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COMPARISONS OF 30-DAY ADMISSION AND 30-DAY TOTAL HEALTHCARE COSTS BETWEEN PATIENTS WHO WERE TREATED WITH ORITAVANCIN (ORI) OR VANCOMYCIN (VAN) FOR A SKIN INFECTION IN THE OUTPATIENT SETTING

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ABSTRACT

Background: Hospital admission is a key cost driver among patients with ABSSSI. Data suggests that many ABSSSI patients are unnecessarily hospitalized and can be effectively and safely managed as an outpatient (OP) at a substantially lower cost. ORI is a single-dose treatment that has the potential to shift care from the inpatient to the OP setting in selected patients. In phase III trials, a single dose of ORI had comparable efficacy and safety to twice daily IV VAN for 7-10 days in ABSSSI patients treated in the OP setting. This study sought to compare the 30-day hospital admission rates and mean (standard deviation (SD)) healthcare costs among ABSSSI patients who received ORI or VAN in the OP setting.

Methods: Retrospective cohort analysis of the Truven Health MarketScan® Databases in 2016. Inclusion criteria: age >18 yrs; prescription/medical claim for ORI or VAN in OPs (index day (d)); a non-diagnostic medical claim with a diagnosis of skin infection ≤ 7 d prior and 3 d after the index d; no hospitalization in previous 3 d of index d; ≥ 180 d of continuous enrollment in medical/pharmacy benefits prior index d; ≥ 60 days of continuous enrollment in medical/pharmacy benefits post index d. Outcomes: 30 days hospital admission and 30 day total healthcare costs.

Results: During the study period, 120 and 6695 pts who received ORI and VAN, respectively, met inclusion criteria. Groups were well balanced at baseline (table). Patients who received ORI had a significantly lower 30-day admission rate vs. patients who received VAN (5.8% vs. 16.2%, respectively, p=0.002). Mean (SD) cost 30 d post index d were comparable between ORI and VAN patients ($10,096 (8865) vs. $12,779 (28,773), respectively, p=0.3).

Conclusion: Results suggest ORI provides a single-dose alternative to multi-dose VAN for treatment of ABSSSI in OPs and may result in lower 30-day hospital admission rates.

INTRODUCTION

- Hospital admission is a key cost driver among patients with ABSSSI. Data suggests that many ABSSSI patients are unnecessarily hospitalized and can be effectively and safely managed as OPs at a substantially lower cost. [1-3]
- Oritavancin (ORI) is a single-dose treatment that has the potential to shift care from the inpatient to the OP setting in selected patients.
  - In phase III trials (SOLO I/II) [4,5], a single dose of ORI had comparable efficacy and safety to twice daily IV VAN for 7-10 days in ABSSSI patients who were treated in the OP setting. [6]
  - In a recently published real-world experience of 112 patients, only 11% of ABSSSI patients were hospitalized at the time of ORI administration. Clinical and microbiologic outcomes and safety were similar to that observed in the SOLO trials despite a more elderly patient population with multiple comorbid conditions. [7]
- This study sought to compare the 30-day hospital admission rates and mean (standard deviation (SD)) healthcare costs among ABSSSI patients who received ORI or VAN as OPs.

METHODS

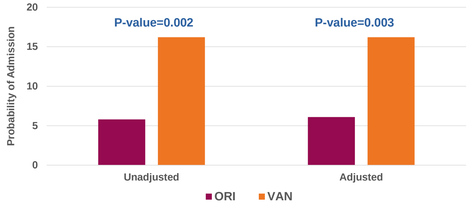
- **Study Design and Population**
  - Retrospective cohort analysis of the Truven Health MarketScan® Databases between 01/01/2016 and 12/31/2016
    - Two *MarketScan® Research Databases* (MarketScan Commercial and Medicare Supplemental Database) were used for this study.
- **Inclusion criteria**
  - Age >18 years
  - ≥ 180 d of continuous enrollment in medical/pharmacy benefits prior index day
  - ≥ 60 days of continuous enrollment in medical/pharmacy benefits post index day
  - Prescription or medical claim for ORI or VAN in an OP setting
    - The date of the earliest of such claims was defined as the index date
  - Non-diagnostic medical claim with a diagnosis of skin infection ≤ 7 day prior and 3 day after the index day
    - Skin infection diagnosis codes (ICD-10-CM) fitting the below categories were included: cellulitis/abscess; surgical/traumatic wound infection, and other skin infections
  - No hospitalization in the 3 days prior to index date
- **Pre-Index Measures**
  - Baseline demographic and clinical characteristics
  - Select skin infection characteristics
  - Select treatment patterns
  - All-cause and skin-related health utilization and costs
- **Post-Index Outcomes**
  - Hospital admission in the 30 days post-index
  - Total healthcare costs in the 30 days post-index
    - Includes: Inpatient, emergency room, outpatient medical services (including physician office visits, labs, radiology, and debridement and irrigation of wounds), and outpatient pharmacy costs (antibiotics and IV administration costs)
- **Statistical Analysis Plan**
  - A series of bivariate analyses were conducted to compare all baseline study variables and the following:
    - Treatment groups (ORI vs. VAN)
    - 30-day inpatient admission (yes vs. no)
    - Total 30-day healthcare costs
  - Multivariable models for 30-day all-cause inpatient admission (logistic regression) and 30-day healthcare costs (generalized linear models with gamma-distributed error and log link function) were conducted.
    - Any variable that is associated with outcome of interest in bivariate analysis with a P-value<0.05, prevalence of at least 5% in the study population, and measured during baseline or on index date was considered for model entry consideration.
    - Treatment (ORI and VAN) were forced into models

RESULTS

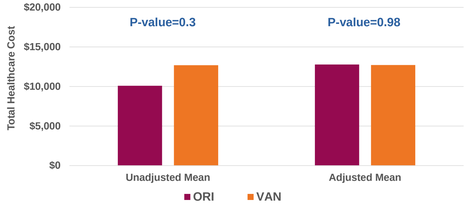
Baseline Comparisons Between ORI and VAN

	ORI N=120	VAN N=6,695	P value
Demographics			
Age (Mean, SD)	54.9 (16.8)	52.9 (16.5)	0.1832
Male	56.7%	55.0%	
Female	43.3%	45.0%	
Primary payer (%)			0.5443
Commercial	77.5%	79.7%	
Medicare	22.5%	20.3%	
Pre-Clinical Characteristics			
Deyo Charlson comorbidity index (mean, SD)	1.3 (1.8)	1.5 (2.2)	0.4141
Comorbid Conditions (%)			
• Obesity	25.0%	19.0%	0.1003
• Diabetes without chronic complication	22.5%	26.2%	0.3607
• Depression	17.5%	15.4%	0.5248
• Diabetes with chronic complications	15.0%	15.5%	0.8833
• Chronic pulmonary disease	14.2%	10.7%	0.2260
• Renal failure	13.3%	11.8%	0.6061
• Cancer (non-leukemia)	13.3%	10.5%	0.3110
• Peripheral vascular disease	8.3%	7.2%	0.6247
• Connective tissue disease	6.7%	9.1%	0.3502
• Cerebrovascular disease	5.0%	4.2%	0.6771
• Congestive heart failure	3.3%	6.5%	0.1602
• Substance abuse	3.3%	3.9%	1.0000
• Coronary artery disease	2.5%	2.1%	0.7391
• Leukemia	1.7%	0.7%	0.2068
• Hemiplegia or paraplegia	0.8%	0.8%	0.6183
• Mild liver disease	0.8%	0.8%	1.0000
• Peptic ulcer disease	0.8%	0.7%	0.5673
• AIDS/HIV	0.8%	0.4%	0.3816
• Myocardial infarction	0.0%	2.2%	0.1161
• Dementia	0.0%	1.5%	0.4231
• Moderate or severe liver disease	0.0%	0.4%	1.0000
• Renal disease without renal failure	0.0%	0.1%	1.0000
Prior Antibiotics			
Beta-lactam agent	50.0%	49.9%	0.9780
Fluoroquinolone	26.7%	20.3%	0.0871
Lincosamide	22.5%	14.2%	0.0097
Tetracycline	22.5%	14.1%	0.0089
Lipoglycopeptide (daptomycin)	11.7%	0.2%	<0.0001
Glycopeptide	10.8%	3.7%	0.0006
Macrolide	10.0%	10.5%	0.8593
Oxazolidone	4.2%	1.0%	0.0095
Other	31.7%	26.1%	0.1725
Type of skin infection at skin infection diagnosis			
Cellulitis/abscess	90.0%	86.6%	0.2722
Wound infection	10.0%	14.4%	0.1715
Other skin infections	17.5%	14.0%	0.2736
Site of infection during skin diagnosis			
Lower extremity	58.3%	42.0%	0.0003
Upper extremity	16.7%	19.2%	0.4783
Limb, unspecified	16.7%	10.1%	0.0178
Abdomen/Pelvis	11.7%	14.0%	0.4629
Chest/Trunk	3.3%	3.9%	1.0000
Unspecified	47.5%	44.6%	0.5266
Infection severity at skin infection diagnosis (N, %)			
Life-threatening	16 13.3%	841 12.6%	0.8005
Non-life-threatening but with systemic symptoms	17 14.2%	1279 19.1%	0.1719
Neither life-threatening nor systemic symptoms	91 75.8%	4994 74.6%	0.7570
Pre-Healthcare Resource Utilization			
Prior inpatient hospitalization (%)	43.3%	36.1%	0.1002
Prior ER visit (%)	43.3%	46.1%	0.5497
Prior outpatient service (%)	98.3%	95.4%	0.1263
Patients with pharmacy claim (%)	95.0%	92.5%	0.3067
Total Healthcare Costs (Mean, (SD))	$31,280 (47,354)	$35,183 (74,109)	0.5655
Median (IQR)	$16,308 (29,290)	$10,389 (36,902)	

Comparison of All-Cause 30-Day Hospital Admission Between ORI and VAN



Comparison of 30-Day Total Healthcare Costs Between ORI and VAN



Predictors of 30-Day Hospital admission in Multivariate Analysis

Patient Characteristic	Odds Ratio	Lower 95% CL	Upper 95% CL	P-value
ORITAVANCIN	0.31	0.14	0.67	0.0033
VANCOMYCIN	1.00	Reference		
Decade increase in age	0.98	0.94	1.03	0.3602
Charlson Comorbidity Index (one additional point)	1.06	1.03	1.10	0.0003
Any inpatient service during baseline	0.70	0.53	0.92	0.0109
10% increase in baseline total cost	1.003	1.000	1.007	0.0965
Life-threatening condition	5.80	4.90	6.87	<.0001
Non-life-threatening condition	2.33	1.94	2.81	<.0001
Neither life threatening nor systemic symptom	1.00	Reference		
Cellulitis/abscess skin infection diagnosis	1.20	0.94	1.54	0.1444
Wound infection diagnosis	1.49	1.20	1.85	0.0004
Other skin infection diagnosis	1.25	1.02	1.54	0.0316
Upper extremity infection site	1.06	0.88	1.28	0.5261
Abdomen/pelvis infection site	1.22	1.00	1.48	0.0486

Predictors of 30-Day Healthcare Cost in Multivariate Analysis

Patient Characteristic	Cost Ratio	Lower 95% CL	Upper 95% CL	P-value
ORITAVANCIN	0.998	0.837	1.191	0.9849
VANCOMYCIN	1.000	Reference		
Decade increase in age	0.96	0.94	0.97	<.0001
Charlson Comorbidity Index (one additional point)	1.09	1.08	1.11	<.0001
Any inpatient service during baseline	0.84	0.76	0.92	0.0001
10% increase in baseline total cost	1.010	1.009	1.011	<.0001
Life-threatening condition	2.67	2.49	2.87	<.0001
Non-life-threatening condition	1.28	1.19	1.37	<.0001
Neither life threatening nor systemic symptom	1.00	Reference		
Cellulitis/abscess skin infection diagnosis	0.93	0.85	1.02	0.1399
Wound infection diagnosis	1.11	1.02	1.21	0.0110
Other skin infection diagnosis	1.19	1.11	1.29	<.0001
Upper extremity infection site	0.92	0.86	0.97	0.0055
Abdomen/pelvis infection site	1.09	1.02	1.17	0.0153

CONCLUSION

- Results suggest ORI provides a single-dose alternative to multi-dose vancomycin for treatment of ABSSSI in OP and may result in lower 30-day hospital admission rates.
  - Patients who received ORI had a significantly lower 30-day admission rate vs. patients who received vancomycin (5.8% vs. 16.2%, respectively, p=0.002).
  - Mean (SD) cost 30 d post index d were comparable between ORI and VAN pts ($10,096 (8865) vs. $12,779 (28,773), respectively, p=0.3).
- Limitations include those associated with administrative databases, including uncontrolled comorbid conditions and data which may have not been coded accurately or fully captured. In addition, related healthcare costs were based on paid amounts of adjudicated claims, including insurer and health plan payments as well as patient cost-sharing in the form of copayment, deductible, and coinsurance; these costs may not be generalizable to all healthcare plans.
- Future randomized multi-center comparator studies are needed to validated these findings. Specific predictors related to hospital admission and total cost should be tested prospectively.

REFERENCES

1. Lodise TP et al. Hospital admission patterns in adult patients with skin and soft tissue infections: Identification of potentially avoidable hospital admission through a retrospective database analysis. Hosp Pract. 2015;43(3):137-43.
2. Talan DA et al. Factors associated with decision to hospitalize emergency department patients with skin and soft tissue infection. *West J Emerg Med.* 2015;16(1):89-97.
3. Nathwani D et al, Pan-European early switch/early discharge opportunities exist for hospitalized patients with methicillin-resistant Staphylococcus aureus complicated skin and soft tissue infections. *Clin Microbiol Infect.* 2014;20(10):993-1000.
4. Corey GR et al. Single-dose oritavancin in the treatment of acute bacterial skin infections. N Engl J Med. 2014; 370:2180–90.
5. Corey GR et al. Single-dose oritavancin versus 7–10 days of vancomycin in the treatment of Gram-positive acute bacterial skin and skin structure infections: the SOLO II noninferiority study. Clin Infect Dis. 2015; 60:254–62.
6. Lodise TP et al. Efficacy and safety of oritavancin relative to vancomycin for patients with acute bacterial skin and skin structure infections (ABSSSI) in the outpatient setting: Results from the SOLO clinical trials. Open Forum Infect Dis. 2017; doi:10.1093/ofid/ofw274.
7. Redell M et al. A real-world patient registry for oritavancin demonstrates efficacy and safety consistent with the phase 3 SOLO program. Open Forum Infect Dis. 2018; doi:10.1093/ofid/ofy051.