Introduction

Cempra conducted a randomized, double-blinded Phase 3 trial which evaluated the efficacy and safety of oral solithromycin (5 days) compared to the oral fluoroquinolone, moxifloxacin (7 days), for the treatment of adult patients with CAPB. As pneumococcal vaccines are becoming widely used worldwide, including PCV13 (Children) and PPVS23 (adults), this phase 3 trial presented a unique opportunity to further evaluate the overall prevalence of pneumococcal types causing CAPB, the correlation between the pneumococcal type isolated from the nasopharynx and those strains isolated from blood or sputum and the use of pneumococcal density in nasopharyngeal specimens for detecting pneumococcal pneumonia.

Methods

• Enrollment criteria included the following: ≥18 years of age, acute onset or worsening of at least 3 of 4 cardinal symptoms (cough, dyspnea, chest pain, and sputum production), must have fever or hypothermia, and/or physical exam findings consistent with CAPB, chest radiograph with lobular or multifocal infiltrates, and no long-acting antibiotic use during the prior 7 days.

• Baseline microbiological evaluation included cultures of blood and sputum, detection of S. pneumoniae and Legionella pneumophila antigen in urine, L. pneumophila and Mycoplasma pneumoniae serotypes (4-fold diagnostic rise in titer), quantitative real-time (qRT) PCR and culture of nasopharyngeal swabs for S. pneumoniae, culture and PCR of oropharyngeal swabs for M. pneumoniae, and sputum multiplex PCR for lower respiratory pathogens (VPIs) (by Cureltek).

• The use of qPCR of NP swabs significantly increased the rate of identification of Spn as the cause of CABP. Diagnosis by NP swab PCR was better correlated with blood culture, sputum culture and UAT, than any of these more traditional diagnostic methods were with one another.

Conclusions:

• S. pneumoniae was the most prevalent bacterial pathogen isolated in the Phase 3 CIBP trial. Whereas 35 different Spn serotypes were identified, vaccine escape types were found in >38% of patients with Spn CAPB.

• We observed a very strong correlation (>98%) between the pneumococcal serotype isolated from blood or sputum, utilized as definitive diagnoses of pneumococcal pneumonia, and those isolated from the nasopharynx of Spn pneumonia patients.

• The use of qPCR of NP swabs significantly increased the rate of identification of Spn as the cause of CABP.

• Diagnosis by NP swab PCR was better correlated with blood culture (87%), sputum culture (55%) and UAT (46%), than any of these more traditional diagnostic methods were with one another.

References


2. Emory University, 1518 Clifton Road Atlanta, GA, USA; a)Cephalospir, Inc., Chapel Hill, NC, USA; b)Das Consulting, San Francisco, CA, USA.
