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Original Research Article

Management of Femur and Tibia with Antibiotic-Impregnated Polymer or Cement Coated Interlocking Nails

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Abstract

Background: Infected fractured bones are exasperating issue faced by orthopedics. Through cleaning of the infected wound and then placing od the antibiotic releasing medullary nails id recommended in such cases. The aim of this study is to evaluate the efficacy of cement coat nails and polymer nails with impregnated antibiotics for treating infected fractured bones of tibia and femur.

Methods: 20 patients who had infected fractured bones were included in the study. Before the treatment the level of infection and the extent of fracture was determined. Patients were then implanted with either cement coated antibiotic impregnated nails or polymer coated antibiotic impregnated nail which was done in single stage procedure or two stage procedure. Culture test and radiological test were repeated to calculate the dose of antibiotics to be given for 6 weeks. Regular follow-ups were conducted to check the healing process.

Results: Four cases had sustained infection out of 20, in 5 cases the fracture did not heal. However excellent to good recovery were observed in the fracture healing for 60 % of the total cases. Similarly, 65% of the cases showed excellent to good restoration of the functional ability.

Conclusions: In this comparative study there was no significant difference reported in the management of infected fractured bones considering cement coated and polymer coated medullary nails

Keywords: Infected non-union, Antibiotic impregnated cement coated interlocking nail (AICCILN); Antibiotic impregnated polymer coated interlocking nail (AIPCILN).

Introduction

The bone fracture can lead to infection in the osseous tissue. The disruption of the osseous tissue and exposure to the environment along with limited blood supply can create exasperating condition to treat [1]. The infected area of fractured bones has high incidences of developing replaces after successful treatment also during replaces there are chances of infection from resistant microorganisms [2, 3]. A decade ago, treatment of such cases involved two procedures. In the first stage involved cleaning of the wound and in the second stage the fracture is treated. Recently single stage procedures involving cleaning and Illizarov's fixator has been used to treat such cases. However, this procedure has disadvantage such as long-term morbidity and occurrence of resistant microorganism [4-7].

The cement coated or polymer coated medullary nails have impregnated antibiotics. These nails provide two benefits in one, it gives optimum concentration of antibiotics locally and provide stability to the fractures. Since the antibiotics are available locally, they are high in concentration and can easily penetrate the film of microorganisms. [8-10]. Such medullary nails have demonstrated marked improvement in the bioavailability of the antibiotics as well as it prevents the complications that could result from external fixator. In the present study the efficacy of the cement coated, and polymer coated medullary nails impregnated with antibiotic are evaluated in 20 cases of infected fractured bones.

Materials and Methods

Study Design*:* A prospective study was conducted. Patients gave informed consent, and the institutional ethics committee gave approval for the study.

Participants: Patients reporting at the outpatient department at DDU Hospital, Hari Nagar, Delhi with infected fractured bones were included in the study. Every patient had abscess from the infection, and they had undergone either one or multiple surgeries. Prior to the treatment WBC count, especially neutrophil percentage, ESR and C-protein activity

was tested. The status of the infection could be determined from the test outcomes and before performing cleaning of the wound the abscess was sent for culture testing. The surgical procedures were conducted either in a single stage or in two phases, contingent upon factors such as the extent of infection, the number of prior operations, and the length of the first n-index surgery. There were two types of nails used in this study, polymer coated nail and cement coated nail which were impregnated with antibiotics.

Method of formation of cement coated nail*:* The nails are made in the operating theatre during the surgical procedure after the removal of dead tissue and the widening of the central cavity of the bone. The necessary instruments included interlocking nails with a secure interlocking mechanism, bone cement mixed with 2 g of gentamicin and 40 g of bone cement, and 2 g of vancomycin, a syringe, a silicon tube of 10 mm, a 1.5 mm K-wire, a file, a BP-blade, a drill bit with a diameter of 3.2 mm, and 3.9 mm interlocking bolts. The steps were as follows: i) A metal scale is used to determine the cavity depth and image intensifier is used to measure the actual length. ii) The diameter of the nail was 4mm, 2mm for the cement coating and the other 2mm made the penetration into the medullary canal easier iii) four gram of bone cement was mixed with gentamycin 2 g and vancomycin 4g iv) equally long silicon tubing with 2 mm diameter greater than the nail diameter was taken v) the mixture formed was put in the silicon tubing with a syringe and the other end of the tube was closed vi) to place the nail at the centre of fracture a K-wire was placed near the holes. vii) once the cement was set approximately after 8 minutes the silicon tube was cut apart and the nail was removed. ix) the nail was smoothened by drilling.

Figure 1: Equipment required for making cement coated antibiotic loaded nail

Figure 2: Cutting of silicone tubing of appropriate size

Figure 3: Mixture formation and filling

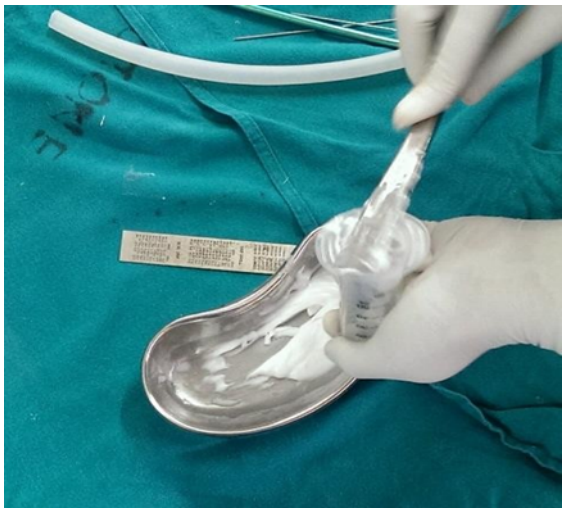

Figure 4: Filling with syringe or cement gun

Figure 5: Filling of cement into tubing

Figure 6: Inserting nail in the tube

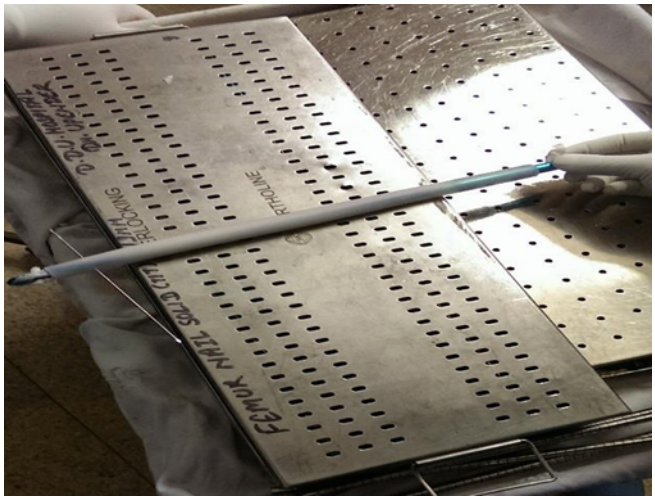

Figure 7: Insertion of 1.5 mm K-wire into distal hole of nail

Figure 8: Rolling the tube to get even distribution

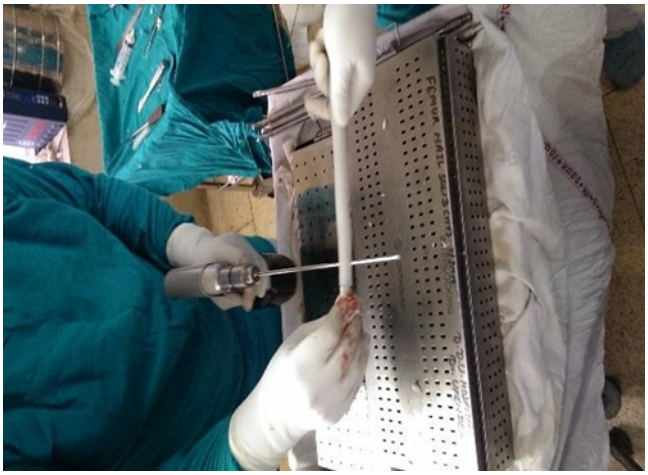

Figure 9: drilling for maintaining patency of distal hole

Figure 10: allowing the cement to settle

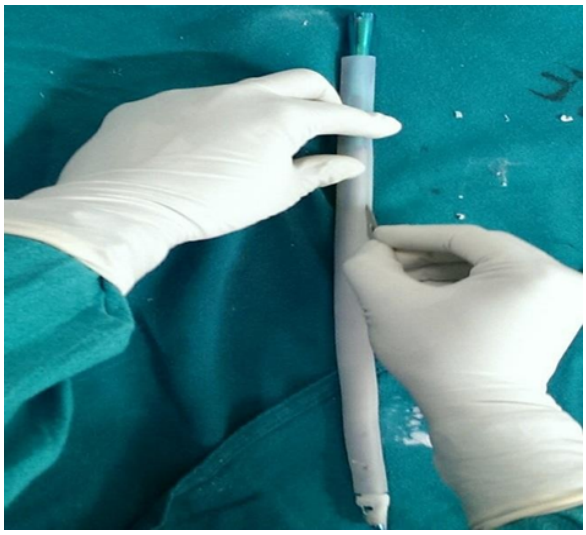

Figure 11 and 12: Cutting the tube

Manufacture of polymer coated medullary nail: polymer coated nails were obtained from the manufacturer. There were two layers of biodegradable polymer, the inner layer had the mixture of antibiotics and then it was coated with biodegradable polymer. The outer layer had also the same polymer and its function was to protect the inner layer from premature rupture, sunlight, and moisture. The main steps are as:

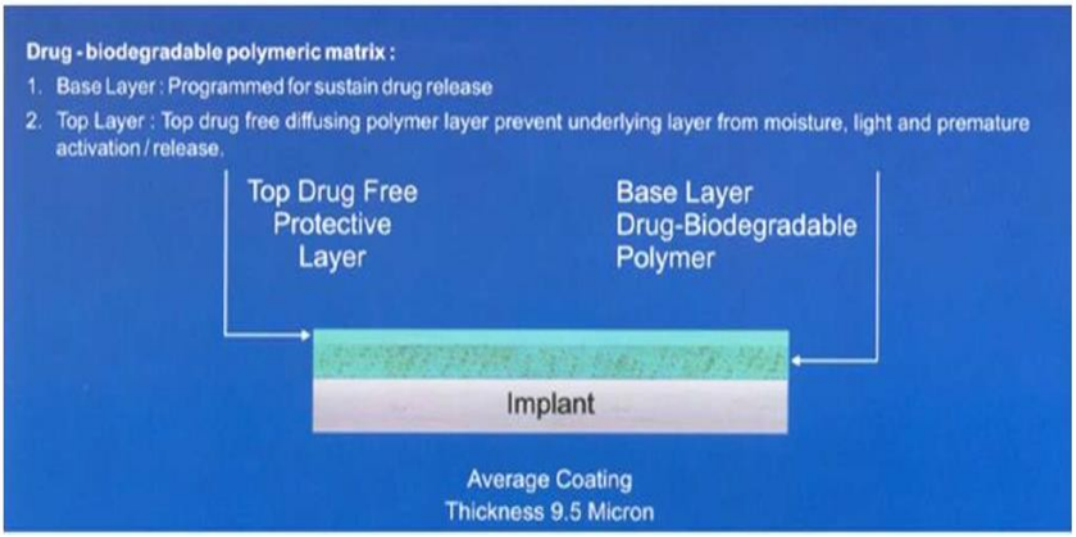

Figure 13: Steps for preparation polymer coated antibiotic loaded polymer nail

Figure 14: Polymer coated nail obtained from the manufacturer

Operative procedure: Following a standard investigation and comprehensive testing to determine the antibiotic sensitivity of the bone cement, the patients were subsequently scheduled for surgery. The procedures undertaken were as follows: i) Following the administration of anaesthesia, patients were positioned appropriately. ii) Following the completion of the painting and draping process on the patient, the C-ARM equipment was appropriately positioned and draped. iii) Whenever feasible, an automated ligature and limb separation were used.

The first procedure conducted was the removal of the implant. The excision of the sinus canals was performed after they had been previously delineated using methylene blue injection. The location of the break was surgically accessed and underwent thorough cleaning, which included removing the contaminated, scarred soft tissue, bone end, and inflammatory tissue. vii) The medullary canal was widened until hemostasis was obtained inside the medullary cavity. The tissues obtained after widening of medullary canal are sent for culture testing. Once the cleaning process was concluded, the tools used for the contaminated phase of the treatment were extracted, and subsequently, the patient's surgical area was draped.

The procedure included the use of a pulsing suction apparatus to conduct flexible intramedullary irrigation, with a volume of 5-10 litres of usual saline solution. The surgeon, along with the other members of the operating team, also underwent a change of gowns and gloves in preparation for the sterile phase of the process. The approach included the selection of an antibiotic-impregnated nail, followed by the implementation of interlocking nailing, which is a commonly used technique. In instances when intramedullary cutting was performed to its fullest extent (e.g., for femur with a diameter of 12 mm). Alternatively, polymer coated nails were selected as the preferred implant in other circumstances.

The diameter of the nail was 2 mm smaller than the diameter of the reamer with the maximum usage. However, the observed disparity was just 1 millimetre for antibiotic impregnated polymer coated nails. In order to prevent the debonding of cement from the nail, it was imperative that no pounding was

permitted during the insertion of the nail. This limitation specifically pertained to the use of antibiotic impregnated cement coated nails. In instances when the infection grade was low, bone grafting procedures were performed. The process of hemostasis was carried out, and thereafter, the wound was closed either with or without the use of a drain.

The chronic infection cases in which there was excess abscess and multiple surgeries were performed were dealt in two stages. At first the infection was cleaned, and the antibiotic beads were placed for 6 weeks. In the second stage the beads were removed, and the nail was placed.

Post operative protocol: Culture test and sensitivity were tested, and the patients were given antibiotics for 2-4 weeks intravenously and for 6 weeks orally. The limb on which surgery was performed was kept in elevated condition. the dressing was performed immediately if there was any wetness of the bandage. In normal cases dressing was done on 4th to 5th day. Non stressful mobilization activities were done if patient felt comfortable. However static activities were done continuously. The patients followed up in every 15 days until 13 months. Erythrocyte sedimentation rate, complete blood count, radiography, and C-protein reactivity was performed at every follow up.When the C- protein was less than 5 mg per litre the infection was controlled if the bridge was seen at the fracture area the bone was mended without weight mobilization of patient was started. Light weight mobilization was permitted at 12 weeks, if the bones were mended in the radiography scan. Complete weight waspermitted after 6 months. The patient was thoroughly monitored during this course for the infection, bone repair and complication if any.

If the infection was cured and the bone was mended than the nail was kept as it is in the medullary space and if not, then the nail was removed and then after 6 to 8 weeks of surgery new nail was placed during the repeat procedure. If there was any deboned cement than it was removed, and the cavity was irrigated thoroughly.

The infection was monitored from the outcomes of the ESR, CBC, and CRP test and the fracture was monitored with radiological testing. The results were assessed on the basis of ASAMI criteria.

Table 1: ASAMI criteria

Sr no.	Criteria	Features
1	Excellent	Repaired bone, controlled infection, deformity less than 7°, limb length difference less than 2.5 cm
2	Good	Repaired bone + (any 2 of them) deformity less than 7°, no infection, and limb length difference of 2.0 cm
3	Fair	repaired bone + one of the following: deformity less than 7°, absence of infection, and Limb Length difference of 2.0 cm
4	Poor	no repair, deformity of 7°, persisting infection, and the limb length difference of 2.0 cm
Functional results		
1	Excellent	Active, minimum stiffness, no limp no reflex sympathetic dystrophy (RSD), insignificant pain
2	Good	Active with one or two of the following: stiffness, limp, RSD and Significant pain.
3	Fair	Active with three or all of the following: stiffness, limp, RSD and Significant pain.
4	Poor	Inactive
5	Failures	Amputation

Results

The research cohort included of a total of 20 individuals, ranging in age from 23 to 50 years, with an average age of 36.05 years. The sample consisted of 13 men, accounting for 65% of the total, and 7 girls, representing 35% of the total. Within our research cohort, it was seen that 12 individuals, constituting 60% of the sample, experienced the condition of infected non-union in their femurs. Conversely, the remaining 6 patients, accounting for 40% of the group, exhibited afflictions in their tibias.

Among the cohort of 20 patients under study, it was seen that 10 individuals, constituting 50% of the sample, had infected non-unions in the context of a compound injury. Additionally, 8 patients, accounting for 40% of the group, presented with closed fractures, while 2 patients, representing 10% of the population, exhibited pathological fractures due to osteomyelitis. The average duration between the first operation and the subsequent procedure was found to be 10.85 months. Typically, an average of 1-2 surgical operations had been performed before to the index surgical surgery.

The cultures were collected from a total of 20 individuals who underwent antibiotic sensitivity testing. The findings of the study are presented in the

following manner: Out of the total number of cultures analysed, 8 (40%) exhibited sensitivity to vancomycin. Conversely, no sensitivity to any culture was observed in 5 specimens. Additionally, 4 cultures demonstrated sensitivity to both ceftriaxone and gentamycin, while 2 (10%) cultures were found to be sensitive to imipenem and gentamycin. Furthermore, 1 culture exhibited sensitivity to meropenem and gentamycin, another 1 culture displayed sensitivity solely to imipenem, and the remaining 1 culture showed sensitivity exclusively to ceftazidime.

Range shortened after the completion of final cleaning procedures ranged from 1 to 8 cm, with an average value of 4.18 cm. In the current series, the majority of instances, namely 16 out of 20 cases (80%), were managed using a single-stage technique. The remaining cases, accounting for 4 out of 20 cases (20%), were addressed using a two-stage procedure. Among a total of 20 instances of infected 20 bone fractures, 11 cases (equivalent to 55% of the total) underwent treatment with an interlocking nail covered with a polymer impregnated with antibiotics. Conversely, the remaining 9 cases (45% of the total) were treated with an interlocking nail coated with cement that was also impregnated with antibiotics.

Problems such as relapsing infection and persistently infected fractured bones were observed to be more prevalent in cases involving the use of cement coated nails, as indicated by P values of 1.010 and 0.191, respectively. Conversely, if the persisting fracture was found to be more common in instances where polymer coated nails were employed, with a P value of 1.01. The obtained P values were not statistically significant, indicating that they were greater than the predetermined significance level of 0.05.

Discussion

In the cohort of 20 patients under investigation, it was seen that 4 individuals (20%) exhibited active discharging sinuses, whereas 6 patients (30%) displayed healed sinuses. The remaining 10 subjects (50%) had intermittent discharge originating from the diseased bone. The average values of the ESR and CRP were determined to be 29.9 mm/hr and 4.89 mg/lt, respectively. Among the cohort of 20 patients, the condition of fracture ends was seen to be atrophic in 4 individuals (20%), hypertrophic in 6 individuals (30%), and neurotrophic in 10 individuals (50%), the organisms identified from the patient's abscess were: Methicillin-resistant Staphylococcus aureus (S. aureus) was detected in 8 out of 20 patients, accounting for 40% of the study population. In 4 patients (20%), no microorganisms were cultured. Mixed growth of several microorganisms was seen in 3 patients (15%). Specifically, S. aureus and Escherichia coli (E. coli) were each found in 2 patients (10%), while pseudomonas was isolated in 1 patient (5%).

The issue of infected fractures is now presenting a significant challenge within the field of orthopaedics [3]. These phenomena are often seen across many ethnic groups, regardless of age and gender. Long bones are often impacted, with open fractures exhibiting a greater occurrence compared to closed fractures [4, 5]. The issue escalates in severity when it undergoes repeated procedures, resulting in the patient exhibiting chronic osteomyelitis of the bone characterised by the presence of an abscess. Inflammatory markers such as erythrocyte sedimentation rate (ESR), total leukocyte count (TLC), and C-reactive protein (CRP) serve as indicators for assessing the severity of infection, while accurate radiographic assessments provide valuable insights on the condition of fracture endpoints [6].

In the present research, infection was effectively managed in 16 out of 20 patients, accounting for 80% of the total cases. However, in the other 4 instances, infection control measures were not successful. The duration of infection control measures varied between 2 and 14 weeks, with an average duration of 7.38 weeks. In the present study, a total of 20 patients were included, of whom 15 individuals (75%) demonstrated successful osseous union, whereas 5 instances (25%) did not reach this outcome. The duration of union incidence varied between a minimum of 20 weeks and a maximum of 33 weeks, with an average duration of 7.38 weeks.

The length of the follow-up period ranged from 32 to 60 weeks (equivalent to 8-12 months), with a mean duration of 41.4 weeks. The assessment of the ultimate result of the limb in all 20 instances included in this research was conducted using the ASAMI (bony) criteria, as shown in Table 1. The study yielded excellent outcomes in 4 instances, accounting for 20% of the total. Good results were exhibited by 8 patients, representing 40% of the sample. Fair results were seen in 3 cases, constituting 15% of the total, while bad outcomes were reported in 5 cases, making up 25% of the sample. The findings are consistent with other studies reported [10, 11].

According to the ASAMI functional criteria, 5 instances (25%) achieved exceptional outcomes, while 8 patients (40%) demonstrated good results. A total of 2 instances, accounting for 10% of the sample, exhibited fair outcomes, whereas 5 cases, representing 25% of the sample, yielded bad results. In total, there were seven cases involving complications. Among these cases, two patients (28.7%) experienced persistent infection, leading to the necessity of implant removal and debridement. Additionally, three patients (42.9%) developed persistent fractures, which required additional process. The remaining two patients (28.7%) presented with

infected non-unions, and thus underwent revision antibiotic nailing. The study findings indicate that the use of antibiotic-impregnated polymer-coated interlocking nails resulted in greater rates of infection control and union compared to other treatment methods. A study reported similar results [12].

However, it is important to note that the observed differences in infection control rate ($p = 0.285$) and union rate ($p = 0.617$) were not statistically significant, suggesting that these differences may have occurred by chance and are not likely to be attributed to the intervention. The results of the study indicate that the end outcome of the limb, as assessed by both bony criteria and functional criteria, was more favourable when antibiotic-impregnated polymer-coated interlocking nails were used. The statistical analysis yielded p-values of 0.502 and 0.876 for the bony and functional criteria, respectively. The observed difference is deemed statistically insignificant, as shown by a p-value greater than 0.05. The findings were in accordance with the studies reported in this domain [13].

The primary therapeutic approach for infected fracture of long bones involves comprehensive debridement, strict fixation, and extended administration of antibiotics. Numerous stepwise techniques have been documented for the treatment of infected non-unions [7]. In the field of medical treatment, intramedullary antibiotic-loaded devices have been used for the purpose of managing infections and facilitating bone regeneration within a single stage. However, it is worth noting that some exceptional circumstances still need the implementation of a two-stage method.

The determination of the appropriate antibiotic for infection management is reliant upon culture testing. Among the several aminoglycosides available, vancomycin is frequently selected for both local and systemic administration of antibiotics [14]. Typically, a course of systemic antibiotics spanning a duration of 2 months is prescribed until the inflammation is treated completely. In general, the use of antibiotic-loaded implants has shown significant efficacy in the treatment of infected non-unions.

Conclusion

It can be inferred that a prospective investigation was conducted on a cohort of 20 patients with infected fracture of long bones who received treatment with antibiotic-impregnated implants at our institution from March 2013 to June 2014. The cases were comprehensively examined with regards to infection management, bone repair, and the ultimate result of the limb according to the ASAMI criteria. The current evidence supports the use of cleaning of wound and fixing it with antibiotic-loaded interlocking nails as a contemporary approach in managing infected fracture of long bones.

This research was prospectively done on a small cohort of 20 patients who had infected fracture of long bones. The patient demographics and illness characteristics were not predetermined and were not explicitly outlined in the protocol. In addition, this research eliminated cases of infected non-unions in skeletally immature individuals, as well as non-unions without infection. Additionally, the length of the follow-up period was comparatively reduced.

Therefore, based on the information provided, it can be inferred that the use of antibiotic-impregnated interlocking nails with cement or polymer coatings represents a new and efficient approach for treating infected non-unions of long bones. In order to establish a standardised treatment plan for the treatment of infected fracture long bone, it is essential to use large sample numbers and conduct randomised controlled trials with extended durations of follow-up.

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