Evaluation of Indigenous Antibiotic Impregnated Cement Rod in the treatment of chronic osteomyelitis of long bones

Yogesh R. Gaikwad[1], Vijay V. Nemade[2,*], Vijayanad R. Lokhande[3], Shardul M. Soman[4], Sandeep D. Shinde[5]

[1]Professor, [2]Associate Professor, [3,4]Assistant Professor, [5]Senior Resident, Dept. of Orthopaedics, Smt. Kashibai Navale Medical College and General Hospital, Pune, Maharashtra

***Corresponding Author:**
Email: nemadevijay5@gmail.com

Abstract

Introduction: Management of chronic osteomyelitis demands prolonged Antibiotic therapy. Antibiotics may be administered systemically or locally. Local antibiotic therapies have definite advantages. In this study we used Indigenous Antibiotic Impregnated malleable PMMA Cement Rod. Aim of this study is to evaluate the efficacy of Indigenous Antibiotic Impregnated Malleable PMMA Cement Rod in the treatment of chronic osteomyelitis of long bones.

Methods: This study involved retrospective evaluation of 63 patients of chronic osteomyelitis of long bones treated at our institute between February 2011 to January 2016. All patients with chronic osteomyelitis of long bones with less than 2 cm of sequestrum formation were included in the study. Patients with infected non-union were treated with other modalities of treatment and were excluded from the study. Initially for first three years we treated 33 patients of chronic osteomyelitis of long bones with surgical removal of infected and dead bone and soft tissue followed by local Antibiotics Impregnated PMMA Beads. These patients were considered as Group A. Later since February 2014 we started treating patients with Indigenous Antibiotic Impregnated Malleable PMMA Cement Rod and these patients were considered as Group B.

Results: There were 33 patients in group A. 26 patients cured with complete irradication of the infection. Cultures performed on tissue sample taken at the time of Beads removal were negative in these cases. In 9 patients removal of Beads was difficult. 7 patients had persistent pain, swelling and inflammation. On investigations they had raised CRP, Total count and Neutrophillia. They all underwent second surgical procedure - removal of Beads and further treatment with Masquelet technique. One of these 7 patients had pathological fracture which was stabilized with Antibiotic impregnated PMMA intramedullary nail. These 7 cases required 16 to 23 weeks for complete cure of infection. The average time required for complete recovery in Group A patients was 17 weeks. There were 30 patients in group B. All patients were completely cured in a mean time period of 8 weeks (range, 6–11 weeks). No patient required a second surgical procedure to achievecontrol of infection. Tissue samples obtained at the time of Rod removal showed no growth on culture in all these patients.

Conclusion: Our study results demonstratesvery effective and complete cure of chronic osteomyelitis in less time period with the use of Indigenous Antibiotic Impregnated Cement Rod technique as against the use of Antibiotic Impregnated Cement Beads.

Keywords: Indigenous Antibiotic Impregnated Cement Rod, chronic osteomyelitis, Antibiotic PMMA Beads.

Introduction

Management of chronic osteomyelitis of long bonesis multifaceted. The goals are to eradicate the infection with minimal soft tissue and periosteal damage, to achieve full function, to minimize complications and to prevent recurrence. Adequate surgical debridement is very important step in the treatment of chronic osteomyelitis. Along with surgical debridement, Antibiotics are essential part of the treatment. Antibiotics may be administered systemically or locally.[1-4] Local antibiotic therapies have definite advantages such as high local concentration, less systemic adverse effects, effective concentration level at poorly vascularised or devascularised tissues, less hospital stay, cost effective and good patient compliance.[1-4]

Locally introduced antibiotics impregnated Polymethylmethacrylate (PMMA) Beads are used traditionally to treat chronic osteomyelitis of long bones.[5,6] This form of treatment has got its own disadvantages due to irregular membrane formation, inability to insert them deep into the medullary cavity and sometimes difficult to remove.[7] Many times medullary canal of affected long bone may be potentially invaded by the micro-organisms to a long distance from the affected site.[8] PMMA Beads cannot be pushed to a long distance in medullary canal. Therefore we used Indigenous antibiotic impregnated malleable PMMA CementRod in this situation. Aim of this study is evaluate the efficacy of Indigenous Antibiotic Impregnated Malleable PMMA Cement Rod and Antibiotics Impregnated PMMA Beads in the management of chronic osteomyelitis of long bones.

Materials & Methods

This study included retrospective analysis of 63 patients of chronic osteomyelitis of long bones treated at our institute between February 2011 to January 2016. The study was approved by the Institutional Review Board. We included patients of chronic osteomyelitis of long bones with less than 2 cm of sequestra formation. We excluded patients with infected non-union. Initially for first three years we treated 33 patients of chronic osteomyelitis of long bones with surgical removal of infected dead bone and soft tissue followed by local Antibiotics Impregnated PMMA Beads. These patients

were considered as Group A. Later since February 2014 we started treating patients with Indigenous Antibiotic Impregnated Malleable PMMA Cement Rod and these patients were considered as Group B.

Culture and sensitivity of the discharge/pus, radiographic examination and routine blood investigations were performed in all patients. Under suitable anaesthesia, the first step was complete excision of the sinus tracts. Then the infected site was exposed and debridement was performed.[9] The entire medullary canal was washed out with 4-5 L of normal saline.[10] We used 2 to 3 Tension band wires of appropriate length and diameter according to the size of bone, twisted around each other and then impregnated with PMMA cement mixed with heat stable Antibiotic. Selection of Antibiotic was done according to culture and sensitivity report. Diameter of the tension band wire to be used for the preparation of Indigenous Rod was calculated from the formula:

D = X/2 - 1.5mm.

D = Diameter of the tension band wire to be used for the preparation of Indigenous Rod.

X= Diameter of medullary canal at Isthmus.

40 g of Bone cement was prepared in a stainless steel bowl by adding reagent liquid in cement powder. While mixing, heat stable Antibioticsuch as 2 g of Vancomycin or 2 g of Gentamicin was added.[11,12] Vacuum mixing is not done as during ordinary mixing porosity remains in cement which provides good elution of Antibiotic at the affected site. Manual mixing of cement was done and the cement was applied to the Rod in a uniform manner. Size of this Indiginous Rod was checked using a nail width measuring scale. Uniform thickness and even surface of this Rodwas gained by passing it through the width measuring scale. Diameter of the Rod was prepared 1 mm less than the diameter of the affected bone at isthmus. At both ends tension band wires were bend to create a loop for easy removal later. Two such Rods were prepared.These Rods wereallowed to dry in operation theatre for 20 min to allow for evaporation of the monomer. Indiginous Rods was implanted into the medullary canal through the defect created in bone during sequestrectomy. The wound was again cleaned with Normal saline and closure was performed.

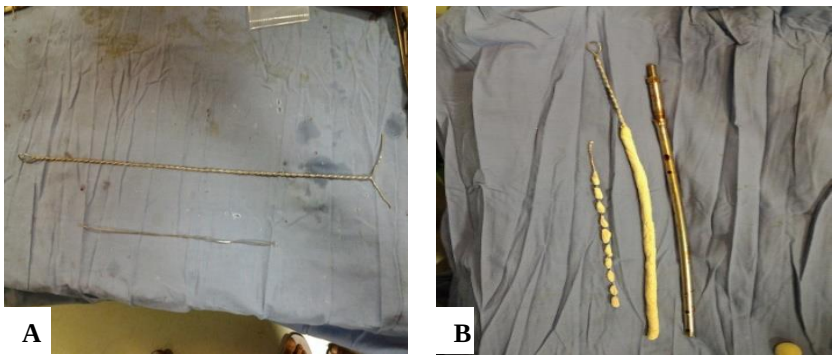


Fig. 1: A: Showing preparation of Indigenous Rod by twisting Tension Band Wires around each other. B: Showing Indigenous Antibiotic Impregnated PMMA Cement Rod curved similar to the curvatures of the interlocking nail of the bone for which it is to be used. Beads are also shown on left side.

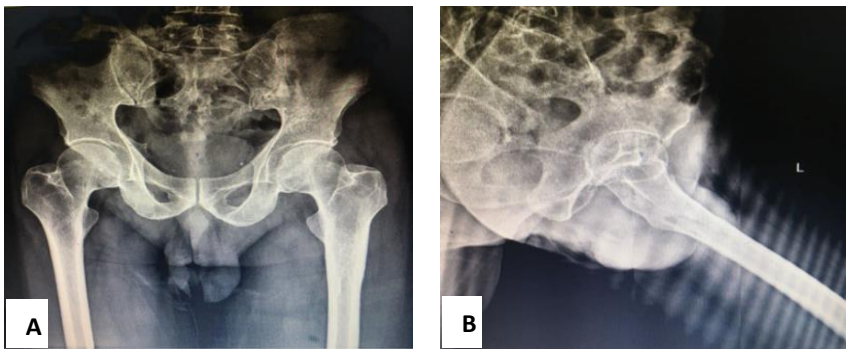


Fig. 2: A: Plain Radiograph of pelvis with both hips AP view showing cystic lesion in proximal femur Left side (Arrow).
B: Plain Radiograph of Left hip Cross table Lateral view.

Fig. 3: Clinical photograph of the Patient showing sinus formation and scar of previous surgery

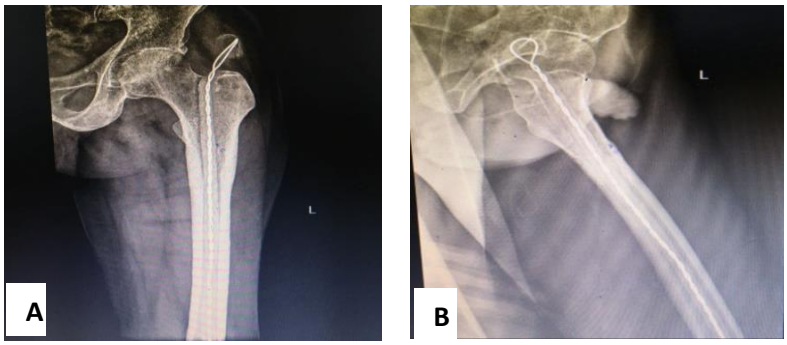


Fig. 4: A. Post-operative Antero-posterior; Lateral B. plain X-Rays showing Indigenous Antibiotic Impregnated PMMA Cement Rod in situ

Fig. 5: A. Clinical photograph showing Post-Operative Range of Movement; B. Plain Radiograph of pelvis with both hips AP view showing complete cure of infective lesion; C. Plain Radiograph of Left hip Cross table Lateral view.

Looped end of the Rod was kept outside the entry site for easy removal later. In patients with diaphyseal osteomyelitis debridement was done, necrotic bone was removed and two small Indiginous Rods were inserted, one in proximal direction and other in distal direction. Looped ends of the Rods were kept near entry site outside the bone for easy removal later.

Surgical wound was closed in layers. Active and passive Range of movement exercises were started from 1st post-operative day. Non weight bearing mobilization with walker/crutches in cases of lower limbs was allowed from 2nd post-operative day. All patients were discharged on 5th to 7th post-operative day and removal of sutures was performed at two weeks follow up. All patients were followed every week for 1st month and every 2nd week till 3 months and every month thereafter till six months. Radiological examinations were performed at 4th, 6th, 8th, 10th, 12th week follow up visits.

At each follow up visit knee functional outcome was assessed with following four parameters:

1. Pain.
2. Range of motion.
3. Daily activities of patients.
4. Radiological examination.

The two groups were compared with following parameters:

1. Complete cure of infection by the primary surgical procedure.
2. Need of second surgical procedure for cure of infection.
3. Complications.
4. Time period required for complete cure of infection.

All above parameters were compared using paired t-test. 'P' value less than 0.05 was considered as significant.

Results

63 patients diagnosed aschronic osteomyelitis of long bones and treated at our institute between February 2011 to January 2016 were studied retrospectively. There were 39 male patients and 24 female patients, with the mean age of 31 years (range, 16–58 years). 45 femora and 18 tibias were treated. All patients had established osteomyelitis with or without sinus formation. We excluded patients with infected non-union.Initially from February 2011 to January 2014. Patients were treated with Antibiotic Impregnated PMMA Beads. These patientswere considered as Group A. From February 2014 to January 2016 we treated patients with Indigenous Antibiotic Impregnated PMMA Rodand they were considered as Group B.

Table 1: Patient characteristics

Patient Characteristic	Group A	Group B
Osteomyelitis in diaphyseal region.	29	27
Osteomyelitis in metaphyseal region.	4	3
Osteomyelitis with single or multiple sinus formation.	23	19
Osteomyelitis without sinus formation.	10	11

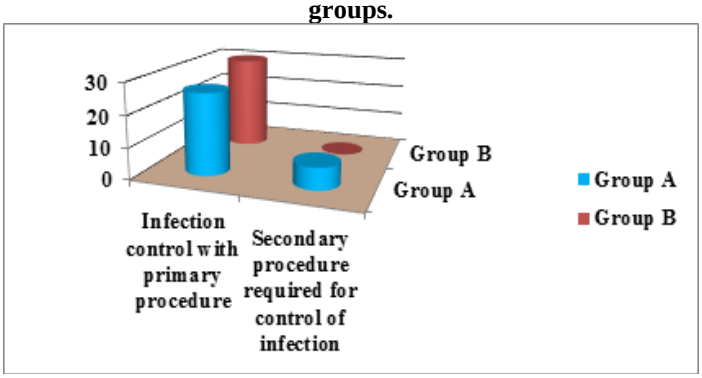
Discharge from sinuses was send for culture and sensitivity in 42 cases where sinus formation was present. Culturereport showed Osteomyelitis due to Staphylococcus aureus in 27 cases, *Enterococcus* species in 9 cases, Pseudomonas aeruginosain 4 cases and *Streptococcus* species in 2 cases. Intra-operative sample of pus, infected soft tissue and sequestrum was send for culture and sensitivity in all cases.

Average follow-up of all patients was 39 months (range, 18–72 months). There were 33 patients in group A. 26 patients got cured completely with negative cultures at the time of Beads removal at 6 to 13 weeks. In 9 patients removal of Beads was difficult. 7 patients had persistent pain, swelling and inflammation. On investigations they had raised CRP, Total count and Neutrophillia. They all underwent second surgical procedure-removal of Beads and further treatment with Masquelet technique. One of these 7 patients had pathological fracture which was stabilized with Antibiotic impregnated PMMA intramedullary nail. These 7 cases required 16 to 23 weeks for control of infection. The average time required for control of infection in Group A patients was 17 weeks.

There were 30 patients in group B. All patients were cured completely in mean time period of 8 weeks (range, 6–11 weeks). No case required a second surgical procedure for cure of infection. Tissue samples taken at the time of Rod removal showed no growth on culture in all these patients.

Complete cure of infection took a longer time in group A patients as compared to group B patients ('P' value 0.0002).

Chart 1: Showing number of patients recovered with primary procedure and secondary procedure in both groups.



Discussion

Chronic osteomyelitis is defined as long-standing infection of the bone by microorganisms, presence of dead bone (sequestrum), inflammation, and sometimes pus formation with discharging sinus or sinuses.[13] Complete cure in chronic osteomyelitis is possible only after eradication of causative micro-organisms.[14,15,16] Its complete cure frequently requires multiple surgical procedures, prolonged hospital stay, and antibiotic therapy. This often leads to loss of functional mobility, high costs and loss of productivity.[17]

Variety of surgical techniques have been described for the treatment of chronic osteomyelitis. But comparative studies are not available.[15] In this study, we have compared the results of treatment with Antibiotic-impregnated cement Beads versus

Indigenous Antibiotic-impregnated Cement Rod in the management of uniformly selectedpatients of chronic osteomyelitis.

Local antibiotic therapy using Antibiotic-Impregnated Cement Beads delivers a high concentration of antibiotics locally. This reduces the need of prolonged parenteral antibiotic therapy.[18] Therefore adverse events associated with prolonged parenteral Antibiotic therapy are reduced. Removal of the Beads sometimes is difficult due to irregular membrane and granulation tissue formation.[18] Furthermore these Beads cannot be implanted deep into the medullary canal of the affected bone. To overcome these disadvantages, we started using Indigenous Antibiotic Impregnated Cement Rod in the treatment of chronic osteomyelitis without large defects and fracture. Recently, the biodegradable calcium sulfate impregnated with antibiotic has been used in the management of chronic osteomyelitis. It has advantage of not requiring removal. But the cost of therapy is more and has few disadvantages such as persistent ooze from the wound in 15.4% of cases.[19]

Our study results demonstrate satisfactory outcomes in all Group B patients. Complications in the form of DVT occurred in one patient but it was treated successfully and full function was achieved in this patient.

Indigenous Antibiotic Impregnated Cement Rod has several advantages:

1. They provides satisfactory concentration of antibiotic at the local site as well as deep into the medullary cavity of the long bone as against the Beads which do not provide adequate Antibiotic concentration deep into the medullary cavity of the long bone.
2. They provide enough stability to mobilise the patient even though there is small bony defect.
3. Small diameter Indiginous Antibiotic Impregnated Rods can be easily prepared for small bones in adults and paediatric patients as against the Antibiotic cement impregnated nails which cannot be prepared in small size diameters.
4. Removal of Indiginous Antibiotic Impregnated Rod is easy as compared to the Beads because it does not lead to formation of irregular membrane and granulation tissue as often seen in Antibiotic impregnated PMMA Beads. Removal of Antibiotic Impregnated intramedullary K-Nail or Interlocking Nail is also difficult many times due to bone overgrowth and they require extractor for their removal.Indigenous Antibiotic Impregnated Rod is easy to remove as Looped end is kept outside the entry point and its removal does not require extractor.
5. Effective cure of Osteomyelitis in an average period of 8 weeks as compared to 17 weeks required for Beads.

Disadvantages of Indigenous Antibiotic Impregnated Rod technique are

1. They cannot be used in cases of Osteomyelitis with large defects (more than 3cm and more than half the circumference of the affected bone)
2. They cannot be used in cases of infected non-union.

Overall, in carefully selected cases of chronic Osteomyelitis Indigenous Antibiotic Impregnated Rod technique is very effective for early and complete cure.

Conclusion

Our study results demonstrates very effective and complete cure of chronic osteomyelitis in less time period with the use of Antibiotic Impregnated Cement Rod technique as against the use of Antibiotic Impregnated Cement Beads.

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