

Prophylactic Use of Antibiotic Coated Inter-Medullary Nail: A Prospective Analysis**Taher Muzaffar Hussain¹, Sharvil Shah², Darshan Mehta³, Nirav Rathi⁴, Chaudhari Chandreshkumar Abherajbhai⁵**^{1,2}Orthopedic Surgeon, Department of Orthopedics, GMERS Medical College and Hospital Sola, Ahmedabad, Gujarat, India³Resident, Department of Orthopedics, Shalby Hospital, Ahmedabad, Gujarat, India⁴Assistant Professor, Department of Orthopedics, GMERS Medical College and Hospital Sola, Ahmedabad, Gujarat, India⁵Senior Resident, Department of Orthopedics, GMERS Medical College and Hospital Sola, Ahmedabad, Gujarat, India

Received: 01-02-2024 Revised: 15-03-2024 / Accepted: 21-04-2024

Corresponding author: Dr. Nirav Rathi

Conflict of interest: Nil

Abstract**Background and Aim:** There has been a significant increase in interest surrounding antibiotic coatings in orthopedic procedures in recent years. There are various coating strategies available for clinical use, including antibiotic-coated nailing, cements, beads, and on-demand antibiotic release. Multiple studies have demonstrated a decrease in implant-related infections with the use of antibiotic-coated implants.**Material and Methods:** This study was conducted in the Department of Orthopaedics at a medical college and associated hospital. During a span of one year, a group of 60 patients received treatment using a tibia interlocking nail coated with gentamicin. Sixty patients were selected with open fracture of shaft tibia, treated operatively with antibiotic coated intramedullary interlocking nail and were followed up for a minimum of six months duration. Radiological Union was assessed using RUST Score and clinical assessment results were graded as excellent, good, fair and poor.**Results:** According to the findings of the study, there were a significantly higher proportion of males, which accounted for 83% of the total. After a period of three months, the majority of patients, twenty-two in total, had an RUST score of eight. Patients who received a score of 10 came in a close second, while the population of patients who received a score of 4 was the least numerous. The length of time spent in the hospital was, on average, fifteen days. Although the majority of patients had a functional outcome that was satisfactory, there were sixteen patients who had a positive outcome.**Conclusion:** The combination of two procedures into one, antibiotic cement impregnated nailing, provides a dependable solution for infection control and stability. When treating open tibial fractures, one treatment option that may prove to be beneficial is the utilization of an antibiotic-coated tibia interlocking nail.**Keywords:** Antibiotic Coating, Gentamicin, Inter-Medullary Nail, Tibial Fractures.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Tibia shaft fractures are a frequently occurring type of long-bone fractures that can affect both adults and children. These incidents have a significant socio-economic impact, resulting in around 26 fractures per 100,000 individuals and 569,000 hospital days annually. It is worth noting that men face a significantly higher risk of fractures compared to women. The incidence of injuries tends to rise among young adults who experience high-energy trauma, as well as among elderly individuals who experience low-energy trauma, particularly if they have weakened bone tissue due to osteoporosis. [1,2] Long bone non-union is a

condition that can greatly impact a person's daily life. It occurs when a fracture remains unresolved for an extended period of time, typically lasting at least nine months without any signs of healing for at least three months. Despite the advancements in orthopedic surgery, the failure of fractures to heal properly remains a significant obstacle for both surgeons and patients. Non-union rates varied between 4.6% and 33% in various studies, and were influenced by factors like fracture type, age group, and anatomical location. [3,4] Infected nonunion continues to pose a significant challenge in terms of treatment, resulting in a high burden on

patients and healthcare expenses, despite the progress made in antibiotics and operative procedures. Several factors contribute to the persistence of the infection, including poorly vascularized tissues, bacteria adhering to bone structures and implants, and a slow bacterial replication rate. [5,6]

Antibiotics have been given through different methods, such as local application, intravenous injection, and oral ingestion. When it comes to orthopedic procedures, it's important to consider the resistance of the surgical site to antibiotics. In these cases, it is recommended to administer antibiotics locally for better effectiveness. Antibiotics like Vancomycin or Gentamicin are often used for this purpose. There has been a significant increase in interest surrounding antibiotic coatings in orthopedic procedures in recent years. There are various coating strategies available for clinical use, including antibiotic-coated nailing, cements, beads, and on-demand antibiotic release. [7-9]

If an implant becomes infected, it may need to be removed, cleaned, and treated with antibiotics for an extended period of time. To prevent implant-related infections, antibiotics are delivered locally to act on the tissue implant interface. An effective method involves the use of a polylactic acid (PLA) coated intramedullary nail that releases gentamicin. Multiple studies have demonstrated a decrease in implant-related infections with the use of antibiotic-coated implants.

Materials and Methods

This study was conducted in the Department of Orthopaedics at a medical college and associated hospital. During a span of one year, a group of 60 patients received treatment using a tibia interlocking nail coated with gentamicin. The patients were provided with comprehensive information about the study, and they signed the consent form before being included in the study. The study followed specific criteria for inclusion and exclusion:

Criteria for Inclusion: Patients who are over 18 years old, Fractures can be classified into different types, such as Gustillo Anderson type 1, 2, and 3A. Patients with diaphyseal fractures of the femur and tibia may experience complications such as infected nonunion, implant failure, and nonunion following infection.

Exclusion Criteria: Related to head injury, pathological fracture, fracture non-union, and delayed union. Patients who are unwilling or medically unfit for surgery, If patients are pregnant, breastfeeding, or planning to become pregnant during the study, or have a known allergy to aminoglycosides, A tibia interlocking nail was

utilized, which had the added benefit of a sustained release of gentamicin due to its antibiotic coating. The coating contains a combination of gentamicin and a biodegradable polymeric carrier called Poly. A typical nail contains 100 mg of gentamicin drug, which is equivalent to 1 mg per square centimeter. All patients underwent surgery under spinal/epidural anesthesia after a thorough pre-anesthetic check-up.

The patient was prepared and sterile draping was applied. The knee was flexed to 90 degrees and the entry point was made from the bare area over the tibial tuberosity under the image intensifier. Serial reaming was performed after successfully passing the guide wire. Ensuring the correct size of the antibiotic coated nail is carefully measured and inserted into the medullary canal. Postoperatively, the patient received a course of I.V. antibiotics for 5 days. The patient was regularly monitored after the operation to assess the outcome. The recorded data was organized and inputted into a spreadsheet computer program, and then transferred to the data editor page of SPSS version 16.

Results

For a period of three months, each and every patient who participated in the study was monitored for their progress. Five hundred males and ten females participated in the study. According to the findings of the study, there were a significantly higher proportion of males, which accounted for 83% of the total. It is highly probable that the fracture was caused by an accident that occurred on the side of the road, which is the most common cause. It involved close to forty-eight patients. In the course of the research, it was discovered that the patients' ages ranged anywhere from 20 to 65 years. The majority of patients were individuals who were between the ages of 20 and 35, followed by those who were between the ages of 36 and 50, and then those who were between the ages of 51 and 65.

In order to determine whether or not the fractured bone had achieved radiological union, a scoring system known as the RUST score was utilized. The clinical evaluation served as the basis for the grading, which divided the results into four categories: excellent, good, fair, and poor. There were a significant number of patients who presented with symptoms that were consistent with a fracture of the fibula. It took less than five weeks for wounds to heal in the majority of patients, with some patients requiring anywhere from five to seven weeks for their wounds to heal. After a period of three months, the majority of patients, twenty-two in total, had an RUST score of eight. Patients who received a score of 10 came in a close second, while the population of patients who

received a score of 4 was the least numerous. The length of time spent in the hospital was, on average, fifteen days. Although the majority of

patients had a functional outcome that was satisfactory, there were sixteen patients who had a positive outcome.

Table 1: Rust score analysis

Rust score at 3 months	No. of patients
4	6
8	32
10	16
12	6
Total	60

Table 2: clinical outcome analysis

Functional outcome	No. of patients
Excellent	6
Good	16
Fair	32
Poor	6
Total	60

Discussion

Osteomyelitis often involves multiple types of bacteria in about 70% of patients. Staphylococcus aureus is the most frequently found infecting organism both in the literature and in our study. Common choices for local delivery of antibiotics include gentamycin and vancomycin.

These antibiotics are known for their broad spectrum of activity, heat stability, and low allergenicity. Studies have demonstrated that they have excellent elution properties from bone cement and do not negatively impact bone healing. [10,11] Using local antimicrobial agents in fracture related infection can potentially enhance the effectiveness of treatment compared to relying solely on systemic delivery. This is to be expected because the antimicrobial agent is applied directly to the surgical area, allowing for high local concentrations. Unlike systemically administered antimicrobials, any vascular issues at the fracture site or surrounding soft tissues do not restrict the effectiveness of the antimicrobial.

Furthermore, when using local delivery, the overall drug dosage may be decreased, but the concentrations in the specific area are higher compared to systemic administration. This enhances the effectiveness of antimicrobial agents, while minimizing the potential for harmful side effects. [12]

This study included a total of 60 patients, with 30 patients having grade-I, 26 patients having grade-II, and 4 patients having grade-III complications. In a study conducted by Bhanu Pratap et al., it was found that 52% of the cases involved grade-I fractures, while the remaining 24 cases were classified differently. Another study conducted by Khaled Hamed et al. showed that eight patients had

Gustilo type I fracture, while three patients had type II fracture.

Fracture union was successfully achieved in 58 out of 60 patients, with only 2 patients experiencing non-union. According to studies conducted by Bhanu Pratap et al. and Thomas Fuchs et al., none of the patients experienced non-union.

Conclusion

The combination of two procedures into one, antibiotic cement impregnated nailing, provides a dependable solution for infection control and stability. When treating open tibial fractures, one treatment option that may prove to be beneficial is the utilization of an antibiotic-coated tibia interlocking nail.

It has been demonstrated to result in favorable functional outcomes and a decline in the number of complications. It is for this reason that it is recommended to take into consideration this treatment whenever it is appropriate.

References

1. Anandasivam, N. S.; Russo, G. S.; Swallow, M. S.; Basques, B. A.; Samuel, A. M.; Ondeck, N. T.; Chung, S. H.; Fischer, J. M.; Bohl, D. D.; Grauer, J. N. J. J. o. c. o.; trauma. Tibial shaft fracture: a large-scale study defining the injured population and associated injuries. 2017, 8, 225-231.
2. Larsen, P.; Elsoe, R.; Hansen, S. H.; Graven-Nielsen, T.; Laessoe, U.; Rasmussen, S. J. I. Incidence and epidemiology of tibial shaft fractures. 2015, 46, 746-750.
3. Wildemann, B.; Ignatius, A.; Leung, F.; Taitsman, L. A.; Smith, R. M.; Pesántez, R.; Stoddart, M. J.; Richards, R. G.; Jupiter, J. B.

- J. N. r. D. p. Non-union bone fractures. 2021, 7, 57.
4. Nicholson, J.; Makaram, N.; Simpson, A.; Keating, J. J. I. Fracture nonunion in long bones: A literature review of risk factors and surgical management. 2021, 52, S3-S11.
 5. Chaudhary, M. M. J. I. j. o. o. Infected nonunion of tibia. 2017, 51, 256-268.
 6. Masrouha, K. Z.; Raad, M. E.; Saghie, S. S. J. S. i. t.; reconstruction, I. A novel treatment approach to infected nonunion of long bones without systemic antibiotics. 2018, 13, 13-18.
 7. Flores, M. J.; Brown, K. E.; Morshed, S.; Shearer, D. W. J. J. o. C. M. Evidence for local antibiotics in the prevention of infection in orthopaedic trauma. 2022, 11, 7461.
 8. Upadhyaya, G. K.; Tewari, S.; Upadhyaya, G. K. J. C. Enhancing Surgical Outcomes: A Critical Review of Antibiotic Prophylaxis in Orthopedic Surgery. 2023, 15.
 9. Patel, S.; Metgud, R. J. J. o. c. r.; therapeutics. Estimation of salivary lactate dehydrogenase in oral leukoplakia and oral squamous cell carcinoma: a biochemical study. 2015, 11, 119-123.
 10. Panteli, M.; Giannoudis, P. V. J. E. o. R. Chronic osteomyelitis: what the surgeon needs to know. 2016, 1, 128-135.
 11. Gogia, J. S.; Meehan, J. P.; Di Cesare, P. E.; Jamali, A. A. In *Tilte2009*; © Thieme Medical Publishers.
 12. Metsemakers, W.-J.; Fragomen, A. T.; Moriarty, T. F.; Morgenstern, M.; Egol, K. A.; Zalavras, C.; Obremskey, W. T.; Raschke, M.; McNally, M. A. J. J. o. o. t. Evidence-based recommendations for local antimicrobial strategies and dead space management in fracture-related infection. 2020, 34, 18-29.