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Poster Session I

Antibiotic choices: clinical studies

ELDERLY EXCLUSION FROM RANDOMIZED CLINICAL TRIALS ON THE TREATMENT OF ANTIMICROBIAL RESISTANT INFECTIONS.

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Objectives: Incidence and mortality of infections due to antibiotic-resistant bacteria in the elderly are significantly higher than in the young population. Despite the recommendations of international regulatory agencies, exclusion of older individuals from therapeutical trials is common. The objective of this study was to check the exclusion of the elderly in randomized controlled trials (RCTs) on treatment efficacy of methicillin-resistant *Staphylococcus aureus* (MRSA) skin and skin tissue infections (SSTI). Target microorganism and infection were selected by incidence and availability of new antibiotics.

Methods: A systematic review of the literature including RCTs on treatment of MRSA SSTI was performed in the study period 2000-2013 through computerized databases (PUBMED, EMBASE) and retrieving of selected references. No restriction of language was applied. Data on study design and outcome were extracted. The assessment of age as a confounder of treatment effects in the RCTs as well as stratification or performance by subgroup analysis by age was evaluated.

Results: On 12 RCTs for the treatment of MRSA SSI, 8 (66%) included hospitalised patients and 9 (75%) were industry sponsored. No trial was designed specifically to study older adults. The mean age of included patients was 50 years both in intervention and control groups (range, 18-96). Compared to a large cohort study of patients with SSTI, mean age of patients included in the RCTs was significantly ($p < 0.001$) younger. The majority of studies (9, 75%) excluded patients with comorbidities, including diabetes and renal insufficiency. Patients enrolled in RCTs including severe comorbidities were significantly younger ($p < 0.001$). One RCT (8%) excluded patients over 75 years. One study showed lower effectiveness in treatment in the group aged ≥ 65 and 75 years, compared to younger population.

Conclusions: Despite the recommendations of international regulatory agencies, the exclusion of older individuals from trials regarding treatment effectiveness in patients with MRSA SSTI is significant. In an era of increase spreading of antimicrobial resistant this exclusion limits the value of the evidence that clinicians use when treating a significant part of the affected population. Specific measures need to be developed to guarantee the involvement of the elderly in RCTs analysing the efficacy of new antibiotics.