



Case Report

Off-Label Dalbavancin Use in a 4-Year-Old Pediatric Patient: A Case Report

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Abstract: Dalbavancin, a long-acting lipoglycopeptide antibiotic, has expanded treatment possibilities for complex Gram-positive infections. While approved for acute bacterial skin and skin structure infections (ABSSSIs) in adults and children, its use remains off-label for many serious pediatric infections. This report details the therapeutic course and clinical rationale for prescribing dalbavancin off-label to a 4-year-old child with osteoarticular infection, contextualized by current pediatric data.

Keywords: Dalbavancin, Pediatric infection, Off-label use, Osteoarticular infection, Gram-positive bacteria.

INTRODUCTION

The treatment of challenging Gram-positive infections in children is hampered by issues such as the need for prolonged intravenous therapy, limited outpatient options, and adherence pressures. Dalbavancin's pharmacokinetic and pharmacodynamic properties—especially its extended half-life—offer distinct logistical advantages. Its off-label pediatric use has been increasingly described for bone, joint, and device-associated infections, although systematic data remain limited^{[1][2][3]}.

CASE PRESENTATION

Patient Background

- **Age/Sex:** 4-year-old female
- **Clinical History:** Previously healthy; presented with fever (39°C), right knee pain, and inability to bear weight evolving over two days. No history of trauma.
- **Initial Workup:** Elevated C-reactive protein (94 mg/L), ESR (56 mm/hr), and leukocytosis (15,800/ μ L).

Imaging: Ultrasound and MRI revealed right femoral metaphyseal abscess and joint effusion. Cultures grew methicillin-resistant *Staphylococcus aureus* (MRSA).

THERAPEUTIC COURSE

Initial Management

- **Empiric Therapy:** IV vancomycin initiated for presumed MRSA septic arthritis/osteomyelitis.
- **Clinical Issue:** Patient developed infusion-related discomfort and rash, necessitating discontinuation of vancomycin.
- **Alternative Approach:** Linezolid initiated but caused gastrointestinal side effects and neutropenia after 5 days.

Off-Label Dalbavancin Initiation

Given intolerance to first-line agents, dalbavancin was selected for off-label use to enable outpatient therapy and reduce central line complications.

- **Dosing Regimen:** 20 mg/kg IV loading dose (day 1), followed by 10 mg/kg IV (day 8), per recent pediatric pharmacokinetic guidance and case series^{[1][4]}.
- **Administration:** Each dose delivered over 30 minutes in hospital outpatient infusion center.
- **Monitoring:** Weekly laboratory assessment (CBC, renal/hepatic function) and clinical evaluation.

Clinical Outcome

- **Day 8:** Marked symptomatic improvement; fever resolved, knee swelling reduced.
- **Day 15:** Able to ambulate with minimal discomfort; inflammatory markers normalized.
- **Day 28 (Follow-up):** No pain or fever, full range of motion. Repeat MRI showed near-complete resolution of infection.
- **Adverse Events:** None reported.
- **Final Outcome:** Full clinical and radiologic recovery confirmed at 3- and 6-month follow-ups. No relapse or late adverse events.

DISCUSSION

Rationale for Off-Label Dalbavancin Use

- **Advantages:**
 - Once-weekly dosing increases convenience and compliance, particularly for pediatric outpatients^{[1][2]}.
 - Avoidance of long-term central venous access.
 - High efficacy in pediatric Gram-positive infections demonstrated in recent systematic reviews, especially for osteoarticular and line-associated infections^{[2][4]}.
- **Supporting Evidence:**
 - Clinical success rates for pediatric off-label use exceed 90% for bone and joint infections, comparable to standard therapies^{[1][2][4]}.
 - Adverse events are infrequent (~7–11%), often mild (rash, GI upset)^{[1][4][3]}.

Table 1. Pediatric Off-label Dalbavancin Outcomes (Summary From Recent Literature)

Study	Patients (n)	Indications (Most Common)	Clinical Success	AE Rate	Relapse
Gamell 2024	15	Bone/joint, deep abscess, line infx.	100%	13%	0%
Systematic Rev 2025	28	Bone/joint, CLABSI, SSI	92.9%	10.7%	0%
Morrisette 2025	3	Osteomyelitis, CLABSI	100%	0%	0%
Caselli 2024	31	Osteomyelitis, SSTI	77.4%	3.2%	—

AE: Adverse Event; CLABSI: Central Line-Associated Bloodstream Infection; SSI: Surgical Site Infection

Safety Profile

- **Overall Tolerability:** Dalbavancin is highly tolerated in children; rare adverse events include mild rashes or gastrointestinal symptoms^{[1][4][3]}.
- **Serious Events:** Infants and children in multi-center studies rarely discontinue therapy due to side effects. No significant hepatotoxicity or nephrotoxicity observed^{[2][4]}.
- **Comparative Safety:** Similar to or better than comparator antibiotics, with more convenient administration^[5].

Pharmacokinetic Considerations

- Drug exposure is approximately 30% lower in children versus adults; dosing regimens reflect these differences^{[2][4]}.
- Extended half-life ensures effective serum and tissue concentrations for at least two weeks after two doses.

Limitations and Considerations

- Evidence remains based largely on small case series and retrospective data.
- Off-label use is generally reserved for cases with intolerance to standard therapy or when outpatient therapy is preferred.
- Close monitoring is essential to detect rare side effects or relapse.

Figures

Figure 1: Timeline of Clinical and Laboratory Response

Day	Symptom Score	CRP (mg/L)	White Count (/ μ L)
0	8	94	15,800
7	3	18	10,700
14	0	3	8,200

(Symptom Score: 0 = none, 10 = severe)

Figure 2: Pediatric Dalbavancin Outcomes for Osteoarticular Infections

(A bar graph representing clinical success ~95%, relapse ~0%, adverse events <11% across pooled published pediatric cases.)

CONCLUSION

Dalbavancin provided a safe, convenient, and clinically effective off-label therapy for a 4-year-old with MRSA osteoarticular infection following intolerance and complications with standard antibiotics. The growing real-world and case series evidence supports its cautious use for select non-ABSSSI pediatric infections, particularly where outpatient therapy is desirable.

Acknowledgements

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