Omadacycline for the Treatment of Extra-Pulmonary Mycobacterial Infections: A Single-Center Retrospective Review

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INFECTIOUS DISEASES

Background

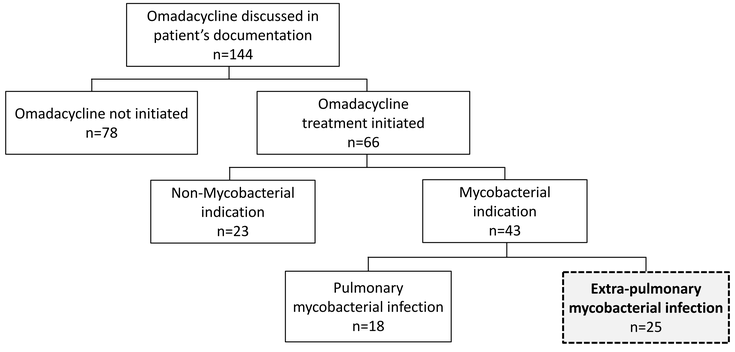
- Infections due to **rapidly growing mycobacteria (RGM)** such as *M. abscessus*, *M. chelonae* and *M. fortuitum* typically require long and toxic multidrug regimens.
- Complex resistance patterns and limited oral options have historically contributed to suboptimal efficacy.
- Approved in 2018, the next generation tetracycline **omadacycline** is a new option for management of RGM infections.
- We report here our clinical experience with the use of omadacycline for RGM extra-pulmonary infections within the Mass General Brigham (MGB) system.

Purpose

- To assess the tolerability and treatment outcomes of omadacycline used for patients with extra-pulmonary RGM infections

Methods

- Electronic ambulatory notes in the MGB Research Patient Data Registry (RPDR) from 2012-2023 were queried / filtered by the term 'omadacycline'.
- Manual chart review was conducted for individuals treated for extra-pulmonary RGM infections, defined as those with SSTIs, bone/joint infections, or disseminated infections.

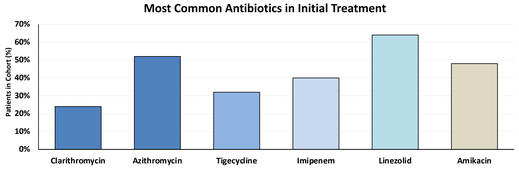


- Process identified 25 individuals with ongoing or completed courses of omadacycline. Tolerability and outcomes data was extracted via chart review

Results

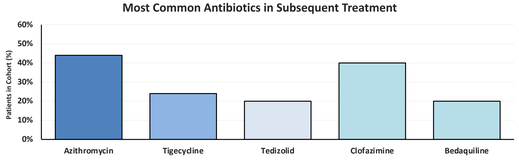
Demographic Characteristics	
Age (median; mean, SD)	50; 51.6 (18.1)
BMI (median; mean, SD)	25.5; 26.7 (4.2)
Sex at Birth	
Male	48% (12)
Female	52% (13)
Race or Ethnicity*	
White	76% (19)
Black or African American	4% (1)
Hispanic, Latino, or Spanish	32% (8)
Unspecified	4% (4)
* Based on 2020 US Census categories; 4 individuals identified with more than one category	
Mycobacterial Species	
M. abscessus	64% (16)
M. chelonae	32% (8)
M. immunogenum	4% (1)
Site of Infection	
Skin & Soft Tissue	72% (18)
Bone & Joint	16% (4)
Disseminated	12% (3)

- **Initial** antibiotic regimens for patients in this cohort included a median of 3 different agents (range: 2-5, mean=3.2). The most commonly selected medications include azithromycin, linezolid, amikacin, and imipenem.



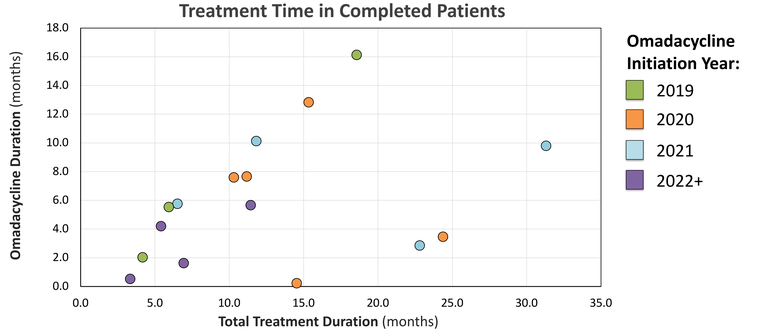
Other Initial Abx (<20%)
Moxifloxacin
Ciprofloxacin
Levofloxacin
Cefoxitin
Doxycycline
TMP-SMX
Clofazimine

- **Subsequent**, outpatient antibiotic regimens for patients in this cohort included a median of 3 agents (range: 1-7, mean=3.0), with some of the most common (non-omadacycline) agents including azithromycin and clofazimine.



Other subsequent Abx (<20%)
Clarithromycin
Linezolid
Moxifloxacin/Ciprofloxacin
Amikacin
Imipenem
Meropenem
TMP-SMX

- Most patients (88%) received omadacycline as part of **subsequent treatment.** Median delay time between start of initial treatment and start of omadacycline in these patients was 2.4 months (range= 0.7-21.2).
- 17 patients (68%) had completed omadacycline regimens as of April 2023. Among these cases, the **median duration of omadacycline use was 5 months** (range=0.25-16).



- Adverse effects, as summarized below, were noted in 6 (24%) cases. **No patients were permanently discontinued** due to the severity of these effects.

	Nausea	GI Upset	Other*	None
# of Patients	4 (16%)	1 (4%)	1 (4%)	19 (76%)

* One regimen (labeled 'Other') was paused due to an elevated lipase level. Whether this was related to omadacycline is unknown. Patient subsequently restarted omadacycline without incident.

- 16/17 (94%) of patients who completed an omadacycline-containing regimen were judged to have resolved their infections.

Conclusion

- Omadacycline is an increasingly common antibiotic in the treatment of extra-pulmonary RGM infections. Use in multidrug regimens appears generally **well-tolerated,** and is associated with **resolution of infection**
- Noted barriers to use include insurance coverage and long treatment durations.
- Limitations of this study include its retrospective nature and evaluation within a single health system.
- To our knowledge, this is the largest series on omadacycline in non-pulmonary RGM infections reported to-date. Additional analysis of omadacycline use among other clinical subpopulations (ie. pulmonary RGM cases) is forthcoming.

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