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Systematic Literature Review of the Clinical Outcomes Associated with Cefiderocol Therapy for *Stenotrophomonas maltophilia* Infections

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INTRODUCTION

- *Stenotrophomonas maltophilia*, an opportunistic Gram-negative bacterium intrinsically resistant to many antibiotics, is associated with high morbidity and mortality in severely ill and immunosuppressed patients with limited treatment options.[1–3]
- The Infectious Diseases Society of America guidance on antimicrobial-resistant infections recommends the use of cefiderocol in monotherapy as the preferred agent for infections caused by *S. maltophilia*. Previous older antibiotics, such as levofloxacin, minocycline, and/or trimethoprim-sulfamethoxazole may be used in combination.[4]

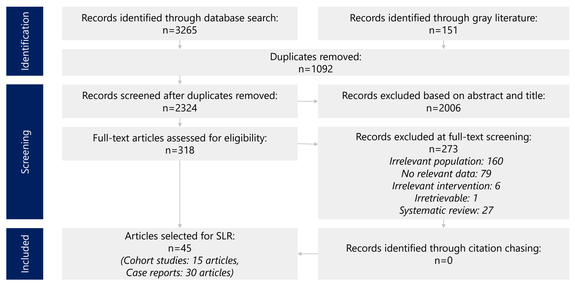
OBJECTIVES

- To conduct a systematic literature review (SLR) of the baseline characteristics and clinical outcomes of patients with *S. maltophilia* infections who were treated with cefiderocol.

METHODS

- Comprehensive database searches were conducted on November 7, 2025 using PubMed, Embase, and The Cochrane Library.
- Additional gray literature searches were conducted in selected relevant infectious disease journals, reports, organizations, and websites.
- Articles were independently screened, and data were extracted for analysis by 2 reviewers based on inclusion criteria and complied with PRISMA guidelines (**Figure 1**).

Figure 1. PRISMA flow of literature



A total of 45 articles were reviewed (15 cohort study publications and 30 case reports) from a total of 2324 records screened.

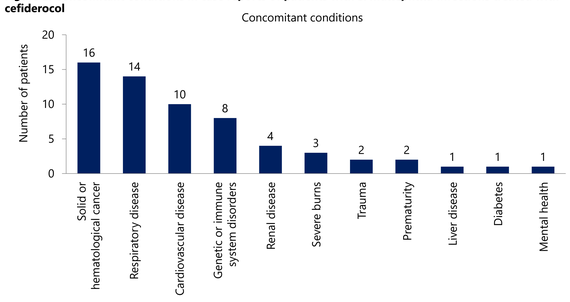
SLR, systematic literature review.

RESULTS

Case reports

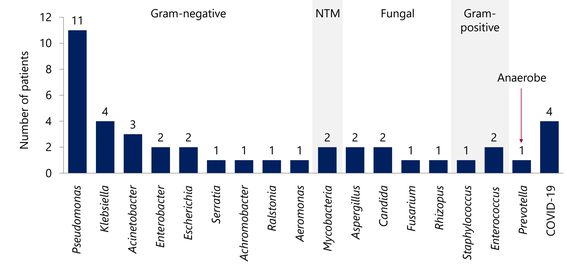
- The 30 case reports included 49 patients with *S. maltophilia* infections treated with cefiderocol. The mean age was 43.5 years (range: neonate to 82 years), with 28 adults (57.1%) and 12 children (24.5%) included (age unreported in 9 cases). There were 18 male (36.7%) and 17 female (34.7%) patients (sex unreported in 14 cases).
- Cases were reported in Italy (n=16), France (n=9), UK (n=8), Spain (n=5), USA (n=5), Australia (n=1), Canada (n=1), Germany (n=1), and Pakistan (n=1) (location unreported in 2).
- The most frequent infection site was the lung/respiratory tract (n=33 [67.3%]) and bloodstream (n=19 [38.8%]). Two cases each of wound infection and skin/soft tissue infection were reported, and 1 case each of bone & joint infection and intra-abdominal infection. Eight patients had multiple infection sites.
- Frequent concomitant conditions reported included cancer (n=16), respiratory disease (n=14), cardiovascular disease (n=10), as well as severe burns (n=3) and genetic or immune system disorders (n=8) (**Figure 2**).

Figure 2. Concomitant conditions in case reports of patients with *S. maltophilia* infections treated with cefiderocol



- Overall, 44.9% of patients (n=22) had co-infections with one or more pathogens (**Figure 3**).

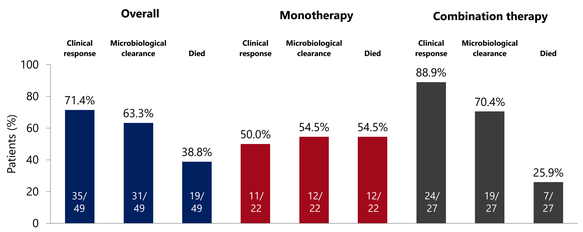
Figure 3. Co-infecting pathogens in case reports of patients with *S. maltophilia* infections treated with cefiderocol



COVID-19, coronavirus disease 2019; NTM, non-tuberculous mycobacteria.

- Cefiderocol was administered in monotherapy to 22 patients (44.9%) and in combination therapy to 27 (55.1%). Antibiotics with activity against Gram-negative bacteria commonly administered included trimethoprim-sulfamethoxazole (n=11), levofloxacin (n=6), ciprofloxacin (n=5), moxifloxacin (n=2), amikacin (n=2), colistin (n=2), tigecycline (n=2), and ceftazidime-avibactam (n=2).
- Clinical response, defined as the composite of clinical cure and either survival or death unrelated to infection, was achieved in 71.4% (n=35) of patients. A total of 19 patients (38.8%) died. Patients who received cefiderocol combination therapy had higher clinical cure and lower all-cause mortality (ACM) rates than patients who received monotherapy (**Figure 4**).

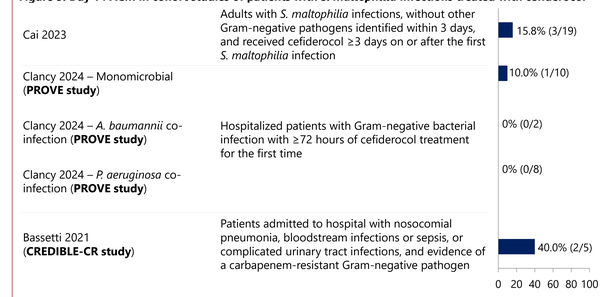
Figure 4. Clinical outcomes in case reports of patients with *S. maltophilia* infections treated with cefiderocol



Cohort studies

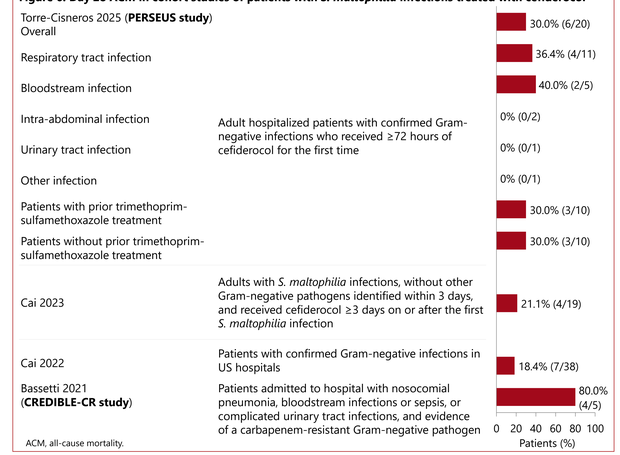
- A total of 262 patients in 15 publications reporting on 9 studies were reviewed (1 global, open-label, randomized, active-controlled study [CREDIBLE-CR] and 8 observational studies [prospective n=2; retrospective n=6]). Patients were treated with cefiderocol in the USA, Europe, Spain, and Italy. The earliest treatment period was 2016–2019, and the most recent was 2023–2024.
- Based on reported data, the mean/median age was 48–66 years, and 67.3% were male. Respiratory tract infection was the most frequent infection site (55.0%–100%), followed by bloodstream infection (5.0%–33.3%).
- Co-infecting pathogens were reported in 10 publications, affecting 15%–66.6% of patients, with *P. aeruginosa* (20.0%–80.0%) and *A. baumannii* (14.8%–40.0%) being most common. Concomitant conditions were reported in 6 publications, suggesting critical illness in a large proportion of patients.
- Eight publications reported clinical cure or clinical response rate: 70.0% clinical cure rate in the PERSEUS study, 57.9%–68.2% in the PROVE study, and no patients had clinical cure in the CREDIBLE-CR study.
- Clinical cure rate by infection site, where reported, was 0%–67% for patients with respiratory tract infections, 0%–100% for intra-abdominal infections, 60% for bloodstream infections, 75%–100% for skin and soft tissue infections, and 100% for urinary tract infections, bone and joint infection, and other infection sites.
- ACM varied between 0% (PROVE) and 40.0% (CREDIBLE-CR) at Day 14 (**Figure 5**), between 0% (PERSEUS) and 80.0% (CREDIBLE-CR) at Day 28 (**Figure 6**), and between 0% (PROVE) and 38.6% (PROVE) at Day 30 (**Figure 7**).

Figure 5. Day 14 ACM in cohort studies of patients with *S. maltophilia* infections treated with cefiderocol



ACM, all-cause mortality.

Figure 6. Day 28 ACM in cohort studies of patients with *S. maltophilia* infections treated with cefiderocol



ACM, all-cause mortality.

CONCLUSIONS

- Evidence in this SLR supports the use of cefiderocol in vulnerable high-risk patients with *S. maltophilia* infections, although mortality risk remains high in respiratory tract infections and bloodstream infections.
- In case reports, patients with combination therapy had more favorable clinical outcomes than those receiving cefiderocol monotherapy, although a few patients died due to their underlying conditions, and outcomes were not adjusted by baseline characteristics.
- On-therapy resistance to cefiderocol was not found.
- Results should be interpreted cautiously due to the heterogeneity in cohort studies and low patient numbers.

On-therapy resistance

- No treatment-emergent cefiderocol resistance or adverse events were reported.

Figure 7. Day 30 ACM in cohort studies of patients with *S. maltophilia* infections treated with cefiderocol

ACM, all-cause mortality.

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Disclosures
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