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Original Research

Dalbavancin as an alternative to traditional outpatient parenteral antimicrobial therapy for deep gram-positive infections – an observational, retrospective review

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Abstract

Background: Treatment of invasive gram-positive infections in complex patient populations is challenging. Dalbavancin, approved for skin and soft tissue infections, offers advantages in this setting due to its long half-life and infrequent dosing. However, less is known about the outcomes of off-label dalbavancin for deeper infections.

Objectives: The objective of this study is to examine the feasibility and outcomes of patients with complex gram-positive infections treated with dalbavancin as an alternative to standard outpatient parenteral antimicrobial therapy (OPAT).

Methods: We conducted a multicenter, retrospective review of adult patients managed within an OPAT program with intravenous dalbavancin for off-label indications. Adult patients were included if they had treatment details and follow-up documented between January 2020 and June 2023. Details of dalbavancin use including indications for prescription were captured. Outcomes of interest included 90-day infection recurrence, prosthesis retention rates, 90-day mortality, and adverse medication events.

Results: In all, 61 patients received dalbavancin, mostly as sequential therapy. Twenty-three percent received dalbavancin strictly in the outpatient setting. Dalbavancin was used primarily for hardware (fracture, spine, or joint), native bone or joint, and complicated soft tissue infections. The predominant pathogen was *Staphylococcus aureus* (61%). Dalbavancin was frequently prescribed as a two-dose 1500 mg regimen (49%) due to persistent infection (23%), difficult line access (30%), difficulty achieving therapeutic vancomycin levels (18%), or substance abuse history (18%). Overall, six patients (10%) had infection recurrence and no patients died during the follow-up period. Three of eight patients with hardware retention had infection recurrence. Adverse effects were minimal and mostly self-limiting.

Conclusion: Dalbavancin is an efficacious and safe alternative to standard OPAT, especially in those with barriers to traditional long-term intravenous antibiotics. Improved outcomes may be achieved with hardware removal. Dalbavancin may facilitate early discharge or prevent hospitalizations. Comparative studies of standard OPAT regimens *versus* dalbavancin are needed.

Keywords: dalbavancin, hardware infection, OPAT

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Introduction

Invasive gram-positive infections caused by *Staphylococcus aureus*, such as osteomyelitis, septic arthritis, and endocarditis, pose a significant therapeutic challenge.[1] These infections often afflict vulnerable populations like people who inject drugs (PWID), unhoused populations, and the elderly.[1] Typically, treatment requires

prolonged intravenous antimicrobial therapy which is challenging in these groups. Outpatient parenteral antimicrobial therapy (OPAT) programs are cost-effective alternatives to prolonged hospitalizations; however, OPAT for PWID is challenging due to unstable housing and social circumstances leading to hospital readmission and loss of outpatient follow-up.[2] Regardless of patient population, OPAT programs continue to struggle with readmissions for drug toxicities and vascular complications, and requirements for diligent monitoring and follow-up.[3] Discharge with vancomycin is an independent predictor of subsequent readmission.[4]

Dalbavancin is a long-acting second-generation lipoglycopeptide antibiotic with activity against most gram-positive bacteria, excellent tissue and bone penetration, and a remarkable terminal half-life of 14.4 days.[5] Unlike other lipoglycopeptides such as telavancin, dalbavancin's long half-life obviates the need for frequent parenteral dosing and laboratory monitoring, and a few administrations of dalbavancin equate to standard long-term intravenous therapy.[6] Initially approved by the Food and Drug Administration for the treatment of acute bacterial skin and soft tissue infections, dalbavancin's role has expanded to off-label indications such as bone and articular infections, endocarditis, and bacteremia.[7–11]

Dalbavancin serves a niche role as an alternative to standard OPAT, facilitates earlier hospital discharge, and can be utilized to avoid hospitalization altogether. One well-recognized limitation of traditional OPAT is the inconvenience of frequent intravenous administrations.[12] Long-acting lipoglycopeptides like dalbavancin can improve patient satisfaction and expedite return to daily life. Despite the growing literature of oral antibiotics for bone and joint infections, dalbavancin still serves a role given its ease of dosing. In challenging patient populations, it is difficult to ensure adherence to oral therapies given the frequency and high doses required for bone and joint infections leading to potential side effects. In addition, in more complex infections with minimal source control, providers may feel reluctance to prescribe oral therapies. In this OPAT cohort, we evaluated outcomes, safety, and patient characteristics in those who received dalbavancin for off-label indications.

Materials and methods

We conducted an observational, retrospective review at a three-hospital health system in the Bronx, New York between January 2020 and June 2023. In July 2015, an OPAT program was established by the Division of Infectious Diseases using a bundled approach including appropriate patient selection, mandatory infectious diseases (ID) consultation, use of a preferred infusion vendor agreement, and close outpatient ID follow-up with monitoring of laboratory parameters.[3] OPAT follow-up appointments are provided within 2–3 weeks of discharge. The inpatient ID consultant documents a detailed treatment plan in the electronic medical record to ensure continuity between all service providers using a preformulated template. The preferred infusion vendor assists with insurance authorization for dalbavancin unless patients have limited or no health insurance, in which case an application for patient assistance from the manufacturer is initiated.[13]

Post-discharge, the OPAT team confirms appointments and documents all doses and dates of dalbavancin receipt within the electronic medical record system, as well as any adverse effects experienced. Dalbavancin is administered *via* peripheral lines either at patients' homes or at a designated infusion suite operated by the infusion vendor (Figure 1).

A list of patients who received dalbavancin was obtained from the infusion vendor. Adult patients (>18 years) who received at least one dose of dalbavancin were included. Patients who received dalbavancin for acute bacterial skin and soft tissue infections and those without 90-day follow-up were excluded. Data collected included demographic data, third-party payer information, comorbidities (e.g. diabetes mellitus, HIV, chronic kidney disease, liver disease, cardiovascular disease) which were used to calculate the Charlson comorbidity index; the presence of immunosuppressive conditions (including cancers and receipt of immunosuppressive agents), treatment setting, infection type, culture source, organism(s) isolated, antibiotics used (prior to, with, and after dalbavancin therapy), hospital length of stay, and details of dalbavancin use including indications for prescription. No specific dalbavancin treatment protocol was utilized; though in 2022 onwards, the dose of 1500 mg

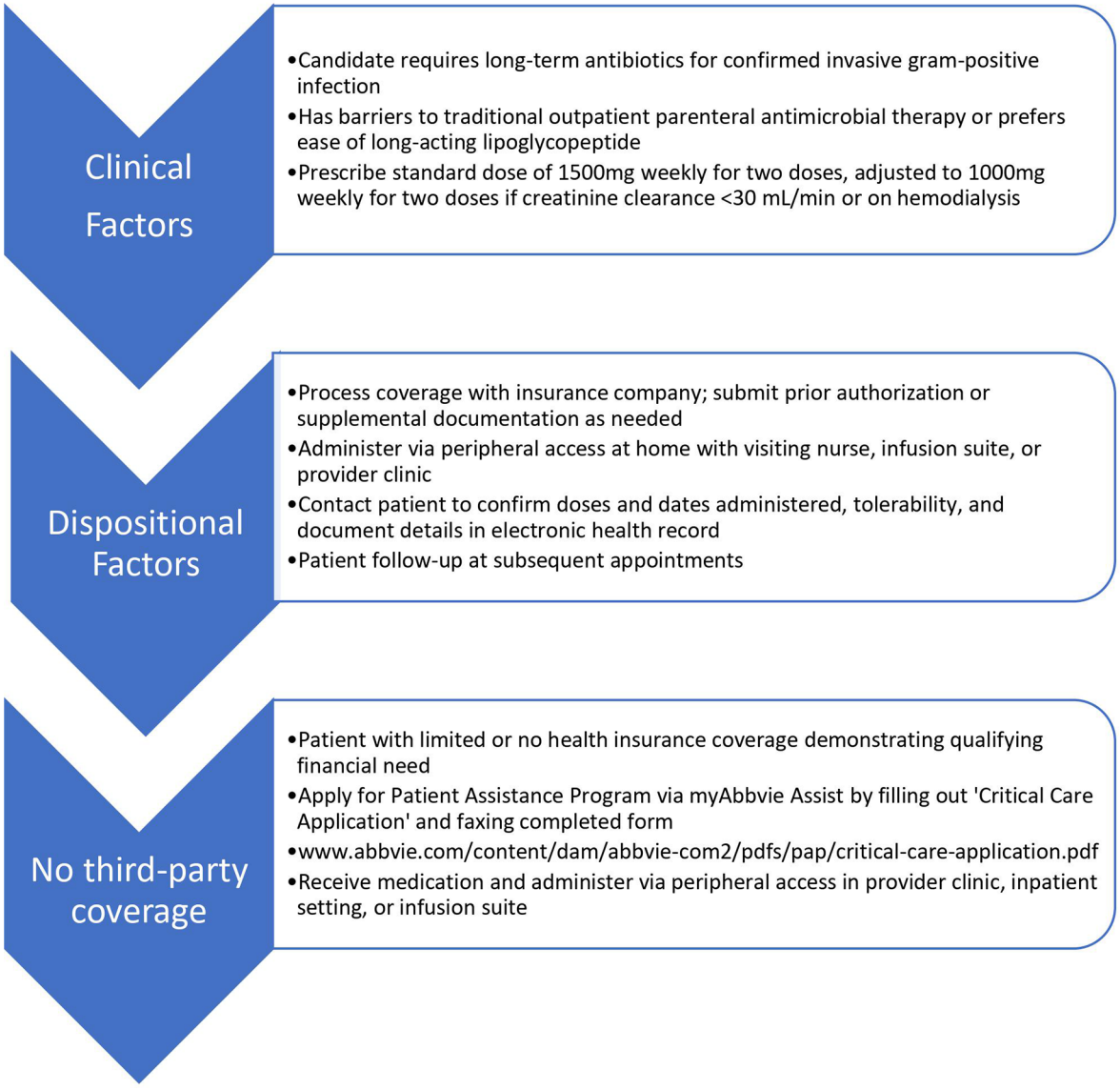

Figure 1. Dalbavancin pathway.

weekly for two doses was more commonly prescribed (or 1000 mg weekly for two doses if creatinine clearance was <30 mL/min), as described by Rappo et al.[8] Otherwise, dose, duration, and use of other antibiotics were determined by the treating ID consultants.

We also assessed the area deprivation index (ADI), which is a neighborhood-disadvantage metric composed of education, employment, housing quality, and poverty measures.[14,15] This was calculated by the census block group of the patients' home addresses.

The primary outcome was 90-day infection recurrence, which was defined as the need for additional antibiotics for worsening infection or the need for repeated infection-related surgical intervention. Patients who received subsequent antibiotics immediately following dalbavancin were not considered to have recurrence. Other outcomes of interest included hardware retention rates, 90-day mortality, and adverse medication events. The reporting of this study conforms to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.[16]

Table 1. Baseline characteristics, *n* (%).

Age, years, median (IQR)	54 (44–64)
Male	37 (60%)
Race	
Hispanic	30 (49%)
Non-Hispanic Black	15 (25%)
Non-Hispanic White	12 (20%)
Asian	2 (3%)
Other	2 (3%)
Body mass index (>30 kg/m^2)	26 (43%)
Comorbidities	
Human immunodeficiency virus	4 (7%)
Solid organ transplant	9 (15%)
Peripheral vascular disease	9 (15%)
Liver disease	4 (7%)
Diabetes mellitus	23 (38%)
Without end organ damage	12 (52%)
End-organ damage	11 (48%)
Chronic kidney disease	17 (28%)
Opioid use disorder	14 (23%)
Ongoing injection drug use	9 (15%)
Charlson Comorbidity Index, median (IQR)	2 (0–5)
Hospital length of stay, days, median (IQR)[a]	9 (7–11)
Third-party payer	
Medicare	17 (28%)
Medicaid	24 (39%)
No insurance	3 (5%)
Commercial	17 (28%)
Area deprivation index – State, deciles, median (IQR)	6 (5–7)

[a]Length of stay calculated from 47 patients initially admitted to the hospital.

Results

In all, 61 patients were included in the study (Table 1). The majority were males (60%) and Hispanic (49%). The median age was 54 years. Most had at least one comorbidity, with diabetes mellitus being the most common (38%). Opioid use disorder and ongoing injection drug use accounted for 23% and 15% of comorbidities, respectively. The most common payer was Medicaid (39%) and the median area deprivation index was ranked in the sixth decile of the state.[14]

The two most common treatment indications were orthopedic hardware infections (36%) and native osteomyelitis and septic arthritis (36%) (Table 2). Concomitant bacteremia was present in 11 (18%) patients and source control was achieved in 42 (69%) patients, primarily through debridement alone or debridement with prosthesis removal. Eight patients had device retention at the start of dalbavancin therapy. The predominant organisms involved in infections are shown in Figure 2. In 13 patients, dalbavancin was used empirically, in which organisms were not identified but there was high clinical suspicion for gram-positive organisms being the causative pathogens. In these cases, dalbavancin was always given sequentially after initial intravenous antibiotics.

Most patients (97%) received dalbavancin as sequential therapy following an initial course of other antibiotics, usually beta-lactam therapy. Among reasons for dalbavancin prescription, the most cited were difficulty managing central venous access (30%), persistent infection after initial therapy requiring intravenous antibiotics (23%), difficulty achieving therapeutic vancomycin levels (18%), and substance use history (18%). Dalbavancin was frequently administered at 1500 mg weekly for two doses (49%). Though the majority of dalbavancin administration was in the outpatient setting following an index admission, 14 (23%) patients received dalbavancin strictly as outpatients without preceding hospital admission. Concomitant antibiotics with dalbavancin were utilized in one-third of patients for a median of 29 days. Further antibiotics after dalbavancin completion were given in 56% of patients, most commonly cephalexin and linezolid.

Six (10%) patients had a recurrence of infection within 90 days of dalbavancin administration (Table 3). Of these six recurrences, three involved hardware that was retained. These three patients had recurrence despite receiving subsequent oral therapy following dalbavancin. The other recurrences involved one case of methicillin-susceptible *S. aureus* femur osteomyelitis which recurred

Table 2. Infection and treatment, *n* (%).

Infection type	
Hardware infection	22 (36%)
Osteomyelitis and septic arthritis	22 (36%)
Complicated soft tissue infection	9 (15%)
Epidural abscess	4 (7%)
Bacteremia and endocarditis	4 (7%)
Concomitant bacteremia	11 (18%)
Source control achieved	42 (69%)
Debridement or amputation of native structures	22 (52%)
Debridement with prosthetic device retention	5 (11%)
Debridement with prosthetic device removal	15 (33%)
Receipt of antibiotics prior to dalbavancin	59 (97%)
Vancomycin	23 (39%)
Daptomycin	7 (12%)
Beta-lactam	42 (72%)
Other	15 (25%)
Duration of therapy, days, median (IQR)	11 (8–21)
Dose(s) of dalbavancin (mg)	
1500, 1500, 1500	4 (7%)
1500, 1500	30 (49%)
1000, 500	18 (30%)
Other	9 (15%)
Frequency of dosing	
Once weekly	54 (89%)
Other[a]	6 (10%)
Location of dosing	
Continuation after inpatient admission	47 (77%)
Outpatient initiation	14 (23%)
Concomitant antibiotics along with dalbavancin	21 (34%)
Rifampin	5 (24%)
Doxycycline	5 (24%)
Quinolone	6 (28%)
Cephalexin	5 (24%)
Duration of concomitant antibiotic, days, median (IQR)	29 (25–40)
Subsequent antibiotics after dalbavancin completion	34 (56%)
Linezolid	8 (23%)
Quinolone	3 (9%)
Bactrim	6 (18%)
Doxycycline	6 (18%)
Cephalexin	11 (32%)
Indication for dalbavancin use	
Persistent infection requiring intravenous antibiotics	14 (23%)
Difficulty managing central line access	18 (30%)
Difficulty with vancomycin therapeutic drug monitoring	11 (18%)
Substance abuse history	11 (18%)
Adverse drug reaction to other antibiotic	7 (11%)

[a]Patients did not receive weekly dosing due to scheduling delays in receipt of dalbavancin.

at the same site, one case of methicillin-resistant *S. aureus* (MRSA) knee osteomyelitis which recurred as a buttock abscess also growing MRSA, and one case of ankle soft tissue infection which recurred at the same site after dalbavancin completion. Five of eight patients with hardware retention at dalbavancin initiation did not recur at 90 days. Three of these patients received subsequent oral therapy following dalbavancin and two did not. Of the 14 patients prescribed dalbavancin as outpatients without initial hospitalization, two patients required subsequent hospitalizations for

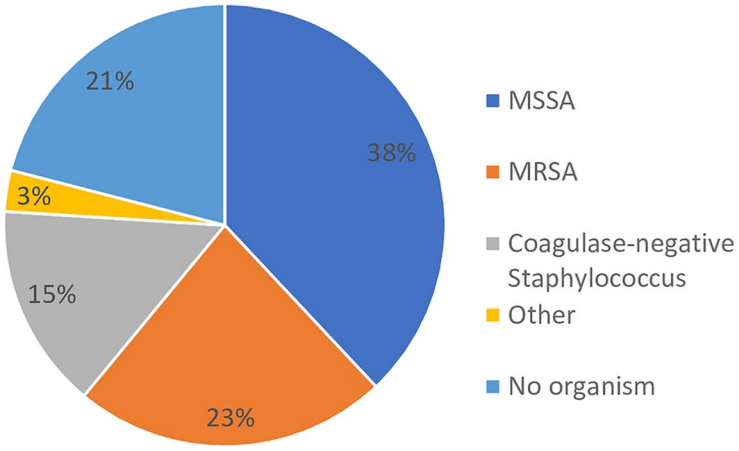

Figure 2. Distribution of organisms.

infection recurrence. No patients died within 90 days of therapy and four patients experienced adverse events (gastrointestinal disturbances – 1, infusion reactions – 2, headache – 1). One patient with an infusion reaction characterized by back pain and fevers declined the second dose but did not have an infection recurrence. The second patient with an infusion reaction developed an itchy throat and the second dose was held and the reaction did not recur. The remaining two patients received all doses, which were tolerated. Fewer adverse reactions were reported after slowing down infusion times to 1–2 h.

Discussion

Dalbavancin use for confirmed or suspected infections caused by gram-positive organisms was associated with high rates of infection cure when combined with surgical management. For complicated soft tissue infections, osteomyelitis, and spinal infections, the cure rate was 91% at 90 days. For prosthetic joint infections specifically, an initial 90-day cure was achieved in 88% of patients, and the remainder demonstrated a cure after hardware removal. These cure rates are comparable to those reported in prior literature.[8,9,17] Previous studies on dalbavancin use for prosthetic joint infections suggest 70–80% clinical success, which is improved when hardware removal is combined with medical management.[9,11,18] As noted in our study, hardware removal is critical to ensuring sustained clinical cure, as three out of eight patients with hardware retention had infection recurrence. Notably, 11 patients in our study had concomitant bacteremia (eight of which involved *S. aureus*) and all were treated successfully with dalbavancin without recurrence. Dalbavancin as an option for treatment of S. aureus bacteremia (DOTS) is a trial that is currently underway to determine the superiority of dalbavancin at a dosing regimen of 1500 mg weekly for 2 weeks compared to standard therapy for complicated *S. aureus* bacteremia.[19]

Though the upfront costs of incorporating dalbavancin into hospital formularies are high, so are potential cost savings of avoiding daily intravenous antibiotics, avoiding serial blood draws for therapeutic drug monitoring, reducing hospital lengths of stay, and avoiding readmissions in those initiated on dalbavancin as outpatients. Our findings support those of prior studies stating that dalbavancin can be utilized in patients with barriers to traditional OPAT.[20] In our study, difficulty managing central line access and ongoing

Table 3. Outcomes, *n* (%).

90-day infection recurrence[a]	6 (10%)
Hardware retention at dalbavancin initiation	8 (13%)
Recurrence with eventual hardware removal	2 (25%)
Recurrence with the inability to remove hardware	1 (12%)
Hardware retention without recurrence	5 (63%)
90-day mortality[a]	0 (0%)
Adverse medication events	4 (7%)

[a]Time measured from the first dalbavancin dose.

substance abuse accounted for nearly half of the dalbavancin indications. A history of opioid use disorder or ongoing substance use was documented in a substantial number of patients in our cohort. Vascular complications during OPAT are a common reason for readmission and ongoing intravenous drug use increases this risk.[21,22] Previous studies have found that less than half of PWID can complete their prescribed OPAT, and frequently leave against medical advice.[23,24] However, no patients in this study required central catheter placement and all were administered dalbavancin *via* peripheral lines.

More importantly, this study demonstrated the ability to successfully use dalbavancin as an alternative to standard OPAT in a socioeconomically disadvantaged population residing in a New York City borough with a higher-than-average ADI. More than a third of dalbavancin recipients in this study were Medicaid recipients and few had no insurance. ADI decile values closer to 10 represent more disadvantaged neighborhoods and the ADI of six in this study is representative of the overall Bronx community.[14] Despite socioeconomic challenges, patients were still able to successfully receive and complete dalbavancin therapy through our OPAT pathway.

Treatment with dalbavancin simplifies the antibiotic regimen and allows for early discharge from the hospital. Morrisette *et al.* estimated that the reduction in hospital length of stay and health-system costs were 9.18 days per person on average and USD 17,205 per person, respectively.[25] The hospital length of stay for dalbavancin recipients in our study was 9 days, emphasizing the need to identify dalbavancin candidates early and coordinate infusion logistics to facilitate earlier discharge. When compared to a historic cohort at our institution with similar infections, those discharged with vancomycin, cefazolin, or daptomycin had a median length of stay of 12 days. Previous studies with a large number of PWID have demonstrated shorter hospital stays in dalbavancin recipients compared to standard OPAT.[17,26] At our institution, the cost of 1 day per average hospitalization was estimated at USD 4307 by the finance department. Prescribing dalbavancin and discharging patients earlier would save an estimated average of USD 12,923 per patient. When using a range of acquisition costs provided by our wholesale distributor (USD 5569 to 9366 for two doses of dalbavancin 1500 mg), cost savings would remain. In 14 patients, dalbavancin was successfully initiated and completed on an outpatient basis to avoid hospitalization, and only two patients required hospitalization for worsening infection, underscoring the success of this approach. At our health system, we have not required a formulary addition of dalbavancin due to the establishment of a dedicated treatment pathway through our preferred infusion vendor, and therefore benefit from cost-savings from early discharge and admission aversion without upfront acquisition costs.

In the United States, potential cost savings offered for 340B-eligible hospitals further incentivize outpatient dalbavancin use. 340B programs allow hospitals serving uninsured and low-income patients to receive upfront discounts for outpatient medications sold by pharmaceutical manufacturers participating in Medicaid. Thus, eligible hospitals can administer standard therapy to inpatients and upon hospital discharge, convert therapy to dalbavancin or other long-acting lipoglycopeptides either at an ambulatory infusion center or during home infusion. This allows healthcare systems to acquire dalbavancin at reduced 340B pricing and receive reimbursement through outpatient third-party payor benefits.

Study limitations include a small number of patients, an observational study without a comparator group, the lack of standardized dosage regimens, and unclear contribution from concomitant or subsequent oral antibiotics, limiting our understanding of dalbavancin as monotherapy for complex orthopedic infections. Moreover, though hardware infections accounted for over a third of total infection types, the heterogeneity of infectious sources limits generalizability. The reasons for concomitant and subsequent antibiotic use were multifactorial. For concomitant antibiotics, we used rifampin (due to the retention of hardware with *Staphylococcus* species) and fluoroquinolones (to provide coverage against gram-negative organisms). Providers also tended to prescribe cephalexin and doxycycline as a bridge while awaiting dalbavancin insurance authorization. For subsequent antibiotic prescribing, we primarily attribute this to complex hardware infections and spinal infections requiring longer courses of antibiotics beyond the 6 weeks of coverage offered by two-dose therapy. In addition, 43% of our patients were obese and due to the uncertainty of dalbavancin pharmacokinetics in this

patient population, we felt inclined to provide antibiotics afterward. Though the choices of adjunctive antibiotics and duration of therapy were ultimately left to the clinical judgment of the treating physician, we are in the process of protocolizing dalbavancin treatment to standardize practice.

Conclusion

Off-label use of dalbavancin as an alternative to standard OPAT is associated with favorable cure rates and tolerability in a vulnerable and economically disadvantaged population. Dalbavancin may successfully facilitate early hospital discharge or prevent admissions when initiated on an outpatient basis. Both paths have substantial cost-saving implications. However, source control and hardware removal are critical in ensuring treatment success. Large, multicenter studies and randomized controlled trials will serve to establish efficacy (compared to standard 6-week regimens), tolerability, standardized dosing, and role of concomitant and subsequent antibiotics for off-label dalbavancin use.

Declarations

Ethics approval and consent to participate

This study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Albert Einstein College of Medicine Institutional Review Board (IRB protocol #2016-6338). The requirement for informed consent to participate has been waived by the Institutional Review Board.

Consent for publication

Not applicable.

Author contributions

Hongkai Bao: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Writing – original draft; Writing – review & editing.

Rita Igwilo-Alaneme: Data curation; Formal analysis; Investigation; Methodology; Writing – original draft; Writing – review & editing.

Fnu Sonia: Data curation; Writing – review & editing.

Kelsie Cowman: Data curation; Writing – review & editing.

Mani Kahn: Project administration; Writing – review & editing.

Priya Nori: Conceptualization; Investigation; Methodology; Project administration; Supervision; Writing – original draft; Writing – review & editing.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

Not applicable.

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