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ORIGINAL RESEARCH

A prospective study to evaluate the outcome of antibiotic cement impregnated intramedullary nailing in infected fractures of femur and tibia

[1]Dr. Intzaar Orkey, [2]Dr. Atin Kundu, [3]Dr. Rajendra Ahire, [4]Dr. Saurabh Jindal, [5]Dr. Pranay Srivastava

[1]PG III, [2,5]Associate Professor, [3]Professor, [4]Assistant Professor, Department of Orthopaedic, Pt.J.N.M. Medical College and Dr Bram Hospital, Raipur, India

Corresponding Author
Dr. Saurabh Jindal
Assistant Professor, Department of Orthopaedic, Pt.J.N.M. Medical College and Dr Bram Hospital, Raipur, India
Email- saurabh1588@gmail.com

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ABSTRACT

Background: Infected nonunion fractures pose significant treatment challenges. The problems in treating them are infection, instability and deformity. This study evaluates the effectiveness of antibiotic cement impregnated intramedullary nails in managing infected fractures of the femur and tibia. **Methods**: A prospective study was conducted on 20 patients with infected fractures of the femur and tibia treated with antibiotic cement-coated intramedullary nails in Pt. J.N.M Medical College & Dr. B.R.A.M Hospital, Raipur.There were 19 males and 1 female, withmean age being The primary outcome was infection control, and the secondary outcome was bony union. **Results**: Infection control was achieved in 90% of cases, and bony union was observed in 80% of patients within an average of 30 weeks. **Conclusion**: Antibiotic cement impregnated intramedullary nailing is effective in managing infected fractures, providing both infection control and promoting bony union.

Key words: Infected non union, long bones, antibiotic cement impregnated nail.

INTRODUCTION

Despite advances in antibiotics and surgical techniques, infected nonunion fractures remain a significant challenge due to poor vascularity, bacterial adherence, and slow bacterial replication. Despite advances in antibiotics and operative treatment, infected nonunion is still difficult to treat, with considerable morbidity and healthcare costs.[1] The presence of poorly vascularized tissues, the adherence of bacteria to bone structures and implants and a slow bacterialreplication rate all contribute to the persistence of the infection [2][3].

Nonunion in the presence of infection presents with the dual problems of controlling infection and providing stability [5]. Several factors contribute to infected nonunions, including open fractures, infection after internal fixation, chronic osteomyelitis with pathological fractures, and surgical debridement of infected bone [4][6].

Traditionally, the treatment strategy consists of surgical debridement with local and systemic antibiotic delivery and then a second procedure for stability, generally either internal or external fixation. Special constructive procedures and soft tissue procedures might also be necessary [7] [8]. Local antibiotic therapy is useful technique that results. in high local concentrations of antibiotics with minimal systemic levels and without systemic side effects.

This method in the form of antibiotic impregnated kuntscher nails is used in the treatment of osteomyelitis and in open fractures of long bones to controls infection and achieve bony union. With the goal of avoiding more than one procedure in these patients, we present our single-procedure technique of treatment with an Kuntscher nail coated with antibiotic impregnated bone cement, which combines local antibiotic delivery with good alignment and intramedullary fixation [9] [10]. This study was undertaken to evaluate the effectiveness of antibiotic cement coated nail in case of infected fractures of long

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bones.

MATERIALS AND METHODS

This was a prospective analytical study conducted in Pt JNM Medical College and Bhimrao Ambedkar Memorial Hospital Raipur, between January 2023 to May 2024. Inclusion criteria were all patients 18 yr or more with infected diaphysial fractures of femur and tibia, patients who with hypersensitivity to antibiotics and bone defect of more than 3 cms were excluded from the study.

Surgical Technique

The surgical technique involved a series of steps, The first step involved opening of the fracture site or infective area and thorough debridement of all the nonviable and infected tissues was done. if any purulent material presents then sent it for aerobic and anaerobic cultures and sensitivity. After through debridement and copious lavage of infected area, adequate reaming was done to accommodate a larger diameter nail which ensures more stability. Reaming was done retrogradely both sides in both femur in tibia bones. Reaming was done till reamer is difficult to negotiate. Thorough saline lavage of the medullary canal and the wound was done. The limb was prepared again and re-draped before antibiotic cement impregnated nail will be prepared.

Intramedullary canal diameter is determined by the diameter of the last reamer that had done and length with help of guide wire intra-operatively.Recommended Size (diameter) of antibiotic cement coated nail is 1mm less than the diameter of the canal (nail was stiff after coated with cement which leads to difficulty in insertion in curved medullary canal of bone.) if diameter of last reamer was 12mm than our nail size should be 11mm. Diameter of kuntscher nail is chosen 2mm less than the diameter of our antibiotic cement coated nail so that cement coated up-to 2mm. If diameter antibiotic cement coated nail is 11 than k nail diameter should be 9mm; but if nail diameter is 10 mm than k nail size is 9mm. K nail diameter should not below 9 mm because 8mm k nail has thin eyelet. In case of the tibia, after selecting the Kuntscher nail of appropriate length, the Herzog bend of 8 degrees is created with bench press, 5cm from the proximal end of nail.

The nail prepared on a separate sterile table, first 4g vancomycin/ heat stable antibiotic as per culture sensitivity in appropriate dose in powder form was put into sterile bowl than add 40 gm gentamycin bone Cement (PMMC) into it than mix both powders. The liquid(monomer) from the ampoule was added to the powder. Stirring was done until a doughy mass like consistency had formed. When the cement reaches doughy consistency, first slot of Kuntscher nail was filled with antibiotic bone cement than coating was done in outer surface. Further cement was manually rolled up-to to uniform diameter. Proximal eye of nail was left open. The diameter required is checked with measuring gauge and excess cement is shaved off with help of Rasp/file. Bone cement was allowed to set for 15 minutes before insertion to prevent cement nail debonding

Post Operative Protocol

All patients were started intravenous antibiotics as per culture sensitivity reports. The wound was inspected at intervals of 48-72 hours and repeat debridement was done whenever required. Active and passive range of movement exercises and non weight bearing mobilisation was encouraged. The patients were followed until there were no evidence of further infection. In patients with knee stiffness knee mobilization exercises were encouraged and in patients with limb shortening heel and sole rise were given.

All the patients were asked to come for follow up at 2 weeks, 6 weeks, 3 months and 6 Months. Clinical & radiological evaluation was done at each followup. Any complications were recorded. Final outcome was measured based on the infection control in terms of pus discharge and progression of bony union in terms of Radiological Union score.

RESULTS

In our study total 20 patients were studied in which 19 were male and 1 was female withmean age of 34.4 yr (range 18-65year), 75% had femur and rest 25% had tibia fractures with mean duration of infection was 4.85 months and most organisms found in culture report was staphylococcus species.

Outcomes of our study was Infection Control Achieved in 90% of patients and rest 10% does not showed infection control with mean duration of infection control was 4.94 weeks. Bony Union achieved in 80 % population and rest 20 % had non union with average time to union was 24.8 weeks. 65% patients had RUST Score of >9 out of 12. Additional procedures was done in 6 patients to achieve bony union in which 3 had bone grafting and in 2 patients debridement was done than in 1 patient bone marrow injection done.

Compilation observed among the study population was Reinfection occurred in 2 patients,bony nonunion in 2 patients, difficult nail removal in 1 patient and debonding of nail cement in 2 patient.

DISCUSSION

The treatment of infected nonunion requires procedures to control the infection and to provide stability in order to achieve union [11] There is no single universally accepted modality of treatment presently available for the management of infected nonunion. Traditionally, infected nonunions have been managed using two-step procedure to control the infection first and subsequently to treat the nonunion. The use of antibiotic-impregnated polymethyl methacrylate cement beads for local delivery of antibiotics without any systemic toxicity has been

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well documented for the management of osteomyelitis and open fractures. [12][13] However, these antibiotic cement beads do not provide any stability across fracture site and cannot be placed in the intramedullary canal as it entails difficult removal due to fibrous ingrowths.

ANTIBIOTIC AND BONE CEMENT

In this study, we evaluated the outcome of antibiotic-impregnated cement coated intramedullary nails in the management of infected fractures of the femur and tibia. Our results demonstrated that this treatment modality led to a high rate of infection control and bone union. The antibiotics that are used for this purpose should have broad spectrum of activity, heat stability, and low allergenicity and should have good elution properties from cement.

In our study, we used a 4 gm of vancomycin to 40 gm of Gentamycin simplex bone cement as most common infecting organism in our study is Staphylococcus aureus that in 65% patients, followed by klebsiella sp. And E. Coli in 15% and 10 % patients respectively. In accordance with our findings, a study by **Ashok K Shyam et. al.** [42] 22 samples were positive for Staphylococcus aureus, 2 samples were positive for Pseudomonas aeruginosa, and 1 sample was positive for Klebsiella. they used 2g of vancomycin and 2g of gentamycin in every 40g bone cement (Infection controlled in all cases). In study by **Vikas Chavan et al**, [47] the most common microorganism isolated was staphylococcus aureus and used 40 gm of Polymethyl-methacrylate cement with 4gm vancomycin and clindamycin 2 g (infection controlled in 90% patients). In study by **Bhatia C et al.** [46] Combination of 2gm vancomycin and 2 gm teicoplanin were used and most common infecting organism was Staphylococcus aureus (Infection Controlled was 95% patients). In another study by **Thonse et al**[37] antibiotic combination of 3.6 g of tobramycin and 1 g of vancomycin per 40 g of cement and most common organisms isolated was MRSA. Gentamycin and vancomycin are common choices for local delivery of antibiotics because of their broad spectrum of activity, heat stability, and low allergenicity. Clinical and experimental studies show them to have good elution properties from bone cement, and no deleterious effects on bone healing.

INFECTION CONTROL

Our study showed a high rate of infection control**,** with 90% of patients having their infection controlled with mean duration to control infection was 4.94 weeks. In relation with our findings, in a study by **Tarun Solanki et al.,** [49] Reported successful infection control in 93.3% patients. In a study by **Bhatia C et al.**, [46] was conducted to assess the role of antibiotic cement coated nailing in infected non union of tibia, which had reported infection was controlled in 95% of the patients. In a study by **Paley et al.**,[24] 9 cases were evaluated, and all cases showed infection control. **Dhanasekar et al**. [45] reported successful infection control in 17 of 18 cases. In another study by **Vikas Chavan et al,** 90% cases had successful infection control. The use of antibiotic-cement impregnated nails can provide local delivery of antibiotics, which can help achieve high local antibiotic concentrations and reduce the risk of systemic side effects [47]. The high success rate of infection control in our study suggests that this treatment modality can be an effective option for managing infected fracture of tibia and femur bones.

BONY UNION

We also observed a high rate of bone union, with 80% of patients having successful bone union with mean rate of union was 24.87 weeks. And Radiological union score of>9 out of 12 was found in 65% of patients. In relation with our findings, in a study by **Tarun Solanki et.al.** [49] who had reported successful bone union was achieved in 90% of patients, with a mean union rate of 22.13 weeks for tibia and 17.21 weeks for femur fractures. In another study by **Bhatia C et.al.**,[46] bone union was achieved in 12 out of 20(60%) patients, with average time of union of 32 weeks. Remaining 8 patients require additional procedures. **Zhang Qiang et.al.[36]** have shown bony union in only 11 out of 19 cases. **Thonse et.al.** [37]have shown bony union in 17 out of 20 cases. A study by **Vikas Chavan et al** [47] achieved boney union in 8 out of 12 cases (66%), with average time of union of 32 weeks.

In a study by **Tarun Solanki et al [**49] successful bony union was achieved in 90 % patients with a mean union rate of 22.13 weeks for tibia and 17,21weeks for femur fractures. among patients with bone union, 60% didn't require additional procedure. In another study by **Bhatia C et al.**,[46] bone union was achieved in 12 out of 20 (60%) patients, with average time of union of 32 weeks. Remaining 8 patients require additional procedures. **Zhang Qiang et al** [36] have shown bony union in only 11 out of 19 cases. **Thonse et al** [37] have shown bony union in 17 out of 20 cases.[37] A study by **Vikas Chavan et al** [47] achieved boney union in 8 out of 12 cases (66%). Although there was no control group in our study, these results suggest that antibiotic-impregnated intramedullary nails can lead to a relatively quick time to union.

ADDITIONAL PROCEDURE

In patients with successful bony union, 65% did not require an additional procedure. For those who required an additional procedure, exchange nailing was performed in 3 patients, bone grafting was performed in 2 patients, debridement was done in 2 patients, and bone marrow injection was done in 1 patient. The need for additional procedures is consistent with previous studies by **Dhanasekar et al.** [45], **Bhatia et al.** [46] **and Giannoudis and Tosounidis,** which have reported similar rates of additional procedures with antibiotic- impregnated

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intramedullary nails. Although additional procedurescan increase the overall cost and length of treatment, the high success rateof infection control and bone union suggests that this treatment modality can still be a favorable option.

COMPLICATION

Complication encountered in our studies are requirement of multiple procedures in 15 % of study populations; Re-infection observed in 10% of study populations ; difficult nail removal in 5% of study population and deboning of nail cement observed in 5% of study population. Other complications are nail breakage and debonding of nail cement in 5% of cases each. In relation to our findings, a study by **Bhatia C at el.,** 2 patients had nail breakage as a part of complications.[46] Similarly in other study by **Tarun Solanki et al,** most common complications were persistent of non union, debonding of nail cement, each occurring in 10 % of patients. Someother complications are persistent of infection in 6.7% of patients, nail breakage occur in 3.3% of patients.[46] Finally, our study showed Infection control in 90 % of patients with Radiological union score of >9 out of 12 in 65% of patients. These results indicate that antibiotic cement loaded intramedullary nailing is effective in controlling and promoting bony union in majority of patients with infected fracture of tibia and femur.

LIMITATIONS

There are some limitations to our study that should be considered. Firstly,this was a single-centre study with a relatively small sample size. Further studies with larger sample sizes and multi-centre designs would be beneficial to confirm our results. Additionally, the lack of a control group limits our ability to draw conclusions about the efficacy of antibiotic-impregnated intramedullary nails compared to other treatment modalities.

CONCLUSION

Antibiotic cement impregnated intramedullary nailing is a promising technique for managing infected fractures of the femur and tibia. It offers effective infection control and facilitates bony union, reducing the need for multiple interventions. Antibiotic cement impregnated nailing is a simple, economical and very effective procedure than the traditional methods in management of infected fracture of femur and tibia.

REFERENCES

1. Toh CL, Jupiter JB. The infected nonunion of the tibia. Clin Orthop Relat Res. 1995; 315:176–91.
2. Costerton, J. W., Lewandowski, Z., Caldwell, D. E., Korber, D. R., & Lappin-Scott, H. M. (1987). Bacterial adherence and the glycocalyx and their role in musculoskeletal infection. The Journal of Bone and Joint Surgery. American Volume, 69(7), 982-990.
3. Patzakis, M. J., Wilkins, J., & Moore, T. M. (1986). Management of infected nonunion of long bones: Biologic and biomechanical considerations. Clinical Orthopaedics and Related Research, 206, 77-85.
4. Sen, C., & Kocaoglu, M. (2009). Treatment of infected nonunion of the tibia by resection of the nonunion, acute shortening, and re- lengthenings. Journal of Orthopaedic Trauma, 23(9), 585-591.
5. Calhoun, J. H., & Manring, M. M. (2005). Management of osteomyelitis with antibiotics and debridement. The Journal of the American Academy of Orthopaedic Surgeons, 13(6), 297-307.
6. Lew, D. P., & Waldvogel, F. A. (2004). Osteomyelitis. Lancet, 364(9431), 369-379.
7. Kanellakopoulou, K., Galanakis, N., Giamarellos-Bourboulis, E. J., & Giamarellou, H. (2000). Antibiotic-impregnated cement use in the treatment of chronic osteomyelitis of long bones: A case series. Journal of Chemotherapy, 12(suppl 1), 17-20.
8. Walenkamp, G. H., Kleijn, L. L., & de Leeuw, M. (1986). Local antibiotic therapy in the treatment of bone and joint infections. Clinical Orthopaedics and Related Research, 205, 90- 99.
9. Sen, C., & Kocaoglu, M. (2009). Treatment of infected nonunion of the tibia by resection of the nonunion, acute shortening, and re-lengthening. Journal of Orthopaedic Trauma, 23(9), 585-591.
10. Kanellakopoulou, K., Galanakis, N., Giamarellos-Bourboulis, E. J., & Giamarellou, H. (2000). Antibiotic-impregnated cement use in the treatment of chronic osteomyelitis of long bones: A case series. Journal of Chemotherapy, 12(suppl 1), 17-20.
11. Winquist, R. A., Hansen Jr, S. T., & Clawson, D. K. (1984). Closed intramedullary nailing of femoral fractures: A report of five hundred and twenty cases. The Journal of Bone & Joint Surgery, 66(4), 529- 539.
12. Weber B, Çech O. Pseudoarthrosen - Pathophysiologie, Biomechanik, Therapie, Ergebnisse. Bern Stuttgart Wien: Verlag Hans Huber; 1973.
13. Zhang Qiang, Pan Zhijun, Xu Jian Jie, Littang, Li Jian birg, and Li Fang cae. Archieves of orthopaedic and Trauma surgery volume 127, Dec 2007.
14. Thonse R. Conway J. Musgrove Park Hospital, Belfast; United Kingdom. Journal of orthopaedic Trauma 2007 Apr 21(4): 258 – 68.
15. Ashok K Shyam, Parag K Sancheti, Salim K Patil, Steve Rocha, Chetan Pradhan and Atul Patil Indian J Orthop.2009 Oct- Dec; 43(4): 369-402
16. Dhanasekhar R, Jacob PJ, Francis: Antibiotic cement impregnated nailing in the management of infected non union of femur and tibia. Kerala J orthop.2013, 26:93-7.
17. Bhatia C, Tiwari AK, Sharma SB, Thalanki S, Rai A. Role of Antibiotic Cement Coated Nailing in Infected Nonunion of Tibia. Malays Orthop J. 2017 Mar;11(1):6-11. doi: 10.5704/MOJ.1703.019. PMID: 28435567; PMCID:PMC5393107.
18. Chavan V, Bairwa VK, Jhanwar P, Bohra AK. Role of antibiotic- impregnated cement intramedullary nail in infected nonunion of long bone diaphyseal fractures. Journal of Orthopaedics, Traumatology and Rehabilitation. 2019 Jan 1;11(1):16-20.
19. Solanki T, Maurya MK, Singh PK. Results of Antibiotic- Impregnated Cement/ Polymer-Coated Intramedullary Nails in the Management of Infected Nonunion and Open Fractures of Long Bones. Cureus. 2023 Aug 13;15(8):e43421. doi: 10.7759/cureus.43421. PMID: 37706117; PMCID: PMC10496935.

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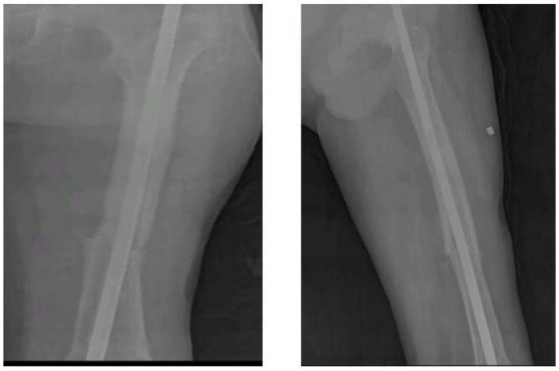
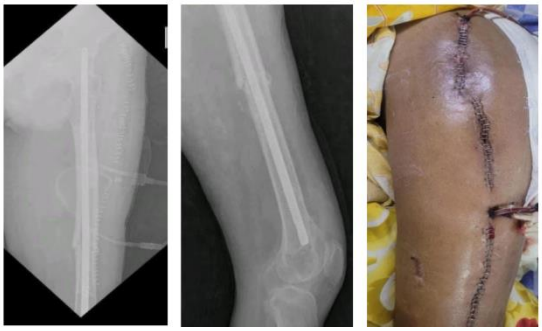
Case1

Pre op

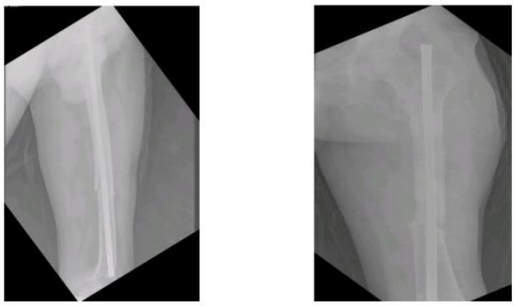
3 Month Follow up:

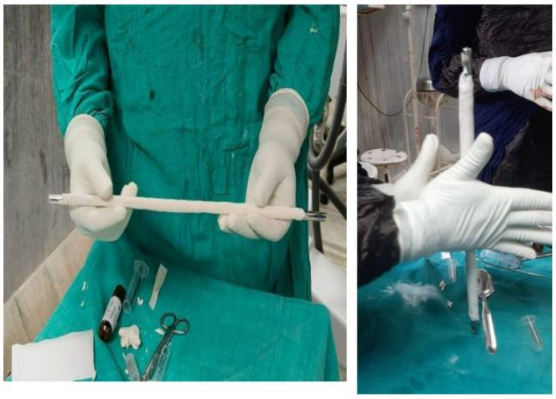


Post op (immediate)



6 Month Follow up:





Antibiotic cement impregnated nail preparation