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Telavancin Outcomes in Infections Treated with Outpatient Parenteral Antibiotic Therapy (OPAT)

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Key Findings

- **OPAT use of TLV was successful for treatment of a variety of infections including bone and joint, complicated skin and skin structure, bacteremia, respiratory, complicated urinary tract infection, and complicated intra-abdominal infection.**
- **Approximately one-third experienced adverse events, all resolved with management or drug discontinuation.**
- **Treatment success overall was 96% in evaluable patients and 95% of those with identified pathogens.**

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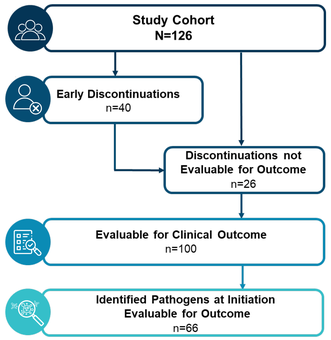
Background

- Telavancin (TLV) is a lipoglycopeptide approved for the treatment of complicated skin and skin structure infection and hospital acquired and ventilator associated bacterial pneumonia caused by susceptible Gram-positive bacteria.[1]
- Daily dosing and no need for therapeutic drug monitoring of TLV is convenient for OPAT.[2]
- Real world data are minimal for published outcomes in OPAT.
- This study evaluated the use and treatment outcomes of TLV in patients receiving OPAT.

Methods

- Adult patients who received at least one dose of TLV during 2021-2023 in OPAT were included.
- Data collection included: demographics, diagnosis, therapy characteristics, laboratory and microbiologic data, adverse events, and clinical outcomes.
- Patients were categorized at the completion of OPAT as clinical success (complete or partial resolution of signs and symptoms of infection without need for escalation of antimicrobials), non-success (persistent infection or discontinuation of TLV due to non-improvement), or non-evaluable (unable to determine clinical response to TLV).
- A subgroup with identified pathogens (presence of Gram-positive bacterial culture data at initiation of therapy) was evaluated for success (improvement/resolution of infection) or failure (persistent growth of a Gram-positive organism or non-improvement of infection).
- Descriptive statistics were used.

Study Cohort



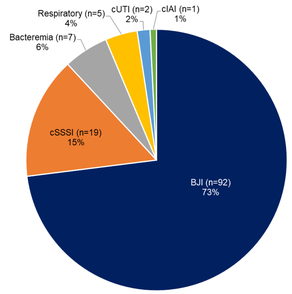
Patient Characteristics

Table 1. Demographics and Patient Characteristics

Characteristic	Results
Age (years), median (IQR)	57 (47-64)
Age ≥ 65 years, n (%)	31 (25)
Male, n (%)	82 (65)
Body mass index ≥30 kg/m², n (%)	67 (53)
Charlson comorbidity index, median (IQR)	2 (1-4)
Comorbidities, n (%)	
Cardiovascular diseases	72 (57)
Diabetes mellitus	51 (40)
Immunocompromised	17 (13)
Malignancy	8 (6)
Asthma/COPD	7 (6)
Chronic kidney disease	6 (5)
Location prior to OPAT, n (%)	
Hospital	78 (62)
Community	48 (38)
IV therapy prior to TLV, n (%)	76 (60)
Vancomycin[a]	48 (38)
Daptomycin[b]	28 (22)

Diagnosis

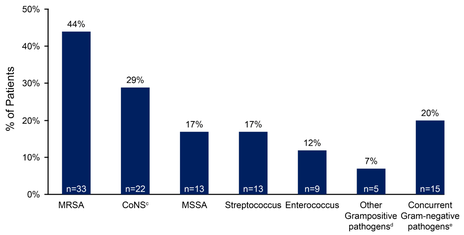
Figure 1. Infection Type (N=126)



Microbiology

- 110 organisms were identified; 98 were Gram-positive pathogens identified in 75 (60%) patients.

Figure 2. Microbiology (N=75)



Treatment Characteristics

Table 2. Treatment by Infection Type (N=126)

Infection Type	TLV dosage mg/day median (IQR)	TLV dosage mg/kg/day median (IQR)	Duration of therapy, days median (IQR)
All Infections	750 (750-750)	8 (7-10)	28 (14-40)
BJI	750 (750-750)	8 (6-9)	33 (14-41)
cSSSI	750 (750-750)	8 (7-9)	27 (12-36)
Bacteremia	750 (750-750)	9 (8-11)	27 (12-31)
Respiratory	750 (638-875)	10 (7-10)	23 (16-62)
cUTI	750	9	10
cIAI	750	8	84

Safety

- 38 adverse events were reported in 31 patients, all with resolution.

Table 3. Adverse Events (N=126)

Treatment-Related Adverse Events	No. of AEs n/N (%)
Increased serum creatinine	10/126 (7.9)
Nausea/vomiting	5/126 (4.0)
Fever/chills	4/126 (3.2)
Rash	4/126 (3.2)
Blood dyscrasias (leukopenia, neutropenia, thrombocytopenia)	3/126 (2.4)
Taste disturbance	3/126 (2.4)
Elevated blood pressure	2/126 (1.6)
Urticaria	2/126 (1.6)
Chest discomfort	1/126 (0.8)
Fatigue	1/126 (0.8)
Hypersensitivity reaction	1/126 (0.8)
Myalgia	1/126 (0.8)
Pruritis	1/126 (0.8)
Total Adverse Events	**38**

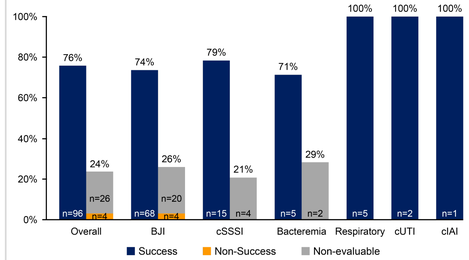
Table 4. Discontinuations (N=126)

Reasons for Early Discontinuations	No. of Patients n/N (%)
Adverse Events	28/126 (22.2)
Catheter Issues	3/126 (2.4)
Patient Choice/Convenience	3/126 (2.4)
Worsening Infection	3/126 (2.4)
Antibiotic not longer needed	1/126 (0.8)
Elective surgery	1/126 (0.8)
Expired, unrelated to telavancin	1/126 (0.8)
Total Early Discontinuations	**40**

- Primary adverse events leading to discontinuation were increase in serum creatinine (n=6), nausea/vomiting (n= 5), and rash (n=4).

Clinical Outcomes

Figure 3. Clinical Outcomes (N=126)



Clinical success was achieved in 76% of all patients and in 96% of evaluable patients

Success was achieved in 95% of evaluable patients with identified pathogens (N=66)

Discussion

This study provides real world data on use of TLV as both monotherapy and combination therapy in OPAT.

- There was a high clinical success rate (96%) in evaluable pts in multiple infection types.
- Success was high also in those with identified pathogens at treatment initiation.
- TLV was successfully used in a population heavily pre-treated with other intravenous antibiotics.
- Adverse events were the primary reason for early discontinuation of therapy and clinicians should be attentive to the variety of AEs.

Limitations

- The majority (60%) of patients received vancomycin or daptomycin prior to TLV OPAT therapy which may confound results.
- Follow-up cultures at end of therapy were not available for most patients for evaluation of microbiologic success.

Abbreviations and Footnotes

Abbreviations: AEs, Adverse events; BJI, bone and joint infections; cIAI; complicated intra-abdominal infection; cSSSI, complicated skin and skin structure infection; cUTI, complicated urinary tract infection; MRSA, Methicillin-resistant *Staphylococcus aureus*; CoNS, Coagulase-negative staphylococci; MSSA, Methicillin-sensitive *Staphylococcus aureus*, NOS, Not otherwise specified; TLV, telavancin.

Footnotes: [a]Included combination therapy with other agents (n=30); [b]Included combination therapy with other agents (n=26); [c]Included *Staphylococcus lugdunensis* (n=4/75, 5%); [d]Included Corynebacterium spp. (n=2), gram-positive cocci, NOS (n=2), *Staphylococcus aureus*, NOS (n=1); [e]Included Proteus spp. (n=4), Enterobacter spp. (n=3), Prevotella spp. (n=3), Pseudomonas spp. (n=3), Klebsiella spp. (n=2), Bacteroides fragilis (n=1)

References

1. Vibativ (telavancin) [package insert]. Nashville, TN: Cumberland Pharmaceuticals, Inc.; 2023.
2. Rodriguez GD, Polo L, Urban C, Turett G, Prasad N, Warren N, Tsapepas D, Ghimire R, Segal-Maurer S. Safety and Efficacy of Telavancin at an Outpatient Parenteral Antibiotic Therapy (OPAT) Unit in New York City. Open Forum Infect Dis. 2017 Oct 4;4(Suppl 1):S337.

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