Antibiotic Impregnated Intramedullary Nailing in Compound Fractures of Long Bones

Chetan Solanki¹, Praveen Khatri², Brajesh Meher³, M. Gopala Rao⁴, Vishal Nigwal⁵, Ankit Prasad⁶, Suneet Tandon⁷

¹PG Resident, Gandhi Medical College, Bhopal
²Senior Resident, Gandhi Medical College, Bhopal
³PG Resident, Gandhi Medical College, Bhopal
⁴PG Resident, Gandhi Medical College, Bhopal
⁵Senior Resident, Gandhi Medical College, Bhopal
⁶PG Resident, Gandhi Medical College, Bhopal
⁷Professor and Head of Department of Orthopaedics, Gandhi Medical College, Bhopal

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Corresponding author: Dr M. Gopala Rao
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Abstract

Objectives: To evaluate the prognostic value of compound femoral and tibial shaft fractures treated with antibiotic impregnated cement coated nailing, as well as the biological and mechanical upsides of primary antibiotic impregnated cement coated nailing in the management of compound femoral and tibial shaft fractures.

Methods: At a tertiary facility in Bhopal, India, 23 individuals with Gustilo Type II and III compound tibial and femoral shaft fractures received antibiotic-impregnated IM nails between December 2019 and June 2021.

Results: Infection was controlled (as indicated by a decrease in inflammatory markers like ESR and CRP, as well as clinical evaluations like any discharge from the lesion, signs of inflammation) and mechanical stability was achieved in 85 percent of cases, with really no restriction of movements across the adjacent joints, after an average follow-up of 6 weeks. After 6 weeks, 16 instances had their nails exchanged.

Conclusion: An antibiotic-impregnated cement coated nail could be a reliable substitute for an external fixator in compound fractures of the tibia and femur, improving stability and limiting infection.

Keywords: antibiotic impregnated nail, compound fractures, long bone fractures

Introduction

Polytrauma patients with complex long bone fractures, extensive soft tissue damage, and wound contamination are becoming more common, putting orthopaedic surgeon skills to the test. Infection and mechanical instability both produce an unfavourable environment for fracture repair [1]. External fixators have traditionally been used to treat complicated fractures. External fixators have a number of drawbacks, including the following: Pin site infection is the most common issue linked with external fixators,
despite rigorous pin tract care and large doses of systemic antibiotics [2]. Soft tissue reconstruction - because this fixator blocks the field, soft tissue reconstruction operations such as flap cover and skin grafting are problematic. Neurovascular impalement can occur if pins are not put into the safe zones, causing injury to nerves and vital arteries. Due to the pin tract infection, there are few options for the future, which makes it challenging for the treating surgeon to choose when and how to execute open reduction and internal fixation while also considering the psychological effects on patients. In order to address all of these issues, numerous studies have shown that antibiotic-impregnated cement coated nailing is a very efficient method of treatment for infected long bone non-union [3]. Patients are substantially more likely to develop an infection following an open tibial and femoral fracture [4]. Because of this, treating difficult tibial and femoral shaft fractures (Gustilo types II or III) with conventional external fixators necessitates a high dose of postoperative systemic antibiotics, which might have systemic side effects and increase morbidity in already ill patients. Additionally, the implantation used for internal fixation turns into a potential site of inflammation for microbes, leading to non-union and necrosis of the fracture ends. Additionally, they need non-union therapy after infection management. In the literature, antibiotic-impregnated cement coated IM nailing for compound fractures of the tibia and femur has been noted [5]. Since it is a load-sharing device, it offers greater stability through the fracture site than a external fixator [6]. Long after the minimum inhibitory concentration has been reached, the antibiotic impregnated nail continues to elute antibiotics near the fracture site [7]. Antibiotic impregnation also increases osteoblast proliferation in the infection free zone around the fracture site, resulting in faster production of new healthy bone tissue and stronger bone formation.

As a result, the proposed study attempted to assess the biological and mechanical benefits, as well as assess the functional outcome of compound tibial and femoral shaft fractures treated with an antibiotic-impregnated cement coated nail.

**Material and Methods**

It’s a prospective observational study which included 23 patients of compound fracture shaft tibia and femur at Gandhi medical college, Bhopal from January 2020 to June 202. Inclusion criteria includes adult patients, hemodynamically stable, compound grade 2 and grade 3 fractures, time interval between injury and surgery >12 hours. Whereas exclusion criteria include poly trauma patients, unstable patients’ paediatric patients with open physeal plate, metaphyseal fracture, compound grade 2 fractures treated within 12 hours of injury, and very narrow medullary canal. Before starting primary management in the emergency room, we greeted the patient and collected basic data such as age, gender, occupation, residence, prior medical history, traumatic history, clinical examination, and medication history. Once the patient was critically stable and the fracture was sufficiently immobilised, x-rays were obtained while the patient was on a stretcher. Blood grouping and typing, random blood sugar, bleeding and clotting time, HIV, HbsAg, ECG, chest X-rays, and X-rays of the affected extremity are all performed before the type of fracture is finally determined, whether it is a unifocal fracture (transverse, oblique, and spiral), wedge fracture, or a complex fracture. The Gustilo Anderson type is examined clinically, whereas the AO type is evaluated radiographically. After the standard investigations, including the requisite ECG and CXR, are completed, the patient's agreement to participate in the study is obtained, and the region to be operated on
is prepared. Bone cements are sterile orthopaedic acrylic radiopaque cements that enable for the quick and secure anchoring of surgical implants into bone. The best antibiotic for bone cement would indeed be available as a powder, broad spectrum effective against MRSA and gram-positive cocci, high thermal stability, least hazardous, rare in terms of resistance, economical, and non-allergic. Amino glycosides and vancomycin both satisfy these requirements. Because they are all destroyed even during exothermic reaction of cement hardening, fluroquinolones, tetracyclines, and polymyxin B cannot be used with bone cement. Vancomycin, meropenam and cefuroxime were used in our study. As these are broad spectrum and heat stable antibiotics with great coverage on gram positive bacteria. Kuntscher nail was used in our study.

Operative Procedure
The compound wound was debrided when the patients were properly positioned. All nonviable, noncontractile, or highly infected muscle was excised till the bleeding margins. Following the removal of dead, infected, and necrotic tissues, the wound was thoroughly irrigated with a sufficient volume of normal saline. After debridement, the wounded limb was painted and draped for the Nailing. In the case of the tibia, a 5 to 6 cm long longitudinal incision well over patellar ligament at the level of the joint is employed, as is a longitudinal split of the tendon. When operating on the femur, start a brief, oblique skin incision that extends proximally and medially two to three centimetres from the proximal tip of the greater trochanter. After passing through the entrance point and distally through the fracture site to the lower end, the guide wire was then inserted. The cement covered nail with the antibiotic impregnated was then ready. 2g of vancomycin, 2 g of meropenem, and 1.5 g of cefuroxime were combined with 20 g of standard viscosity bone cement powder. The liquid from the ampoule is combined with the powder. Up until a dough-like consistency forms, stir constantly. Then, a properly-sized Künscher nail was created, and it was coated with the dough-like substance. Manipulation and shaping of the nail are carried out. In the instance of the tibia, the Herzog’s bend is formed place at a single end before covering with antimicrobial cement after selecting the right length k-nail. After the cement had cured, the nail was implanted intramedullary and checked under the c arm, and in a few cases of the femur, the nail was fastened distally by inserting a cortical screw into the distal eye of the nail. Wherever practicable, primary closure was carried out. If closure is not attainable, only stay sutures are used, followed by secondary closure after 5-7 days. Layer by layer, surgical wound was closed the leg was dressed and kept elevated on a pillow after surgery. Complications such as fat embolism, compartment syndrome and neurovascular damage were monitored after surgery. Secondary closure techniques such as flap cover or skin grafting were used when primary closure was not achievable. Parenteral antibiotics were given for 5 days and then oral antibiotics were given till suture removal on day 14.

Up to the sixth month, patients were followed up on an outpatient basis every second, fourth, and sixth week, as well as necessary in between. The nail is changed out for an interlocking intramedullary nail after 4–8 weeks. To guarantee infection control, inflammatory markers including total and differential leucocytes, erythrocyte sedimentation rate, and C reactive protein were assessed at each follow-up. In addition to assessing the patients’ infection prevention and bony unification, we also evaluated the data into bone and functional categories based on a modified version of the assessment method previously published by Paley and Maar [8].
Results

Our study included a total of 23 participants, with 5 females and 18 males. The study covered 16 tibia and 7 femur cases. Out of which 4 cases were compound grade II, 15 cases were grade IIIA, and 4 cases were grade IIIB, according to Gustilo Anderson classification. There were 2 compound grade II tibia cases, 12 compound grade IIIA tibia cases, and 2 compound grade IIIB tibia cases. There were 2 compound grade II femur cases, 3 grade IIIA and 2 grade IIIB femur cases. The incidence was greater in the 20–60-year age group. All of the incidents were the result of car accidents. Our study contains 8 cases ranging in age from 21 to 30, 6 cases ranging in age from 31 to 40, 4 cases ranging in age from 41 to 50, and 5 cases ranging in age from 51 to 60.
from 41 to 50, 3 cases ranging in age from 51 to 60, and 2 cases over the age of 60. Three patients were not followed up on out of the 23 instances. After an average of 6 months, there was no infection (indicated by a decrease in inflammatory markers such as total leucocyte count, Erythrocyte sedimentation rate, and C reactive protein, as well as wound condition as there was no discharge and no sign of inflammation) and stability was achieved in 17 out of 20 patients. Three patients became infected. 16 instances required primary and secondary closures, while 4 instances required soft tissue restoration, which included flap cover and skin grafting. After 4-8 weeks of primary surgery, we exchanged the nails in 16 cases, while in four patients, we persisted the antibiotic impregnated cement coated nail because there was early clinical and radiological union on follow-up x rays and the nail was snugly fitted in the medullary cavity, providing good rotational stability while taking the patient's age and medical condition into account. Two patients did not disclose after the first surgery in the 16 tibia cases, and no infection was found in 12 of the other 14 cases. One patient did not turn up after the first procedure in seven femur cases, and no infection was found in five of the remaining six cases. In 18 of the 20 cases, bony union was accomplished (90%).

In four cases where there was serious soft tissue compromise and skin loss, further treatments such as flap cover and skin grafting were performed when the wound was appropriate for repair. There were 17 great outcomes, 1 acceptable result, and 2 poor results in accordance with Paley’s Bony criterion. (FIG. 1)

Meanwhile 17 excellent results, 2 good results, and 1 fair result were accomplished applying Paley's functional outcome criteria. FIG 2.

Discussion

Treatment plans for compound fractures must include measures to prevent infection as well as assistance across the fracture site to encourage union. Orthopaedic surgeons are still concerned about musculoskeletal infections. Bone offers bacteria a special habitat due to its low vascularity and rapid turnover rate. Microorganisms that build biofilm are responsible for the majority of orthopaedic injury infections; once established, biofilm shields the microbe from phagocytosis and antibiotics, leading to persistent infections. Antibiotic concentrations in healthy bone could be as low as 20% of blood levels. Antibiotic penetration is decreased by biofilms, further decreasing their effectiveness. As a result, localised bone tissue lacks bactericidal concentration and does not prevent bacterial growth even with prolonged systemic antibiotic therapy. A tried-and-true treatment approach for treating bone infections is antibiotic-impregnated cement coated nailing. It delivers large antibiotic concentrations locally, for even avascular regions that systemic medicines are unable to reach. These concentrations are strong enough to be effective even against species that are impervious to systemic medication dosage. The danger of poisoning is considerably diminished due to their extremely low concentration in systemic circulation. Complex fractures have historically been treated with external fixators. Staphylococcus aureus is the most frequent bacterium linked to these kinds of fractures, and pin site sepsis is the most frequent complication correlated with fixators. Numerous studies have demonstrated the physiological activity and advantages of internal fixation with primary nailing utilising antibiotic impregnated cement over external fixitors.

The Department of Orthopaedics at MIMER Medical College in Pune conducted research
wherein they likened external fixator with primary intramedullary nailing and antibiotic bone cement bead placement, and found that infection rate after nailing was 6.67 percent, compared to 40 percent for external fixator, and that healing time was 4.5 months in nailing compared to 7.5 months for external fixator, and that overall complication rate was higher with external fixator. Primary nailing with antibiotic-impregnated cement was considered superior to prolonged nailing after initial external fixation in their investigation [8]. Because of its broad spectrum of activity, particularly strong coverage against gram positive cocci, heat stability, and minimal allergenicity, vancomycin, Meropenem, and cefuroxime are popular antibiotics for local delivery. The Korean Association of Orthopaedics looked into the results of therapy with antibiotic cement coated unreamed nailing for infected non-union of long bones. Six of the ten people they studied had femur fractures, and four of them had tibia fractures. They were successful in achieving bony union in each instance.

The average union time for the femur was 31.5 weeks, and the tibia was 26.4 weeks [9]. The research was carried out at the Catholic University of Korea's College of Medicine in Korea. They compared fixing with antibiotic cement loaded IM nailing with fixing with antibiotic cement loaded external fixator in the management of infected non-union of long bones. Three cases of infected non-union of the long bone shaft were treated with IM nailing and the insertion of antibiotic cement beads, placeng them in group I(n=9). The remaining six instances of infected non-union of the long bone shaft were handled with an external fixator and the insertion of antibiotics cement beads, placeng them in group II (n=6). They arrived to the conclusion that IM nailing with antibiotic cement is preferred to external fixate in the treatment of infected non-union of long bones with substantial bone loss and shortening of less than 1 cm. Antibiotic nail enhances clinical outcomes like bone integrity, early mobility, and stiffness [10]. Kuntscher nails were employed in our investigation because they have several advantages over interlocking nails. Infected non-union cases treated with an antibiotic-coated interlocking nail had a significant rate of cement debonding during exchange nailing, resulting in cement in the canal. With kuntscher nails, there is no cement debonding.

It has a cloverleaf form that retains cement in a slot that can hold a substantial amount of cement. And because we removed the nail after 4-8 weeks, we required an implant that was easy to remove, and the k-nail has an eye on both ends, making removal simple. In comparison to interlock nails, antibiotic impregnated cement coated kuntscher nails have a lower rotational stability. Using the gentamicin-coated nail in patients who are at risk of inflammation (GAIII) was affiliated with a 75 percent reduced level of contamination and economic advantages for all would include facilities; the huge cost of the prosthesis was mitigated by savings from fewer infections, inpatient days, and overall costs in the study by D. Franz et al., 2021.

This conclusion was supported by comprehensive sensitivity analysis, which were strengthened by additional sensitivity studies [11]. In patients who were more likely to develop implant-related infections, an intramedullary tibial nail with an antibiotic coating proved to have been a helpful aid in the therapy of tibia fractures, according to Raschke MJ et al. Antibiotic-soaked tibia nails reduced deep infections and avoided permanent external fixation [12].

In a study on the effectiveness of antibiotic-impregnated intramedullary nails in compound tibial fractures, Dr. Harish Khichy and collegues discovered that all patients
healed with no non-union. If complete asepsis care is adhered to along with the implant, they claim that antibiotic interlocking nailing is the mainstay of therapy for compound tibial shaft fractures Gustilo grades I and II [13].

Tibia fractures brought over by an antibiotic-impregnated cement coated nail were fixed by Metsemakers WJ and associates. Of these, 5 were complicated revision cases, and 11 (68.8%) were acute fractures that were addressed with just an antibiotic-impregnated cement coated nail (31.2 percent). No indication of a severe infection was present [14]. In compound tibia fractures with bony non-union, Desouuza C et al. also documented and promoted the use of cement-coated antimicrobial nails. 95 percent of the patients have been free of infection, and bone union has been achieved in 60 percent of patients who underwent antibiotic cement nailing during a 32-week period [15].

Therefore, past studies have demonstrated that antibiotic-impregnated cement coated nailing is significantly superior than external fixators in difficult tibial and femoral shaft fractures [16].

**Conclusion**

Cement coated nails with antibiotic impregnation help to keep compound wounds tidy and stable, fostering union. It has a higher rate of patient adherence than external fixates and lessens the difficulties that come with them. It is a risk free, patient friendly, readily available and acceptable technique that can be easily used in hospitals. The methods effectively handle a complicated problem by utilising readily available, already existing equipment and resources. Compound fractures of the tibia and femur shafts can be treated much more quickly, inexpensively, and effectively with antibiotic-impregnated cement coated nailing than with traditional techniques.

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