

Session: P066 Various agents against Gram-positive bacteria

Category: 5c. New antibacterial agents: clinical trials

24 April 2017, 12:30 - 13:30
P1348

Multi-national studies comparing solithromycin, a new macrolide, to moxifloxacin in the treatment of CABP: response by geographical region

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Background: Community-acquired bacterial pneumonia (CABP) is a common and serious infection requiring antibiotic therapy. CABP remains a prevalent illness worldwide with resistance rates to macrolides and other classes of antibiotics growing across geographic regions. Despite increasing resistance, no new oral antibiotics have been approved for CABP use in over a decade, creating a medical need for new agents.

Material/methods: A subgroup analysis was conducted based on geographic region in two multinational, phase 3, randomized, double-blind, non-inferiority studies. Both studies enrolled adult patients with CABP. In the first study, patients were randomized to oral solithromycin for 5 days (+2 days placebo) or oral moxifloxacin for 7 days. In the second study, patients received IV solithromycin or IV moxifloxacin for 7 days and were eligible to be switched to oral therapy within the 7 day treatment period when clinically stable. The primary endpoint for both studies was early clinical response (ECR) defined as improvement at 72 [-12/+36] hours after the first dose in at least 2 of the following 4 cardinal symptoms: cough, shortness of breath, chest pain, and difficulty with sputum production.

Results: A total of 859 patients were treated with solithromycin and 860 with moxifloxacin in the two Phase 3 studies with enrollment occurring across 27 different countries. Patients were equally

distributed between treatment groups across geographic regions: Europe (solithromycin 60.9%, moxifloxacin 58.4%), North America (solithromycin 14.9%, moxifloxacin 15.9%), Latin America (solithromycin 6.6%, moxifloxacin 7.6%) and rest of world (solithromycin 14.9%, moxifloxacin 15.9%). In total, 78.7% of patients in the solithromycin group (676/859) and 78.8% of patients in the moxifloxacin group (678/860) achieved ECR (treatment difference: -0.16; 95% CI: -4.0, 3.7) in the pooled studies. Solithromycin and moxifloxacin demonstrated comparable responder rates for the ECR endpoint within each geographic region: Europe (solithromycin 80.3%, moxifloxacin 83.3%); North America (solithromycin 72.8%, moxifloxacin 66.0%); Latin America (solithromycin 73.7%, moxifloxacin 73.8%), and rest of world (solithromycin 81.3%, moxifloxacin 79.6%).

Conclusions: Effective new antibiotic treatments are needed for CABP due to growing antimicrobial resistance in regions across the globe. Solithromycin, a new macrolide antibiotic, demonstrated non-inferiority to moxifloxacin, a potent fluoroquinolone, in the treatment of CABP in multinational studies conducted in > 25 countries. Solithromycin demonstrated a comparable treatment effect to moxifloxacin in each geographic region where the studies were conducted, indicating it is a promising potential new empiric therapy for CABP.