ABSTRACT

ANALYSIS OF ADVERSE EVENTS OCCURENCE IN DRUG RESISTANT TUBERCULOSIS REGIMENTS (Study at TB MDR Unit of Dr Soetomo Teaching Hospital)

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Background – Prevalence of Adverse event in Drug Resistant TB regiment is very high. Adverse event is one of the most important factor in compliance, morbidity, mortality and outcomes of Drug Resistant TB therapy. Identification and prevention of adverse event is very necessary for better management of adverse events in Drug Resistant TB regiment therapy.

Objective – The aim of this study was to analyze incidences and factors that influence the incidence of adverse events in Drug Resistant TB regiment and to increase our understanding about how to prevent, identify and manage this adverse event.

Method – This observational cross sectional retrospective study was approved by the Ethics Committee of Dr Soetomo Teaching Hospital. Data was collected from medical record of patients who visit MDR TB unit from April 2015 to March 2017. Adverse event were identified using CTCAE v4.03 and their casuality relatioanship were analyzed using Algorithm Naranjo and WHO-UMC Methods. The relationship batwaeen non parametric data were analyzed using chi square test, and relationship between parametric and non parametric data were analyzed using binary logistic regression test. Odds ratio were analyzed using Mantel-Haenszel test.

Result – 106 patients were included in this study. The most common adverse events are hiperuricemia in 69 (66%) patients, hipokalemia in 43 (41%) patients, nephrotoxicity in 35 (33%) patients, GIT disturbance in 30 (28%) patients, ototoxicity in 16 (15%) patients and hepatoxicity in 13 (12%) patients. There were 3 cases wich fulfill the certain/definitif criteria and 35 cases were categorized as probable. There were no correlation between dose per kilogram body weight and the occurence of adverse event. Correlations were existed between age ($p<0.05$), body weight ($p<0.05$) dan comorbid diabetes melitus ($p<0.05$) with nephrotoxicity and lower pre eGFR values with incidences of hiperuricemia ($p<0.05$). Renal function decreasing is identified as factors that increase the occurence of hyperuricemia and hipokalemia OR 3.746 (CI 95% 1.383-10.145) and OR 2.326 (CI 95% 1.017-5.318). There is a trend of higher incidence of nephrotoxicity in capreomicin containing regiment compare to kanamicyn regiment (OR 2.328 (CI 95% 1.011-5.362)).

Conclusion–adverse evens are very common in TB MDR regiment therapy. It is very necessary to established an interdiciplinary collaboration for identification, prevention and more effective managements of adverse event in TB MDR regiment.

Keywords: TB RR, TB MDR, TB XDR, Drug Resistant TB regiment, hyperuricemia, hypokalemia, nephrotoxicity, ototoxicity, hepatotoxicity