



Few randomized controlled studies have compared antibiotic regimens against diabetic foot infections (DFIs) in Chinese patients. We evaluated the efficacy and safety of ertapenem versus piperacillin/tazobactam for the treatment of DFIs in Chinese patients” Xu et al (2016).

Abstract:

**Objectives:** Few randomized controlled studies have compared antibiotic regimens against diabetic foot infections (DFIs) in Chinese patients. We evaluated the efficacy and safety of ertapenem versus piperacillin/tazobactam for the treatment of DFIs in Chinese patients.

**Methods:** Patients with moderate to severe DFIs requiring parenteral antibiotics were randomized in a 1:1 ratio to receive ertapenem (1.0 g once daily) or piperacillin/tazobactam (4.5 g every 8 h) by 30 min intravenous (iv) infusions for  $\geq 5$  days. The primary outcome was favourable clinical response at discontinuation of iv therapy (DCIV). An evaluable-patient population was identified for primary analysis of non-inferiority at  $-15\%$ . Safety was assessed. ClinicalTrials.gov: NCT01370616.

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Results: Of 565 patients randomized, 443 patients (ertapenem = 219 and piperacillin/tazobactam = 224) were clinically evaluable for primary analysis. In the clinically evaluable population, the proportions of patients with favourable clinical response at DCIV were 93.6% (205/219) and 97.3% (218/224) in the ertapenem and piperacillin/tazobactam groups, respectively (difference: -3.8%, 95% CI: -8.3%, 0.0%). Ertapenem had a significantly lower favourable clinical response rate (91.5% versus 97.2%, 95% CI for difference: -12.1%, -0.3%) at DCIV in severe DFI patients. In the modified ITT population, 88.8% (237/267) and 90.6% (241/266) of patients in the ertapenem and piperacillin/tazobactam groups, respectively, had favourable clinical responses at DCIV (difference: -1.9%, 95% CI: -7.3%, 3.3%). Microbiological eradications of causative pathogens and adverse events were similar between treatment groups.

Conclusions: Treatment with ertapenem was non-inferior to piperacillin/tazobactam in Chinese patients with DFIs. Ertapenem treatment resulted in a markedly lower rate of clinical resolution in severe DFIs.

Reference:

Xu, Z-R., Ran, X-W., Xian, Y., Yan, X-D., Yuan, G-Y., Mu, S-M., Shen, J-F., Zhang, B-S., Gan, W-J. and Wang, J. (2016) Ertapenem versus piperacillin/tazobactam for diabetic foot infections in China: a Phase 3, multicentre, randomized, double-blind, active-controlled, non-inferiority trial. *Journal of Antimicrobial Chemotherapy*. (2016) 71 (6): 1688-1696.

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