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Dalbavancin for Bloodstream Infections and Endocarditis: Real-World Outcomes From the DRIVE Registry

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CONCLUSIONS

In this real-world study in patients with Gram-positive bacteremia and/or endocarditis, dalbavancin resulted in high rates of clinical and microbiological success, including in those patients with implanted devices

Most patients required one 1500 mg dose of IV dalbavancin to achieve clinical success

There were no adverse events related to dalbavancin treatment, and dalbavancin was well tolerated

RESULTS

Study Population

- Among 1092 evaluable patients treated with dalbavancin for any indication, 32 had baseline bloodstream pathogen data and Gram-positive bacteremia
- 29 of these 32 patients (91%) had been previously treated with antibiotics
  - Median duration 8.5 days
  - The 3 patients with endocarditis were among those most heavily pretreated: 9, 4, and 4 prior antibiotics each
- Patient baseline demographics, and laboratory values are shown in **Tables 1** and **2**

Table 1. Baseline Demographics

	Bacteremia ± endocarditis (n=32)
Age (median, range; years)	42 (19, 80)
Sex (m/f)*	16/15
Ethnicity, n (%)	
Hispanic or Latino	2 (6.3)
Not Hispanic or Latino	30 (93.8)
Race n (%)	
White	23 (71.9)
Black or African American	6 (18.8)
Not reported	3 (9.4)

*1 not recorded.

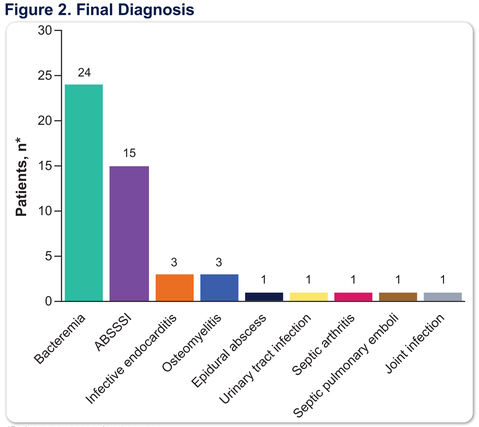
Table 2. Baseline Laboratory Assessments

	Bacteremia ± endocarditis (n=32)
White blood cell count (× 10^9/L), median (range)	n=26 10.2 (3.6,17.9)
Serum creatinine (mg/dL), median (range)	n=28 0.74 (0.26, 13.65)

Final Infection Diagnosis

- 15 (46.9%) patients had a final diagnosis of ABSSSI and 17 (53.2%) had non-ABSSSI
- 7 patients had a prior history of bacteremia: 4 injection drug users, 3 with an indwelling device
- **Figure 2** shows the final diagnosis for all 32 patients

Figure 2. Final Diagnosis



*Patients may appear in >1 category.

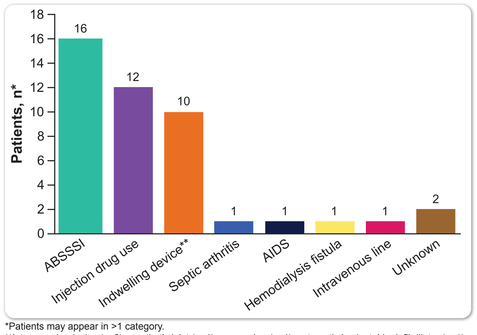
Treatment History

- 2 (6.3%) patients were receiving IV treatment at home at the onset of index infection
- 10 (31.2%) patients had been hospitalized for ≥2 days within 90 days prior to the onset of index infection

Bacteremia Risk Factors

- Where available the presumed source of bacteremia and any additional risk factors were recorded (**Figure 3**)

Figure 3. Presumed Source and Additional Risk Factors for Bacteremia

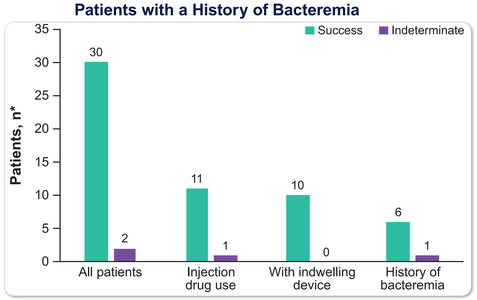


*Patients may appear in >1 category.
**Intravascular device (n=2), prosthetic joint (n=1), pacemaker (n=1), automatic implantable defibrillator (n=1), not specified (n=5)

Clinical Outcome

- Clinical outcome is shown in **Figure 4**

Figure 4. Clinical Outcome for All Patients, Those With Indwelling Devices, Injection Drug Users, and Patients with a History of Bacteremia

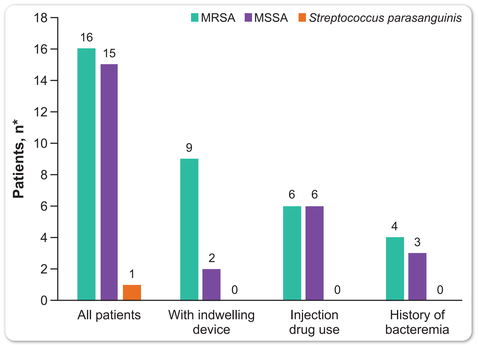


*Patients may appear in >1 category.

Pathogens Isolated at Baseline

- Pathogens isolated from patients' bloodstream at baseline are shown in **Figure 5**
  - MRSA was the most common pathogen isolated from the bloodstream among patients overall and those with an indwelling device
  - MSSA was isolated from the bloodstream of 15/32 patients overall
  - 1 patient had infection with *Streptococcus parasanguinis*
  - Other pathogens isolated from the bloodstream were *Chrysobacterium indologenes* and *Mycoplasma pneumoniae* (1 patient each)

Figure 5. Baseline Bloodstream Pathogens



*Patients may appear in >1 category.

Dalbavancin Use

- Median (range) cumulative dose of dalbavancin received was 1500 mg (1000 mg–6000 mg)
- The majority of patients (18/32; 60%) received 1500 mg of dalbavancin per Dalvance label; all achieved clinical success despite some having been heavily treated previously
- 17 patients received 1 IV infusion (1500 mg [n=16]; 1000 mg [n=1]), 10 received 2 IV infusions (1500 mg weekly x 2 [n=4], 1500 mg x 2 [2 weeks apart; n=2], 1000 mg then 500 mg [1 week later; n=2], 1000 mg x 2 [2 weeks apart; n=1]; 1125 mg x 2 [2 weeks apart; n=1], 4 received 3 IV infusions (1500 mg weekly x 3 [n=2], 1000 mg, 500 mg x 2 weekly [n=2]), and 1 patient received 4 IV infusions (1500 mg weekly x 4 [n=1])
- There was no apparent correlation between cumulative dose or number of dalbavancin infusions and number of prior IV antibiotic therapies
- The 3 patients who required ≥4500 mg of dalbavancin had a history of injection drug use and 2 of them also had an indwelling device; all achieved clinical success
- Those patients who were most heavily pretreated all achieved clinical success (5, 3, 1, 1, and 1 patients had received 3, 4, 5, 7 and 8 prior IV antibiotics, respectively)

Location of Care and Discharge Destination

- 11 patients were treated as hospital inpatients, 18 were treated with outpatient parenteral antibiotic therapy (OPAT), and 3 patients who received ≥2 doses of dalbavancin were treated both as an inpatient and with OPAT
- Final discharge destination of all 32 patients was home

Safety

- There were no dalbavancin-related adverse events

INTRODUCTION

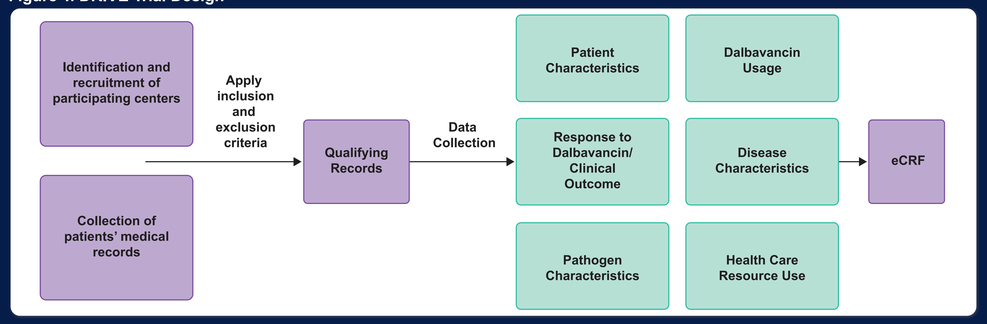
- Dalvance™ (dalbavancin; Allergan, Dublin, Ireland), a long-acting lipoglycopeptide approved by the US Food and Drug Administration and the European Medicines Agency for the treatment of acute bacterial skin and skin structure infections (ABSSSI), has potent activity against Gram-positive pathogens including methicillin-resistant *Staphylococcus aureus* (MRSA)[1,2]
  - Dalbavancin may be administered in either a 2-dose intravenous (IV) regimen (2 weekly doses on days 1 and 8), or as a single dose regimen
- Real-world evidence—health care data collected outside the structure of formal clinical trials—provides a more complete and realistic picture of the evaluated treatment and may reveal safety and efficacy information not apparent during clinical trials
  - Limited data are available in the public domain on the efficacy and safety of dalbavancin in real-world clinical practice in subsets of patients with specific types of infection
- Bloodstream infections and endocarditis are challenging to treat, and typically require 4-6 weeks of treatment. In two retrospective real-world studies dalbavancin was shown to be an effective treatment for Gram-positive bacteremia with infective endocarditis[3,4]
- We describe the clinical efficacy of dalbavancin in 32 patients with bacteremia or endocarditis from a retrospective registry study, including 10 patients with implantable devices.

METHODS

Study Design and Patients

- DRIVE is a phase 4 observational, multicenter, retrospective cohort study designed to characterize the real-world use of dalbavancin in adult patients (≥18 years) across the United States
  - This subanalysis included evaluable patients with confirmed Gram-positive pathogen at baseline

Figure 1. DRIVE Trial Design



Data Collection

- Data were abstracted from the medical charts of eligible patients who had received ≥1 dose of dalbavancin at 34 sites, from the date of infectious disease diagnosis until 60 days after the last IV dose of dalbavancin (data collection period: March 25, 2017 to November 27, 2018)
  - Demographic information; disease characteristics, baseline pathogen characteristics; systemic antibiotic administration; safety data (coded using the MedDRA, ver. 20.0 or later)

Clinical Outcome of Dalbavancin Treatment

- Success: presumed or documented clinical or microbiological cure **and** no need for rescue IV antibiotic therapy with antibiotics active against Gram-positive pathogens
- Failure: a need for rescue IV antibiotic therapy to treat the index infection until 60 days after the last IV dose of dalbavancin, **or** presumed or documented clinical or microbiologic failure, **or** death related to the index infection after the first dose of dalbavancin
- Indeterminate: insufficient data to determine status at 60 days, **or** outcome unknown/lack of data for clinical or microbiological status at 60 days after the last IV dose of dalbavancin

Analysis

- All data are descriptive

DISCLOSURES

This study was supported by Allergan (Dublin, Ireland; prior to its acquisition by AbbVie). Allergan (prior to its acquisition by AbbVie) was involved in the design and decision to present these results. Pedro Gonzalez and Jennifer McGregor are employees of AbbVie and may hold stock. Urania Rappo and Lisa Dipompo-Day were employees of Allergan (prior to its acquisition by AbbVie). Matthew McCarthy received consulting fees and research support from Allergan (prior to its acquisition by AbbVie).

Acknowledgments

Editorial support for development of this abstract was provided by Moira A. Hudson, PhD and John E. Fincke, PhD, at ICON plc (North Wales, PA), and funded by Allergan plc, prior to its acquisition by AbbVie. All authors met the ICMJE authorship criteria. Neither honoraria nor payments were made for authorship.

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Presented at IDWeek 2020, October 21–25, 2020, Virtual

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