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New and not so new antibiotics

DAPTOMYCIN FOR THE TREATMENT OF INFECTIONS IN OVERWEIGHT/OBESE PATIENTS: RESULTS FROM THE EUROPEAN CUBICIN® OUTCOME REGISTRY AND EXPERIENCE

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Objectives: Obesity can lead to altered tissue distribution and clearance of antimicrobials which may affect efficacy and safety. However, information on dosing in this patient population is scarce. A pharmacokinetic study of daptomycin in moderately/morbidly obese volunteers concluded that daptomycin may be dosed based on total body weight and that no additional dose adjustments are required for obesity[1]. Here, we compare the clinical outcomes and safety of daptomycin in patients with different body mass index (BMI), from the European Cubicin® Outcomes Registry and Experience (EU-CORE^{SM}).

Methods: EU-CORE^{SM} is a retrospective, non-interventional study in patients on daptomycin therapy. Data were collected for patients who received at least one dose of daptomycin from January 2006 to April 2012. Treatment outcome was assessed by the investigator post-treatment as cured, improved, failure or non-evaluable. Clinical success is defined as the sum of cured and improved. Safety was assessed up to 30 days following treatment.

Results: BMI data were available for 1576 (Table) out of 5551 patients (59% male; 61% >=65 years of age). 88% of overweight and obese patients had significant underlying disease (66% cardiovascular disease and 35% diabetes mellitus). 10% of overweight and 6% of obese patients had an estimated creatinine clearance <30 mL/kg with 8% and 9% on dialysis, respectively. The most common primary infections in normal, overweight and obese patients were complicated skin and soft tissue infections (28%, 32% and 33%. respectively), with wound infections occurring most frequently. Of the isolated pathogens, in the normal/overweight/obese patients 50%/41%/42% were *Staphylococcous aureus* and 21%/27%/26% were coagulase negative staphylococci, respectively. The most frequent initial dose of daptomycin was 6 mg/kg (41% in normal/overweight and 40% in obese patients). 21% normal/overweight and 13% obese patients received daptomycin at doses >=8mg/kg. 60% of overweight and obese patients were treated empirically with daptomycin (i.e. before availability of culture results). 62% of the overweight and obese patients had prior antibiotics use and 64% were receiving concomitant antibiotics. Clinical outcome in normal, overweight and obese patients is shown in the table below. Daptomycin was generally well tolerated. Adverse events (AEs), possibly daptomycin-related, were reported in 4% each of normal weight, overweight and obese patients (including 1.2%, 1.4% and 0.6% of increased blood CPK level, respectively). Serious AEs, possibly daptomycin-related, were reported in 0.3% normal weight, 1.1% overweight and 1.7% of obese patients, respectively. Discontinuation due to any AE was 4% for normal weight, overweight and obese patients.

Conclusion: Results from EU-CORE^{SM} demonstrate that success rates and safety profile of daptomycin in normal, overweight and obese patients were similar, with the use of comparable doses.

Reference

1. Dvorchik BH & Damphouse D. J Clin Pharmacol. 2005; 45: 48-56

Patient Groups	Clinical success n (%)	Failure n (%)	Non evaluable n (%)
Normal weight (BMI ≥ 18.5 and < 25 kg/m²), N=598 (38%)	504 (84)	27 (5)	67 (11)
Overweight (BMI ≥ 25 and < 30 kg/m²), N=558 (35%)	484 (87)	26 (5)	48 (9)
Obese (BMI ≥ 30 kg/m²), N=345 (22%)	286 (83)	16 (5)	43 (13)