Evaluation and Analysis of Oritavancin (ORI) in an Infectious Diseases Physician Owned Infusion Center (POIC)

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Revised Abstract

Background: Infections due to resistant gram-positive organisms have steadily increased with hospitalization being required for the care of complicated infections, severe sepsis and to monitor for acute decompensation. However, unnecessary hospitalization is costly. There is growing literature demonstrating a number of infections can be managed safely and effectively in the outpatient environment.

Methods: This study was a retrospective chart review to describe the efficacy and safety of ORI infused at a POIC between Jan 1 and Dec 31, 2016. All patients who completed oritavancin (ORI) infusion were included. Primary efficacy endpoint was infection outcome (cure, improved or failure) as determined by treating physician. Data collected included demographics, vital signs, comorbidities, prior antimicrobial exposure, concomitant anticoagulant use, hospitalization within prior 30 days, infection type, severity, site, pathogen, adverse events (AE) and final disposition.

Results: 120 patients were treated with ORI with 17 patients (14.2%) receiving ≥2 doses. The majority were male (61.7%); mean age was 56 years (range 21-90); most frequent comorbid conditions included hypertension (52.5%), diabetes (35.8%) and dyslipidemia (25.8%) with 95% of patients being hospitalized within the prior 30 days. Infection types included cellulitis (50%), wound (11%), diabetic foot infection (7%), abscess (11%), mixed cellulitis/abscess (9%), mixed cellulitis/osteomyelitis (6%), septic arthritis/bursitis (5%) and prosthetic joint infection (1%). Overall 95% of patients treated with ORI were either improved or cured. All patients received prior antibiotic therapy. 63 patients (52.5%) had positive cultures with the predominant pathogen being Staphylococcus aureus (52) with 33 being methicillin resistant (63.5%). ORI was generally well tolerated with only 9 patients (7.5%) reporting AEs.

Conclusions: Outpatient administration of ORI in a POIC was well tolerated, highly effective (95% improved or cure) and facilitated either hospital avoidance or rapid transition to outpatient care for previously hospitalized patients.

Introduction

Resistance among gram-positive organisms has steadily increased and is paralleled with a discouraging track record of new antibacterial development to address this unmet need (1)

Oritavancin (ORI) is a structurally modified derivative of vancomycin with potent, rapid, concentration dependent bactericidal activity with extensive tissue distribution and a long terminal half-life of 245 hours (2)

Due to ORI's spectrum of activity, lack of requirement for therapeutic drug monitoring, lack of need for a peripherally inserted central catheter (PICC) line and unique PK/PD properties, it may be an ideal candidate for managing gram-positive infections in outpatient settings, such as outpatient infusion centers (3)

Birmingham ID and Infusion is well-positioned to optimize patient care and satisfaction by using antimicrobials such as ORI to avoid unnecessary hospitalizations, facilitate a more rapid discharge of hospitalized patients and reduce hospital readmissions and has been previously demonstrated elsewhere (4-7)

The purpose of this study is to describe the clinical experience with ORI in a physician owned infusion center (POIC)

Methods

This was a retrospective review of medical records for all patients treated with ORI at Birmingham ID and Infusion from January 1 – December 31, 2016

De-identified patient data was collected using a standardized data collection form and included patient demographics, comorbid conditions, co-administration of anticoagulants, hospitalization within previous 30 days, prior antibiotic administration, infection description, infecting pathogen, adverse events and final disposition.

Final disposition (efficacy) was defined as:

Clinical Cure: complete resolution of the signs and symptoms of infection without the need for additional antibiotics

Clinical Failure: no improvement in signs and symptoms of infection and requiring rescue antimicrobial therapy

Clinical Improvement: partial resolution of the signs and symptoms of infection, but requiring additional antimicrobial administration for complete response

Lost to Follow Up: did not return to office for follow assessment

Safety assessment was conducted on all patients.

Results

120 patients contributed 121 infections between January 1 and December 31, 2016

Overall, 95% of patients treated with ORI were either improved or cured

ORI was generally well tolerated with few adverse events

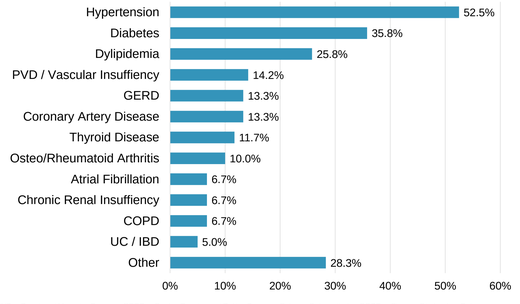
- Seventeen patients received two or more doses of ORI with a median of 21 days apart (range 11–285 days) depending upon patient response to first dose, type of infection and patient availability to return to infusion center. One patient with history of recurrent cellulitis was treated with ORI in March and then again in December when the cellulitis recurred accounting for the 285 day outlier.
- Eight patients received a single dose of ORI to replace the final two weeks of multi-week therapy (i.e., mop up therapy). 100% of patients in this cohort were cured.
- Nearly all (114/120; 95%) of patients receiving ORI were hospitalized prior to their ORI infusion. Coordination of care and transfer of the patient to the lower acuity outpatient facility at Birmingham ID and Infusion Center facilitated earlier discharge from the hospital compared to a patient receiving a full course of multi-day IV therapy as an inpatient. Though not measured in this study, this may have facilitated earlier return to patients' daily lives and increase patient satisfaction.
- Utilization of ORI in the Infusion center was able to completely avoid a hospitalization in 5% of patients.
- There were no bleeding or thrombotic adverse events in the patients concomitantly on anticoagulants.
- Overall, ORI was well tolerated with adverse events consistent with those seen in the clinical trials. Seven patients experienced mild severity adverse events of itching (n=4), nausea / vomiting (n=4), rash (n=1) and diarrhea (n=1). Two patients experienced a moderate severity adverse event of shortness of breath.
- After the first patient experienced shortness of breath, a protocol using either steroid ± diphenhydramine (for patients with family support to assist in driving home) was established.

Table 1: Patient Demographics

Variable	Value
Race	
White n/N (%)	110/120 (91.7%)
Black n/N (%)	9/120 (7.5%)
Latino n/N (%)	1/120 (0.8%)
Male gender, n/N (%)	74/120 (61.7%)
Mean age, years (range)	56 (21-90)
Mean weight, Kg (range)	95.2 Kg (52-175)
BMI*	
<25, n (%)	16 (13.3%)
25-30, n (%)	33 (27.5%)
>30, n (%)	62 (51.7%)
Unable to calculate	9 (7.5%)
Hospitalized within prior 30 days, n/N (%)	114/120 (95%)
Concomitant anticoagulant use, n/N (%)	13/120 (10.8%)

* Missing either weight (n=8) or height (n=1) data needed for BMI calculation

Figure 1: Comorbid conditions



PVD = Peripheral Vascular Disease; GERD = Gastro-Esophageal Reflux Disease; Osteo = Osteoarthritis; COPD = Chronic Obstructive Pulmonary Disease; UC / IBD = Ulcerative Colitis / Irritable Bowel Disease

Other = Ischemic Heart Disease, Congestive Heart Failure, Neuropathy, Myocardial Infarction, Asthma, Gout, Lupus, Fibromyalgia, Cerebral Vascular Accident, Stroke

Figure 2: Primary Sites of Infection

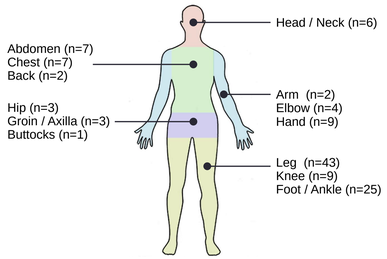
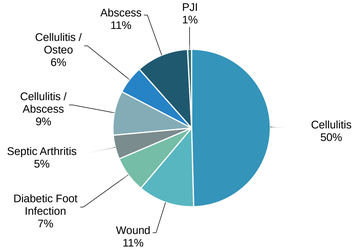
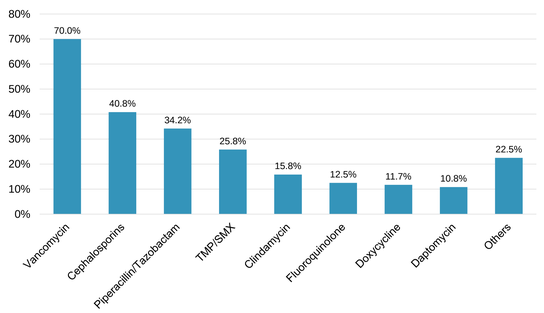


Figure 3: Types of Infection



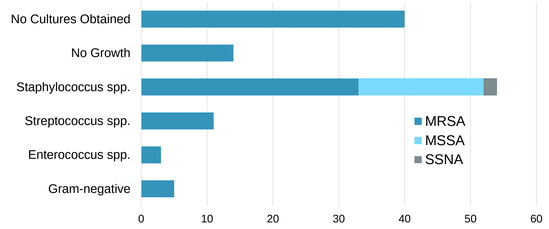
* One patient had two distinct cases of cellulitis in different body locations separated by a 4 month timeframe

Figure 4. Prior Antibiotic Exposure



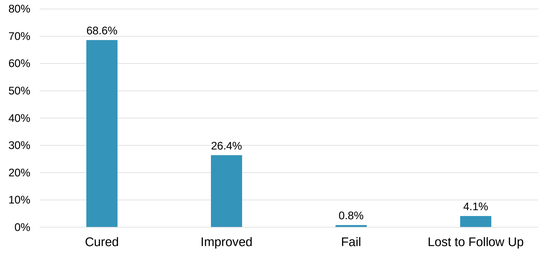
TMP/SMX = Trimethoprim/Sulfamethoxazole
*Others: BL/BLI (n=7); PCN (n=5); Carbapenem (n=5); Linezolid (n=4); Rifampin (n=2); Aztreonam (n=2); Aminoglycoside (n=1); Metronidazole (n=1)

Figure 5. Culture results



MRSA = Methicillin resistant Staphylococcus aureus; MSSA = Methicillin susceptible Staphylococcus aureus; SSNA = Staphylococcus species non-aureus
NOTE: 63 patients had positive cultures, some with multiple pathogens. In cases where gram-negative pathogens were involved, gram negative antibiotic coverage was added.

Figure 6. Final Disposition



Conclusions

Outpatient administration of ORI in a POIC was well tolerated, highly effective (95% improved or cured) and facilitated either hospital avoidance or rapid transition to outpatient care for previously hospitalized patients

Birmingham ID and Infusion provides the most innovative technology, latest advancement in treatment options and same day evaluation to patients with moderate/severe infections in Birmingham and surrounding communities in a convenient, comfortable and friendly outpatient setting.

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Disclosures

No disclosures

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