Omadacycline for Skin and Soft Tissue Infections: A Multicenter Retrospective Analysis of Efficacy and Safety in Real-World Clinical Practice

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Background

- Skin and soft tissue infections (SSTIs) present significant challenges in clinical practice, especially due to the growing issue of antibiotic resistance[1]
- Omadacycline a first-in-class aminomethylcycline, provides broad-spectrum activity and is available in both oral and intravenous formulations[2]
- Omadacycline was approved in 2018 for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) and community acquired bacterial pneumonia[2]
- Studies assessing omadacycline for treating SSTIs in real-world setting are lacking

Study objective:
This study aims to assess the real-world effectiveness and safety of omadacycline in treating SSTIs.

Methods

Study design

- A multicenter, retrospective, observational, descriptive analysis of patients treated with omadacycline between July 2019 and December 2023

Inclusion

- Age ≥ 18 years
- Received omadacycline for ≥ 48 hours
- Patients with a SSTI

Outcomes

- **Primary outcome:** clinical cure, defined as the absence of any signs or symptoms of infection during treatment or within 14 days after discontinuation of omadacycline
- **Secondary outcome**: Incidence of adverse effects related to omadacycline

Analysis

- Mean (standard deviation [SD]), median (interquartile range [IQR]), n (%), and comparative analyses were performed with SPSS v. 29.0 (IBM Corp, Armonk, NY, USA)

Results

Table 1. Baseline demographics [a]

	Overall (n= 24)
Age, median (IQR)	63 (48.0–70.3)
Caucasian	18 (75.0)
Female	12 (50.0)
BMI (kg/m^2), median (IQR)	35.5 (26.1–45.3)
Obesity (BMI ≥30 kg/m^2)	14 (58.3)
Creatinine clearance (mL/min), median (IQR)	65.8 (35.1 – 119.5)
Treatment setting	
Strictly inpatient	9 (37.5)
Strictly outpatient	12 (50.0)
Inpatient, then outpatient	3 (12.0)
Charlson comorbidity index, median (IQR)	6.5 (2.0 – 9.3)
Immunosuppression factors[b]	6 (25.0)
Clinical presentation	
WBC >12 x 10^9/liter or < 4 x 10^9/liter or >10% bands	10 (41.7)
Heart rate >90 beats/min	10 (41.7)
Respiratory rate >20 breaths/min	5 (20.8)
Temperature <35.6°C or >38°C	4 (16.7)
≥2 SIRS criteria	8 (33.3)

[a] data presented as n (%) or otherwise specified.
[b] Absolute neutrophil count <500, CD4<200 or AIDS defining illness, splenectomy, solid organ transplant in past 90 days, bone marrow transplant in past 90 days, cytotoxic chemotherapy in past 90 days, high dose steroids (>200 mg hydrocortisone for ≥2 weeks or equivalent)

Table 2. Infection and treatment characteristics

	Overall (n= 24)
Culture specimen	
Wound	15 (62.5)
Tissue	7 (29.2)
Blood*	1 (4.2)
Polymicrobial infection	15 (62.5)
Surgical consultation	16 (66.7)
Planned surgical intervention for source control	
Debridement	9 (37.5)
Incision and drainage	7 (29.2)
Amputation	1 (4.2)
None	11 (45.8)
Omadacycline regimen	
Loading dose	
200mg intravenous single dose	8 (33.3)
450mg oral once daily for two days	7 (33.3)
300 mg oral twice daily for one day	1 (4.2)
No loading dose	8 (33.3)
Maintenance dose	
100mg intravenous once daily	7 (29.2)
300mg oral once daily	16 (66.7)
300mg oral twice daily	1 (4.2)
Type of treatment	
Targeted	15 (62.5)
Empiric	7 (29.2)
Suppression	3 (12.5)
Duration of omadacycline therapy, days, median (IQR)	13.5 (6.3 – 33.0)

abbreviations: IQR, interquartile range; PICC, peripherally inserted central catheter; SIRS, systemic inflammatory response syndrome; WBC, white blood cell
*The isolated pathogen from blood was vancomycin resistant *Enterococcus faecium*

Results

Figure 1. Comorbidities (%)

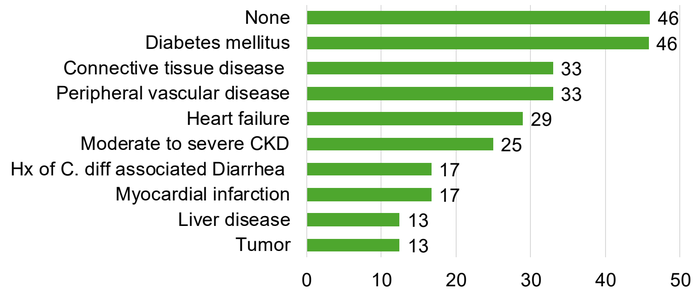

Figure 2. Type of skin and soft tissue infection (%)

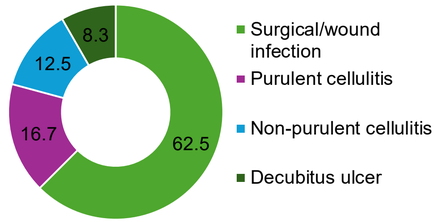

Figure 3. Reasons for omadacycline utilization (%)

Figure 4. Pathogens omadacycline used for (%)

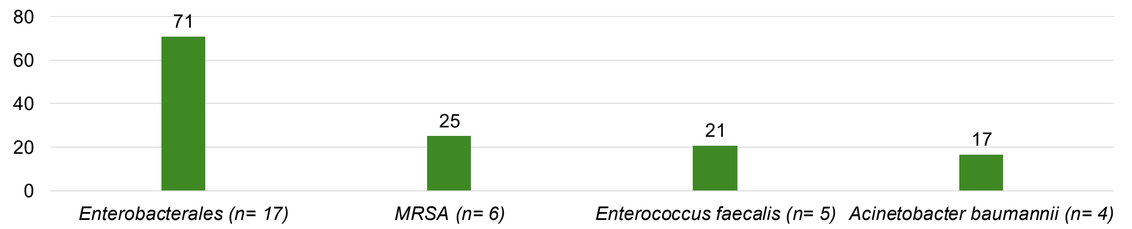

Table 3. Clinical outcomes

	Overall (n = 24)
Clinical cure	21 (87.5)
Adverse effects	
Gastrointestinal intolerance	2 (8.3)
Electrolyte disturbance	1 (4.2)
Discontinuation secondary to an adverse effect	0 (0.0)

Conclusions

- Omadacycline demonstrated promising efficacy and tolerability in treating SSTIs, with a high clinical cure rate of 87.5% and minimal adverse effects.
- These results are encouraging and in line with the results of the registrational trials. Larger real-world studies are warranted.

References: 1. Eisenstein BI. Treatment challenges in the management of complicated skin and soft-tissue infections. Clin Microbiol Infect. 2008 Mar;14 Suppl 2:17-25. doi: 10.1111/j.1469-0691.2008.01922.x. PMID: 18226086. 2. Gallagher JC. Omadacycline: amodernized tetracycline. Clin Infect Dis. 2019;69:S1-5.
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