ORAL ABSTRACTS

907. Clinical Characteristics and Outcomes of Patients With Community-Acquired Pneumonia—Real-Life Versus Food and Drug Administration (FDA) Trials: Results From the Community-Acquired Pneumonia Organization (CAPO) International Cohort Study

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Background. The FDA approval of antibiotics for community-acquired pneumonia (CAP) is based on Phase III clinical trials. For most trials, there is a consistent effect of 90% clinical cure rate for the experimental antibiotic, with a very low rate of mortality in both arms. Since these trials have significant numbers of exclusion criteria, the proportion of CAP patients in FDA trials may not be representative of a "real-life" CAP population. The objective of this study was to compare clinical outcomes in hospitalized patients with CAP for a population of patients that would be included in FDA trials versus a population of real-life CAP patients.

Methods. This was a secondary data analysis of the Community-Acquired Pneumonia Organization (CAPO) international cohort study. The FDA population was defined via exclusion of patients with the following: cancer, severe renal disease, severe liver disease, nursing home residency, prior antibiotic use in 30 days, and HIV or other immunosuppressive conditions.

Results. A total of 1676 patients were included in the FDA population, and 3397 in the real-life population. In-hospital and 30-day mortality were significantly lower in the FDA population compared to the real life population (6% versus 9%, respectively for in-hospital mortality, $P < 0.001$; 8% versus 12% for 30-day mortality, $P = 0.002$).

Conclusion. This study indicates that FDA populations in clinical trials of CAP have significantly lower mortality than real life populations. Healthcare workers treating patients with CAP should be aware that results of FDA clinical trial may not translate to real life populations of CAP patients.

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