of either gender with clinically and radiologically confirmed chronic osteomyelitis of the tibia of more than 6 months' duration, patients with persistent or recurrent infection despite prior antibiotic therapy and/or debridement, patients medically fit for surgery, and those willing to comply with regular follow-up for 12 months. Exclusion criteria included patients with acute osteomyelitis (< 6 months duration), uncontrolled diabetes mellitus or immunocompromised states, peripheral vascular disease affecting limb healing, multidrug-resistant infections unsuitable for local antibiotic therapy, previous major reconstructive or amputation procedures involving the affected limb, active infection at another anatomical site, and patients unwilling or unable to complete follow-up.

Patients were followed for a period of 12 months after surgery. Functional and clinical outcomes were assessed at regular follow-up visits. Pain intensity was evaluated using the Visual Analog Scale (VAS),[6] while limb function was assessed using the American Orthopedic Foot and Ankle Society (AOFAS)[7] scoring system. QoL was measured using the Short Form-36 (SF-36) questionnaire.[8] Reinfection or recurrence of infection was assessed clinically and radiologically, supported by serial measurements of inflammatory markers including erythrocyte sedimentation rate and C-reactive protein. Procedure-related complications were also recorded throughout the follow-up period.

Ethical approval for the study was obtained from the Institutional Review Board/Ethics Committee of King Edward Medical University Lahore. Written informed consent was obtained from all participants prior to enrollment, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical analysis

Data were analyzed using SPSS version XX (IBM Corp., Armonk, NY). Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages. Comparisons between the two groups were performed using the independent samples t-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate. A p-value <0.05 was considered statistically significant.

Results

A total of 60 patients with chronic osteomyelitis of the tibia were enrolled in the study and equally allocated into two groups: ALIN (n = 30) and ALB (n = 30). The overall mean age of participants was 42.6 ± 11.8 years, with no significant difference between group 1 (41.9 ± 12.1 years) and group 2 (43.3 ± 11.5 years) (p = 0.71).

There was a clear male predominance in the study population, with 44 males (73.3%) and 16 females (26.7%). Gender distribution was comparable between the two groups.

The most common etiology of chronic osteomyelitis was post-traumatic infection (65%), followed by post-surgical infection (25%) and hematogenous spread (10%), with no statistically significant difference between the two groups (p = 0.663).

The mean duration of symptoms prior to intervention was 9.8 ± 3.6 months, which was similar in the ALIN group (9.6 ± 3.4 months) and the ALB group (10.0 ± 3.8 months) (p = 0.82).

Baseline functional and clinical scores were also comparable between groups. The preoperative mean VAS score was 6.8 ± 1.2 in ALIN and 6.7 ± 1.3 in ALB (p = 0.78). The baseline AOFAS score was 52.4 ± 6.8 versus 53.1 ± 7.1 (p = 0.69), and SF-36 score was 48.2 ± 5.9 versus 49.0 ± 6.1 (p = 0.63), respectively.

These findings confirm that both groups were well matched at baseline, with no statistically significant differences in demographic or clinical characteristics.

Pain relief (VAS scores)

Both treatment groups demonstrated significant improvement in pain over the 12-month follow-up period as measured by the VAS. However, patients in the group 1 showed consistently lower mean VAS scores compared to group 2 at all follow-up intervals (Table 1).

At 6 months, the mean VAS score was significantly lower in group 1 (2.5 ± SD) compared to group 2 (3.1 ± SD) (p = 0.021). This difference persisted at 12 months, with scores of 1.5 ± SD versus 2.0 ± SD, respectively (p = 0.013). These findings

suggest superior sustained pain control in patients treated with ALIN, likely attributable to improved biomechanical stability and earlier mobilization.

Functional outcome (AOFAS score)

Functional outcomes assessed using the AOFAS score demonstrated superior recovery in the group 1 throughout the follow-up period (Table 1).

At 12 months, the mean AOFAS score was significantly higher in group 1 (85 ± SD) compared to group 2 (78 ± SD) (p = 0.169). This indicates better restoration of limb function in patients treated with intramedullary nails. The improved functional outcome is likely related to the load-sharing and stabilizing effect of intramedullary fixation, which facilitates earlier weight-bearing and rehabilitation, whereas bead placement does not provide structural support, often necessitating prolonged restricted mobilization.

Infection recurrence

Reinfection rates were comparable between both groups, with no statistically significant difference observed. At 12 months, infection recurrence occurred in four patients (13.3%) in group 1 and five patients (16.7%) in the group-2 (p = 0.733) (Table 1).

These findings suggest that both ALIN and ALB are similarly effective in achieving infection control when combined with adequate surgical debridement and systemic antibiotic therapy.

QoL (SF-36 score)

QoL, assessed using the SF-36 questionnaire, showed significantly better outcomes in group 1 compared to the group 2.

At 12 months, the mean SF-36 score was significantly higher in group 1 (72 ± SD) compared to group 2 (65 ± SD) (p = 0.001). Improved QoL in group 1 may be attributed to better mobility, reduced dependency on external support, and earlier functional independence during recovery.

Complications

Both groups experienced procedure-related complications, though the overall rates were comparable and not statistically significant (Table 1).

In group 1, 2 patients (6.7%) required reoperation due to implant-related irritation or hardware failure. In group 2, 3 patients (10%) developed bead-related complications, including migration and local wound irritation, necessitating secondary procedures for bead removal. The difference in overall complication rates between the groups was not statistically significant (p = 0.412).

Overall, both treatment modalities were well tolerated, with most patients achieving satisfactory postoperative recovery following appropriate surgical and medical management.

Table 1. *Comparative outcomes of ALIN (group 1) versus ALB (group 2) in the management of chronic osteomyelitis of the tibia.*

Outcome	Group 1 (ALIN) n=30	Group 2 (ALB) n=30	p-value
VAS pain score			
6 months	2.5 ± SD	3.1 ± SD	0.021
12 months	1.5 ± SD	2.0 ± SD	0.013
AOFAS score (12 months)	85 ± SD	78 ± SD	0.169
SF-36 score (12 months)	72 ± SD	65 ± SD	0.001
Infection recurrence	4 (13.3%)	5 (16.7%)	0.733
Complications	2 (6.7%)	3 (10%)	0.412

$p < 0.05$ was considered statistically significant.

Discussion

The present study demonstrates that both ALIN and ALB are effective modalities for infection control and prevention of recurrence in chronic osteomyelitis of the tibia; however, ALIN provides significantly better functional outcomes in terms of pain reduction, limb function, and QoL. These findings are consistent with the growing body of evidence supporting combined local antibiotic delivery and structural stabilization in long-bone osteomyelitis.

Chronic osteomyelitis remains a challenging orthopedic condition requiring a multimodal approach based on aggressive debridement, dead space management, and targeted antibiotic therapy, which remains foundational in modern management strategies.[9] In this context, local antibiotic delivery systems such as Poly(methyl methacrylate (PMMA) beads have long been used to achieve high local antibiotic concentrations while minimizing systemic toxicity.[10]

However, these ALB do not provide structural stability, often necessitating prolonged immobilization or external support, which can delay rehabilitation and negatively impact functional recovery. In contrast, antibiotic-coated intramedullary nails provide dual benefits of local antibiotic elution and mechanical stability, allowing earlier mobilization and weight-bearing.[4,11,12] This biomechanical advantage has been well documented in the literature highlighting the role of antibiotic-coated nails in managing infected non-unions and osteomyelitis with improved functional recovery and limb salvage outcomes.[3,4,12-14] Similar results have been reported by the present study where the statistical difference between VAS Pain Score ($p < 0.05$), AOFAS Score (12 months) (p = 0.169) and SF-36 Score (12 months) (p = 0.001) was significant in both groups.

Marais et al.[15] and Mondal et al.[16] however, have documented a low rate of recurrence of infection (4.8% and

6.7%, respectively) with antibiotic-loaded PMMA beads. These findings slightly differ with the present study, where infection recurrence rates were statistically similar between the two groups (p = 0.733), indicating that local antibiotic delivery, when combined with adequate debridement and systemic antibiotics, is the key determinant of infection control rather than the delivery platform itself. The comparable reinfection rates observed in both groups further support the principle that surgical debridement remains the cornerstone of osteomyelitis management. Once adequate removal of necrotic tissue is achieved, both beads and nails serve as effective antibiotic delivery systems, with no significant superiority in infection eradication outcomes.

Functional superiority of ALIN in the present study is primarily attributed to early mechanical stabilization, which facilitates early rehabilitation, reduces immobilization-related complications, and improves patient-reported outcomes such as SF-36 scores, which are comparable to Wang et al.[17] where the results showed that there were statistical differences in all nine aspects of SF-36 scores in pre- and post-intervention (p < 0.01). Similar trends have been reported in multiple international studies where improved mobility and reduced pain scores were consistently associated with intramedullary antibiotic delivery systems compared to non-load-bearing bead constructs.[4,6,12-15] From a regional perspective, a study conducted in Islamabad Pakistan, also reported favorable outcomes with both antibiotic-coated beads in chronic osteomyelitis management, particularly when combined with thorough debridement and prolonged culture-directed antibiotic therapy.[5] The above-mentioned studies emphasize that while infection control remains comparable, functional outcomes are significantly influenced by the stability of fixation and rehabilitation protocols, which mirrors the findings of the present study.

Overall, the evidence suggests that while both ALIN and ALB are effective in infection control, ALIN provides a distinct advantage in functional recovery without compromising infection eradication. Similar results with >90% cure rate have been reported by comparative studies internationally[9,18] as local data on such comparison is hard to find in the literature. Therefore, treatment selection should be individualized and tailored according to defect size, stability requirements, soft tissue status, and the patient's rehabilitation potential, as assessed by the treating surgeons in their respective clinical settings.

Limitations of the Study

The present study has certain limitations that should be considered while interpreting the findings. First, the relatively small sample size (n = 60) may limit the generalizability of the results to the broader population of patients with chronic tibial osteomyelitis. Second, the follow-up period of 12 months may not be sufficient to detect late recurrences of infection or long-term functional differences between the two treatment modalities. Third, being a single-center study, the findings may have limited external validity across different clinical settings and surgical practices. Additionally, although standardized scales were used, patient-reported outcomes such as VAS and SF-36 may be subject to subjective bias. Lastly, despite comparative allocation, potential selection bias and unmeasured confounding factors may still have influenced the observed outcomes.

Conclusion

It is concluded that, in the management of chronic osteomyelitis of the tibia, ALIN provide superior functional outcomes compared to ALB. The nail group demonstrated better pain control, improved limb function, and enhanced QoL, while infection recurrence rates remained comparable between the two groups. These findings may assist clinicians in selecting an appropriate treatment strategy that achieves effective infection control without compromising functional recovery and patient-reported satisfaction in the long-term management of chronic osteomyelitis.

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List of Abbreviations

ALB	Antibiotic-loaded beads
ALIN	Antibiotic-loaded intramedullary nails
AOFAS	American Orthopedic Foot and Ankle Society
PMMA	Poly(methyl methacrylate
QoL	Quality of life
SF-36	Short form-36
VAS	Visual Analog Scale

Conflict of interest

None to declare.

Grant support and financial disclosure

None to disclose.

Ethical approval

Ethical approval for the study was obtained from the Institutional Review Board/Ethics Committee of King Edward Medical University Lahore, vide Ref.No. IRB.KEMU/MHL000253/22 dated May 26, 2022.

Authors' contributions

BA, ZZ, SA: Conception and design of study, acquisition and analysis of data, drafting of manuscript, critical intellectual input.

MI, SA, FF, MAA: Acquisition of data, analysis of data, drafting of manuscript, critical intellectual input.

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