A Cluster-Randomized Controlled Trial of Trained Pharmacists and Infectious Disease Fellows for Approval of Restricted Antibiotics in Hospitalized Medical Patients at Siriraj Hospital

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Background: Siriraj Hospital has implemented antibiotic post-authorization program (piperacillin/tazobactam, meropenem, imipenem/cilastatin and doripenem) for nearly 10 years. Currently, antibiotic approval is implemented by ID-fellows.

Methods: During February-September 2013, we conducted a cluster-randomized controlled trial in 6 general medical wards at Siriraj hospital to compare the impact of antibiotics approval by ID-fellows vs. trained general pharmacists in terms of clinical/microbiological outcomes and antibiotic consumption/expenditure. Three wards were randomly assigned to the pharmacist group while the other three wards were assigned to the fellow group. The target antibiotics can be prescribed by responsible physicians during the first 72 hours, after that an approval from the fellows or the pharmacists is required.

Results: The preliminary analysis included 161 patients (178 prescriptions) in the pharmacist group and 168 patients (181 prescriptions) in the fellow group. The equivalence can only be proved in the superimposed infection outcome ($\Delta=-0.44\% [-4.83-5.71]$) but the non-inferiority of the pharmacist group could be assumed in the ID-death ($\Delta=-3.68\% [-10.65-3.3]$), favorable clinical outcome ($\Delta=3.53\% [-6.75 to 13.82]$) and favorable microbiological outcome ($\Delta=7.67\% [-1.34-16.67]$). The defined daily dose (DDD) of target antibiotics/prescription was significantly higher in the pharmacist group (11.76 ± 11.96 vs. 10.16 ± 9.50; $P=0.02$). However, there was no difference in the DDD of all antibiotics/prescription (32.52 ± 38.27 vs. 30.09 ± 39.62; $P=0.36$).

Conclusion: Although the patients who received antibiotic approval by the pharmacists had significantly higher consumption of target antibiotics, there was no significant difference in antibiotic expenditure and important treatment outcomes. Therefore, the trained pharmacists could be an alternative to ID specialists for antibiotic approval in the resource limited setting. (ClinicalTrials.gov number, NCT 01797133)