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Effectiveness and Safety of Generic Formulation of Piperacillin/Tazobactam (Astaz-PR) for Treatment of Infected Patients at Siriraj Hospital

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Abstract

Objective: To determine effectiveness and safety of generic piperacillin/tazobactam (Astaz-PR) that has been available as a substitute for original piperacillin/tazobactam (TazocinR) in Siriraj Hospital since October 2011.
Material and Method: Medical records of hospitalized adult patients who received piperacillin/tazobactam for at least 48 hours from January 2011 to June 2012 were reviewed. The data on demographics, clinical features of infections, antibiotic treatments, clinical courses and outcomes of the patients who received original piperacillin/tazobactam and generic piperacillin/ tazobactam were analyzed and compared.
Results: The medical records of 300 patients who received original piperacillin/tazobactam and 300 patients who received generic piperacillin/tazobactam were included. The characteristics of the patients and clinical and microbiological features of infections of the patients in both groups were not significantly different. Overall favorable clinical outcome and overall mortality were comparable between generic and original groups (74.0% vs. 74.7%, p = 0.93; 18.3% vs. 18.0%, p = 1.00, respectively). No significant difference of adverse effect was found between two groups. The non-inferiority test indicated that the clinical outcome and overall mortality of the patients who received generic piperacillin/tazobactam were not inferior to those who received original piperacillin/tazobactam (p = 0.004 and p = 0.001, respectively).
Conclusion: Generic piperacillin/tazobactam (Astaz-PR) was not inferior to original piperacillin/ tazobactam (TazocinR) for therapy of infections in the hospitalized patients at Siriraj Hospital.

Keywords: Piperacillin/tazobactam, Original, Generic, Non-inferiority, Effectiveness, Safety

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