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Dalbavancin Utilization and Associated Clinical Outcomes within a Large, Integrated Health System

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Dalbavancin Utilization and Associated Clinical Outcomes within a Large, Integrated Health System

Meagan Greckel, PharmD; Brent Footer, PharmD, BCPS, BCIDP

Background

- Dalbavancin is an intravenous (IV) lipoglycopeptide approved by the FDA for acute bacterial skin and skin structure infections (ABSSSI) and has a spectrum of activity similar to vancomycin.
- In bacterial infections that require prolonged antimicrobial therapy, such as infective endocarditis or osteomyelitis, extended antibiotic courses may pose as a challenge due to:
  - Multiple or daily doses of IV antibiotics.
  - Intermittent therapeutic drug monitoring (TDM).
  - Need for strict compliance from the patient and caregivers on infusions and follow-up appointments.
  - The inconvenience, cost, and commitment alone may be difficult for most patients, especially those who struggle with mental health disorders or IV drug use (IDU).
- Dalbavancin exhibits an elimination half-life of roughly 14.4 days, allowing for bi-weekly dosing.
- This could potentially decrease length of inpatient stay by two weeks per dose and limit concerns of therapeutic failure due to poor compliance.
- Currently, there is limited data published supporting the use of dalbavancin in infections other than ABSSSIs. The data that does exist largely focuses on bone and joint infections.

Objectives

- To analyze the efficacy and safety of dalbavancin and its role as an alternative therapy in serious gram-positive infections.
- To assess the population of patients within the cohort to determine who may benefit from dalbavancin therapy.

Methodology

- Institutional Review Board (IRB) approved.
- Electronic health record (EHR) based retrospective analysis.
- Study population:
  - Patients ≥18 years old.
  - Received a dose of dalbavancin within study period from any hospital or infusion clinic within the health system.
- Study period:
  - December 2019 through December 2021.
- Exclusion criteria:
  - Negative specimen culture result or received dalbavancin as empiric therapy.
  - Predominant pathogen was not a gram-positive bacteria.
  - Had a vancomycin-resistant isolate.
- Primary outcomes:
  - 30-day all-cause readmission, reoccurrence, and mortality.
- Secondary outcomes:
  - Resolution of infection per an infectious diseases (ID) specialist’s discretion at follow-up.
  - Rate of adherence to follow-up visits within 90 days of last dalbavancin dose.
  - 90-day all-cause readmission, reoccurrence, and mortality.
  - Rate of adverse events.

Definitions:

- Clinical cure: no clinical, laboratory, or microbiological evidence of persistent or recurring infection during the 90-day follow-up period.
- Presumed clinical cure occurred if a patient was lost to follow-up but was not readmitted within 90 days after the last dose.
- Treatment failure: received other IV antibiotics, worsening or recurrence of infection, unable to control source, or new infection within 30-days after the last dose.
- CCI score: Charlson Comorbidity Index score.
- MSSA: methicillin-susceptible Staphylococcus aureus.
- MRSA: methicillin-resistant Staphylococcus aureus.
- SSI: skin and soft tissue infection.
- LFT: liver function test.
- PICC: peripherally inserted central catheter.
- CoNS: Coagulase-negative Staphylococcus spp.

Table 1-2. Cohort demographics and characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of initial dose given</td>
<td>Infected, n=164 (85.9)</td>
</tr>
<tr>
<td>Age in years, average (SD)</td>
<td>72.1 (13.7)</td>
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<tr>
<td>Male sex</td>
<td>105 (64.0)</td>
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<tr>
<td>Body mass index, average (SD)</td>
<td>28.0 (4.9)</td>
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<tr>
<td>CCI score, average</td>
<td>3.2 (2.5)</td>
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<tr>
<td>Predominant pathogen</td>
<td>MRSA 72 (44.5)</td>
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<tr>
<td></td>
<td>SSI 13 (8.0)</td>
</tr>
<tr>
<td></td>
<td>CoNS 10 (6.1)</td>
</tr>
<tr>
<td></td>
<td>3 Other gram-positive pathogens 1 (0.6)</td>
</tr>
<tr>
<td>Mixed infection (gram-positive plus other pathogen or fungus)</td>
<td>Yes 6 (3.7)</td>
</tr>
</tbody>
</table>

Results

Primary Outcomes

Graph 1. 30-day all-cause readmission, reoccurrence, and mortality based on primary infection site for patients with appropriate follow-up (n=137)

Graph 2. >30 to 90-day all-cause readmission, reoccurrence, and mortality based on primary infection site for patients with appropriate follow-up (n=137)

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of initial dose given</td>
<td>Infected, n=164 (85.9)</td>
</tr>
<tr>
<td>Number of doses given (inpatient or outpatient)</td>
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<tr>
<td></td>
<td>2</td>
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<td>7</td>
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<tr>
<td></td>
<td>Other</td>
</tr>
</tbody>
</table>

Secondary Outcomes

Discussion

Patient Population:

- Out of 224 patients analyzed, 191 met criteria for inclusion.
- Of the 224, 106 (55.5%) were male; average age was 50.1 ± 16.5 years.
- The most common pathogen treated was MSSA (43%), and the most common site of infection was osteomyelitis/native joint infection (38.7%).
- 137 (71.7%) had appropriate follow-up within 90 days of the last dose of dalbavancin.

Clinical Outcomes:

- 30-day all-cause readmission, reoccurrence, and mortality occurred in 17 (12.4%), 2 (1.5%), and 0 (0%), respectively.
- >30 to 90-day all-cause readmission, reoccurrence, and mortality occurred in 20 (14.6%), 11 (8%), and 3 (2.2%), respectively.
- Of those with appropriate follow up, clinical cure occurred in 122 (89%) cases.
- Clinical cure per ID discretion occurred in 88 (64.2%) of cases.
- Including those who were lost to follow-up, clinical cure was presumed in 162 (84.8%) of cases.
- Of the 94 patients given dalbavancin due to IDU, 47 (50%) were lost to follow up; 82 (87.2%) had confirmed or presumed clinical cure.
- Adverse events occurred 10 (5.2%) of cases. The most frequent adverse event was infusion site reactions (2.1%).
- Bacteremia was commonly associated with the primary infection site (44.5%). No cases had recurrent bacteremia with the initial organism within the 90-day follow-up.

Limitations:

- Retrospective, medication utilization analysis.
- Select data was pulled from EHR via retrospective chart evaluation by single reviewer.
- Patients lost to follow-up without readmission data were presumed to have unknown clinical cure or reoccurrence.

Conclusions

- Dalbavancin is more commonly being used off-label for serious infections, other than ABSSSI, in patients who would benefit from minimal long-term IV infusions.
- Presumed clinical cure was comparable to previous studies, ranging from 84-89%.
- Treatment failure occurred in 16 cases (11.7%), primarily due to patients receiving other IV antibiotics within 30-days of the last dalbavancin dose.
- Dalbavancin appears to be a safe, effective, and convenient treatment alternative for gram-positive infections requiring long-term treatment.
- It should be used cautiously in those who may not return for follow-up appointments or additional dalbavancin doses.

References