

Prevalence of Pneumococcal Serotypes in Adults Enrolled in a Phase 3 Trial that Evaluated the Efficacy and Safety of Oral Solithromycin (CEM-101) versus Moxifloxacin in Adults with CABP

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Background: We investigated the prevalence and geographic distribution of *Streptococcus pneumoniae* (Spn) serotypes in patients from a randomized, double-blind Phase 3 trial to evaluate the efficacy and safety of oral solithromycin compared to oral moxifloxacin in the treatment of adults with CABP.

Methods: Key inclusion criteria included ≥ 18 years of age, chest x-ray showing lobar or multilobar infiltrates and consistent signs and symptoms. Spn was identified as an etiologic agent on the basis of blood or sputum culture, urine antigen testing (BINAX), sputum multiplex PCR (Unyvero™ by Curetis) and quantitative Spn PCR of nasopharyngeal (NP) swabs. Spn isolates recovered from patients by culture from blood, sputum, or nasopharyngeal (NP) swabs were serotyped by Quellung reaction.

Results: 860 patients were enrolled from 16 countries across Europe (52.1%), Latin America (12.3%), North America (23.7%) and South Africa (11.9%). The overall Spn diagnosis rate for the trial was 23%. Spn isolates from blood (N=16), sputum (N=72) or NP swab (N=79) from 123 unique patients were available for serotyping. With 3 exceptions, the serotype of blood or sputum Spn was the same as Spn from the nasopharynx. 35 different serotypes were detected, with serotype 3 as the most prevalent (10.6%), followed by 19F (7.3%) and 19A (5.7%). Overall, 43.9% of patients with serotyped Spn had types in the 13-valent pneumococcal conjugate vaccine (PCV13), 60.2% had types in the pneumococcal polysaccharide vaccine (PPSV23) and 38.2% had Spn not represented in either vaccine. The prevalence of patients with Spn serotypes contained in PCV13 and PPSV23 by region are shown below.

	Europe	Latin America	North America	South Africa
Number of Randomized Patients	448	106	204	102
Patients with any Pathogen Diagnosis, N (Rate)	257 (57.4%)	68 (64.2%)	84 (41.2%)	52 (51%)
Patients with Pneumococcal Pneumonia, N (Rate)	114 (25.4%)	32 (30.2%)	24 (11.8%)	27 (26.5%)
Patients with Serotyped Spn, N	79	15	13	16
PCV13	50.6%	73.3%	15.4%	25%
PPSV23	63.3%	86.7%	53.8%	43.8%

Conclusion: Since there was very good correlation between the serotypes in the NP and blood/sputum of CABP patients, NP swabs may be able to replace sputum cultures if a quantitative threshold diagnostic of pneumonia is met. 38.2% of patients had isolates not represented in the PCV13 or PPSV23 vaccines.