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Original Research

Utilizing Antibiotic-Impregnated Cement Coated Nailing for the Treatment of Infected Non-union in Long Bone Diaphyseal Fractures

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ABSTRACT:
Background:Nonunion of long bones with infection poses a persistent and incapacitating challenge. Managing such cases involves addressing issues of infection, instability, and deformity. Conventionally, a two-stage approach is employed, tackling infection initially and subsequently addressing the nonunion. **Methods**:A cohort of 30 patients, all aged 18 years and above, presenting with infected non-union of the femur and tibia, underwent surgical intervention involving the application of an antibiotic cement-coated intramedullary nail (ILN). The preparation of the antibiotic cement nail utilized the endotracheal tube method, with vancomycin administered at a dosage of 4 mg. The assessment of functional outcomes focused on the effectiveness in controlling infection, achieving bony union, and monitoring any associated complications.**Results**:In 80% of the patients, infection was successfully controlled. Over an average follow-up period of 12 months, bony union was attained in 20 out of 30 patients (66%) using antibiotic cement nailing as the sole procedure, with an average union time of 32 weeks. The remaining 10 patients necessitated additional interventions such as bone grafting or exchange nailing; these procedures were performed in 4 patients, resulting in fracture union. Recurrence of infection was observed in 4 cases. Complications included challenges in nail removal in 4 cases, a broken nail in 2 cases, and a bent nail in 2 cases.**Conclusion**:The utilization of antibiotic cement-impregnated nailing emerges as a straightforward, cost-effective, and efficacious single-stage procedure for managing infected nonunion of long bones. This approach boasts improved patient compliance and is characterized by its simplicity. The required instruments are readily available, making it a feasible procedure that can be performed at any orthopediccenter.
Keywords:Antibiotic cement coated nail, bone cement,vancomycin,infected nonunion.

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INTRODUCTION

Infected nonunion of the tibia and femur represents a prevalent and intricate issue within the realm of clinical orthopedics. The multifaceted nature of this condition stems from diverse causes, encompassing scenarios such as open fractures, the loss of soft tissue or bone, infections post-internal fixation, the presence of chronic osteomyelitis leading to pathologic fractures, and surgical debridement of infected bone.[1] Despite the continuous evolution of medical practices, orthopedic surgeons continue to grapple with the complexities inherent in treating infected nonunion cases involving the tibia and femur.A pivotal aspect contributing to the complexity of orthopedic trauma infections is the involvement of biofilm-forming bacteria. These biofilms serve as protective matrices that cloak microorganisms, conferring resistance against antimicrobials, opsonization, and phagocytosis. The formation of biofilms creates a resilient environment that fosters the chronicity of infections, posing a significant challenge for orthopedic surgeons seeking to effectively manage and resolve infected nonunion cases in the tibia and femur.[2] As the understanding of these intricate dynamics continues to evolve, so too does the imperative for innovative strategies and treatments to address the persistent hurdles faced in the field.

According to Gustilo, the intricate challenges associated with infected nonunion underscore the diverse impediments encountered in the clinical management of these cases. Notably, avascularity at the fracture site emerges as a critical issue, a consequence of scarring and cicatrization resulting from the cumulative impact of multiple surgeries.[3] This vascular compromise not only hampers the natural healing processes but also sets the stage for a complex cascade of events.Another formidable hurdle highlighted by Gustilo is the development of drug resistance among pathogenic organisms, adding a layer of complexity to the treatment landscape.[4,5] This resistance amplifies the difficulty in eradicating the infectious agents, necessitating a nuanced and strategic approach to antimicrobial therapy.Furthermore, Gustilo underscores the impact of infected nonunion on the adjacent joint motion, emphasizing the need to consider the broader functional implications of such cases. Joint restriction poses challenges not only to the affected limb but also to overall patient mobility and quality of life.Gap nonunion, as elucidated by Gustilo, introduces yet another layer of complexity. The presence of a gap in the bone union complicates the healing process and demands specialized attention to bridge the void and promote successful union.In the context of infection, which inherently creates an adverse environment for fracture healing, mechanical instability further exacerbates the intricacies of treatment. Gustilo emphasizes the pivotal role of a deep understanding of the pathophysiology of lesions and the biomechanical principles governing fixation techniques.[6] This knowledge forms the bedrock for devising treatment strategies that not only address the infection but also restore stability and function.Traditionally, the treatment paradigm for infected nonunion adopts a two-stage approach. The initial phase involves meticulous debridement, with or without the adjunct use of antibiotic cement beads, coupled with systemic antibiotics. This concerted effort aims to transition the infected nonunion to an aseptic state, laying the groundwork for subsequent interventions. The second stage focuses on achieving stability through external or internal fixation, with or without the incorporation of bone grafting. This comprehensive strategy aligns with the sequential needs of addressing infection first and then concentrating on the mechanical aspects of stability, embodying a holistic approach to the intricate challenge of infected nonunion management.[7]

Single-stage procedures, such as debridement coupled with the application of external fixators or the utilization of antibiotic cement-impregnated intramedullary nails (ACIINs), have been documented in the literature for addressing infected nonunion of tibia and femur fractures. While these approaches offer potential advantages, concerns have been raised about the notable prevalence of complications associated with external fixation, including pinsite infections, muscle contractures, and joint stiffness.[8,9]In contrast, the use of antibiotic cement-impregnated intramedullary nails presents a promising alternative. This method, well-established in the literature, provides stability across the fracture site, surpassing the limitations associated with the use of cement beads. Achieving osseous stability is crucial in managing infected nonunion cases, and the antibiotic cement in intramedullary nails allows for a higher concentration of antibiotics locally than is achievable with systemic administration, minimizing side effects.The local antibiotic therapy employed in this study involves the use of broad-spectrum antibiotics such as clindamycin and vancomycin. Incorporating two antibiotics into the bone cement broadens the spectrum of activity, enhancing the elution properties of both antibiotics. This approach maximizes the therapeutic impact at the local site while mitigating potential side effects associated with systemic antibiotic use.[10]The advantages of antibiotic cement-impregnated intramedullary nails (ACIINs) are manifold. They offer a high concentration of antibiotics locally, effectively fill dead spaces, provide robust mechanical stability at the fracture site, and consequently, facilitate the promotion of bone healing. In essence, ACIINs combine the benefits of cement beads, offering a comprehensive solution to the challenges posed by infected nonunion of long bones. This study was initiated to systematically evaluate and validate the efficacy and utility of ACIINs in addressing the complex clinical scenario of infected nonunion in long bones.

MATERIALS AND METHODS

This study spanned a duration of one year, focusing on individuals meeting specific inclusion criteria for infected nonunion of the tibia and femur. The criteria included cases without evidence of union and devoid of bone loss. Patients with a radiologically visible or intraoperative gap nonunion exceeding 1 cm were also considered. Conversely, individuals with multiple medical comorbidities and those exhibiting hypersensitivity to antibiotics were excluded from the study, ensuring a more homogeneous participant group.A meticulous preoperative assessment was conducted for all included patients through a combination of clinical and radiological evaluations. A total of 30 cases of infected nonunion, comprising 24 tibia and 6 femur cases, involving individuals aged 18 years and above, formed the cohort for this study. The chosen treatment approach involved the utilization of an antibiotic cement-coated nail. This intervention was applied to both primarily infected fractures, where no prior intervention had been performed, and secondarily infected fractures, where the initial intervention had occurred but subsequently became infected. Importantly, these cases exhibited no significant bone defects.Comprehensive preoperative investigations were an integral component of the study protocol. Parameters such as complete blood count, erythrocyte sedimentation rate, C-reactive protein levels, and pus discharge culture and sensitivity were systematically assessed for each patient. This rigorous investigative approach aimed to provide a detailed baseline understanding of the patients' clinical and laboratory profiles, facilitating a robust analysis of the treatment outcomes for infected nonunion cases in the tibia and femur.

The management approach for infected nonunion of the tibia and femur, as outlined in this study, involves a systematic and multifaceted strategy. The initial step centers around radical thorough debridement at the fracture site, aiming to eliminate all infected and devitalized tissue, establishing a clean foundation for subsequent healing processes. Complementing this, thorough reaming and lavage of the medullary canal play a crucial role in clearing residual infection and debris within the bone's internal structure. An essential component of the treatment protocol is the application of antibiotic-impregnated cement coating over the intramedullary nail. This dual-purpose intervention not only provides mechanical stability to the fracture site through intra-medullary interlocking nails but also delivers a concentrated dose of antibiotics locally, directly combating the infection. By integrating these elements, the management strategy seeks to comprehensively address the complexities of infected nonunion, fostering an environment conducive to both infection control and successful bone healing.

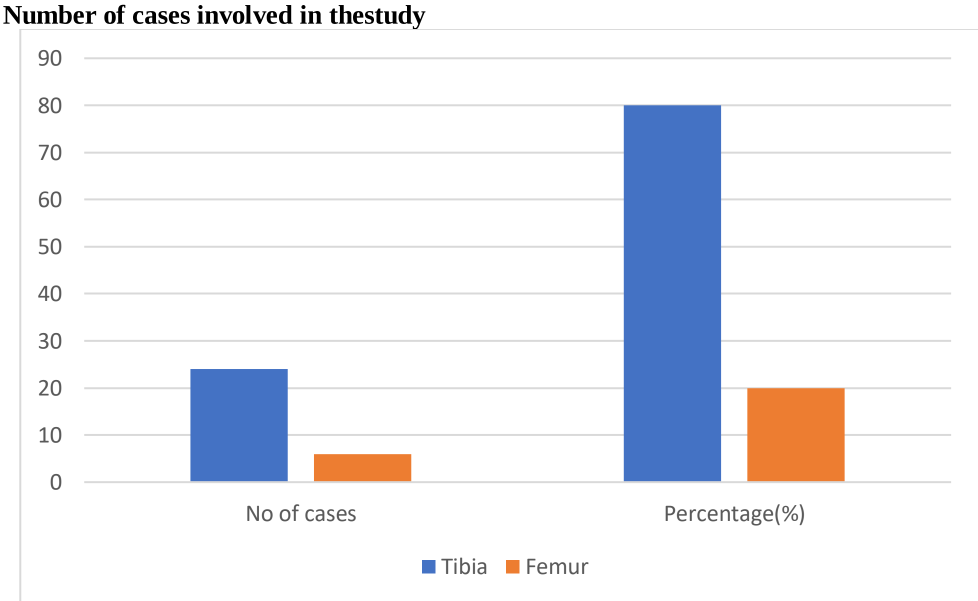
RESULTS

Out of the total cohort comprising 30 cases of nonunion, a predominant majority involved the tibia, accounting for 24 cases. In contrast, the femur was the site of nonunion in the remaining 6 cases. This distribution highlights a higher prevalence of nonunion occurrences in the tibia within the studied population. Such differentiation in the anatomical distribution of nonunion cases underscores the need for tailored and site-specific approaches in the management and treatment of these conditions. The varied incidence between the tibia and femur may also prompt further exploration into potential factors influencing the development and treatment outcomes of nonunion in these distinct long bones.

Table 1: Number of cases involved in the study

	No of cases	Percentage(%)
Tibia	24	80
Femur	6	20

Figure1: Number of cases involved in thestudy

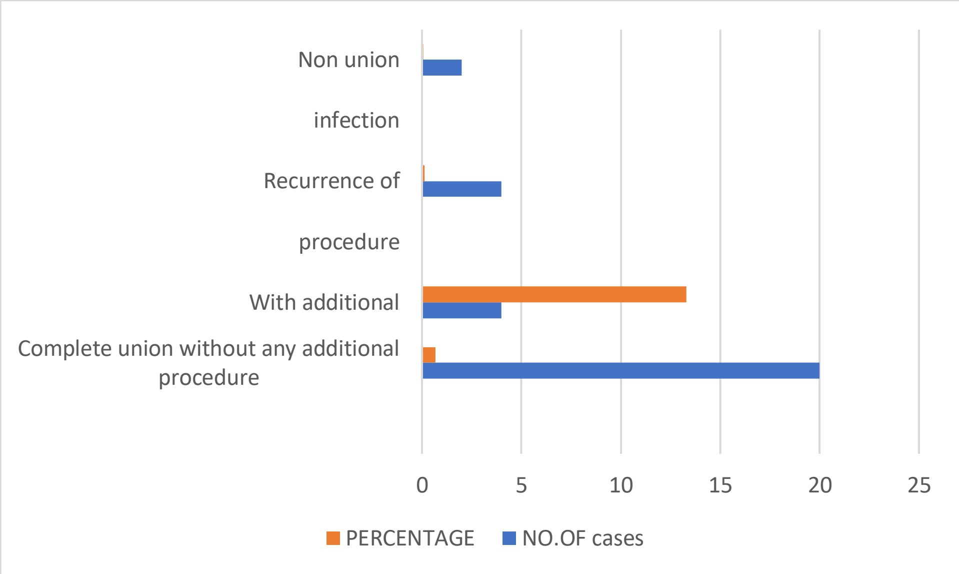


Following an average follow-up period of 12 months, noteworthy outcomes were observed in the cohort of 30 nonunion cases. In a significant majority, complete bone union was achieved in 20 out of 30 cases, obviating the necessity for any additional procedures. However, a subset of 4 patients exhibited no signs of fracture healing during the follow-up period, prompting the requirement for further intervention. These cases underwent additional procedures involving bone grafting and exchange nailing after 40 weeks of follow-up, emphasizing the importance of tailored approaches for cases presenting challenges to the natural healing process.Despite the overall positive outcomes, there were instances of infection recurrence observed in 4 cases, with 2 cases localized in the tibia and 2 in the femur. The management of recurrent infections involved the administration of intravenous antibiotics, showcasing a proactive approach to tackle and control infectious complications. However, in one specific case, nonunion ensued despite these interventions, underscoring the complexity and variability in treatment responses. These findings underscore the necessity for ongoing vigilance and adaptability in the management of nonunion cases, especially when confronted with challenges such as recurrent infections and resistance to conventional treatments.

Table2: number of cases with different results

Results	No. of Cases	Percentage
Complete unionwithout any additional procedure	20	66.66%
With additional procedure	4	13.33%
Recurrence of infection	4	13.33%
Nonunion	2	6.66%

Figure2: number of cases with different results



DISCUSSION

In managing infected nonunion long bone fractures, the primary objectives center around the dual goals of infection control and the provision of stability to foster bone union. The conventional two-stage procedure has emerged as a standard approach, delineating a sequential process wherein infection control takes precedence before addressing the nonunion aspect.The initial stage of this protocol involves surgical debridement, a meticulous process aimed at removing infected and compromised tissue. Concurrently, a combination of local and systemic antibiotic delivery is employed to combat the infection. Notably, the utilization of local antibiotic therapy is strategically chosen to maximize the concentration of antibiotics at the infection site while minimizing systemic levels, thereby mitigating potential systemic side effects.[11]Having successfully curtailed the infection in the first stage, the subsequent focus shifts to treating the nonunion. Stability becomes a paramount consideration in this phase, and interventions such as fixation procedures play a pivotal role. The two-stage strategy reflects a systematic and holistic approach, ensuring that infection is effectively addressed before attention turns to the mechanical aspects crucial for promoting successful bone union.By delineating infection control and stability provision into distinct stages, this approach acknowledges the interconnected yet distinct challenges posed by infected nonunion long bone fractures. It aims to optimize outcomes by strategically navigating the complexities inherent in both infection management and the subsequent facilitation of bone healing.

Various delivery systems have been innovatively developed to achieve the desired concentration levels of antibiotics, both systemically and locally, as a critical aspect of controlling infections. Among the spectrum of options, polymethylmethacrylate (PMMA) cement emerges as a preeminent and widely employed material for this purpose, recognized not only for its effectiveness but also for its cost efficiency.Once incorporated into PMMA cement, antibiotics undergo a controlled and sustained release mechanism. This process involves the steady diffusion of antibiotics from the surface of the cement matrix, as well as from any existing cracks and voids within the cement structure. The versatility and adaptability of PMMA cement as a delivery vehicle make it a pragmatic choice in clinical settings.[12]The appeal of PMMA cement lies in its practicality, accessibility, and economic viability. Its use not only serves as a carrier for antibiotics but also facilitates a prolonged and measured release of antimicrobial agents. As the cement solidifies, it forms a durable matrix that actively retains antibiotics, enabling a gradual and consistent release. This feature is particularly advantageous in the management of infected nonunion long bone fractures, where sustaining an optimal antibiotic concentration at the infection site is crucial for therapeutic success.The controlled release from PMMA cement translates into a localized antibiotic therapy, precisely targeting the infection while minimizing the potential for systemic side effects. This dual-action mechanism positions PMMA cement as a comprehensive and efficient delivery system, aligning with the multifaceted challenges inherent in treating infected nonunion long bone fractures. In essence, the strategic utilization of PMMA cement underscores not only its versatility but also its efficacy in addressing the intricate demands of infection control in the context of long bone fractures.

The utilization of antibiotic-impregnated polymethylmethacrylate (PMMA) cement beads as a localized delivery system for antibiotics, offering a solution to circumvent systemic toxicity, has been extensively documented in the medical literature. Among the antibiotics employed for this purpose, Gentamycin and Vancomycin stand out due to their broad spectrum of activity, heat stability, low allergenicity, and notable elution properties.[13] The controlled release of antibiotics from the cement beads ensures a sustained and concentrated therapeutic effect.The advantages of this approach become especially apparent in the context of the broader surface area of elution, facilitating a high antibiotic concentration throughout the entire length of the bone. This feature is crucial, particularly in segments of the bone that are necrotic or avascular, where systemic parenteral antibiotic therapy may encounter barriers to permeation. The local delivery of antibiotics through PMMA cement beads addresses this challenge, ensuring effective treatment even in regions that might otherwise be resistant to systemic interventions.In the pursuit of stability across the fracture site, healthcare professionals weigh the options of external and internal fixation. External fixation, while effective, is associated with drawbacks such as a heightened prevalence of pin-site infections, muscle contractures, and joint stiffness.[14] The Ilizarov fixator, acknowledged for its effectiveness in treating infected nonunion, may face challenges due to its perceived cumbersome nature and lower patient acceptability.Internal fixators, while contributing to stability, introduce a different set of complexities. Acting as foreign bodies, they have the potential to form biofilms, making eradication through systemic antibiotics a challenging endeavor. Biofilm formation poses a significant obstacle to the efficacy of antibiotic treatment, necessitating a more targeted and localized approach, exemplified by the use of antibiotic-impregnated cement beads.In navigating the multifaceted landscape of infected nonunion management, the choice between external and internal fixation methods entails a nuanced consideration of clinical efficacy and patient acceptability. This underscores the importance of tailoring treatment strategies to individual cases, recognizing the unique challenges and preferences that each patient brings to their healing journey.

The application of antibiotic-impregnated intramedullary nailing, offering both localized high concentrations of antibiotics and stability at the nonunion site, represents a groundbreaking approach.[15] This technique not only circumvents systemic toxicity but also streamlines the traditional two-stage procedure for treating nonunion into an efficient single-stage process.In the context of our study, the advantages of this single-stage procedure were evident, demonstrating success in achieving infection control and stability at the nonunion site. However, it is crucial to address certain complications observed within our cohort. Notably, 2 patients reported a broken nail, while 2 others presented with a bent nail. These complications were attributed to non-compliance and early unprotected weight bearing, emphasizing the significance of patient education and adherence to postoperative guidelines to ensure optimal outcomes.A notable complication observed in our study was the challenge of difficult nail removal, encountered in 4 patients.[16] This difficulty may be linked to factors such as improper nail preparation or a delay in seeking medical attention for nail removal. These instances underscore the importance of meticulous preoperative planning and timely patient presentation for postoperative care and interventions.Recurrence of infections was observed in 4 patients in our study, highlighting the persistent challenges associated with managing infected nonunion cases. The recurrence underscores the need for ongoing vigilance, adaptability in treatment strategies, and potentially further refinement of the chosen approach.[17]While the single-stage procedure offers a promising avenue for treating nonunion effectively, the identified complications in our study underscore the importance of a comprehensive and patient-centric approach. Addressing factors such as patient compliance, postoperative care, and meticulous surgical techniques remains paramount in ensuring optimal outcomes and minimizing potential complications in the management of infected nonunion.

CONCLUSION

The utilization of antibiotic cement-coated nailing emerges as an economical and effective single-stage procedure aimed at achieving infection control and providing stability for bone union in infected long bone fractures without significant bone gaps. In the context of our study, infection control was successfully achieved in 80% of cases, showcasing the efficacy of this approach. Furthermore, bony union was attained in 66% of cases, demonstrating the positive impact of antibiotic cement-coated intramedullary nailing on promoting bone healing.While the majority of cases exhibited favorable outcomes, 4 cases necessitated additional procedures, including interventions such as bone marrow infiltration, plasma-rich protein infiltration, or bone grafting. These supplementary procedures were deemed essential to address specific challenges and optimize the conditions for successful bone union in select cases.Recurrence of infection was noted in 4 cases, underscoring the persistent challenges associated with managing infected nonunion cases. Despite these challenges, the overall findings of the study support the conclusion that antibiotic cement-coated intramedullary nailing is a cost-effective and viable single-stage procedure with relatively few complications in cases of infected nonunion in the tibia and femur shaft fractures. This conclusion highlights the potential of this approach to streamline the treatment process, providing a pragmatic and resource-efficient solution for a subset of complex fractures.

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