Necrotising Skin and Soft tissue infections (SSTIs): European Cubicin® Outcomes Registry and Experience EU-CORESM
(2006-2012)

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ABSTRACT

Aims: Necrotising SSTIs are rapidly progressive, life-threatening infections caused predominantly by Gram positive organisms (beta-haemolytic streptococci and staphylococci) which originates from the skin and soft tissues. Prompt and effective medical and surgical management is required. Cubicin® is a rapidly bactericidal antibiotic with anti-endotoxin activity. Outcomes from patients with necrotising SSTIs included in the European Cubicin® Outcomes Registry and Experience (EU-CORE)® database are reported.

Methods: Data were collected from the non-interventional multicentre registry for patients diagnosed with necrotising SSTIs who received treatment between January 2006 and June 2012. Treatment and outcome information were assessed (cured, cured but relapsed, failed). Safety assessments were conducted up to 90 days after completion of antibiotics treatment.

Results: 48 patients with necrotising SSTIs were included in the registry of 5265 patients. Mean (SD) age: 56.3 (17.7) years, male: 33 (69%), female: 15 (31%). 20 (42%) received treatment in intensive care units. Cubicin® was used at the median therapeutic dose of 6 mg/kg/day (range: 4 mg/kg to 12 mg/kg). A total of 10 (21%) adverse events were reported in 9 (19%) patients. One death (2%) was recorded. Treatment failure and resistance were the two most frequently documented reasons for treatment failure or failure to respond to therapy.

Conclusion: Cubicin® is an effective agent in the management of these infections. Positive outcome for necrotising SSTIs.

BACKGROUND

Necrotising soft tissue infections include necrotizing forms of cellulitis, myositis, and fasciitis. These infections are characterized clinically by fulminant tissue destruction, systemic signs of toxemia, and high mortality. Although rare, they are frequently life-threatening, and are predominantly caused by Gram-positive organisms: notably Streptococcus pyogenes and Staphylococcus aureus.

Accurate diagnosis and appropriate treatment must include early surgical intervention and antibiotic therapy.

Daptomycin is an alycosilipidic antibiotic with bactericidal activity against Gram-positive organisms. Daptomycin has been successfully used in the treatment of complicated infections due to Gram-positive multidrug-resistant pathogens, including skin and soft tissue infections.

PURPOSE

To evaluate the clinical outcomes of daptomycin therapy in patients with necrotizing skin and soft tissue infections from the European Cubicin® Outcomes Registry and Experience (EU-CORE®) database.

METHODS

Data collection

Data were collected from a multicentre, retrospective, non-interventional registry (EU-CORE®) from patients with necrotizing infections across European countries, Russia, Latin America and India.

A standardised case report form was used by the investigators to collect patient information, including demographic characteristics, comorbidities, daptomycin dosage and duration of therapy, prior and concomitant antibiotics, therapy-related function, creatine phosphokinase concentrations, details of infection and primary pathogen, and clinical outcomes.

All patients with necrotizing faciitis enrolled in EU-CORE® who received treatment with daptomycin from January 2006 to June 2012 were selected for this analysis.

Eligibility criteria

Patients treated with at least one dose of daptomycin with a minimum of 30 days post-treatment follow-up.

Efficacy and safety assessments

Safety analysis included reports of adverse events (AEs) and serious AEs (SAEs); the severity of AEs was determined by the investigators.

Clinical outcomes at the end of daptomycin therapy were assessed by the investigators using protocol-defined criteria (Table 1).

RESULTS

Patient demographics and characteristics

Of the total 551 patients enrolled in the EU-CORE®, all patients had necrotizing fasciitis.

Table 2 shows the patient demographics. 69% of patients were male and 45% were overweight or clinically obese.

REFERENCES


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