### UNIVERSITI TEKNOLOGI MARA

# EFFICACY AND SAFETY OF FONDAPARINUX AGAINST ENOXAPARIN AMONG PATIENTS UNDERGOING ORTHOPAEDIC SURGERY IN HOSPITAL SELAYANG

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Dissertation submitted in partial fulfilment of the requirements for the degree of **Master of Pharmacy Practice** 

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#### **CONFIRMATION BY PANEL OF EXAMINERS**

I certify that a Panel of Examiners has met on 23th January 2017 to conduct the final examination of Siti Syarihan Binti Abdullah on her Master of Pharmacy Practice dissertation entitled "Efficacy and Safety of Fondaparinux against Enoxaparin Among Patients Undergoing Orthopaedic Surgery in Hospital Selayang" in accordance with Universiti Teknologi MARA Act 1976 (Akta 173). The Panel of Examiners recommended that the student be awarded the relevant degree. The panel of Examiners was as follows:

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#### **AUTHOR'S DECLARATION**

I declare that the work in this dissertation was carried out in accordance with the regulations of Universiti Technologi MARA. It is original and is the results of my own work, unless otherwise indicated or acknowledge as referenced work. This dissertation has not been submitted to any other academic institution or non-academic institution for any degree or qualification.

I, hereby, acknowledge that I have been supplied with the Academic Rules and Regulations for Postgraduate, Universiti Technologi MARA (UITM), regulating the conduct of my study and research.

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#### **ABSTRACT**

Venous thromboembolism (VTE) is a common complication in orthopaedic surgery patients. Malaysian Clinical Practice Guidelines (CPG) on Prevention and Treatment of Venous Thromboembolism (2013) has recommended both enoxaparin and fondaparinux as the VTE prophylaxis. Although many studies had been conducted to evaluate the safety and efficacy of fondaparinux as VTE prophylaxis, there is no study ever conducted in Malaysia to determine the efficacy and safety of fondaparinux against enoxaparin among orthopaedic patients. Furthermore, the genetic diversity between patients in Malaysia and in overseas may limit the generalizability of the previous study's findings. The objective of this study was to evaluate the efficacy and safety of fondaparinux against enoxaparin as VTE prevention among patients undergoing orthopaedic surgery in Hospital Selayang. This study was conducted retrospectively by examining electronic medical records of all patients receiving either fondaparinux or enoxaparin as a VTE prophylaxis for orthopaedic surgery in Hospital Selayang from 1<sup>st</sup> January until 31<sup>st</sup> December 2015. A total of 99 patients in enoxaparin group and 38 patients in fondaparinux group were included in the study. There were 3 cases of VTE observed in enoxaparin group, while no VTE incidence was observed in fondaparinux group. The number of major bleeding events detected was 42 cases (42.4%) in enoxaparin group and 13 cases (34.2%) in fondaparinux group. No association was found between these two groups for VTE and major bleeding incidences (p = 0.56 and 0.38 respectively). Variable associated with VTE incidence was obesity (p=0.02). While independent predictor for major bleeding incidence was the timing start of propylaxis (p=0.01). When adjusted for confounders like timing start of prophylaxis and concomitant antiplatelet, the number of concurrent medication also had a significant relationship with major bleeding (p=0.037). In conclusion, fondaparinux had similar efficacy and safety profiles with enoxaparin in preventing VTE in orthopaedic surgery patients. VTE incidence following orthopaedic surgery was associated with obesity, while major bleeding incidence was influenced by the timing start of VTE prophylaxis. The number of concurrent medication was also a significant contributor to major bleeding, when adjusted for other confounders.

Keywords: fondaparinux, enoxaparin, VTE, major bleeding, orthopaedic surgery

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