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### Efficacy of solithromycin for treatment of community-acquired pneumonia (CAP) by patient age: pooled analysis of 2 multinational, double-blind, randomized, controlled studies

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**Background:** CAP is a common and serious pulmonary infection that disproportionately affects the elderly, with increasing morbidity and mortality by age.  We evaluated the efficacy of solithromycin versus moxifloxacin, an approved and potent fluoroquinolone, for treatment of CAP in patients by age group.

**Material/methods:** Subgroup analyses were conducted by patient age in two phase 3, randomized, double-blind, non-inferiority studies. Both studies enrolled adult patients with a diagnosis of CAP; randomization was stratified by geographic area, history of asthma and/or COPD, and PORT Risk Class (II vs III/IV). In SOLITAIRE-Oral patients received oral solithromycin for 5 days (+2 days placebo) or oral moxifloxacin for 7 days.  In SOLITAIRE-IV, 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 cardinal symptoms: cough, shortness of breath, chest pain, and difficulty with sputum production.  Study investigators also assessed patient clinical response at a short-term follow-up visit 5 to 10 days after last dose as a secondary efficacy endpoint.

**Results:** A total of 859 patients were treated with solithromycin and 860 with moxifloxacin in these studies. The mean age for patients treated with solithromycin was 59.5 years and with moxifloxacin was 58.9 years. The overall responder rate for the primary endpoint of ECR in the pooled data set was 78.7% (676/859) vs 78.8% (678/860) in solithromycin and moxifloxacin recipients, respectively. ECR rates for patient subgroups by age were comparable between treatment groups: <65 years [solithromycin 78.7% (407/517) vs moxifloxacin 81.0% (426/526)], ≥ 65 years [solithromycin 78.7% (269/342) vs moxifloxacin 75.4% (252/334)], and ≥ 75 years [solithromycin 79.3% (115/145) vs moxifloxacin 75.7% (106/140)]. Clinical success rates as determined by the investigator 5 to 10 days after last dose were also comparable between treatment groups by age: <65 years [solithromycin 83.2% (430/517) vs moxifloxacin 87.8% (462/526)], ≥ 65 years [solithromycin 86.8% (297/342) vs moxifloxacin 87.1% (291/334)], and ≥ 75 years [solithromycin 84.1% (122/145) vs moxifloxacin 86.4% (121/140)].

**Conclusions:** Solithromycin and moxifloxacin were comparably effective in the treatment of CAP across patient age subpopulations, including for at-risk elderly patients ≥ 65 or ≥ 75 years of age.