Early Experiences with Eravacycline for the Treatment of Pneumonia Caused by Extensively Drug-Resistant Acinetobacter baumannii: A Case Series and Review of Relevant Literature

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Abstract

Acinetobacter baumannii is perhaps the most clinically relevant species of Acinetobacter given its predisposition to develop drug resistance due to numerous intrinsic and acquired resistance mutations, including the production of chromosomally encoded AmpC beta-lactamases, overexpression of efflux pumps, and acquisition of carbapenemases. Treatment of severe infection with A. baumannii frequently relies on combination therapy, often incorporating tigecycline. Eravacycline is a novel tetracycline antibiotic with enhanced activity against many gram-negative bacilli, including carbapenem-resistant Enterobacterales and carbapenem-resistant A. baumannii. Compared to its ancestor tigecycline, eravacycline demonstrates more potent in vitro activity against gram-negative bacilli and has enhanced penetration into lung tissue, making it a more ideal option for the treatment of respiratory tract infections caused by gram-negative organisms. Here, we present a series of three patients who received eravacycline for lower respiratory tract infections caused by extensively drug-resistant strains of A. baumannii.

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INTRODUCTION

Acinetobacter, a genus comprised of over 30 genomic species, are aerobic, gram-negative, coccobacilli which are frequently linked to hospital-acquired and healthcare-associated infections [1]. Treatment options for infections with *Acinetobacter* spp. are limited, given numerous intrinsic and acquired resistance mutations, including production of chromosomally-encoded AmpC beta-lactamases, overexpression of efflux pumps, and acquisition of carbapenemases [2]. Perhaps the most clinically relevant species of *Acinetobacter* is *Acinetobacter baumannii*, given its predisposition to develop multidrug (MDR; defined as non-susceptibility to ≥1 agent in ≥3 antimicrobial categories) and extensive drug-resistance (XDR; defined as non-susceptibility to ≥1 agent in all but ≤2 antimicrobial categories) [3]. Over the last several years, there has been an increased observance of XDR isolates, particularly in healthcare institutions [4]. Given the lack of clinical trial data, treatment of infections with XDR *A. baumannii* often relies on clinical experience and data from case reports,

often utilizing combination therapy.

Eravacycline (ERV) is a novel tetracycline (i.e. fluorocycline) approved by the Food and Drug Administration in 2018 for the treatment of complicated intra-abdominal infections [5-6]. Substitution of a fluorine atom at C-7 and a pyrrolidinoacetamido group at the C-9 position in the tetracycline D-ring increase stability against tetracycline-specific resistance mechanisms, including efflux mediated by *tet*(A), *tet*(B), *tet*(K), and ribosomal protection encoded by *tet*(M) and *tet*(Q) [7]. This chemical modification increases activity against gram-negative bacilli that produce the following: extended-spectrum beta-lactamase (ESBL) and AmpC cephalosporinases (AmpC), Ambler Class A (i.e. Klebsiella pneumoniae carbapenemase [KPC]), Class B (i.e. NDM [New Delhi metallo-beta-lactamase]), and Class C (i.e. OXA-48 [oxacillinase] carbapenemases. Eravacycline possesses activity against many gram-negative bacilli, including carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *A. baumannii* (CRAB), and carbapenem-resistant *Stenotrophomonas maltophilia*. It also possesses activity against some gram-positive organisms including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci [7-9].

Here, we present the first case series of patients with lower respiratory tract infections caused by XDR *A. baumannii* who were treated with eravacycline. The main characteristics of the three cases can be found in Table 1.

CASE 1

A 67-year-old male with past medical history (PMH) of SARS-CoV-2 pneumonia, end-stage renal disease on hemodialysis, anxiety, anemia, hypertension, hyperlipidemia and Type 2 diabetes mellitus presented from his nursing home due to low hemoglobin. The patient was found to be tachycardic and febrile to 101.3°F, with a white blood cell (WBC) count of 22.9 K/uL. Chest x-ray (CXR) revealed right lower lobe infiltrates and a diagnosis of healthcare-associated pneumonia (HCAP) was made. Blood and urine cultures were obtained and he was started on vancomycin and meropenem. On Day 4 of hospitalization, sputum cultures were obtained due to worsening leukocytosis and vancomycin was discontinued as the patients MRSA nares screen returned negative. By Day 6, fevers were noted to be worsening. On Day 8, sputum culture revealed pandrug-resistant A. baumannii. Polymyxin B and eravacycline 1 mg/kg twice daily were initiated and additional susceptibilities for polymyxin B were requested, which returned as sensitive the following day. The patient subsequently expired on Day 10 of hospitalization due to septic shock.

CASE 2

A 74-year-old male with past medical history of SARS-CoV-2 pneumonia, chronic obstructive pulmonary disease, hypertension and dementia presented from his nursing home with shortness of breath and fever. A diagnosis of HCAP was made after CXR revealed near complete consolidation of the left lung, and the patient was started on meropenem and vancomycin. Given persistent fevers, sputum cultures were obtained on Day 5 of hospitalization, which returned on Day 8, revealing XDR *A. baumannii*, sensitive only to polymyxin B. Polymyxin B and rifampin were added in combination with meropenem, and after 14 days, antibiotics were stopped due to clinical cure. On Day 28 of hospitalization, the patient began to have low-grade fevers with worsening leukocytosis, with new-onset left-shift. Eravacycline 1 mg/kg twice daily and polymyxin B were initiated. Sputum cultures were obtained which revealed persistence of XDR *A. baumannii*. Although he defervesced, the patient continued to have worsening leukocytosis; tachycardia and tachypnea were also noted. Given his poor response to antibiotics and the absence of fevers, the decision was made to discontinue all antibiotics on Day 36 and monitor the patient. Ultimately, he remained afebrile and was discharged back to his nursing home on Day 42 of hospitalization.

CASE 3

A 79-year-old female with PMH of SARS-CoV-2 pneumonia, hypertension, gout, chronic kidney disease and ventilator-dependent respiratory failure originally presented from her assisted living facility with fatigue and loss of appetite. Her initial hospital course was complicated by ventilator-associated bacterial pneumonia (VABP) caused by *Klebsiella oxytoca* and extended-spectrum beta-lactamase producing *Escherichia coli* and *C. albicans* fungemia, for which she received appropriate treatment. On Day 54 of hospitalization, chest CT was performed due to the presence of increased purulent secretions and new-onset leukocytosis. A right upper lobe abscess was noted, and the patient was started on meropenem and tobramycin inhalation. On Day 58, sputum cultures were obtained due to new-onset fevers, which returned on Day 61, revealing XDR *A. baumannii* sensitive only to polymyxin B. Polymyxin B and rifampin

were initiated while tobramycin and meropenem were discontinued. By Day 67, WBC count had normalized and the patient remained afebrile. On Day 74, given new-onset leukocytosis, meropenem was restarted and rifampin was discontinued. Despite initiation of meropenem, leukocytosis continued to worsen. Bronchoalveolar lavage (BAL) was performed on Day 76, and eravacycline 1 mg/kg twice daily was added and meropenem was stopped. BAL fluid returned on Day 79, revealing persistence of XDR *A. baumannii*, sensitive only to polymyxin B and ampicillin/sulbactam. Polymyxin B was discontinued and ampicillin/sulbactam was initiated. The patient continued to have worsening leukocytosis and all antibiotics were ultimately discontinued on Day 86 of hospitalization due to lack of treatment response. The patient ultimately expired on Day 88 of hospitalization due to cardiac arrest secondary to uremia.

REVIEW OF PUBLISHED LITERATURE

Overall data regarding the use of eravacycline for the treatment of pulmonary infections is limited, and data on eravacycline for treatment of infections with *A. baumannii* is scarce. To date, no case reports on eravacycline for the treatment of XDR *A. baumannii* have been published. Van Hise et al. [10] reported on 50 patients who received eravacycline during inpatient acute care admission or as part of outpatient antibiotic therapy. Clinical resolution in patients with respiratory infections was 92%, while clinical resolution was noted in 100% of patients (n=7) with *A. baumannii* infection. In a retrospective observational study conducted by Sara et al. [11], 35 patients received eravacycline. 30-day survival in patients with respiratory infections was 70%. Seven patients had infection with *A. baumannii* – 29% of which were MDR strains. 29% of patients with *A. baumannii* infection did not meet 30-day survival, one of whom was being treated for a respiratory infection. Molina et al. [12] reported the clearance of a polymicrobial bacteremia secondary to severe skin and soft tissue infection. One of the isolated organisms was CRAB, and the patient received eravacycline as part of combination therapy.

COMPARISON AMONGST NOVEL TETRACYCLINES

Tigecycline was historically utilized as part of salvage regimens for severe infections caused by CRE and CRAB. At FDA-approved doses, tigecycline achieves low concentrations in the serum and epithelial lining fluid (ELF) [13]. To combat this, high-dose tigecycline has been utilized by clinicians; however, this is limited by significant gastrointestinal side effects including nausea and vomiting. Omadacycline, a novel tetracycline, has modest activity against CRE and CRAB when compared to its predecessor tigecycline. It achieves lower concentrations in ELF, limiting its use for respiratory infections [13]. Minocycline, although less-broad when compared to tigecycline and omadacycline, has in vitro activity against many strains of CRAB [14]. Use of this agent is limited by high drug costs. Although available in an oral formulation which is significantly cheaper, many patients with CRAB are seriously ill and require intravenous therapy.

Eravacycline has a broad spectrum of activity similar to tigecycline. Compared to tigecycline, eravacycline demonstrates more potent in vitro activity for both gram-positive cocci (2 to 4 fold) and gram-negative bacilli (2 to 8 fold) [15-16]. Additional advantages of eravacycline over tigecycline include the possibility of once-daily dosing (at a dose of 1.5 mg/kg daily) [17], greater serum concentrations [7], fewer gastrointestinal side effects, and improved penetration into lung tissue. Connors et al. [18] found ELF concentrations greater than plasma by 6-fold and in alveolar macrophages (AM) by 50-fold, whereas tigecycline AM concentrations have been found to be greater than plasma only by 23-fold. In an animal study, Petraitis et al. [19] found that eravacycline achieves intrapulmonary concentrations which exceed those required for the treatment of infections caused by MRSA, *Acinetobacter*, and carbapenemase-producing non-Pseudomonal respiratory pathogens. A full comparison of spectrum of activity and additional pharmacokinetic parameters can be found in Tables 2 and 3, respectively.

Table 1

Table 1. Characteristics of Patients Treated with Eravacycline

			A. baumannii	BAL			PMB, SAM		SAM [8]	
Case	Age	Gender	Pathogen	Source(s)	Diagnosis	ID Consult	History of CRAB	Susceptibility Pattern[a]	Days of ERV	Concomitant Antibiotics[b]	Outcome
Case 1	67	M	*A. baumannii*	Sputum	HCAP	Yes	No	PMB	3	MEM, PMB	Expiration[c]
Case 2	74	M	*A. baumannii*	Sputum	HCAP	Yes	No	PMB	9	PMB	Failure[d]
Case 3	79	F	*A. baumannii*	Sputum	VABP complicated by lung abscess	Yes	No	PMB	11	PMB [3]	Failure[d]
			A. baumannii	BAL			PMB, SAM		SAM [8]	

Abbreviations: BAL, bronchoalveolar lavage; CRAB, carbapenem-resistant *Acinetobacter baumannii*; ERV, eravacycline; HCAP, healthcare-associated pneumonia; ID, infectious diseases; MEM, meropenem; polymixin B, PMB; RIF, rifampin; SAM, ampicillin-sulbactam; VABP, ventilator-associated bacterial pneumonia.

[a] Isolates deemed susceptible to the listed antimicrobials in accordance with the 2019 Clinical and Laboratory Standards Institute (CLSI) Performance Standards for Antimicrobial Susceptibility Testing.

[b] Brackets indicate the number of days a specific antimicrobial agent was given in combination with ERV.

[c] Death was attributed to acute respiratory failure secondary to septic shock due to pneumonia.

[d] Treatment failure, defined as lack of adequate response at the discretion of the treating provider.

Table 2

Table 2. Indications and Activity of Novel Tetracyclines Against Multidrug-resistant Gram-negative Pathogens

Agent	Approval	Indications	Activity							
			Enterobacteriaceae							
			Class A Carbapenemase (i.e., KPC)	Class B Carbapenemase (i.e. NDM)	Class D Carbapenemase (i.e. OXA-48)	AmpC	ESBL	*A. baumannii*[a]	*P. aeruginosa*[a]	*S. maltophilia*[a]
Eravacycline	2018	cIAI	+	+	+	+	+	+	-	+
Minocycline	2019[b]	HABP, VABP[b]	-	-	-	-	-	+[b]	-	+
Omadacycline	2018	ABSSSI, CABP	+/-	+/-	-	+	+	+/-	-	+
Tigecycline	2005	cSSSI, cIAI, CABP	+	+	+	+	+	+	-	+

\+ Coverage provided
+/- Minimal coverage
\- No coverage provided

Abbreviations: *A. baumannii*, *Acinetobacter baumannii*; ABSSSI, acute bacterial skin and skin structure infections; AmpC, AmpC cephalosporinase; CABP, community-acquired bacterial pneumonia; cSSSI, complicated skin and skin structure infection; cIAI, complicated intraabdominal infection; ESBL, extended-spectrum beta-lactamase; HABP, hospital-acquired bacterial pneumonia; KPC, *Klebsiella pneumoniae* carbapenemase; NDM, New Delhi metallo-beta-lactamase; OXA, oxacillinase; *P. aeruginosa*, *Pseudomonas aeruginosa*; *S. maltophilia*, *Stenotrophomonas maltophilia*; VABP, ventilator-associated bacterial pneumonia.

[a] Refers specifically to the intravenous formulation of minocycline, which was designated in 2015 as a Qualified Infectious Diseases Product under the GAIN Act. Indicated for certain infections caused by gram-negative pathogens, including those with infections caused by multidrug-resistant *Acinetobacter spp.*

[b] Potential use in combination with other agents for treatment of extensively drug-resistant *A. baumannii*.

[c] Active against carbapenem-resistant strains.

Table 3

Table 3. Characteristics of Novel Tetracyclines

Agent	Formulation(s)	Dose	Renal/Hepatic Adjustments	PK/PD Index	AUC (μg*hr/mL)	Vd	Lung plasma	Protein Binding (%)	$T_{1/2}$ (hr)	Metabolism	Excretion
Eravacycline	IV	1-1.5[a] mg/kg q12H	Hepatic: Child-Pugh class C	24-hr AUC/MIC	6.31 (12 hr)	321 L[c] (~4 L/kg)	ELF: 6-fold AM: 30-fold	79-89	20	Primarily by CYP3A4, FMO-mediated oxidation	Urine: 34% (20% unchanged drug) Feces: 47% (37% unchanged drug)
Minocycline[d]	Capsules, IV, tablets	LD: 200 mg MD: 100 mg q12H	Renal: CrCl < 80 mL/min: do not exceed 200 mg/day	24-hr AUC/MIC	48.3 (0-∞)	80-114 L[c] (~0.14-0.7 L/kg)	ELF: 3-fold	76	16	Hepatic metabolism to inactive metabolites	Urine: 5-12% (unchanged drug) Feces: 20-34%
Omadacycline[e]	IV, tablets	LD: 200 mg MD: 100 mg q24H	N/A	24-hr AUC/MIC	12.14 (24 hr)	190 L[c]	ELF: 1.5-fold AM: 26-fold	20	15.5-16.8	Not metabolized	Primarily urine (27% unchanged drug)
Tigecycline	IV	LD: 100-200 mg MD: 50-100 mg q12H	Hepatic: Child-Pugh class C	24-hr AUC/MIC	4.7 (24 hr)	7-9 L/kg	ELF: 8-fold, 23-fold[f] AM: 21-fold	71-89	42	Hepatic metabolism, via glucuronidation, N-acetylation, and epimerization	Urine: 33% (22% unchanged drug) Feces: 59% (primarily unchanged drug)

Abbreviations: AM, alveolar macrophages; AUC, area under the curve; CrCl, creatinine clearance; hr, hour; ELF, epithelial lining fluid; FMO, flavin-containing monooxygenase; IV, intravenous; kg, kilogram; L, liter; LD, loading dose; MIC, minimum inhibitory concentration; MD, maintenance dose; N/A, not applicable; PD, pharmacodynamic; PK, pharmacokinetic; $T_{1/2}$, half-life; μg, microgram; Vd, volume of distribution;

[a] Refers specifically to the IV formulation unless otherwise specified.

[b] 1.5 mg/kg dose warranted in patients receiving concomitant strong CYP3A4 inducers (i.e. rifampin, phenytoin).

[c] Vd at steady state.

[d] Increased penetration into the ELF observed in infected lung models.

DISCUSSION

Infection with *A. baumannii* is associated with increased mortality rates [20-21]. The virulence factors that lead to the development of antimicrobial resistance complicate treatment, given limited therapeutic options. Eravacycline, compared to its ancestors, represents a possible option for the treatment of respiratory infections, including pneumonia, given its increased penetration into the ELF and AM. Although data on eravacycline use for respiratory infections caused by *Acinetobacter spp*. is limited, it has successfully been used in the treatment of respiratory infections caused by *Achromobacter spp.*, another gram-negative bacterium which may exhibit multidrug-resistance [22].

In our series, all three patients had lower respiratory tract infections caused by XDR *A. baumannii* and received eravacycline as part of combination therapy. Interpreting the true utility of eravacycline, however, in these patients is difficult for several reasons. The first patient received a limited course of eravacycline. Microbiological eradication from previous *A. baumannii* pneumonia was never documented in the second patient; eradicating this pathogen is challenging even in the setting of [previous] clinical cure. And in the third, eravacycline was not started for 18 days following new-onset fevers and leukocytosis, potentially limiting the drugs overall effectiveness. Additionally, eravacycline susceptibilities, as well as those for tigecycline and minocycline, were not available for any patient.

While none of our patients had a previous history of infection with *A. baumannii*, all had extensive contact with the healthcare system: all patients presented from nursing homes/assisted living facilities, and had recent, prolonged hospitalization for SARS-CoV-2, during which they received intravenous antibiotics. Additionally, the first patient received hemodialysis and the third was chronically ventilated. These characteristics not only increase the risks for infection with *A. baumannii,* but particularly for infection with MDR/XDR strains.

Treatment failure in our three patients highlights the difficulty surrounding treatment of these infections especially in the absence of susceptibility data. Further investigation, including routine susceptibility testing and earlier initiation, particularly if specific risk factors exist for infection with *A. baumannii*, may be necessary to examine the utility of eravacycline in the treatment of these types of infections.

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