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Telavancin versus vancomycin for the treatment of complicated skin and skin-structure infections caused by gram-positive organisms.

Stryjewski ME, Graham DR, Wilson SE, O'Riordan W, Young D, Lentnek A, Ross DP, Fowler VG, Hopkins A, Friedland HD, Barriere SL, Kitt MM, Corey GR; Assessment of Telavancin in Complicated Skin and Skin-Structure Infections Study.

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BACKGROUND: Telavancin is an investigational, rapidly bactericidal lipoglycopeptide with a multifunctional mechanism of action.

METHODS: We conducted 2 parallel, randomized, double-blind, active-control, phase 3 studies with a prespecified pooled analysis design. Patients aged \geq 18 years who had complicated skin and skin-structure infections caused by suspected or confirmed gram-positive organisms were randomized to receive either telavancin (10 mg/kg intravenously every 24 h) or vancomycin (1 g intravenously every 12 h).

RESULTS: A total of 1867 patients were randomized and received \geq 1 dose of study medication. In the clinically evaluable population, at 7-14 days after receipt of the last antibiotic dose, success was achieved in 88% and 87% of patients who received telavancin and vancomycin, respectively (95% confidence interval for the difference, -2.1 to 4.6). Methicillin-resistant *Staphylococcus aureus* was isolated at baseline from samples from 579 clinically evaluable patients. Among these patients with methicillin-resistant *S. aureus* infection, cure rates were 91% among patients who received telavancin and 86% among patients who received vancomycin (95% confidence interval for the difference, -1.1 to 9.3). Microbiologic eradication among patients infected with methicillin-resistant *S. aureus* was 90% in the telavancin treatment group and 85% in the vancomycin treatment group (95% confidence interval for the difference, -0.9 to 9.8). Therapy was discontinued because of adverse events in 8% and 6% of patients who received telavancin and vancomycin, respectively. Except for mild taste disturbance, nausea, vomiting, and serum creatinine concentration elevation in the telavancin treatment group and pruritus in the vancomycin treatment group, adverse events were similar between groups with regard to type and severity.

CONCLUSIONS: Telavancin given once daily is at least as effective as vancomycin for the treatment of patients with complicated skin and skin-structure infections, including those infected with methicillin-resistant *S. aureus*.

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