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## Use of Dalbavancin in the Treatment of Infected Bone Nonunion: A Report of Two Cases

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### Abstract

We present the cases of two female patients, ages 30 and 45, who were treated for culture-confirmed gram-positive infected nonunions of the leg with irrigation and debridement (I&D) by the Synthes Reamer-Irrigator-Aspirator (RIA) system followed by placement of an antibiotic-laden intramedullary nail (IMN). They were treated with two doses of intravenous (IV) dalbavancin (1.5g), one week apart. Both patients recovered from their infections and are doing well. These cases highlight that treatment with IV dalbavancin, I&D with RIA, and antibiotic IMN placement is a viable treatment option for septic nonunions where traditional antibiotic regimens are less desirable.

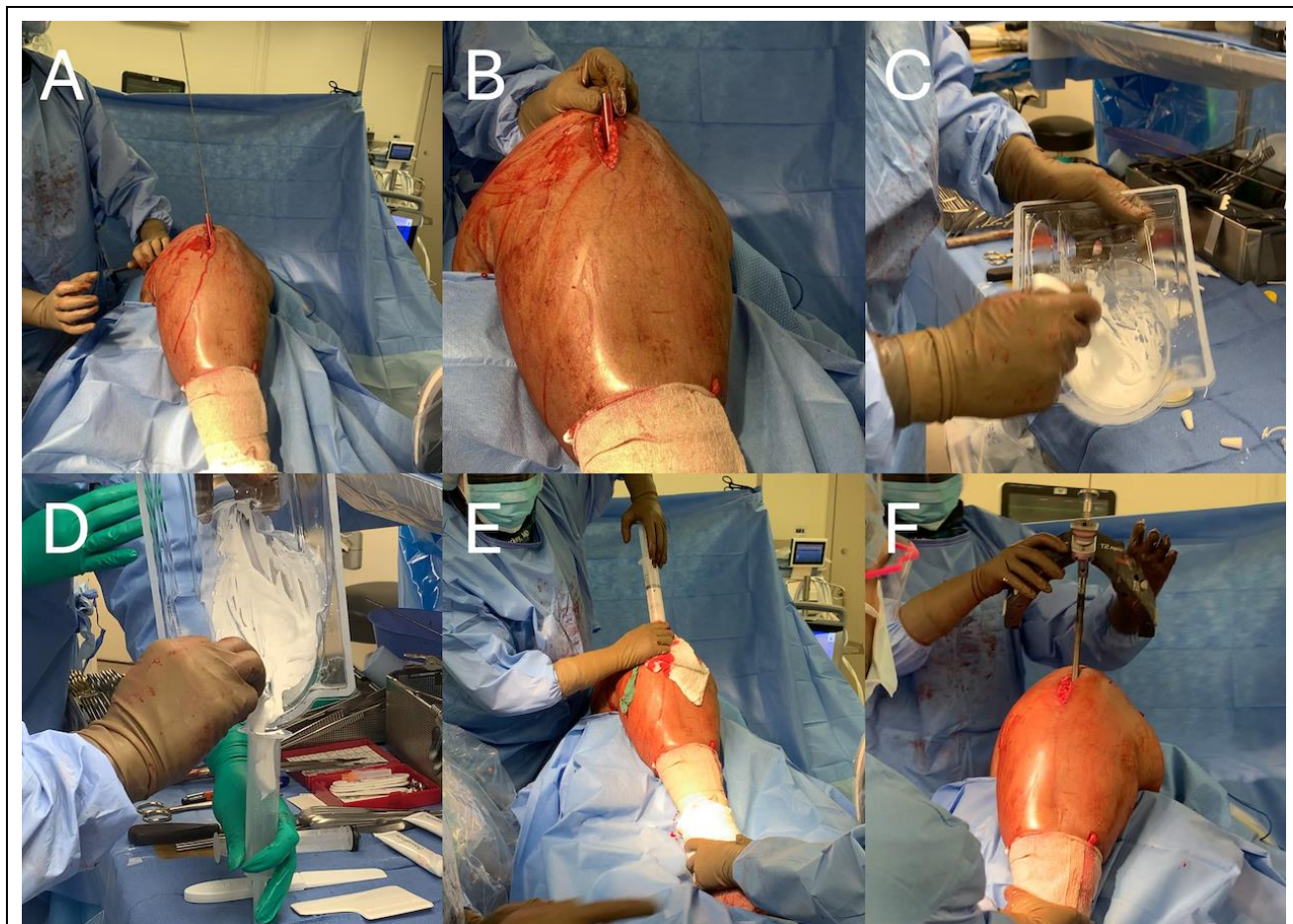
**Keywords:** Dalbavancin; Long bone nonunion; Infected nonunion; Septic nonunion; Antimicrobial stewardship; Barriers to outpatient parenteral antibiotic therapy (OPAT)

### Introduction

Long bone nonunions are physically and financially burdensome for patients and clinically challenging for orthopedic surgeons, especially when complicated by deep infection [1]. Patients with septic nonunions require more surgeries to achieve union compared to aseptic nonunions [2]. Treatment of septic nonunion involves thorough irrigation and debridement (I&D), bone defect management, possible soft tissue coverage, and local and prolonged systemic antibiotics [3,4]. Antibiotic-coated intramedullary nail (IMN) placement can successfully augment the treatment of septic nonunions (Figure 1) [3,4]. Furthermore, reaming the intramedullary canal before IMN placement adds biomechanical and biological advantages to facilitate union [5]. The Synthes Reamer-Irrigator-Aspirator (RIA) system removes infected and necrotic bone from the canal, offering additional utility in the treatment of long bone osteomyelitis [6,7].

Dalbavancin is a second-generation lipoglycopeptide with an excellent safety profile and efficacy against most gram-positive bacteria [8-10]. Notably, dalbavancin has a terminal half-life of 14.4 days, allowing for two doses one week apart [11]. This unique dosing regimen can substantially decrease hospital stay length and reduce both direct and indirect costs associated with septic nonunion treatment, allowing earlier discharge with simpler treatment regimens and requiring less system resources [12,13]. Dalbavancin is currently indicated for the treatment of acute bacterial skin and skin structure infections caused by gram-positive organisms, including *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Enterococcus faecalis* [14]. The use of dalbavancin to treat deep gram-positive bone and joint infections is also associated with high rates of eradication when combined with surgical management. Such off-label use of dalbavancin is a feasible alternative to standard outpatient parenteral antibiotic therapy (OPAT) in vulnerable populations for whom daily intravenous (IV) therapy is not ideal [8,13,15].

This series aims to demonstrate the success of treating septic long bone nonunions with dalbavancin following I&D using RIA and the placement of an antibiotic-coated IMN.



**Figure 1:** Intraoperative images demonstrating antibiotic nailing using calcium sulphate carrier. Steps include: placing a chest tube in the canal over the guidewire (A), removing the guidewire (B), mixing the antibiotics and calcium sulphate with sterile water (C), placing the slurry in the Toomey syringe (D), connecting the syringe to the chest tube and injecting the depot (E), and placing the IMN (F).

## Case Presentation

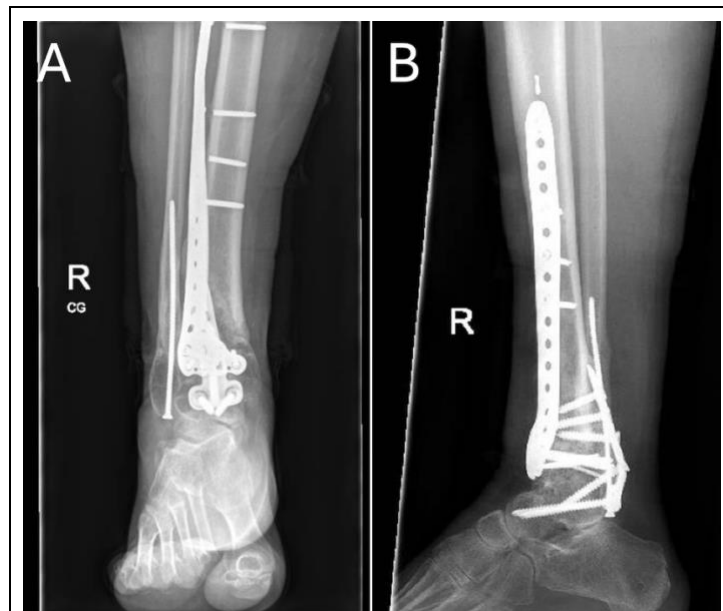
Two adult patients with infected nonunion of the leg were treated with a staged approach, with the first stage involving I&D using the RIA system and antibiotic-coated IMN placement followed by postoperative dalbavancin administration. Second-stage reconstruction was performed after infection resolution. Patient characteristics and treatment courses are summarized in Table 1. Informed consent was obtained from both patients for the publication of all clinical details and images included in this manuscript.

**Table 1:** Patient history and demographics.

Case	1	2
<b>Patient and Infection Characteristics</b>		
Age at dalbavancin	32	46
Sex	female	female
Relevant comorbidities	T2DM, morbid obesity, asthma	none
Anatomic location of nonunion	right tibia	left femur
History of prior infection	yes	yes
Surgery	ROH, I&D with RIA, antibiotic-coated IMN, antibiotic spacer	ROH, I&D with RIA, antibiotic-coated IMN, antibiotic spacer
<b>Inflammatory markers before dalbavancin</b>		
ESR	80	44
CRP	0.4	0.8
Culture positivity	yes	yes
Pathogen(s)	<i>Staphylococcus epidermidis</i>	<i>Cutibacterium acnes</i> , <i>Paeniclostridium sordellii</i>
Draining sinus tract	no	yes
Antibiotic(s) given before dalbavancin	IV vancomycin, IV ceftriaxone	IV cefazolin
Reason for dalbavancin	Preferred to daily antibiotic administration	Preferred to daily antibiotic administration
Dalbavancin dose prescribed	1.5g IV x 2, 1 week apart	1.5g IV x 2, 1 week apart
Adverse reaction	no	no
Outcome	cure	cure
Follow-up duration	37 months (ongoing)	23 months (ongoing)

### Case 1

A 30-year-old female with uncontrolled diabetes, morbid obesity, smoking, and asthma presented with a right distal tibia pilon nonunion with pain, deformity, and inability to ambulate. She sustained an open ankle fracture in a motor vehicle collision 18 months prior and underwent seven surgeries at multiple centers, including external fixation and serial I&Ds, resulting in nonunion. She underwent staged nonunion correction surgery 15 months later, beginning with revision tibia pilon open reduction and internal fixation (ORIF), I&D via an anteromedial approach, and polymethylmethacrylate (PMMA) cement spacer placement for a partial medial metaphyseal defect, with spacer removal and bone grafting one month later. She subsequently developed equinus deformity and suspected ankle arthritis. After 17 months, the patient underwent tibiotalar arthrodesis via a separate posterior approach with Achilles tendon lengthening. 13 months after successful ankle realignment and fusion, she suffered gradual anterolateral plate hardware failure with progressive pain and deformity. She presented to our trauma service at this stage in her course with persistent distal tibia nonunion (Figure 2).



**Figure 2:** AP (A) and lateral (B) preoperative X-rays of patient 1 status post ORIF showing persistent lucency at the distal tibia fracture site with multiple fractured screws in the tibial diaphysis and elevation of the surgical plate.

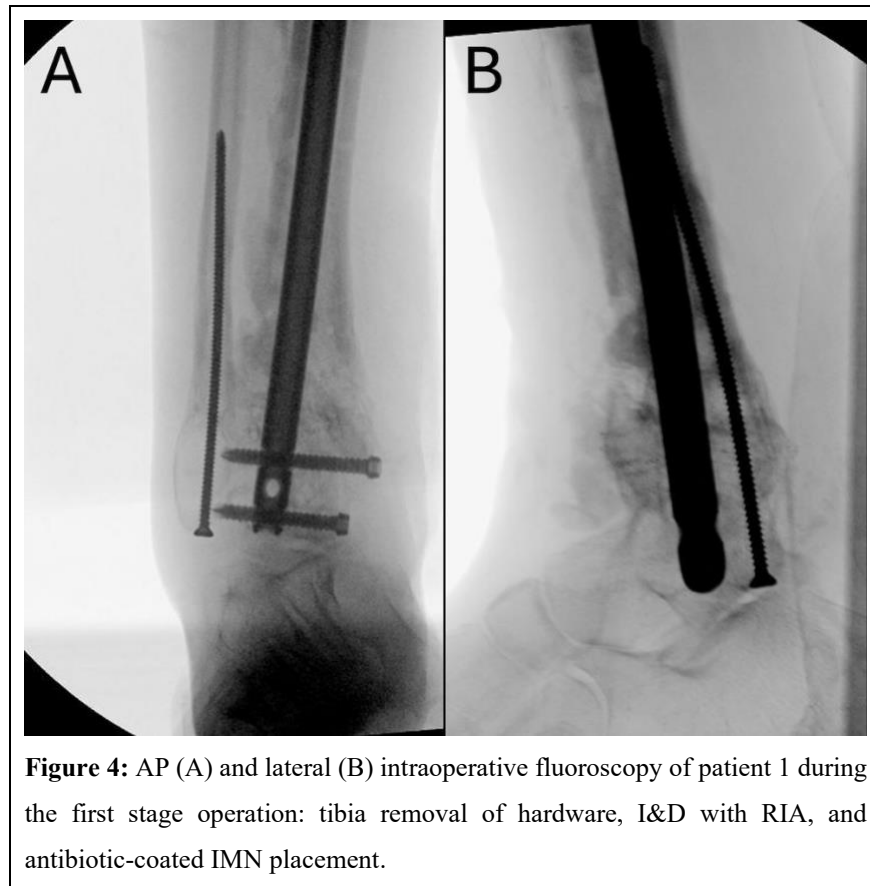
An open biopsy performed one month later, based on elevated serology, revealed *Staphylococcus hominis*.

Two months later, hardware removal and I&D with RIA were performed, and an antibiotic-coated IMN (40cc calcium sulphate mixed with 4g vancomycin and 2.4g tobramycin) was placed spanning the tibiotalar fusion site (Figure 3A-B) (Figure 4). There was a partial medial bone defect measuring 4 x 3 x 3 cm that was managed with an antibiotic spacer (3g vancomycin mixed with 2.4g tobramycin and one bag of gentamicin-loaded PMMA cement). Two of five intraoperative cultures grew *Staphylococcus epidermidis*. Infectious diseases (ID) was consulted and recommended IV vancomycin/ceftriaxone while admitted, then two doses of IV dalbavancin 1500mg (7 days apart) upon discharge, which she completed. She tolerated both doses without side effects.

With normalization of inflammatory markers and infection successfully treated, she underwent reconstruction of her nonunion with balanced cable bone transport via a ring fixator, as described by Quinnan and Lawrie, followed by a subsequent fibula osteotomy and frame revision for tandem leg lengthening to address a 1.75 cm discrepancy [16]. After nine operations and 38 months since injury, in her final procedure, frame removal was performed coupled with placement of a second antibiotic-coated IMN (60cc stimulan with 6g vancomycin and 3.6g tobramycin) augmented with iliac crest bone grafting of the docking site. The nonunion and regenerate site both healed successfully without further signs of infection (Figure 3C-D). She is currently 37 months post-operation and continues to follow up with our orthopedic practice.



**Figure 3:** AP (A) and lateral (B) postoperative X-rays of patient 1, 10 days post right distal tibia removal of hardware, I&D with RIA, and antibiotic-coated IMN placement, highlighting a nail placed across the tibiotalar fusion site to support bone fusion. Final results after staged treatment are shown on AP (C) and lateral (D) X-rays.



## Case 2

A 45-year-old female with no significant medical history presented with a left distal femur nonunion. She sustained an open left distal femur fracture and tibial spine fracture with suspected knee dislocation in a motorcycle collision two months prior and was treated with ORIF abroad. She developed wound drainage and underwent I&D one month after initial surgery.

She presented to our center with infected nonunion and knee arthrofibrosis (Figure 5). After extensive workup, she underwent a first stage operation that started with arthroscopic lysis of adhesions, left distal femur removal of hardware, and extensive I&D (Figure 6). During the operation, extensive bone and articular necrosis was noted with near complete erosion of the lateral articular surface. Intramedullary debridement was performed using RIA, followed by placement of an antibiotic-coated retrograde IMN (60cc calcium sulphate mixed with 6g vancomycin and 3.6g tobramycin) and an antibiotic-loaded PMMA bone cement spacer (one bag of gentamicin-loaded PMMA mixed with 3g vancomycin and 2.4g tobramycin) (Figure 7A). IV cefazolin was administered pending cultures.

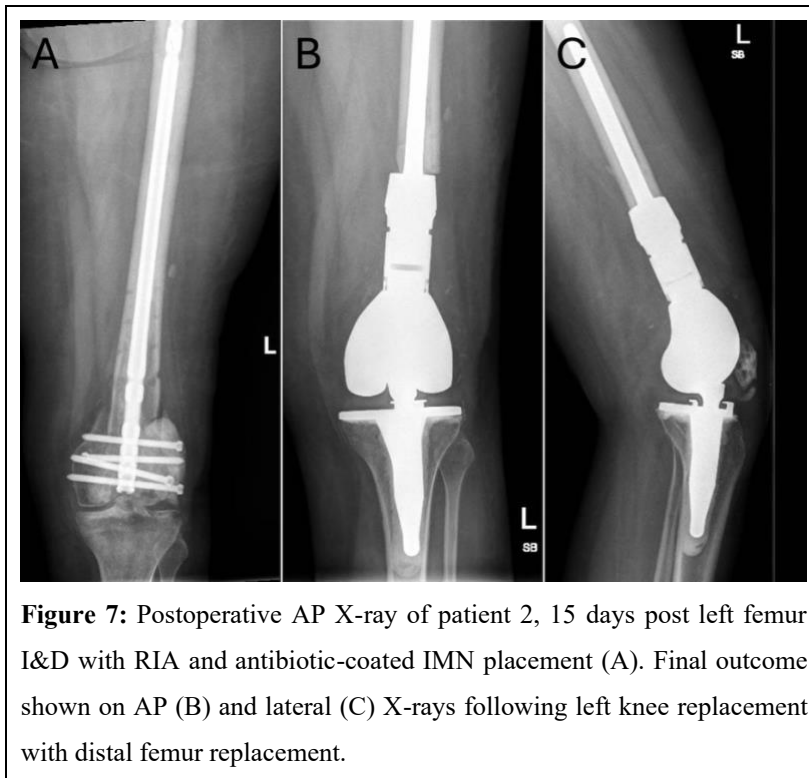
Intraoperative cultures grew few *Cutibacterium acnes* and *Paeniclostridium sordellii*, which, per the literature, can cause significant deep-space infections. ID recommended two doses of dalbavancin 1500mg one week apart. She tolerated both doses without side effects. After resolution of deep infection, she underwent removal of the IMN and spacer and a left distal femur replacement 3 months after her initial stage (Figure 7B-C). No obvious signs of infection were noted intraoperatively. The patient is currently 23 months post-original surgery with no signs of infection; knee range of motion is 0-40°. She is doing well and continues to follow up with our orthopedic practice.



**Figure 5:** AP (A) and lateral (B) preoperative X-rays of patient 2 status post ORIF showing persistent supracondylar distal femur fracture.



**Figure 6:** Intraoperative image of patient 2 after I&D prior to antibiotic-coated IMN and antibiotic spacer placement.



**Figure 7:** Postoperative AP X-ray of patient 2, 15 days post left femur I&D with RIA and antibiotic-coated IMN placement (A). Final outcome shown on AP (B) and lateral (C) X-rays following left knee replacement with distal femur replacement.

## Discussion

These outcomes demonstrate the effectiveness of dalbavancin in conjunction with RIA and antibiotic-coated IMN placement in clearing deep gram-positive infections associated with nonunion with hardware infection when coupled with bone debridement and staged reconstruction. RIA before IMN insertion in the setting of deep infection is more effective than traditional reaming alone at limiting the dissemination of dormant organisms. Using RIA and an antibiotic-coated IMN allows patients to remain functional without the burden of external fixation in the first stage of infection and bone defect management. This allows second-stage management to be developed based on findings and course.

Our group previously reported indications for the incorporation of a two-dose dalbavancin regimen, including persistent infection, difficult line access, and difficulty achieving therapeutic vancomycin levels [8]. This study also found that of 61 patients who received dalbavancin, six (10%) had infection recurrence, including three of eight patients with hardware retention [8]. Thus, the adjunct of an antibiotic-coated IMN is an additional measure that may reduce the risk of local infection recurrence, as suggested in the literature [17].

The management of deep bone infections in patients with barriers to OPAT poses an additional challenge [15]. People without stable housing, who inject drugs, or have alcohol use disorder are often not candidates for OPAT. They may require a skilled nursing facility transfer to complete antibiotics, which is more costly, often less desirable than discharge home, and not a guaranteed option [10,18]. Studies also show that loss of follow-up is strongly associated with an increased risk of readmission and catheter-related bloodstream infection in patients receiving OPAT [19,20].

Two doses of dalbavancin given 1 week apart have been shown to provide tissue exposures above the minimum inhibitory concentration for *Staphylococcus aureus* for up to eight weeks [13]. Loss to follow-up is a significant concern in the management of deep infections, and this potent, short-term regimen may increase the likelihood of successful acute eradication. Limitations of this series include differences in surgical management due to inherent differences in presentation, surgical history, infection severity, and nonunion complexity. This makes it difficult to ascertain which components contribute most to treatment success, which is best accomplished through a prospective study.

## Conclusion

The proposed regimen of dalbavancin following RIA and antibiotic IMN placement for infected nonunions shows promise in the eradication of persistent gram-positive infections. Additional advantages include suitability for patients at risk of loss to follow-up, low medication adherence, and IV drug use. The financial considerations of this medication should be weighed against the costs of lengthy admissions and frequent reoperations to resolve infected nonunions.

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