Clinical Outcomes of Off-label Dalbavancin Use within an Outpatient Antibiotic Therapy Program (OPAT)

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BACKGROUND

- Dalbavancin is approved for the treatment of acute bacterial skin and skin structure infections (ABSSSI).
- There is less data on outcomes of off-label use of dalbavancin for complex orthopedic infections.
- The objective of this study was to analyze clinical outcomes of deep-seated infections treated with IV dalbavancin as an alternative to daily, long-term IV antibiotics post hospital discharge.

OUTCOMES OF INTEREST

- Primary outcome was 90-day infection recurrence
- Secondary outcomes:
  - ~ Hardware retention rates
  - ~ 90-day mortality
  - ~ Adverse events
  - ~ Characteristics of antibiotic regimens

METHODS

Study Design

- Observational, retrospective case series conducted at an urban health system in the Bronx, New York between January 2020 and February 2022
- List of patients obtained via outpatient parenteral antibiotic therapy (OPAT) program insurance claims

Inclusion Criteria	Exclusion Criteria
• ≥18 years old • Received at least one dose of dalbavancin for off-label indications	• Received dalbavancin for ABSSI

- Data collected included demographics, comorbidities, infection type, organism, treatment setting, details of dalbavancin dosing and surgical management
- IRB approval waived

RESULTS

Table 1. Patient Summary, Infection Characteristics, Treatment

	N = 21
Male, n (%)	14 (67%)
Age, years, median	51
Race	
Hispanic	13 (62%)
Black	2 (10%)
White	6 (29%)
Charlson Comorbidity Index, median	1
Infection type	
Hardware infection	8 (38%)
Spinal abscess	3 (14%)
Osteomyelitis	4 (19%)
Complex soft tissue infection[1]	5 (24%)
Septic arthritis	1 (5%)
Hardware infection (n=8)	
Prosthetic device removal prior to dalbavancin treatment	3
Prosthetic device retention prior to dalbavancin treatment	5
MSSA	7 (33%)
MRSA	6 (29%)
Receipt of antibiotics prior to dalbavancin	21 (100%)
Concomitant antibiotic treatment (along with dalbavancin)	6 (29%)
Doses of Dalbavancin (milligrams)	
1000mg followed by 500mg 1 week apart	13 (62%)
1500mg followed by 1500mg 1 week apart	5 (24%)
Received antibiotics after dalbavancin completion	11 (52%)
Location: Outpatient/ER	20 (95%) / 1 (5%)

[1]Silicone implanted-related cellulitis (1), deep surgical wound infection (1), bullous erysipelas (1), complex fracture with cellulitis (1), hidradenitis suppurativa (1)

Table 2. Outcomes

	N = 21
90-d infection recurrence	2 (10%)
Hardware retention at dalbavancin initiation	5 (27%)
Eventual hardware removal due to recurrence within 90 days	2 (40%)
Eventual hardware removal due to recurrence within 180 days	1 (10%)
Hardware retention without recurrence	2 (40%)
90-d mortality	0 (0%)
Adverse effects	0 (0%)

DISCUSSION

- Most common reasons for dalbavancin use were persistence of infection after initial therapy, difficulty with vancomycin dosing and line access, and intravenous drug use history.
- Our study showed high rates of infection cure with dalbavancin. For hardware infections overall, the 90-d cure rate was 75% (6 of 8 patients), and 100% (3 of 3 patients) when combined with surgical management. For all other infections, there were no recurrences.
- Limitations include a small number of patients, the observational nature without a comparator group, the lack of standardized dosage regimens, and unclear contribution from ongoing oral antibiotics.

CONCLUSION

- Use of dalbavancin for hardware infections, osteomyelitis, complicated soft tissue infections and spinal infections is associated with favorable cure rates, safety profile and tolerability
- For hardware infections, source control is essential for clinical cure
- Substantial cost-saving implications through reduction in hospital length of stay and readmissions
- Large, multicenter studies and randomized controlled trials will serve to establish efficacy, tolerability, standardized dosing, and role for concomitant antibiotics

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