MANAGEMENT OF INFECTED NON-UNION OF TIBIA USING INTRAMEDULLARY ANTIBIOTIC CEMENTED COATED NAIL

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ABSTRACT

Background: Infected nonunions of the tibia pose significant challenges for complete resolution and functional restoration. Local bone tissue remains without bactericidal concentrations, thus not interfering with bacterial growth. So acrylic bone cement is the gold standard for dead space management and the standard carrier for local antibiotic delivery in the management of orthopaedics infections. The aim of this study is to assess the outcome after treatment of infected non-unions of tibia treated by Antibiotic cement impregnated intramedullary nailing (ACIIMN). Patients and methods: This study included 12 cases with infected non union tibia were admitted to Orthopedic Surgery Department, Faculty of Medicine, Zagazig University Hospitals. The used methods of the study includes and preoperative evaluation, methods of treatment and postoperative follow up and methods of postoperative evaluation. All patients were followed-up, with an average follow-up time of 18 months. Results: Age was distributed as 44.66±9.48 and majority were male with 83.3% and DM was present in 25% of studied group. The mean duration of infection was 9.58±2.06. Union time was distributed as 32.33±6.44 weeks. Only three cases needed additional method. The overall outcome showed 75% had successful union without any additional methods and 25% of our studied group had persistent infection. Unfavorable outcome significantly associated with higher age. Conclusion: Antibiotic cement impregnated nailing is a safe and simple and effective procedure than other methods in the management of infected nonunion of tibia. It is the best option that significantly reduce the union time without causing much problem. The method utilizes existing easily available instrumentation and materials and is technically less demanding at any orthopaedic center.

Keywords: Non-Union Tibia, Intramedullary Antibiotic, Coated Nail

INTRODUCTION

Infected nonunions of the tibia pose significant challenges for complete resolution and functional restoration. The infection is chronic and resistant to treatment. Stiffness of the ankle and knee creates functional handicaps. Prolonged treatment causes psychological, social, and economic hardships (1).

Debridement remains the cornerstone of treatment of infection. Large sinus tracks and infected scars need excision. Cultures are taken from the depths of the wound and antibiotics started only after sensitivity testing (2). Debridement of soft tissue may lead to loss of cover which may best be filled with a muscle flap. The muscle flap brings much needed vascularity and helps in early union and complete eradication of infection (3).
An antibiotic impregnated cement block obliterates dead space. It allows elution of the antibiotic in very high concentrations at the local site, in many multiples of the minimum inhibitory concentration (MIC). The cement can be fashioned into a block to occupy the entire bony gap. Alternatively, the cement may be fashioned as a cylinder and Rush or Ender nails passed through it to secure the cement block to the bone (4).

After control of infection, the tasks that remain are achieving union, correcting deformities, equalizing limb length, and filling defects and bone gaps. Union needs three basic requirements: stable fixation, biological stimulation, and restored function. Posterolateral and central bone grafting achieve union by approaching the nonunion away from the infected site and achieving fusion between tibia and the fibula over the interosseous membrane (5). Antibiotic loaded bone cement can be customized intraoperatorively to different shapes and forms. In intramedullary infections they offer local delivery of antibiotics, while filling the dead space and offering stability to the fracture/nonunion site, if present (6).

The aim of this study is to assess the outcome after treatment of infected non-unions of tibia treated by Antibiotic cement impregnated intramedullary nailing (ACIIMN).

PATIENTS AND METHODS

This study included 12 cases with infected non union tibia were admitted to Orthopedic Surgery Department, Faculty of Medicine, Zagazig University Hospitals. An informed consent was obtained from all patients. All data was confidential with secret codes and private file for every patient.

Inclusion and exclusion criteria:

Patients of infected non-union of tibia, Middle third infected tibia. Patients above 15 years old who medically fit for surgery. While, patients with non-union with bone defects more than 6 cm, patients aged below 15 years, deformed tibia, patients allergic to vancomycin and medically unfit patients were excluded.

All patients were subjected to full history and clinical examination. Patients underwent a pre-operative evaluation including the following parameters: complete blood count, ESR, C-reactive protein, culture and sensitivity. Radiological evaluation as X-ray for assessment of the length and size of the defect if present and signs of osteomyelitis. All patients were followed-up, with an average follow-up time of 18 months.

Surgical procedure:

The surgical technique that had been done involved debridement of the infected bone and soft tissues and copious lavage. All the infected tissues, including the skin, soft tissue and bone were excised until bleeding viable tissue was present at the resection margins. Adequate reaming was done to accommodate the largest diameter nail which ensures more stability. Thorough saline lavage of the medullary canal and the wound was done. The limb prepped again and re-draped before antibiotic cement impregnated nail was prepared. vancomycin powder 1.2-g vials. The silicon tube has been cut to the appropriate length. vancomycin powder (2 gm) added to the two packs of bone cement powder and mixed. Liquid polymer is added and mixed by hand mixing technique. Once the bone cement hardens, the silicon tube has been cut with a scalpel and gently stripped of the antibiotic nail. Then antibiotic nail was inserted in the medullary canal with gentle tap. Proximal and distal screws
inserted and wound edges closed well coated without tension nail ready for insertion (7).

Postoperative care and follow up:

Postoperatively, the patient is kept on appropriate intravenous antibiotics based on the culture reports for 1 week, followed by oral antibiotics for 6 weeks. Follow-up includes complete blood cell count, erythrocyte sedimentation rate, and C-reactive protein for activity of infection with series of x-rays for follow up of fracture union.

Statistical analysis

Data analyzed using Microsoft Excel software and imported Statistical Package for the Social Sciences (SPSS version 20.0) software. According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD, the following tests were used to test differences for significance: difference and association of qualitative variable by Chi square test (X²). Differences between quantitative independent groups by t test. P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULT

The study included 12 cases of ununited infected tibial fracture. The study aimed to assess the role of antibiotic cement coated nailing in infected nonunion of tibia. Postoperatively, 9 of 12 patients achieved full union and elimination of infection with early mobilization by the advantage of interlocking nail application. 3 of 12 patients needed more operative intervention.

Age was distributed as 44.66±9.48 and majority were male with 83.3% and DM was present in 25% of studied group (Figure 1). The mean duration of infection was 9.58±2.06 (Figure 2). The estimated laboratory parameters were shown in Table (1). Union time was distributed as 32.33±6.44 weeks (Table 2).

Only three cases needed additional method (Table 3). The overall outcome showed 75% had successful union without any additional methods and 25% of our studied group had persistent infection (Figure 3). Unfavorable outcome significantly associated with higher age (Figure 4).

A case of male patient 48 years old with history of motorcycle accident and fracture both bone distal one third left leg a year ago treated by traditional intramedullary interlocking nail. After one week signs of infection started by elevation of WBCs, ESR&CRP with pus discharging from distal portion of the leg, the nail has been removed with debridement and external fixator patient came to the outpatient clinic with persistent infection and pus discharging (A and B). External fixator removal with good debridement and application of antibiotic cemented interlocking nail (C). After removal of stitches by 2 weeks regular monthly visits for six months, and every six months up to the end of follow up (D) (Figure 5).
Figure (1): Age and sex distribution among studied patients

Figure (2): Duration of infection distribution among studied patients

Table (1): Laboratory parameter distribution among studied groups

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean± SD</th>
<th>Median (Range)</th>
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<tbody>
<tr>
<td>HB</td>
<td>11.93±0.58</td>
<td>11.95 (10.9-13)</td>
</tr>
<tr>
<td>WBCs</td>
<td>10.26±1.41</td>
<td>10.3 (7.9-12.5)</td>
</tr>
<tr>
<td>PLT</td>
<td>228.5±47.3</td>
<td>214.0 (183-320)</td>
</tr>
<tr>
<td>ESR</td>
<td>95.91±13.52</td>
<td>94.5 (73-119)</td>
</tr>
<tr>
<td>CRP</td>
<td>+VE: 8 66.7%  -VE: 4 33.3%</td>
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Table (2): Union time distribution of successful cases

<table>
<thead>
<tr>
<th>Union time/W</th>
<th>Mean± SD</th>
<th>Median (Range)</th>
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<tr>
<td></td>
<td>32.33±6.44</td>
<td>30.0 (24-44)</td>
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Table (3): Additional procedure needed

<table>
<thead>
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<th>Additional procedure</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>9</td>
<td>75.0</td>
</tr>
<tr>
<td>Additional procedure</td>
<td>3</td>
<td>25.0</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>100.0</td>
</tr>
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</table>
Figure (3): Overall outcome among studied patients

Figure (4): Relation of age with outcome

**Figure (5):** A case of male patient 48 years old with history of motorcycle accident and fracture both bone distal one third left leg a year ago treated by traditional intramedullary interlocking nail. (A) anetro-posterior & lateral views of infected non united both bone leg treated by intramedullary interlocking nail. (B) antro-posterior & lateral views of infected non united both bone leg treated by external fixator. (C) postoperative imaging after the application of antibiotic cemented coated interlocking nail. (D) 9 months post-operative follow up anterior-posterior and lateral views x ray.

**DISCUSSION**

Non-union of long bones secondary to infection is a nightmare to the treating orthopedic surgeon. Despite thorough careful pre-operative, intra operative and post-operative precautions taken to prevent infections, still infected non unions are more common (8).

Early and late onset infections during the management of tibial fractures are known complications. The overall incidence of deep infection following intramedullary nailing for closed fractures ranges from 0%-1% and 0%-11% for open
fractures, depending on the severity of the soft-tissue injury, contamination, and fixation (9).

Treatment of infection is still a major problem. With the advent of better antibiotics and techniques such as the antibiotic bead pouch, the rate of infection has been reduced significantly. The current management of infected tibial nails consists of two main objectives (10).

The use of an antibiotic impregnated cement coated IM nailing for infected nonunion of tibia and femur fractures has been well-documented. The cement nail provides stability across the fracture site, unlike cement beads and osseous stability is important in the management of an infected nonunion. Secondly, antibiotic cement allows higher concentration of antibiotic at the local site than is achievable with systemic antibiotics and is associated with fewer side effects. Antibiotic cement has been shown to elute antibiotic at the local sites for up to 36 weeks thus having a therapeutic effect on infection (11).

In our study, we used the vancomycin as it has the desired properties. The purpose of our study was to evaluate the outcome of treatment of infected nonunions of tibia by antibiotic cement impregnated intramedullary nailing (ACIIMN). All studied cases were subjected to history, general and local examination, preoperative laboratory investigations (including complete blood count, ESR, C-reactive protein, culture and sensitivity) and X-ray.

In our study nine cases achieved eradication of infection by the antibiotic cemented nail which is the main step of the technique. Four of the nine cases undergoes exchanging nail with standard interlocking nail and bone graft to achieve full union and difficult nail removal observed in three cases.

Dhanasekhar et al. (12) evaluated the results of antibiotic cement impregnated nailing in the management of infected non-union of femur and tibia. Antibiotic cement impregnated nailing provides effective infection control and good stability to promote union and has good patient compliance. It is a safe, patient friendly, versatile procedure that can be adapted easily. The method utilises existing easily available instrumentation and materials to manage a complex problem in a highly cost effective way. Thus, antibiotic cement impregnated nailing is a simple, economical and very effective procedure when compared to the traditional methods in management of infected non-unions of long bones.

Wasko and Borens (13) concluded that the antibiotic cement-coated nail seems to be an effective treatment for intramedullary infections of the fractured tibia.

Rashed et al. (14) evaluated the effectiveness of antibiotic-impregnated bone cement in the management of infected nonunions for infection control. They reported that conversion of septic nonunion to aseptic nonunion is the main step of the protocol. Indigenous antibiotic-impregnated cement is an ideal modality of treatment to achieve the union.

Santosh et al. (8) studied the outcome of treatment of infected non-union of femur and tibia treated with antibiotic cement impregnated nailing (ACIIMN). They found that ACIIMN was a good procedure to achieve early infection control in cases of infected non-union with bone defect <6 cm. It is a highly economical and cost effective method utilizing easily available instruments and materials and very effective procedure when compared to the other methods. Effective infection control and good stability to enhance union is obtained by antibiotic cement impregnated nailing and it has got good patient compliance also. It is patient friendly and it can be easily done at any center.
Bhatia et al. (15) concluded that antibiotic cement impregnated nailing is a simple, economical and effective single stage procedure for the management of infected nonunion of tibia. It is advantageous over external fixators, as it eliminates the complications of external fixators and has good patient compliance.

CONCLUSION
Antibiotic cement impregnated nailing is a safe and simple and effective procedure than other methods in the management of infected nonunion of tibia. It is the best option that significantly reduce the union time without causing much problem. The method utilizes existing easily available instrumentation and materials and is technically less demanding at any orthopaedic center.

NO conflict of interest.

REFERENCES