

ORIGINAL RESEARCH

A hospital-based study evaluating the impact of the prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures

¹Dr. Antariksh Waghmare,²Dr. Anurag Chandrakar,³Dr. Saurabh Chandrakar,⁴Dr. Shashank Sharma

^{1,2}Associate Professor, Department of Orthopaedics, SSIMS, Bhilai, Chhattisgarh, India

³Assistant Professor, Department of Orthopaedics, SSIMS, Bhilai, Chhattisgarh, India

⁴Junior Resident, Department of Orthopaedics, SSIMS, Bhilai, Chhattisgarh, India

Corresponding Author

Dr. Anurag Chandrakar

Associate Professor, Department of Orthopaedics, SSIMS, Bhilai, Chhattisgarh, India

Received: 12 March, 2023

Accepted: 18 April, 2023

ABSTRACT

Aim: The aim of the present study was to assess the impact of the prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures. **Methods:** This prospective study was conducted in the Department of Orthopedics. 50 patients were treated over a period of 16 months with gentamicin coated tibia interlocking nail after taking written and informed consent. **Results:** All 50 patients (36 males and 14 females) were followed up for minimum of six months duration. This study comprised of 50 patients, out of them 25 patients had grade-I, 20 patients had grade-II and 5 patients had grade-III compounding. Time taken in wound healing in majority of patients was less than 5 weeks (46%). Majority of patients (48%) had RUST score 8 at six months of duration. Large numbers of patients had fair outcome 40%. **Conclusion:** Implant related infection pose an important challenge in the surgical treatment of tibia shaft fracture. Local administration of antibiotics might minimize the risk of infection. In this study we showed that use of antibiotic coated nail to treat open tibial fracture was associated with an absence of deep wound infections.

Key words: Open fracture, intra medullary nail, antibiotic coated

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

INTRODUCTION

Health care-associated infections (HAI) are the most frequent adverse events affecting patient safety worldwide. Such infections are challenging to treat, requiring prolonged antibiotic treatment and often repeated surgical operations.^{1,2} A major risk factor for an SSI is the presence of an indwelling device.³ Bacteria can adhere to the surfaces of invasive devices such as implants by forming a biofilm. This causes difficulties in treating infections as the biofilm significantly reduces the impact of systemic antibiotics. Eradication of the bacterial biofilm requires up to 1000 times higher antibiotic concentrations than those required for “free-floating” bacteria.⁴ Implant coatings have gained attention due to their potential to prevent implant-related infections by delivering high local concentrations.⁵

Due to specific anatomical features, such as poor soft tissue coverage, poor vascularization, high-energy traumatic mechanism, bone comminution with frequent open fractures, infections are common in

tibial fractures.⁶ In this bone segment, open fractures showed the highest infection rate (8.8%) compared to closed fractures, where the rate reaches 2%.⁷ Intramedullary nailing is the gold standard for tibial shaft fracture, with lower infection rate compared to external fixation or internal fixation with plate and screws.⁸ Currently, the prevention and treatment of implant-associated infections in open fractures involves the use of high doses of systemic antibiotics which, while reducing the absolute risk of early wound infections by 60%,⁹ on the other can cause many systemic side effects. After using advance surgical techniques and antibiotics, there are chances of wound infection and osteomyelitis. Gustilo grade III open fractures, rate of deep infection is about 80%. According to other studies, on increasing grades of Gustilo the chances of infection increase. The effectiveness of systemic antibiotics is limited in reducing risk of infection with use of prosthesis and osteosynthetic devices.¹⁰⁻¹² Once implant gets infected, then it requires implant removal,

debridement and long-term antibiotic therapy. This implant related infection is prevented by delivering the antibiotics locally acting on tissue implant interface. One of such method is using a polylactic acid (PLA) coated intramedullary nail releasing gentamicin.^{12,13} Findings from this meta-analysis included that the absolute risk of infection was lower for all GA grades when local antibiotics (PMMA bead chains impregnated with vancomycin or tobramycin or coated nails) were administered as adjunctive prophylactic therapy to standard of care. For the more severe GA III fractures, adding local antibiotics or antibiotic coated nails in addition to the systemic antibiotic prophylaxis reduced the infection rate from 14.4% to 2.4%. For the most severe cases (GA IIIB/C), the incidence of infections was reduced from over 31% for patients who received systemic antibiotics only to below 9% when local antibiotics or coated nails were added to standard of care.¹⁴

The aim of the present study was to assess the impact of the prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.

MATERIALS AND METHODS

This prospective study was conducted in the Department of Orthopaedics. 50 patients were treated over a period of 16 months with gentamicin coated tibia interlocking nail after taking written and informed consent.

INCLUSION CRITERIA

- >18years of age.
- Open fractures gustillo Anderson type 1, 2, 3A fracture.

RESULTS

Table 1: Gender wise distribution of study participants

Gender	Number	Percentage (%)
Male	36	72
Female	14	28
Total	50	100
Grade of compounding		
Grade I	25	50
Grade II	20	40
Grade III	5	10

All 50 patients (36 males and 14 females) were followed up for minimum of six months duration. This study comprised of 50 patients, out of them 25

EXCLUSION CRITERIA

- Associated with head injury.
- Pathological fracture, fracture non-union and delayed union.
- Patients not willing and medically unfit for surgery.
- Patients who are pregnant, breast-feeding or planning to become pregnant during the study, a known allergy to aminoglycosides.

Antibiotic coated tibia interlocking nail with property of sustained release of gentamicin was used. The coating contains combination of gentamicin and biodegradable polymeric carrier Poly. An average size nail carries 100 mg (1 mg/cm²) gentamicin drug. After performing pre-anesthetic check-up, all patients were operated under spinal/epidural anesthesia. Patient was painted and sterile draping done. Knee flexed to 90° and entry point was made from the bare area over the tibial tuberosity under image intensifier. After passing the guide wire, serial reaming was done. Appropriate size of antibiotic coated nail measured and inserted into the medullary canal. I.V. antibiotics were given for 5 days post-operatively. Patient followed post-operatively at 1, 2, 3 and 6 months for outcome assessment.

STATISTICAL ANALYSIS

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). For all tests, confidence level and level of significance were set at 95% and 5% respectively.

patients had grade-I, 20 patients had grade-II and 5 patients had grade-III compounding.

Table 2: Time taken in wound healing

Time taken in wound healing in weeks	Number	Percentage (%)
≤5 weeks	23	46
5-7 weeks	14	28
8-10 weeks	8	16
Not healed	5	10
Total	50	100

Time taken in wound healing in majority of patients was less than 5 weeks (46%).

Table 3: Radiological union at six months (RUST score)

Radiological union at 6 months (RUST score)	Number	Percentage (%)
4	8	16
8	24	48
10	12	24
12	6	12
Total	50	100

Majority of patents (48%) had RUST score 8 at six months of duration.

Table 4: Clinical outcome

Functional outcome	Number	Percentage (%)
Excellent	7	14
Good	15	30
Fair	20	40
Poor	8	16
Total	50	100

Large numbers of patients had fair outcome 40%.

DISCUSSION

Fractures of the tibia are the most common long bone fractures. Open injuries of tibia account for almost 50% of all open injuries and are more prone to infection than other long bones.^{15,16} The annual incidence of open injuries is 11.5 per 100,000 with 40% occurring in the lower limb, commonly in the tibia shaft.¹⁷⁻²⁰ These usually result from high-energy injuries and are frequently associated with polytrauma, high rates of infection and other complications which may threaten the limb and occasionally life and are generally a therapeutic challenge to the orthopedic surgeon.²¹ Management of open shaft tibial fractures have been atherapeutic challenge since past. The goal of orthopedic surgeon is to decrease the infection rate and improve fracture healing after surgical treatment of open tibial shaft fractures reducing the complications. By providing stable internal fixation with intramedullary nail, motion of adjacent joints and early rehabilitation can be started; thus preventing the frequent problem of joint stiffness.

Delivery of antibiotics to the infection site systemically or locally is essential in order to control infection. Long term infection and repeated debridement create excessive fibrosis around the nonunion site and hinder antibiotic permeability.²² Hence, delivery of antibiotics to the local site is far more beneficial than systemic administration of antibiotics. The use of antibiotic-impregnated polymethylmethacrylate cement beads for local delivery of antibiotics without any systemic toxicity has been well documented for the management of osteomyelitis and open fractures.^{23,24}

All 50 patients (36 males and 14 females) were followed up for minimum of six months duration. Time taken in wound healing in majority of patients

was less than 5 weeks (46%). Majority of patents (48%) had RUST score 8 at six months of duration. Large numbers of patients had fair outcome 40%. This study comprised of 50 patients, out of them 25 patients had grade-I, 20 patients had grade-II and 5 patients had grade-III compounding. In a study by Bhanu Pratap et al.²⁵ 13 (52%) cases were of grade-I fractures and 12 (48%) cases were others. In other study by Khaled Hamed et al²⁶ also exhibited eight (72.72%) patients had Gustilo type I fracture while three (27.27%) patients had type II fracture. It is also important to note that compared to beads, by using a gentamicin-coated nail a second operation to remove the beads is not required. Although the use of gentamicin-loaded PMMA beads is accepted in clinical practice, the beads themselves can act as a biomaterial surface that microorganisms preferentially adhere to and grow on and potentially develop antibiotic resistance.²⁷

CONCLUSION

Implant related infection pose an important challenge in the surgical treatment of tibia shaft fracture. Local administration of antibiotics might minimize the risk of infection. In this study we showed that use of antibiotic coated nail to treat open tibial fracture was associated with an absence of deep wound infections. Antibiotic coated tibia interlocking nail is a good treatment option for open tibial fractures, yields good functional outcome with less complications in these fractures and should be used whenever indicated. Randomized controlled trials with large sample size and longer duration of follow up are needed to devise a standard treatment protocol for management of open tibia fractures.

REFERENCES

- Darouiche RO. Treatment of infections associated with surgical implants. *N Engl J Med* 2004;350(14):1422-9.
- Leaper D, McBain AJ, Kramer A, Assadian O, Sanchez JL, Lumio J, *et al.* Health-care associated infection: novel strategies and antimicrobial implants to prevent surgical site infection. *Ann R Coll Surg Engl* 2010;92(6):453-8.
- HPA English national point prevalence survey on healthcare-associated infections and antimicrobial use, 2011: preliminary data. London: Health Protection Agency; 2012.
- Macià MD, Rojo-Molinero E, Oliver A. Antimicrobial susceptibility testing in biofilm-growing bacteria. *Clin Microbiol Infect* 2014;20(10):981-90.
- Metsemakers WJ, Reul M, Nijs S. The use of gentamicin-coated nails in complex open tibia fracture and revision cases: a retrospective analysis of a single centre case series and review of the literature. *Injury* 2015;46(12):2433-7.
- Metsemakers WJ, Reul M, Nijs S. The use of gentamicin-coated nails in complex open tibia fracture and revision cases: a retrospective analysis of a single centre case series and review of the literature. *Injury*. 2015 Dec 1;46(12):2433-7.
- Greco T, Cianni L, Polichetti C, Inverso M, Maccauro G, Perisano C. Uncoated vs. antibiotic-coated tibia nail in open diaphyseal tibial fracture (42 according to AO classification): a single center experience. *BioMed Research International*. 2021 Oct 14;2021.
- Lillo M, El Ezzo O, Cauteruccio M, Ziranu A, De Santis V, Maccauro G. Infections in primary intramedullary nailing of open tibial fractures: A review article. *Eur Rev Med Pharmacol Sci*. 2019 Apr 1;23(2 Suppl):195-200.
- Gosselin RA, Roberts I, Gillespie WJ. Antibiotics for preventing infection in open limb fractures. *Cochrane Database of Systematic Reviews*. 2004(1).
- Gaebler C, Berger U, Schandelmaier P, Greitbauer M, Schauwecker HH, Applegate B, Zych G, Vecsei V. Rates and odds ratios for complications in closed and open tibial fractures treated with unreamed, small diameter tibial nails: a multicenter analysis of 467 cases. *Journal of orthopaedic trauma*. 2001 Aug 1;15(6):415-23.
- Diefenbeck M, Mückley T, Hofmann GO. Prophylaxis and treatment of implant-related infections by local application of antibiotics. *Injury*. 2006 May 1;37(2):S95-104.
- Schmidmaier G, Wildemann B, Stemberger A, Haas NP, Raschke M. Biodegradable poly (D, L-lactide) coating of implants for continuous release of growth factors. *Journal of Biomedical Materials Research: An Official Journal of The Society for Biomaterials, The Japanese Society for Biomaterials, and The Australian Society for Biomaterials and the Korean Society for Biomaterials*. 2001;58(4):449-55.
- Howard M. Epidemiology and management of open fractures of the lower limb. *Br J Hosp Med* 1997;57(11):582-7.
- Craig J, Fuchs T, Jenks M, Fleetwood K, Franz D, Iff J, Raschke M. Systematic review and meta-analysis of the additional benefit of local prophylactic antibiotic therapy for infection rates in open tibia fractures treated with intramedullary nailing. *International orthopaedics*. 2014 May;38:1025-30.
- Littenberg B, Weinstein LP, McCarren M, Mead T, Swiontkowski MF, Rudicel SA, Heck D. Closed fractures of the tibial shaft. A meta-analysis of three methods of treatment. *JBJS*. 1998 Feb 1;80(2):174-83.
- Patzakis MJ, Wilkins J. Factors Influencing Infection Rate in Open Fracture Wounds. *Clin OrthopRelat Res*. 1989;243:36-40.
- Court-Brown CM, Rimmer S, Prakash U, McQueen MM. The epidemiology of open long bone fractures. *Inj*. 1998;29(7):529-34.
- Court-Brown CM, Bugler KE, Clement ND, Duckworth AD, McQueen MM. The epidemiology of open fractures in adults. A 15-year review. *Inj*. 2012;43(6):891-7.
- Howard M. Epidemiology and management of open fractures of the lower limb. *Br J Hosp Med*. 1997;57(11):582-7.
- O'Hara NN, Mugarura R, Slobogean GP, Bouchard M. The Orthopaedic Trauma Patient Experience: A Qualitative Case Study of Orthopaedic Trauma Patients in Uganda. *PLoS ONE*. 2014;9(10):e110940.
- Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones. *J Bone Jt Surg*. 1976;58(4):453-8.
- Akinyoola AL, Adegbehingbe OO, Aboderin AO. Therapeutic decision in chronic osteomyelitis: sinus track culture versus intraoperative bone culture. *Archives of orthopaedic and Trauma surgery*. 2009 Apr;129:449-53.
- Beals RK, Bryant RE. The treatment of chronic open osteomyelitis of the tibia in adults. *Clin OrthopRelat Res* 2005;433:212-7.
- Henry SL, Ostermann PA, Seligson D. The prophylactic use of antibiotic impregnated beads in open fractures. *J Trauma* 1990;30:1231-8.
- Pratap B, Gaur A, Joshi V. Functional outcome of antibiotic coated interlocking intramedullary nail in open tibia diaphyseal fracture. *Int J Orthop Sci* 2019;5(2):803-7.
- Salem KH. Critical analysis of tibial fracture healing following unreamed nailing. *Int Orthop* 2012;36(7):1471-7.

27. Neut D, van de Belt H, Stokroos I, van Horn JR, van der Mei HC, Busscher HJ. Biomaterial-associated infection of gentamicin-loaded PMMA beads in orthopaedic revision surgery. *Journal of Antimicrobial Chemotherapy*. 2001 Jun 1;47(6):885-91.