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ANTIBIOTIC COATED NAIL [A NOVEL TECHNIQUE FOR TAILOR MADE PATIENT MANAGEMENT]

Orthopedics

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ABSTRACT

Background: Infected Non-Union Of long bones is a notorious condition. We describe a novel technique of tailor made Antibiotic coated nails that have shown considerable promise with respect to simplicity of procedure and reduction of management duration.

Material Methods: A prospective study was conducted on 6 patients with long bone infected non-unions and results were inferred in terms of 2 parameters those being infection control and bony union.

Results: Out of 6, 5 patients showed satisfactory outcomes whereas an additional secondary procedure was needed in 1 patient to achieve set goals. The range of time taken for infection control was between 3-6 weeks (average 4 weeks) and bony union was achieved within a span of 26-36 weeks (average 29 weeks).

Conclusion: Antibiotic coated nails achieved satisfactory results in patients of long bones infected non-unions with bone gap less than 2cm.

KEYWORDS

Infected Non-Union, Antibiotic Coated Nail, Infection Control, Bony Union.

INTRODUCTION

Infected nonunion of long bones is a chronic and debilitating disorder. Various factors contribute to infected nonunion, including open fractures, infection after internal fixation[1], chronic osteomyelitis with pathological fractures, and surgical debridement of infected bone. It's usually treated as a 2 stage procedure by controlling the infection first followed by nonunion part.

It is more difficult to deal with when the implant used for internal fixation itself becomes a potential media for infection because of bacterial adhesion and biofilm formation. [2] Most of the orthopedic trauma infections are caused by biofilm-forming bacteria. [2] These infections become difficult to handle because IV antibiotics are not able to penetrate this biofilm and act upon the causative organism which may result in infection not being curbed and eventually non-union.

In our study antibiotics used have been either broad spectrum or culture sensitive antibiotics. The purpose of our study was to evaluate the outcome of use of antibiotic coated nail in treatment of infection and nonunion in cases of long bones.

MATERIALS AND METHODS

A prospective study was conducted in MMIMSR, Mullana, Department of orthopedics from January 2017 to January 2019 on a total of 6 patients with compound fractures, inclusion and exclusion criteria for selection of which is detailed below. The study sample consisted of 4 males and 2 females within age group 20-60 years (mean age 43 years)

INCLUSION CRITERIA

1. Patients with compound diaphyseal fractures of long bones (femur and tibia)
2. Bone gap less than 2 cm.
3. Age more than 18 years
4. No radiological signs of union despite previous mode of treatment used.

EXCLUSION CRITERIA

1. Patient with large bone gaps (>2 cm)
2. Infection involving the joint
3. Allergy to the antibiotic which was to be used in cement

CRITERIA TO ASCERTAIN CONTROL OF INFECTION

- Stoppage of discharge.

CRITERIA TO ASCERTAIN UNION

- No Pain at fracture site and radiologically 3 cortices united.

POST OP PROTOCOL

- Post Op Prophylactic antibiotics were administered for an average of 5 days.
- Patients were allowed partial weight bearing after 2 weeks and full weight bearing on radiological union.

FOLLOW UP PROTOCOL

- Patient discharged on 7th post op day. Suture removal done on POD 14. Weekly follow up rest of the month. Monthly follow up for next 2 months and 3 monthly follow l-up later on till completion of 1 year.

Table 1 – Depicts Age wise Pre-Operative Patient Profiles

Sr No.	Age/sex	Grade	Bone involved	Outside procedure	Duration of infection
1.	40/M	III-A	Femur	I.M nailing	9 months
2.	45/F	II	Tibia	Cast with window	3 months
3.	57/M	II-A	Femur	I.M nailing	4 months
4.	35/M	III-A	Tibia	External-Fixator	6 months
5.	42/F	III-A	Tibia	I.M Nailing	8 months
6.	38/M	II	Femur	I.M Nailing	1 year

Table 2 – Depicts Pre-Operative Microbiological Profile and nail size used

Sr. No	Organism Isolated	Antibiotic Cement	Nail Size (Original and With Coating)
1.	Staph Aureus	Vancomycin	8 and 10
2.	Staph Aureus	Vancomycin	7 and 9
3.	Klebsiella	Gentamycin	9 and 11
4.	Staph Aureus	Vancomycin	8 and 10
5.	Klebsiella	Tobramycin	8 and 10
6.	None	Vancomycin + Gentamycin	9 and 11

SURGICAL PROCEDURE

After all pre-op investigations and clinical evaluation, patients were explained about the procedures and taken up for surgery with due consent Pre-Op AP and Lateral radiographs along with measurements noted down. Procedure done under spinal anesthesia.

Previous nail, if present was removed followed by copious irrigation of

inter-medullary canal with hydrogen peroxide, betadine and normal saline.

Sinus tract exploration and excision was done. Fracture site was opened and debridement performed with excision of infected bone ends, soft tissue and granulation tissue. This was followed by reaming with flexible power reamer in graded sequential manner. The contents of reaming and excised granulation tissue were sent for Gram staining, histopathology, Culture and sensitivity. Reaming was done one or two sizes (1-2mm) more than that of the intramedullary nail removed or until fresh bleed was reached. In cases where there was no intramedullary nail in-situ reaming was done 1-1.5mm more than size of antibiotic coated nail.

An appropriate size antibiotic impregnated nail was prepared on a separate sterile table. I.M nail of size 7 to 9 mm diameter was chosen and coated with bone cement up to 2 mm in a pre-manufactured custom dye. 40 gm of cement was thoroughly mixed with 25 ml of antibiotics depending upon pre-op culture and sensitivity. The nail was coated with antibiotic mixed with cement in the mould. It was allowed to settle down for 15 minutes the proximal and distal locking sites were kept uncovered.

The nail was then inserted using standard entry point already prepared, the fracture was reduced and nail inserted into the distal fragment. The Proximal and Distal locking done depending on the type or severity of fracture. Intravenous antibiotics were given intra operatively once culture sensitivity samples were taken. Wound was washed thoroughly and Incision closed in layers without drain. Aseptic dressing was done and patient shifted to post-operative ward.

RESULTS

Out of six, 5 patients showed satisfactory outcomes whereas an additional secondary procedure was needed in 1 patient to achieve set goals. Mean duration of time period of infection amongst these patients was around 7 months as evidenced by presence of discharge. The range of time taken for infection control was between 3-6 weeks (average 4 weeks) and bony union was achieved within a span of 26-36 weeks (average 29 weeks).

Results after carrying out the procedure are depicted in table 3.

Table 3 – Depicts Durations of Post Op Infection control and time taken to achieve Bony Union

Sr. No.	Union Achieved	Infection Control	Infection Recurrence	Any Secondary Procedure	Infection Controlled	Union Achieved
1.	36 weeks	4 weeks	NO	-	-	-
2.	20 weeks	3 weeks	NO	-	-	-
3.	NO	3 weeks	YES (6 Weeks)	Ilizarov with Bone Transport	Yes	Yes
4.	26 weeks	4 weeks	NO	-	-	
5.	30 weeks	4 weeks	YES (6 Weeks)	NO	Yes (8 weeks)	Yes (30 Weeks)
6.	32 weeks	6 weeks	NO	-	-	-

DISCUSSION

There is no single universally accepted modality of treatment presently available for the management of infected non-union. Thorough debridement, rigid fixation, and prolonged antibiotics are the mainstay in treatment of infected non-union of the long bone.[6-8] Infected non-union has been generally managed using two-step procedure to control the infection first and subsequently to treat the nonunion.

The infected foci within the bone are surrounded by a sclerotic, relatively avascular bone covered by a thickened periosteum, scarred muscle and subcutaneous tissue. This avascular envelope of scar tissue leaves systemic antibiotics essentially ineffective.[9] Hence, delivery of antibiotics to the local site is far more beneficial than systemic administration of antibiotics. The choice of antibiotic is culture dependent heat stable broad-spectrum antibiotic such as gentamycin and vancomycin. Main advantage is Local concentration of antibiotics is far higher than what can be achieved with systemic antibiotics. Antibiotic cement has been shown to elute antibiotic at the local sites for up to 36 weeks thus having a therapeutic effect on refractory infection.[4,5]

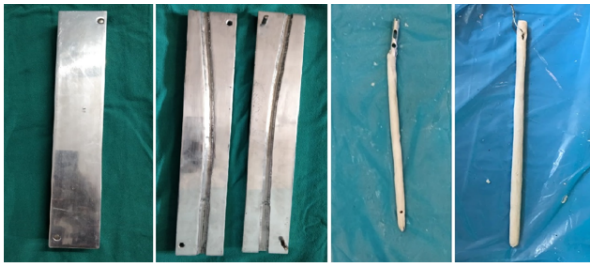
In order to cure biofilm-related infection, four principles formulated by Cierny and Mader must be observed:

(1) complete surgical debridement with dead space management
(2) fracture/nonunion stabilization
(3) soft tissue coverage, and
(4) adequate antibiotic levels[3]

The use of antibiotic cement was first noted by Buchholz and Engelbrecht.[9] Klemm was first to use antibiotic cement beads in cases of osteomyelitis.[9] The efficacy of cement beads to control infection are well established. The use of antibiotic nail has been first reported by Paley and Herzenberg.[9]

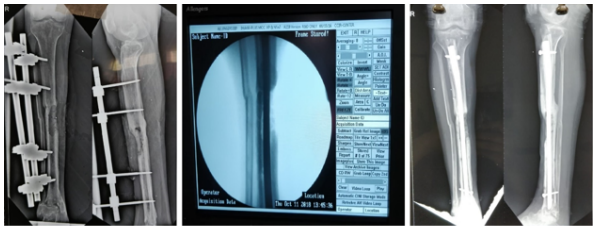
The advantage of using cemented nail over beads is that it provides with mechanical stability as well as second procedure for bony union is not needed. So post op rehabilitation becomes easier early mobilization and weight bearing can be done.

Although limited by sample size, but our study shows antibiotic coated nail to be a better alternative to conventional techniques used to manage infected non unions and it is less traumatic to the patient as well as to the surgeon.



A B C D

[Image-1(L to R): A & B Mould for coating the nail. C & D Nail coated with antibiotic Cement]



A B C

[Image-2(L to R): A. Pre-Op X ray, B. Intra-Op X-Ray, C. Post-Op X-Ray)

CONCLUSION

Antibiotic coated nail provides effective infection control and bone union with bone defect <2cm.

It is economical, effective and can be tailor made for patient.
It has good patient compliance and can be used as a single stage management.

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