Real-world effectiveness and safety of cefiderocol in critically ill patients with MDR Gram-negative infections: Results from a retrospective study

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Abstract. The increasing prevalence of multidrug-resistant (MDR) Gram-negative bacteria, particularly *Acinetobacter baumannii* (*A. baumannii*), represents a major clinical challenge, especially in critically ill patients. Cefiderocol, a siderophore cephalosporin, has emerged as a promising therapeutic option for infections caused by carbapenem-resistant organisms. The present study aimed to evaluate the real-life efficacy and safety of cefiderocol in a high-risk hospital population. A monocentric, retrospective observational study was conducted at the University Hospital 'Gaetano Martino' in Messina, Italy, from July 2021 to April 2022. Adult patients treated with cefiderocol for ≥48 h for documented or suspected infections caused by MDR Gram-negative bacteria were included. Primary endpoints were clinical resolution and mortality at discharge. Secondary outcomes included adverse drug reactions, hospital epidemiology of MDR organisms, and correlation with colonization status. Data were analyzed using descriptive and inferential statistics. A total of 55 patients were included, with a median age of 65 years; 67.3% were male. Most infections were pneumonia (80.0%) and bloodstream infections (BSI; 45.5%). *A. baumannii* was the most frequently isolated pathogen (87.3%), with 73.7% being extensively drug-resistant. Clinical success was observed in 40% of ventilator-associated pneumonia, 66.7% of BSI, and 100% of skin and soft tissue infections. Overall mortality was 47.3%, significantly associated with colonization by MDR organisms (P=0.028) and septic shock (P=0.001). No serious adverse events related to cefiderocol were reported. In conclusion, in a real-world setting involving severely ill patients with limited therapeutic options, cefiderocol showed favorable efficacy and favorable tolerability, particularly in bloodstream and soft tissue infections. These results support its role as a valuable treatment option for MDR Gram-negative infections, especially in intensive care unit settings, although further controlled studies are warranted.

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Introduction

Antimicrobial resistance (AMR) poses a significant global health threat, driving morbidity and mortality worldwide (1,2). The emergence and spread of multidrug-resistant (MDR) Gram-negative bacteria, particularly carbapenem-resistant *Enterobacterales*, *Acinetobacter baumannii* (*A. baumannii*) and *Pseudomonas aeruginosa* (*P. aeruginosa)*, are of critical concern, severely limiting therapeutic options for serious infections (1-4). The overuse of broad-spectrum antibiotics, including carbapenems, has contributed significantly to this challenge.

In response to this urgent need, new antimicrobial agents have been developed. Cefiderocol is a novel siderophore cephalosporin designed to overcome several common resistance mechanisms in Gram-negative bacteria (3). Its unique mechanism of action, utilizing bacterial iron transport systems for cell entry, allows it activity against numerous difficult-to-treat resistant (DTR) pathogens, including those producing carbapenemases (5,6).

While pivotal clinical trials such as CREDIBLE-CR (7), APEKS-NP (8) and APEKS-cUTI (9) have provided essential data on cefiderocol's efficacy and safety in specific patient populations, understanding its performance in routine clinical practice is crucial. Real-world settings often involve patients with complex comorbidities, polymicrobial infections, and prior treatment failures who may not have been fully represented in trial cohorts (3).

Therefore, the primary aim of the present study was to evaluate the real-life efficacy and safety of cefiderocol in treating patients hospitalized at the University Hospital 'Gaetano Martino' in Messina, Italy. The present study specifically focused on patients with proven mono- or poly-microbial infections caused by MDR/DTR Gram-negative bacteria, for whom cefiderocol was prescribed due to the failure of previous therapeutic lines or the absence of other suitable antibiotic options. The present retrospective observational study examines clinical outcomes and tolerability in this challenging patient population.

Materials and methods

Study design and setting. A monocentric, retrospective observational study was conducted at the University Hospital 'Gaetano Martino' in Messina, Italy, from July 2021 to April 2022. The present study was approved by the Provincial Ethics Committee of Catania (approval no. 101/CECT2; Catania, Italy), with authorization from the local institution. All participants provided written informed consent to participate in the study.

Study objectives. The primary objectives were assessment of in-hospital mortality and evaluating clinical and/or laboratory resolution of infection following cefiderocol treatment. The secondary objectives included: Evaluation of adverse drug reactions related to cefiderocol, description of hospital epidemiology of MDR organisms, and analysis of associations between MDR colonization at admission and subsequent development of healthcare-associated infections.

Inclusion and exclusion criteria. Adult patients (≥18 years) who: i) Were hospitalized at the study center during the observation period; ii) received cefiderocol for ≥48 h for any suspected or microbiologically confirmed infection; and iii) had complete medical records and microbiological data available. Pregnant women, patients who received cefiderocol for <48 h and patients in whom cefiderocol was prescribed but not administered were excluded.

Antimicrobial stewardship and indication for cefiderocol. Cefiderocol use was restricted to the Infectious Diseases Unit as part of the hospital's antimicrobial stewardship protocol. It was prescribed in accordance with the drug's technical sheet and local stewardship guidelines in the following cases: Confirmed infection by carbapenem-resistant Gram-negative organisms based on antibiogram; and severe infection with strong clinical suspicion of carbapenem resistance, in the presence of: i) documented failure of prior carbapenem-based treatment; ii) known rectal colonization by carbapenem-resistant organisms; and iii) known endemicity of carbapenem-resistant Gram-negative bacteria in the treating ward.

Data collection and definitions. Patient data (including demographics, comorbidities, microbiological results, treatment regimens and outcomes) were extracted from electronic medical records and Infectious Diseases consultation logs using a structured Excel database. Microbiological diagnoses were established via FilmArray PCR panels and/or standard cultures of relevant biological specimens (for example, blood, urine and bronchoalveolar lavage). Organisms were classified as MDR, extensively drug-resistant (XDR), or pan-drug-resistant (PDR) based on the criteria of Magiorakos *et al* (10).

Cefiderocol was administered at 2 g every 8 h (adjusted in renal impairment), in accordance with the drug's prescribing information. Clinical success was defined as the complete resolution or significant improvement of signs, symptoms and laboratory parameters of infection (for example, normalization of white blood cell count and C-reactive protein) at the end of cefiderocol therapy. Clinical failure was defined as death attributable to the infection, persistence or worsening of infection-related signs and symptoms, or the need to discontinue cefiderocol due to a lack of efficacy.

Statistical analysis. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 29.0 (IBM Corp.). Categorical variables were summarized as absolute frequencies and percentages, while continuous variables were assessed for normality using the Shapiro-Wilk test. Normally distributed variables were expressed as the mean ± standard deviation (SD), and non-normally distributed variables were presented as median and interquartile range (IQR). Group comparisons were conducted using the Chi-square test or Fisher's exact test for categorical variables, and the unpaired Student's t-test or Mann-Whitney U test for continuous variables, as appropriate.

To explore factors independently associated with in-hospital mortality, a multivariate logistic regression analysis was performed, including variables that showed a $P<0.10$ in univariate analysis. Results were reported as odds ratios (ORs) with 95% confidence intervals (CIs). Missing data were handled through case-wise deletion. A two-tailed $P<0.05$ was considered to indicate a statistically significant difference.

Results

Patient characteristics. During the study period, cefiderocol was prescribed to 65 patients. A total of 10 patients were excluded: 8 received treatment for <48 h, and 2 were not administered the drug. Therefore, 55 patients were included in the final analysis. A total of 2 patients received cefiderocol twice (one in separate hospital admissions, the other during a single admission).

The median age was 65.0 years (IQR 49.0-73.5), and 67.3% were male (n=37). Most patients had severe illness: 43 (78.2%) required intensive care unit (ICU) admission-15 (34.9%) directly and 28 (65.1%) following transfer from other hospital wards. Mechanical ventilation was needed in 32 patients (58.2%): 8 (14.6%) received non-invasive and 24 (43.6%) invasive ventilation.

Infection types. The most common infection treated was pneumonia (80.0%, n=44), followed by bloodstream infections (BSI; 45.5%, n=25), acute bacterial skin and soft tissue infections (16.4%, n=9), intra-abdominal infections (IAI; 14.5%, n=8) and urinary tract infections (UTI; 14.5%, n=8) (Fig. 1). One patient experienced cystic fibrosis reactivation.

Microbiology and resistance mechanisms. Among the 55 patients, 48 (87.3%) had confirmed *A. baumannii* infection,

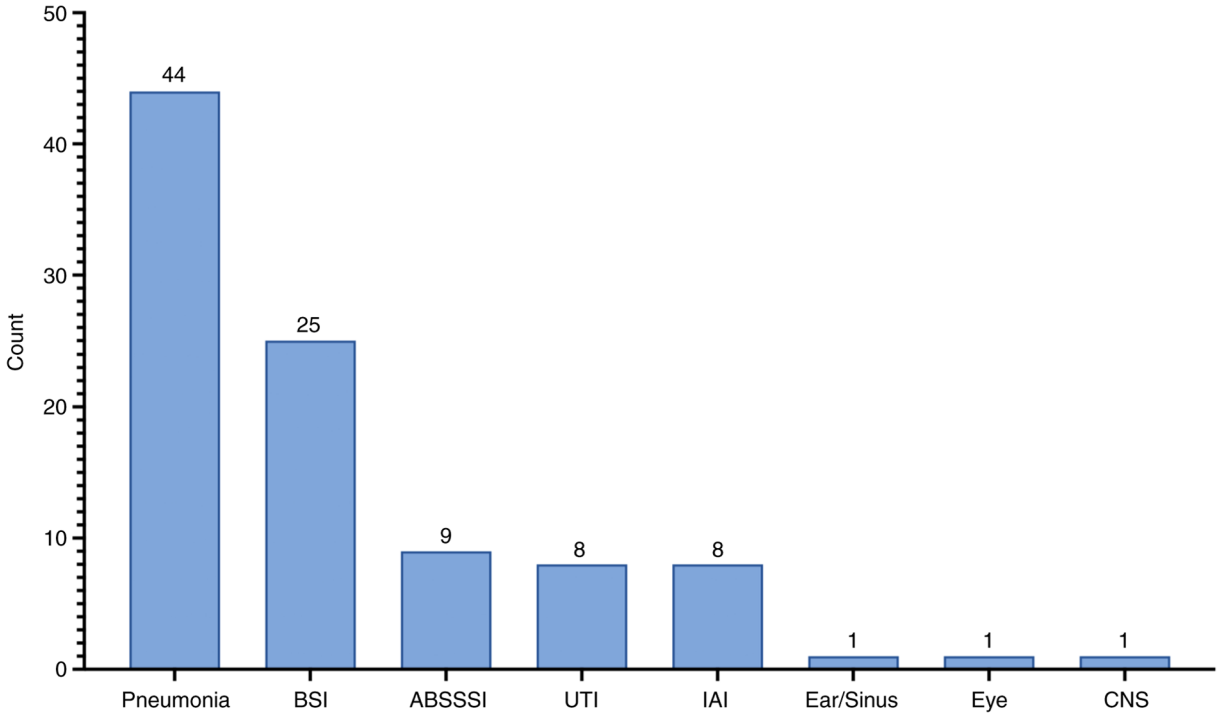

Figure 1. Distribution of infection sites among patients treated with cefiderocol. BSI, bloodstream infections; ABSSSI, acute bacterial skin and soft tissue infections; IAI, intra-abdominal infections; UTI, urinary tract infections; CNS, central nervous system.

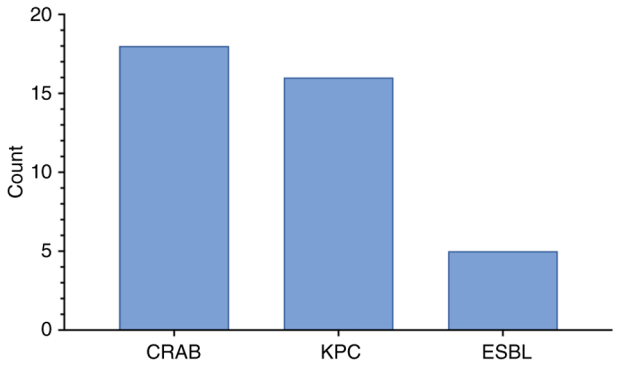

Figure 2. Distribution of main resistance mechanisms among Gram-negative pathogens isolated in patients treated with cefiderocol. CRAB, carbapenem-resistant *Acinetobacter baumannii*; KPC, *Klebsiella pneumoniae* carbapenemase; ESBL, extended-spectrum beta-lactamase.

73.7% of which were XDR. Additionally, 5 (10.5%) isolates were possibly PDR, 1 (2.1%) was confirmed PDR, and 2 (4.2%) were not MDR. A total of 5 isolates were identified via FilmArray only and not cultured.

Co-infections were frequent: 36 of the *A. baumannii* cases involved at least one additional pathogen, including *P. aeruginosa*, *Klebsiella pneumoniae* (*K. pneumoniae*), *Escherichia coli* and *Staphylococcus aureus*. The most frequently observed resistance profiles were carbapenem-resistant *A. baumannii*, *K. pneumoniae* carbapenemase-producing *K. pneumoniae* and extended-spectrum beta-lactamase-producing Enterobacterales (Fig. 2).

Colonization and prior antibiotics. A total of 31 patients (57.4%) were colonized with MDR organisms on admission, based on positive rectal swabs. Colonization was significantly associated with increased mortality (P=0.028). Additionally, 40 patients (72.7%) received empiric in-hospital antibiotics prior to cefiderocol (Fig. 3).

Comorbidities and risk factors. A total of 30 patients (54.5%) had ≥2 comorbidities; this was not significantly associated with mortality (P=0.126). The most common comorbidities were cardiovascular disease (67.3%), COVID-19 (52.7%), lymphopenia (47.3%), thrombocytopenia (34.5%) and chronic kidney disease (29.1%). The median Charlson Comorbidity Index was 4, indicating an estimated 10-year survival of 53% (Table I).

Clinical outcomes. The overall in-hospital mortality was 47.3% (n=26). Mortality was significantly associated with septic shock (P=0.001) and MDR colonization (P=0.028), but not with age (P=0.054), COVID-19 status (P=0.215), or number of comorbidities (P=0.126). Septic shock occurred in 30 patients (54.5%) with a median duration of 5 days (IQR 0-15).

Median hospital length of stay was 40 days (IQR 28.5-60.0), significantly shorter in non-survivors (31.5 vs. 57.0 days; P=0.004), likely reflecting early death. Treatment success (defined as clinical/laboratory improvement) varied by infection site: ventilator-associated pneumonia (VAP), 40%; BSI, 66.7%; UTI, 50%; skin and soft tissue infections (SSTI), 100% and IAI, 50%.

Treatment details and adverse events. Cefiderocol was administered for a median of 14 days (IQR 8.1-16.7). Only 2 patients (3.6%) received cefiderocol in monotherapy. The majority received combination therapy, with colistin used in

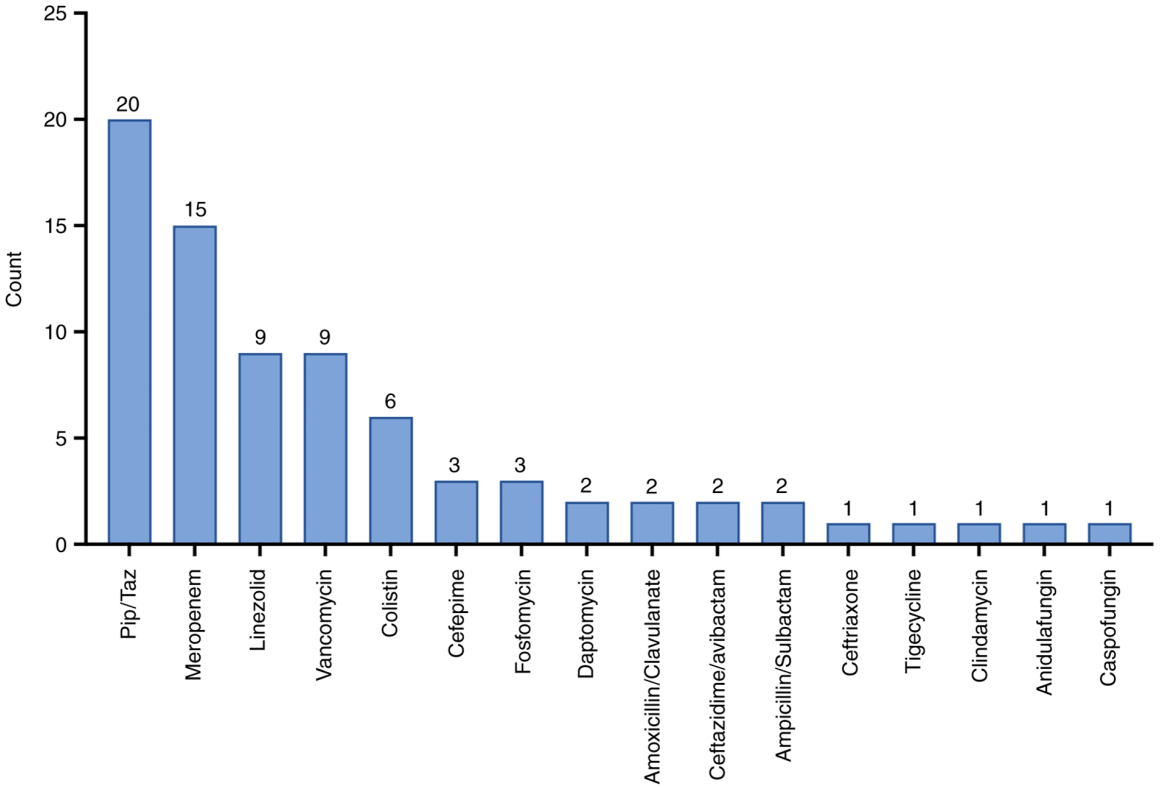

Figure 3. Empiric antibiotic treatments administered prior to cefiderocol.

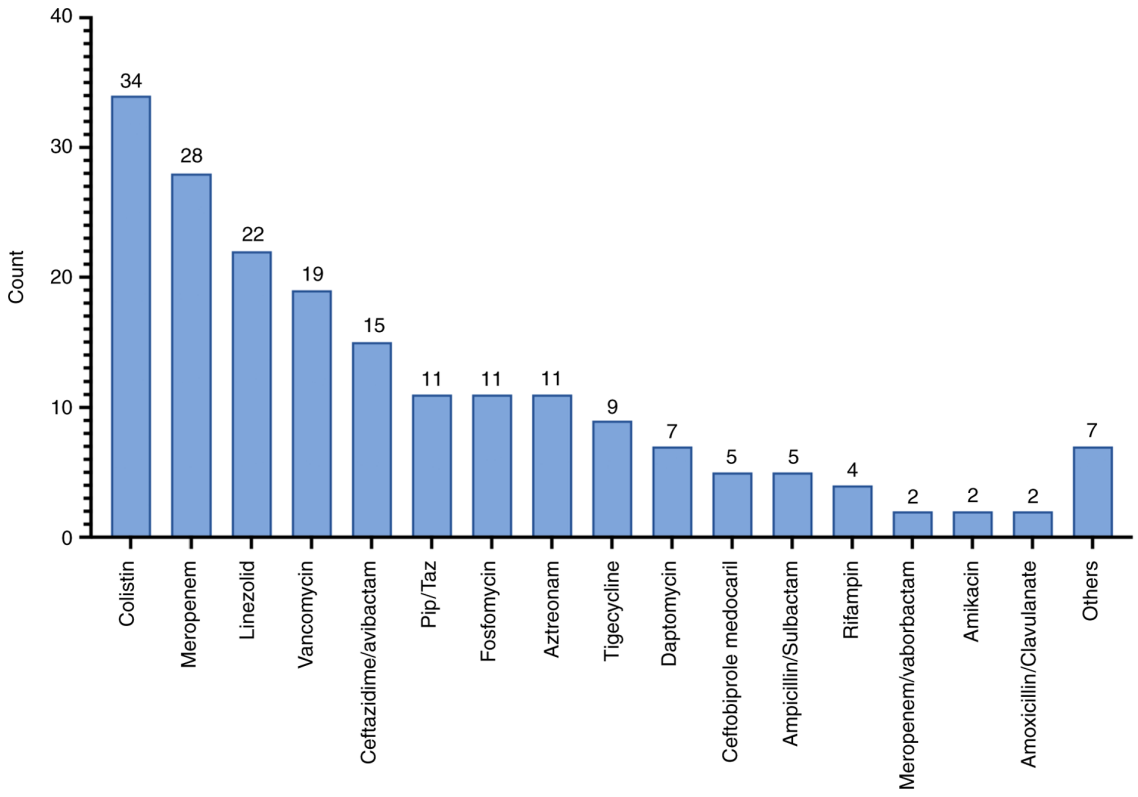

Figure 4. Antibiotics' combination along with cefiderocol.

34 cases (61.8%) (Fig. 4). There was no significant difference in mortality between patients treated with or without colistin (P=0.104). The median number of antibiotics (excluding cefiderocol) used per patient was 3 (IQR 2-5). No serious cefiderocol-related adverse events were reported. Minor adverse effects-such as rash, thrombocytopenia, joint pain

Table I. Comorbidities in the population studied.

Comorbidities	n	Percentage %
Cardiovascular disorder	37	67.3
COVID-19	29	52.7
Lymphopenia	26	47.3
Thrombocytopenia	19	34.5
Hemodialysis	17	30.9
Chronic kidney failure	16	29.1
Diabetes	15	27.3
Cancer	5	9.1
Chronic obstructive pulmonary disease	5	9.1
Neutropenia	4	7.3
Hematologic cancer	3	5.5
Chronic liver failure	2	3.6
HIV infection	1	1.8

and sore throat-occurred in a few patients but did not lead to drug discontinuation.

Discussion

The present retrospective observational study evaluated the real-life use of cefiderocol in a critically ill population infected with MDR Gram-negative bacteria, predominantly *A. baumannii*. The current findings suggest that cefiderocol may be a valuable therapeutic option in patients with limited treatment alternatives, particularly for bloodstream and soft tissue infections.

Clinical success was achieved in 66.7% of patients with BSI, closely aligning with findings from the CREDIBLE-CR trial (65.5%) (7) and the cohort study by Falcone *et al* (11). Similarly, a 100% success rate in skin and soft tissue infections (SSTI) mirrors the strong *in vitro* activity of cefiderocol against carbapenem-resistant pathogens documented in multiple studies (12,13). Conversely, the lower efficacy observed in VAP (40% success) reflects the ongoing challenges in treating this condition; this high mortality rate highlights an urgent need for optimized therapeutic strategies for VAP caused by MDR pathogens. Future studies should investigate whether alternative dosing regimens, such as prolonged or continuous infusion of cefiderocol, could improve pharmacokinetic/pharmacodynamic target attainment in the lung parenchyma and lead to improved clinical outcomes (14).

A key finding was that cefiderocol was predominantly used as part of a combination regimen (96.4%), with colistin being the most frequent partner antibiotic. This reflects a common clinical practice in treating severe infections caused by XDR pathogens such as *A. baumannii*, where combination therapy is often employed to achieve potential synergistic effects and mitigate the risk of resistance development (15,16). While the addition of colistin did not show a statistically significant mortality benefit in our analysis (P=0.104), the choice is often guided by the severity of illness and local resistance patterns, despite ongoing debates regarding colistin's efficacy and potential toxicity, particularly its limited pulmonary penetration.

The microbiological landscape in our cohort was dominated by *A. baumannii* (87.3%), a significantly higher prevalence than in previous trials such as CREDIBLE-CR (46%) (7), APEKS-NP (16%) (8) and Meschiari *et al* (5.9%) (17). The high rate of ICU admission and mechanical ventilation suggest these infections were primarily nosocomial, with VAP being a major source.

Notably, over 70% of the isolates were classified as XDR, with several cases potentially PDR. These findings emphasize the severity of infections managed in our setting and underscore the urgent need for effective antimicrobial options.

Septic shock was observed in 54.5% of patients and was significantly associated with mortality (P=0.001), consistent with global data estimating sepsis-related mortality at 30-40% (18). Colonization with MDR organisms at admission also associated with worse outcomes (P=0.028), highlighting the prognostic value of routine rectal swabs and active surveillance cultures in ICU settings.

The present study also sheds light on the positioning of cefiderocol in clinical practice. The indications for its use included both microbiologically confirmed infections and cases of strong clinical suspicion based on risk factors such as known colonization. This suggests a role for cefiderocol not only as a targeted therapy for confirmed DTR pathogens but also as a highly selective empiric option in critically ill patients with a high pre-test probability of having such an infection, particularly when prior broad-spectrum antibiotics have failed.

Cefiderocol demonstrated favorable tolerability in our cohort, with no serious adverse effects leading to discontinuation. Minor side effects (for example, rash, thrombocytopenia and myalgia) were infrequent and self-limiting. This safety profile aligns with published studies from randomized trials and pharmacokinetic-pharmacodynamic studies (7,19). Our findings are broadly consistent with prior clinical trials and real-world studies (20-24).

Despite these encouraging observations, the present study has important limitations. Its retrospective, single-center nature limits external validity and introduces selection bias. The absence of detailed molecular resistance testing (such as16S rRNA sequencing) and minimum inhibitory concentration (MIC) data restricts our ability to correlate outcomes with specific resistance mechanisms and precise susceptibility profiles. Additionally, the lack of a comparator arm precludes evaluation of cefiderocol's relative efficacy. Lastly, the small sample size, particularly within infection subgroups, limits the statistical power of some analyses.

Furthermore, due to the retrospective data collection, the precise timing of cefiderocol initiation relative to hospital admission or infection onset could not be consistently determined, although it was generally used after failure of prior therapies. Lastly, the small sample size, particularly within infection subgroups, limits the statistical power of some analyses. Nevertheless, our study adds valuable real-life evidence to the increasing body of literature supporting cefiderocol use in critically ill patients with few alternative treatment options. In particular, its observed efficacy in BSI and SSTI, combined

with its tolerability, support its consideration in the management of infections caused by XDR *A. baumannii* and other MDR Gram-negative bacteria (25). Future prospective, multicenter studies are needed to further define optimal patient selection, combination therapy strategies, and the potential for resistance emergence. Moreover, long-term strategies to combat AMR will require a multifaceted approach, including robust antimicrobial stewardship, infection control, and the exploration of novel therapeutic paradigms beyond conventional antibiotics.

In conclusion, in the present real-life, retrospective study involving critically ill patients with infections caused by MDR Gram-negative bacteria-primarily *A. baumannii*-cefiderocol demonstrated promising efficacy and favorable tolerability, particularly in bloodstream and soft tissue infections. Despite the complexity of the cohort, which included a high prevalence of septic shock, ICU admission and XDR pathogens, clinical outcomes were comparable to those observed in controlled trials and recent observational data. Colonization with MDR organisms and septic shock were independently associated with higher mortality, emphasizing the importance of early identification and targeted antimicrobial therapy in high-risk settings. Cefiderocol was well tolerated, with no serious adverse events reported, further supporting its use in fragile and treatment-limited populations. While the retrospective, single-center design and lack of MIC data limit the generalizability of the present findings, our results contribute to the increasing body of real-world evidence supporting the role of cefiderocol as a valuable treatment option in severe infections caused by DTR Gram-negative bacteria. Future prospective, multicenter studies are needed to define optimal therapeutic strategies, including the role of combination therapy and resistance prevention.

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Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

AM, EVR and GFP conceived the study. AM, EVR, CI and GN designed the study. MV, CM, MC and AEC collected the data. EVR and YR analyzed data. AM and EVR wrote the manuscript. GN and GFP reviewed the manuscript. GFP and CI supervised the study. All authors read and approved the final version of the manuscript. AM and GN confirm the authenticity of all the raw data.

Ethics approval and consent to participate

All participants provided written informed consent to participate in the study. The present study was conducted in accordance with the Declaration of Helsinki and was approved by the Provincial Ethics Committee of Catania (approval no. 101/CECT2; Catania, Italy).

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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