Prophylactic use of antibiotic-coated intramedullary nails in the treatment of open fractures of the tibia: A clinical observational assessment

Dr. Ashok J Sampagar, Dr. Bhavya L and Dr. Amit Bilagi

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Abstract

Aim: To evaluate the efficacy of antibiotic-coated intramedullary locking nail in the open tibia fractures. Materials and Methods: It was a one-year clinical observational research at the Department of Orthopaedics, BIMS Medical college, Belagavi, which was conducted in a clinical setting. An interlocking tibia nail was used to treat 70 patients. Those with open fractures of the gustillo type 1, 2, and 3A, 3B were included in this research. There were excellent, good, fair and bad grades for RUST Scores and clinical evaluation scores.

Result: Of the 70 patients, 44.28 percent belonged to 30-40 years age group, 28.57 percent were in the age group 40-50, and 20 percent were above 50. Males (72.86%) outnumbered females. The most prevalent cause of injury was a car collision, accounting for 55 (78.57%) of cases. 92.86 percent of the endosteal blood supply was roughly 80%. Gustilo's grade raises the risk of infection, according to previous research. The primary purpose of locally given antibiotics is to reduce the risk of implant-related infections by preventing bacterial colonisation of the implant surface.

Keywords: fracture, tibia, antibiotic-coated nail

Introduction

When it comes to long-bone fractures in adults, tibia shaft fractures are the most prevalent [1]. Approximately 26 fractures per 100,000 people and 569,000 hospital days are attributed to them each year [1, 2]. Men are three times more likely than women to have a fracture. High-energy trauma in young individuals or low-energy trauma in older persons with osteoporosis is associated with an increased risk of fracture [3]. Approximately 12 percent of tibia fractures in the general population and up to 23 percent in open fractures have a nonunion rate [4]. Two out of every thousand injuries are caused by open tibia fractures [5]. It's worth noting that older patients had a higher risk of open fractures than any other age group, with a 10% nonunion rate and a 17% malunion rate, respectively, in this population [6]. High-energy injuries are often linked with polytrauma, high infection rates, and other consequences that might jeopardise the limb and even the patient's life, making them a difficult therapeutic challenge for orthopaedic surgeons [7]. Plaster immobilisation, debridement, and surgical stabilisation are all options for therapy. For comminuted fractures, the locking of intramedullary nails reduced the incidence of malunion. It was formerly common practice to ream out the endosteal blood supply [8] and promote heat necrosis using interlocking intramedullary nails. Most surgeons oppose the use of intramedullary nailing with reaming for Type III open tibia fractures because of the high incidence of infection after therapy. Osteomyelitis and a wound infection may occur after the use of cutting-edge surgical procedures and medications. The risk of profound infection in Gustilo grade III open fractures is roughly 80% [9]. Gustilo's grade raises the risk of infection, according to previous research. The primary purpose of locally given antibiotics is to reduce the risk of implant-related infections by preventing bacterial colonisation of the implant surface.
Additionally, large concentrations of antibiotic may be obtained in the targeted location without the need for high systemic dosages and accompanying adverse effects [10]. While systemic antibiotics may reduce the risk of infections from prosthetic and osteosynthetic devices, their potency is limited [10, 11]. Implant removal, debridement, and long-term antibiotic treatment are required if an implant becomes infected. Antibiotics may be delivered directly to the tissue-implant interface to avoid this kind of implant-related illness.

A polyactic acid (PLA) coated intramedullary nail releasing gentamicin is one example of this [10, 12]. Antibiotic-coated implants have been shown to reduce the risk of implant-related infection [13]. Hence the present study was undertaken to assess the outcome of prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.

**Material and Methods**

This prospective observational study was carried out in the Department of Orthopaedics, BIMS Belagavi for the period of 1 year, after taking the approval of the protocol review committee and institutional ethics committee. Total 70 patients were treated with gentamicin coated tibia interlocking nail.

**Inclusion criteria**

Patients with Open fractures gustillo type 1, 2, 3A, B fracture Exclusion criteria. Types III C and D Gustilo patients excluded, pregnant women, patients with cancerous primary illness, patients with weakened vascular systems, and those who were allergic to the antibiotic employed were excluded.

**Methodology**

An antibiotic-coated tibia interlocking nail with the ability to release gentamicin over time was employed in this study's experimentation. Gentamicin and a biodegradable polymeric carrier Poly are included in the coating (D, L-Lactide). A 100 mg (1mg/cm²) dose of gentamicin is contained in a typical sized nail. Pre-operative evaluation and treatment of any life-threatening conditions were assessed and treated. Before any anaesthetic was administered, each patient had a thorough pre-anesthetic examination. The patient was painted and sterile drapes were applied. Excess skin and bone were removed from above the tuberosity of the tibia using an image intensifier before the knee was bent to 90 degrees. Serial reaming was performed once the guide wire was passed. An antibiotic-coated nail is placed into the medullary canal in the correct size. Patients requiring falks and grafts accordingly were performed. After surgery, patients received five days of intravenous antibiotics. The patients were monitored for up to six months after surgery to evaluate the recovery.

**Results**

All 70 patients (51 men and 19 females) were followed up for minimum of 3 months length. The radiological Union was rated using RUST Score (Table 1) and clinical evaluation findings were classified as outstanding, acceptable, fair and bad (Table 2). The research contained 44.28 percent of the patients between 30-40 years of age, 28.57 percent of the patients between 40-50 years of age and 20 percent beyond 50 years and 7.14 percent of patients below 30 years. The mean age of such fractures to be 35.65 years in this research, there was preponderance of male population. Males were 72.86 percent versus females 27.14 percent (Table 3). The most prevalent cause of injury was determined to be related to road traffic collision and accounted for 55(78.57%) of cases. Fibula fracture was related with 65(92.86%) of patients. Time required in wound healing in majority of patients was shorter than 6 weeks 35 (50%), 6-8 weeks 22 (31.43%), 8-10 weeks 7(10%) and those were not healed 6 (8.57%) (Table 4). Majority of patients 57.14% had RUSH score 9 at six months of duration, 21.43% of patients had RUSH score 11 and 8.57% patients RUSH score was 6 at six months (Table 5). 6 patients became infected in this research and in 4 cases there was non-union. Average length of hospital stay was 16.5 days. Out of 70 patients, 8 (11.14 percent) patients had outstanding result, 15 (21.43 percent) had good and 41 (58.57 percent) fair and only 6 (8.57 percent) patients had bad outcome (Table.6). Average period of wound healing in our research was 4.25 weeks. Out of 70 patients, fracture union was accomplished in 68 (97.14%) patients and two patient (2.86%) patients underwent non unions. This research composed of 70 patients, out of them 41 patients (58.57%) had grade-I, 23 patients (32.86 percent) had grade-II and 6 patients (8.57 percent) had grade-III compounding. (Table.7)

**Table 1:** Radiological union scale in tibial (RUST) fractures

| Score per cortex | Callus | Fracture line |
|------------------|--------|---------------|
| 1                | Absent | Visible       |
| 2                | Present| Visible       |
| 3                | Present| Invisible     |

**Table 2:** Criteria for assessment of the result

| Variable                                      | Excellent | Good | Fair | Poor        |
|-----------------------------------------------|-----------|------|------|-------------|
| Infection at 4 weeks                          | Control   | Control| Control| Not Control |
| Wound healed at 6 weeks                       | 6 weeks   | 8 weeks| 10 weeks| Not Healed  |
| Radiological union at 6 month (RUST Score)    | 13 score  | 11 score| 9 score| 6 score     |
| Weight bearing without pain at 4 months       | Yes       | Yes   | No    | No          |
| Neurovascular complication                    | Absent    | Absent| Absent| Absent/present|
| Patient compliance                            | Excellent | Good | Fair | Poor        |

**Table 3:** Demographic profile

| Gender   | Number of patients ≥70 | %  |
|----------|------------------------|----|
| Male     | 51                     | 72.86%|
| Female   | 19                     | 27.14%|
| Age      |                        |    |
| Below 30 years | 5 | 7.14% |
| 30-40 years  | 31 | 44.28% |
| 40-50 years  | 20 | 28.57% |
| Above 50 years | 14 | 20%   |
| RTA       | 55                     | 78.57%|

**Table 4:** Time taken in wound healing

| Time taken in wound healing in weeks | Number of patients=70 | %  |
|--------------------------------------|------------------------|----|
| ≤6 weeks                             | 35                     | 50% |
| 6-8 weeks                            | 22                     | 31.43%|
| 8-10 weeks                           | 7                      | 10% |
| Not healed                           | 6                      | 8.57%|

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Table 5: Radiological union at four month (RUST score)

| Radiological union at 6 month (RUST score) | Number of patients=70 | Percentage |
|------------------------------------------|------------------------|------------|
| 6                                        | 6                      | 8.57%      |
| 9                                        | 40                     | 57.14%     |
| 11                                       | 15                     | 21.43%     |
| 13                                       | 9                      | 12.86%     |
| Total                                    | 70                     | 100%       |

Table 6: Clinical outcome

| Functional outcome | Number of patients=70 | %     |
|--------------------|------------------------|-------|
| Excellent          | 8                      | 11.44%|
| Good               | 15                     | 21.43%|
| Fair               | 41                     | 58.57%|
| Poor               | 6                      | 8.57% |
| Total              | 70                     | 100%  |

Table 7: Grade compounding of patients

| Grade | Number of patients=70 | %     |
|-------|------------------------|-------|
| I     | 41                     | 58.57%|
| II    | 23                     | 32.86%|
| III   | 6                      | 8.57% |

Discussion

Infected long bone fractures need a technique to manage infection, stabilise the fracture, and accomplish a successful union of the bones. The infection is controlled by surgical debridement and the introduction of antibiotics both locally and systemically. With local treatment, a high concentration of antibiotic may be achieved while having a little effect on the body as a whole [14].

Injuries to the tibia’s shaft account for a large percentage of all long bone injuries treated in emergency rooms. For an open tibial shaft injury, there is no one-size-fits-all method of therapy, and this may be harmful. An increased risk of open and infected tibia fractures due to its close proximity to skin. Particularly in spiral and oblique fractures, after swelling subsides, pieces tend to reposition themselves. The alignment or rotational position of the pieces is imprecise since the knee and ankle joints generally move on the same parallel axis. This might create cosmetic and functional handicap.

Surgical treatment of open tibial shaft fractures is aimed at lowering the risk of infection and improving the healing of the fracture. Providing secure internal fixation with an intramedullary nail prevents the common issue of joint stiffness by allowing for early recovery and flexibility of surrounding joints.
Using antibiotic-coated intramedullary locking nails in complex tibia fractures, the researchers set out to see how effective they were. Compared to Javed Aziz et al., our research found a mean age of 35.65 years for such fractures (33.28 years) [18].

Males were found to account for 72.86 percent of all fractures, compared to 27.14 percent for females. It's on par with the findings reported by Lin J et al. [16].

In the present study half of the patients (58.57 percent) had grade-I compounding; the remainder had grade-II compounding (32.86 percent), and six patients (8.57 percent) had grade-III compounding. There were 13 instances of grade-I fractures and 12 occurrences of other fractures in a research by Bhanu Pratap et al. [17].

Only three patients (27.27%) in the research by Khaled Hamed et al. [18] had Gustilo type II fractures, whereas eight (72.72%) had type I. Fifty-eight (97.14 percent) of the patients had their fractures healed, whereas the other two patients (2.86%) had non-unions. Bhanu Pratap et al. [17] and Thomas Fuchs et al. [19] found that none of the patients had non-union as a result of treatment. In our research, the average healing period for a wound was 4.25 weeks. Bhanu Pratap et al. [17] found cases of infection in two of the 25 individuals studied. Thomas Fuchs et al. [19] found that just one of the 19 participants in their research had an infection. In our investigation, only six of 70 patients were confirmed to be infected, which is consistent with our results. There were 8 patients who showed excellent outcome, 15 showed good outcome and 41 fair outcomes among the 70 patients studied in this research. Only 6 of the patients had poor outcome.

**Conclusion**

Implant-related infection is a major stumbling block in the surgical treatment of tibia shaft fracture, according to the present study. Antibiotics given at the site of the injury may help prevent an infection from developing.

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