UNIVERSITI TEKNOLOGI MARA

EVALUATION OF VIROLOGICAL AND IMMUNOLOGICAL RESPONSE, AND INCIDENCE OF ZIDOVUDINE-INDUCED ANAEMIA AMONG INNOVATOR AND GENERIC ZIDOVUDINE/LAMIVUDINE

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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 Teknologi MARA. It is original and is the result of my own work, unless otherwise indicated or acknowledged as referenced work. This writing 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 Post Graduate, Universiti Teknologi MARA, regulating the conduct of my study and research.

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ABSTRACT

Zidovudine/Lamivudine (AZT/3TC) are commonly used in HAART regimen as the backbone NRTI for first-line therapy in developing countries. A generic combination tablet of AZT/3TC is currently used in all government hospitals in Malaysia. Studies comparing safety and efficacy of generic AZT/3TC are very limited. Thus, a retrospective observational cohort study was conducted to evaluate virological and immunological response, and anaemia incidence among patients treated with AZT/3TC. A total of 109 samples were recruited, with 65 samples initiated innovator and 44 generic. Virological and immunological response in both cohort were similar. Although viral load suppression to undetectable level (< 50 copies/ml) in generic group was slightly earlier as compared to innovator (median: seven months vs. eight months), this was not statistically significant ($p = 0.550$). Similarly, mean difference in terms of increment of CD4 cell count post 12 months therapy and median duration to achieve CD4 count >350 cells/µl were not statistically significant ($p = 0.505$ and $p = 0.190$). Incidence of Zidovudine-induced anaemia were found in 10.8% ($n = 7$) in innovator and 15.9% ($n = 7$) in generic cohort, with median time to develop anaemia was two and three months respectively ($p = 0.169$). In conclusion, our findings demonstrated similar clinical outcomes in patients treated with either innovator or generic formulation of AZT/3TC in terms of virological and immunological response. The risk of developing Zidovudine–induced anaemia was also similar in both groups. Therefore, it is justifiable to use generic AZT/3TC as the backbone NRTI in HAART regimen.

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