SCOPING REVIEW

Use of antibiotic-loaded bone cement for paediatric chronic osteomyelitis: a scoping review

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Abstract

Objective: To systematically map the research done on the use of antibiotic-loaded bone cement for paediatric chronic osteomyelitis.

Method: The scoping review was conducted in July 2023, and comprised research on PubMed, Scopus, Cochrane, Google Scholar and ScienceDirect databases for original research articles on paediatric chronic osteomyelitis using antibiotic-loaded bone cement. Data items extracted included basic bibliographic details, patient demographics, patient presentation, pathogen, systemic and local antibiotic treatment, operative techniques, follow-up, outcomes, and complications.

Results: Of the 1,569 studies identified, 158(10.07%) were assessed for eligibility, and, of them, 9(5.7%) were reviewed in detail. All the 9(100%) studies were retrospective, 6(66.6%) were case series, and 1(11.1%) was from a developing country. Of the total 73 patients in the studies, 58(79.5%) were males, and tibia was the most commonly involved bone 21(46%). Vancomycin was most commonly used in bone cement (60 (83.6%)). All 73 (100%) patients were infection-free at the end of the follow-up period, with no major complications in 55 (75.3%) patients.

Conclusion: Current literature on the use of antibiotic-loaded bone cement in paediatric chronic osteomyelitis is limited, but favours its use.

Key Words: Paediatric, Chronic osteomyelitis, Antibiotic, Bone cement, Bone infection

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Introduction

Bone infections are challenging to eradicate due to pathogen virulence, immune evasion by hiding intracellularly, and colonising the osteocyte-lacuno-canalicular network[1–5]. Chronic osteomyelitis treatment requires an interdisciplinary approach, with two basic principles: debridement of necrotic or insufficiently vascularised bone that cannot eradicate infection, and appropriate antibiotic therapy [6].

Chronic infection destroys normal bone anatomy, compromising effective blood supply to the bone. Therefore, the dose of intravenous (IV) antibiotics required to achieve effective local concentration at the site of infection causes significant systematic side effects, such as myelosuppression, renal failure and hepatitis[7]. A reasonable alternative to achieve prolonged effective antibiotic concentration at the site of infection is required. Polymethylmethacrylate (PMMA), also known as bone cement, provides a non-biodegradable scaffold in which antibiotics can be loaded and placed at the site of infection after debridement. Due to heat-generation by PMMA, only heat-stable antibiotics can be used in this process[8]. However, PMMA must be removed in a second operation, particularly in paediatric patients, since this foreign body is non-biodegradable.

Although all these treatments are relatively well-studied in adult patients, there is a dearth of literature on paediatric patients. The Paediatric Orthopaedic Society of North America currently recommends surgical debridement and IV antibiotics for the treatment of paediatric chronic osteomyelitis [9]. It does not mention the use of antibiotic-loaded bone cement because the current evidence on the best treatment strategy is not robust. The studies evaluating the use of antibiotic-loaded cement beads for chronic osteomyelitis in paediatric patients are sparse and heterogeneous, therefore, there is a need to synthesise the information. The current scoping review was planned to systematically map the research by evaluating antibiotic-loaded cement implants (beads, nails, screws, or rods) for chronic osteomyelitis in paediatric patients.

Materials and Methods

The scoping review was conducted in July 2023 in line with Joanna Briggs Institute's guidelines[10] and the

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Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR)[11].

The review comprised research on PubMed, Scopus, Cochrane, Google Scholar and ScienceDirect databases for original research articles on chronic osteomyelitis cases aged <18 years using antibiotic-loaded bone cement. Articles that included adult patients, but reported paediatric patient details and outcomes separately, were also included. For these articles, the data only for paediatric patients was extracted. Articles not exclusively on paediatric patients, not reporting the use of antibiotic-loaded bone cement, not explicitly mentioning chronic osteomyelitis, animal studies, theoretical frameworks, reported in a language other than English, bone chapters, theses, and conference abstracts were excluded. Exclusions based on the year of publication or geographical location were not used, except for Google Scholar which was searched for 2022 onwards due to the inability to bulk-download queried articles from the platform.

The search was based on key words and their variations, including "antibiotic", "osteomyelitis", "chronic", "paediatric", "polymethylmethacrylate", "bone cement", "nail", "plate" and "screw". References of all the articles included in this review were also searched to find any relevant studies that were not included in the results of the database searches.

Search results from the bibliographic databases were imported into Rayyan[12] software and potential duplicates identified by it were cross-checked manually and removed. Two reviewers independently screened the titles and abstracts of the remaining articles to assess eligibility. Full texts of the articles deemed to be relevant were retrieved and reviewed independently by the two reviewers. Conflicts, if any, were resolved through mutual discussion and in consultation with another reviewer.

After finalising the articles for inclusion, data was extracted using Microsoft Excel. Data extraction was done by one reviewer, and cross-checked by another for errors. Any conflicts were resolved through mutual discussion. Data items extracted included basic bibliographic details, patient demographics, patient presentation, pathogen, systemic and local antibiotic treatment, operative techniques, follow-up, outcomes, and complications. After extraction, the data was segregated descriptively.

Results

Of the 1,569 studies identified, 158(10.07%) were assessed for eligibility, and, of them, 9(5.7%) were reviewed in detail[13-21] (Figure).

The sample sizes ranged 1-21 and the ages of the patients ranged from 18 months to 18 years. Of the total 73 patients in the studies, 58(79.5%) were males, 46(63%) received antibiotic-loaded bone cement, and 27(37%) served as controls. All the 9(100%) studies were retrospective, 6(66.6%) were case series, and 1(11.1%) was from a developing country. However, Bar-on et al.[13] reported that their patients came from neighbouring developing countries. None of the authors reported any conflict of interest, and only Shi et al.[14] reported a source of funding. Overall, 2(2.7%) patients in one case series were lost to follow-up (Table 1).

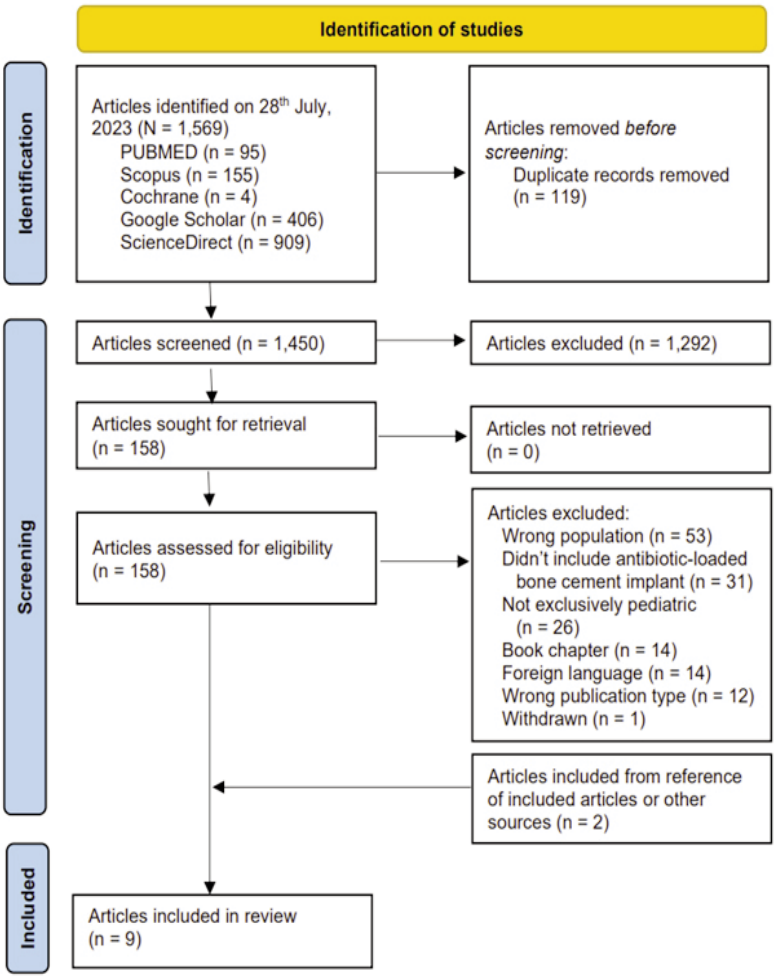

Figure: PRISMA-ScR Flow Diagram of Selection of Sources of Evidence

Table-1: Baseline Characteristics.

Article†	Study Design	Sample Size	Age, mean (range), years	Sex	Country
Yeargan 2004[19]	Retrospective Review	Abx-bead group (3 patients)* Other group (27)	8.5 (18 months - 16 years)	22 Males 8 Females	USA
Kinik 2008[18]	Case Series	6**	5 – 16	6 Males	Turkey
Bar-on 2010[17]	Case Series	4	9.3 (5.5 - 14.6)	4 Males	Israel
Baumbach 2011[21]	Case Series	3	7 – 10	1 Male2 Females	Austria
Canavese 2017[16]	Case Series	5	11 (4 - 14)	4 Males 1 Female	France
Li 2019[15]	Case Series	1**	14	1 Male	China
Mahi 2022[14]	Case Report	1	14	1 Male	India
Scharf 2023[13]	Case Series	2	11 - 13	1 Male 1 Female	Germany
Shi 2023[20]	Retrospective Review	21	10.4 (2.0 – 18.0)	18 Males3 Females	China

† There were conflicts of interest in any article. Only Shi 2023 reported a source of funding.
* 2 lost to follow-up
**Results from pediatric patients with chronic osteomyelitis are reported only, excluding any adult patients or patients without chronic osteomyelitis

Supplementary Table 2: Clinical Presentation.

Article	Patient Presentation	Affected Bone	Pathogen	Source	Systemic Antibiotics
Yeargan 2004[20]	Clinical/radiographic evidence of tibial osteomyelitis without previous surgical intervention (15 patients) Bone loss (4 patients) Tibial nonunion (4 patients) Angular deformity (3 patients) Equinus contracture (2 patients) Previous incision and drainage (5 patients) Previous ORIF (1 patient) Opening wedge osteotomy (1 patient)	3 Tibia	Staph Aureus (14, 48%) Staph Epidermidis (2, 7%) MRSA (4, 14%) Pseudomonas (3, 10%) Beta-hemolytic Streptococcus (2, 7%) E. Coli (2, 7%) Enterobacter (2, 7%) (Note – In Abx-Loaded Beads group: 2 had MRSA and 1 had S. Aureus)	Hematogenous (14, 47%) Percutaneous (3, 10%) Traumatic (2, 7%) Unknown (8, 27%) Open Fracture (2, 7%) S/P ORIF (1, 3%) (Note - Abx-Load beads group: 2 had hematogenous and 1 had unknown)	0 - 24 months Note: Antibiotic names were not given
Kinik 2008[18]	Pain and functional limitation (for 1 - 96 months)	5 Femur 1 Tibia 1 Humerus	1 - MRSA5 - S. Aureus1 - Enteroccoci	Not Reported	Teikoplanin, Ciprofloxacin, Trimethoprim-sulfamethoxazole, Fuscidic A, Vancomycin
Bar-on 2010[13]	- Recurrent swelling and a draining sinus	2 Tibia 2 Femur	S. Aureus in all 4 patientsAdditionally, pseudomonas aeruginosa and streptococcus viridians in one patient each	1 Hematogenous osteomyelitis2 Closed fractures followed by fixation1 Direct contusion - infected hematoma	Intravenous antibiotics were continued for 6 weeks (3-13), and total antibiotic treatment length was 16 weeks (10-37)IV cephalothin was initiated in all 4 patients and supplemented with ciprofloxacin, trimethoprim-sulfamethoxazole, or methicillin and rifampicin in some patients. Oral cephalexin was continued after intravenous antibiotics

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Article	Patient Presentation	Affected Bone	Pathogen	Source	Systemic Antibiotics
Baumbach 2011[19]	Internal rotation of leg, leg length discrepancies, and decreased range of motion of the leg	2 Tibia 1 Femur	Not reported	1 Hematogenous 2 Unknown	Not reported
Canavese 2017[21]	Pain, swelling, fever, limited range of motion, draining sinus, pseudoarthrosis.	2 Femur 2 Humerus 1 1st metatarsal	4 MSSA1 Cronobacter Sakazakii	4 had an accident or a fall1 had unknown source	Oxacillin, gentamicin, levofloxacin, rifamycin, Fucidin, dalacin, ceftriaxone, TMP-SMX, amoxicillin
Li 2019[16]	Not reported	Tibia	Not reported	Not Reported	Empiric intravenous antibiotics were started and then changed based on culture and sensitivity results.
Mahi 2022[15]	14 year old immunocompetent, otherwise healthy, male had an open fracture treated by local healers (non-medical) that led to deformity. 1 month later patient developed fever and was treated with antibiotic impregnated bone cement at a hospital; however, the patient failed to present for the cement-removal procedure. One year later patient presented with acute tense swelling, unbearable pain, and toxemia, with a cement spacer and multiple cement beads in situ.	Humerus	Pseudomonas aeruginosa	Chronic Osteomyelitis due to failure to remove bone cement after earlier treatment of osteomyelitis	IV antibiotics included piperacillin-tazobactam, amikacin, oral ciprofloxacin
Scharf 2023[13]	Pain, swelling, redness, and discharge 4 weeks after k-wire fixation of distal radius fracture in one patient, and 5 weeks after removal of k-wire in the second patient. No signs of infection were present at k-wire removal in the second patient.	Radius	Staphylococcus Aureus	Fracture related infection	Perioperative cefazolin 2g
Shi 2023[14]	Not reported	5 Femur 12 Tibia 1 Humerus1 Radius 1 Ulna 1 Fibula	6 – Staph Aureus 2 – Enterobacter Cloacea 1 – Staph Epidermidis 12 – no growth	Not reported	Not reported

Most patients presented with classic signs of chronic osteomyelitis, including pain, fever, localised redness, swelling, discharge and restricted mobility of the involved site. Some patients had a history of a previous procedure or implant placement. In the case report by Mahi et al.[15], the patient had chronic osteomyelitis for which antibiotic-loaded cement beads were placed, but the patient failed to present for removal of the beads, and subsequently presented with another episode of chronic osteomyelitis in the same bone. Two of the studies did not report the signs at presentation[14,16].

The tibia (21(46%)) was the most commonly affected bone, followed by the femur (15 (33%)), humerus (5(11%)), radius (2(4%)), first metatarsal (1(2%)), ulna (1(2%)), and fibula (1(2%)). Staphylococcus (S.) aureus was the most implicated pathogen (36 (49.3%)), and the most common sources of osteomyelitis were haematogenous spread (16 (21.9%)), open injury (7 (12.3%)), or a previous procedure (5 (6.8%)) (Supplementary Table).

Vancomycin was the most commonly used antibiotic in bone cement (60 (83.6%)), followed by gentamycin (11 (15.1%)). Overall, 2(22.2%) studies[15,17] reported a

Table-2: Treatment.

Article	Antibiotic in Bone Cement	Antibiotic-loaded implant removal time	Follow-up Duration after Surgery, (range)
Yeargan 2004[20]	Vancomycin	-	0.6 - 1.7 years Length of stay in Hospital: 6 – 8 months
Kinik 2008[18]	Vancomycin	2 months (3 weeks - 3 months)	2 – 5 years
Bar-on 2010[13]	Gentamycin	2 - 9 weeks	41 (36 - 46) months
Baumbach 2011[19]	Refobacin-Palacos	8 weeks*	Approximately 7-16 months**
Canavese 2017[21]	Gentamycin	-	2 (2 - 5) years
Li 2019[16]	Vancomycin(in combination with vacuum sealing drainage and skin flap transplantation)	-	24 months
Mahi 2022[15]	Vancomycin & Tobramycin	-	32 weeks
Scharf 2023[17]	Gentamycin, Clindamycin, & Vancomycin	4 - 9 weeks	16 - 18 months
Shi 2023[14]	Vancomycin	-	31.7 (21 - 61) months

* Only mentioned for 1 out of the 3 patients in this case series.** Exact follow-up period was not reported

combination of antibiotics in bone cement, and 4(44.4%) studies[13,17–19] reported the time to remove antibiotic-loaded bone cement, which ranged from 2 weeks to 3 months. The follow-up of patients for recurrence varied across the studies, and ranged from 6 months to 5 years (Table 2).

All the 9(100%) studies reported full recovery of all the 73(100%) patients who had antibiotic-loaded bone cement for chronic osteomyelitis. The criteria for resolution of infection were not reported in most of the studies (5 (55.6%) studies), except for no signs of infection at the end of the follow-up period. Li et al.[16] reported that the patient had occasional pains at the operative site, however, details were missing. The need for pharmacological, medical or surgical intervention required for this pain, and the effect on the patient's functionality or growth was not detailed. Yeargan et al.[20] was the only study that included a comparison group with no antibiotic-loaded bone cement use. The average follow-up in this study was 2.5 years (0-9 years) The comparison group had less optimal outcomes compared to the treatment group. A good outcome was defined as pain-free, leg length discrepancy <2.5cm, and no residual infection. In the treatment group, 3 (100%) patients had good outcomes compared to [19] (70%) in the comparison group.

None of the studies reported any major complication, or the need for unplanned re-operation. Of the total, 2(22.2%) studies[13,20] reported fractures following the

Table-3: Outcomes and Complications.

Article	Outcomes	Complications
Yeargan 2004[20]	Abx-Loaded Bead (100% - Good Outcome) Others (Fair 22%, Good 70%, Unknown 8%) **Definitions Good:** pain-free, leg length discrepancy < 2.5 cm, and no residual infection **Fair:** Can perform activities of daily living without pain and leg length discrepancy < 3.5 cm, and no persistent infection	Abx-Bead (1 out of 3 patients had a tibial fracture) Other (11 out of 25 patients had a complication, including leg length discrepancy, nonunion, recurrent osteomyelitis, fracture, and infection)
Kinik 2008[18]	All of the patients are ambulatory and have returned to their pretreatment activity level or better. They have no drainage, no pain, and no signs of inflammation, and all of the radiographic and laboratory parameters are normal	None mentioned
Bar-on 2010[13]	All patients are asymptomatic and fully functional with no clinical signs of infection, with resolution of infection taking an average of 8 (2 - 18) months.	- 1 patient developed a superficial cervical abscess after rod removal that was treated with Incision and drainage - 1 patient developed catheter-associated candida infection (that did not involve bone) - One patient had minor persistent sterile drainage after rod removal, which was treated with repeat debridement and lavage. - One patient had a soft tissue defect over the site of reaming, that was treated with vacuum-assisted closure. He subsequently sustained a fracture requiring osteotomy and correction, leading to full-union.

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Article	Outcomes	Complications
Baumbach 2011[19]	Patients were able to walk without any assistance and had an active knee range of motion of 0-0-40^{0}.	- One patient (with osteomyelitis in the femur) fell and had an undisplaced tibial fracture 2 weeks after antibiotic bone cement placement. This was successfully treated with a long leg cast. In the same patient, due to the presence of pus at the time of removal of refobacin-palacos coated cement, gentamicin chains were placed.- One patient showed possible signs of distal, lateral sealed tibial physis.
Canavese 2017[21]	Laboratory values took 3 weeks to 1 month to normalize. At the last follow-up, clinical and laboratory evaluation had normalized, the bone had healed, and all patients had resumed daily living and sports activities.	No major complications were seen, with no signs of growth arrest or disturbances based on radiological and clinical assessment. Only one patient had a slight reduction in knee range of motion (125° flexion on the affected side versus 135° on the contralateral normal side)
Li 2019[16]	Outcome: Good (occasional pain in local regions; no swelling, heat, and pain; no pathological features detected through x-ray radiography; and affected bone segment recovery) Enneking score - Preoperative (10) to postoperative (27)	None reported
Mahi 2022[15]	A follow-up radiograph at 12 weeks postoperatively showed complete absorption of the calcium sulfate beads and new bone formation along the site of the defect. The nail was removed after 20 weeks and at 32 weeks; the bone showed excellent healing.	None
Scharf 2023[17]	Complete resolution of the infection and union of the fractures	Epiphyseal plates were impaired by the infection and closed prematurely.
Shi 2023[14]	By the last follow-up visit, all of the patients achieved bone union and were pain-free; their inflammatory markers remained within the normal range; no infection recurrence was noted; and they resumed daily living and sports activities The mean radiographic bone union occurred in 4.3 months (range, 2–11 months), and full weight bearing was noted at 5.5 months (range, 3–12 months)	- Two (out of 21) patients required repeated operation due to recurrent infection after placement of antibiotic cement spacer.- One patient fell and broke the internal fixation, resulting in surgery to replace it. This patient had a delay of 9 months in a bony reunion.- One patient with distal tibial osteomyelitis had a varus deformity of 17^{0} at the ankle joint at 16 months, but no pain, no lameness, or any other symptoms- One patient fell and re-fractured the bone after healing. This was treated with reduction, fixation, and grafting, with a healed fracture 6 months after the surgery.

placement of antibiotic-loaded bone cement. However, only Yeargan et al.[20] had a comparison group, and it reported a lower rate of complications in the treatment group. These complications included leg length discrepancy, non-union, recurrent osteomyelitis, fracture and infection. Scharf et al.[17] reported impairment of epiphyseal plates, but they attributed it to chronic osteomyelitis, not the treatment. Baumbach et al. [19] also reported possible signs of epiphyseal injury without specifying if it was because of the primary infection or the treatment. Shi et al.[14] reported that 1(4.8%) patient developed varus deformity (17°) at the ankle joint, but the patient was asymptomatic. Other minor complications included a slight reduction in range of motion (ROM) (from 135° to 125°) at the knee, and a superficial wound complication. Overall, the complications reported were not serious, and most were treatable (Table 3).

Discussion

The current review found that the literature on the use of antibiotic-loaded bone cement for paediatric chronic osteomyelitis is limited to retrospective case reports and case series. Only one study had a comparison group. None of the studies reported a recurrence of chronic osteomyelitis after the use of antibiotic-loaded bone cement together with systemic antibiotics, favouring its use in this age group.

Regulatory approval of the use of bone cement in the paediatric population is an important factor to be considered. A paucity of literature on the topic may be stemming from the fact that chronic osteomyelitis is not very prevalent in high-resource settings with adequate research infrastructure and funding, while low-resource settings do not have the research infrastructure and funding to generate high-quality evidence for cost-

efficient treatment.

The current review has limitations as the search was restricted to English-language articles, while the burden of chronic osteomyelitis is particularly high in developing countries[22] from where little evidence has surfaced[23]. Moreover, it was difficult to reliably record the numbers of pathogens and their sources since these were not reported in all studies, and, in some cases, a single patient had more than one pathogen. The description of systemic antibiotics was poor, with sparse details. Most studies did mention the name of the antibiotic and the route of administration, but did not mention the dose or duration. Reports of culture and antibiotic sensitivities were also inconsistent and almost non-existent. These may have limited the generalisability of the findings.

Conclusion

Current literature on the use of antibiotic-loaded bone cement in paediatric chronic osteomyelitis favours its use, but this is based on limited evidence. Further prospective studies with control groups are needed for more definitive evidence.

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Conflict of Interest: None.

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