UNIVERSITI TEKNOLOGI MARA

DRUG-INDUCED THROMBOCYTOPENIA IN MALAYSIA FROM 2011 UNTIL 2015

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ABSTRACT

Background: Adverse drug reaction (ADR) is an unintended and harmful response to body after drug intake. Thrombocytopenia is any disorder that related to platelets. When the amount of platelets in blood is low than normal, the person are exposed to mild or serious bleeding. The serious bleeding occurs if the platelet count less than 10,000 or 20,000 per microliter of blood. Drug-induced thrombocytopenia can be refer as medicine or drugs caused low platelet count in body.

Objectives: This study focus on identify the trend of drug induced thrombocytopenia and severity reported in Malaysia from 2011-2015, determine an association between patient characteristics (age, gender and race) with severity of thrombocytopenia, identify the most common drug-induced thrombocytopenia and determine the management on drug induced thrombocytopenia.

Methods: This is a retrospective study between years 2011 until 2015. The data was collected at the Pharmacovigilance Section, National Pharmaceutical Control Bureau (NPCB) through the data from the Quest 2 database or MADRAC. All drug-induced thrombocytopenia reported (2011-2015) were recorded.

Results: The highest cases of drug induced thrombocytopenia happen at year 2013 (n = 121; 26.6%) and lowest cases at year 2011 (n = 52; 11.4%). Female (n= 238; 52.3%) had slightly more risk towards drug induced thrombocytopenia (DIT) compare to male (n= 210; 46.2%) and Malay (n=178; 39.1%) had higher DIT compared to other race. Majority patients had moderate (n= 215; 47.3%) thrombocytopenia. There is no association between patient characteristics with severity of DIT. The highest common drug in which lead to DIT was rifampicin (n= 60; 25.2%) and the lowest were heparin and phenytoin. The total cases of patient death due to thrombocytopenia were twenty four cases with thirteen different of drugs. The main management was stop the suspected medication (n= 265; 58.2%) when DIT happened.

Conclusion: The most common drug for DIT was rifampicin. There is no association between the patient characteristics (age, gender and race) with severity of DIT. DIT cannot be predicted because it is differ in each person. Physician and hospital staff need to put extra precaution on common drug that lead to DIT. Hence patients will be protected or the event DIT could be lessen or prevented.

CHAPTER 1

INTRODUCTION

1.1 Overview of Adverse drug reaction and thrombocytopenia

Adverse drug reaction (ADR) is an unintended and harmful response to body after drug intake. National Patient Safety Agency (NPSA) (2007) stated that when the medicine lead to harm on patient but no error happened, the incident called 'non-preventable' or adverse drug reaction (ADR). Edwards and Aronson (2000) define ADR as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product. The severe ADR can be occur at any dose in which results in death, need hospital admission, results in persistent or significant disability, or life threatening.

Thrombocytopenia is a platelet disorder. Platelets have function to clot the bloods. The normal platelets count for adult is 150,000 to 450,000 platelets per microliter of blood. When the amount of platelets in blood is low than normal, the patients are exposed to mild to serious bleeding. The bleeding can happen inside the body (internal) and below or surface skin (external). The serious bleeding occurs if the platelet count less than 10,000 or 20,000 per microliter. Whereas the mild bleeding will be happen when the platelets less than 50,000 per microliter (PubMed 2013). When there are not enough amount of platelets, the thrombocytopenia will be happened. Drug-induced thrombocytopenia can be referred as medicine or drugs caused low platelet count in body (Medlineplus-NIH n.d.).