Developing pharmacokinetics–pharmacodynamics model of valproic acid syrup based on prediction of population pharmacokinetics parameter and seizure frequency in Indonesian pediatric epilepsy outpatients

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Abstract

Objectives

Valproic acid (VPA) is a broad-spectrum antiepileptic drug with known efficacy profile in pediatric patients, despite of its narrow therapeutic index. There is lack of VPA's pharmacokinetics profile in Indonesian pediatric subjects, partly due to limited pediatric blood volume taken for conducting therapeutic drug monitoring. This study aimed to determine the correlation between VPA pharmacokinetics parameters based on population data and seizure frequency in pediatric epilepsy outpatients.

Methods

This observational study was conducted at Sanglah General Hospital during June–December 2019. The subjects of this research were 38 pediatric epilepsy patients who adhered to VPA syrup monotherapy for at least 3 weeks. Five subjects randomly selected for blood sample collection. Thus, VPA concentration level in the blood being analysed as a comparison to its concentration predicted from Yukawa's steady state equation. Monolix2019R2® software was used to identify VPA population pharmacokinetics–pharmacodynamics (PK–PD) parameters at steady state level.

Results

Population PK–PD of VPA syrup at steady state level were $ka_{pop} = 6.25/h$, $Vd_{pop} = 3.36 L$, $Cl_{pop} = 3.17 \times 10^{-11} mL/min$, $IC_{50\_pop} = 1.85 \times 10^{-6}$, correlation of Vd_{pop} and $Cl_{pop} = 0.966$. Kendall Tau Correlation of predicted VPA steady state concentration and frequency of seizure was -0.66 . Mean prediction error between predicted steady state concentration of five subjects and their related blood levels was $\pm 25\%$ and considered as within clinically acceptable limit.

Conclusions

It needs further study to develop best matched PK–PD model of VPA syrup at steady state condition in pediatric epilepsy.

Keywords: [pediatric](#); [population pharmacokinetics](#); [prediction of concentration](#); [seizure frequency](#); [valproic acid](#)

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Competing interests: Authors state no conflict of interest.

Informed consent: Informed consent was obtained from all individuals included in this study.

Ethical approval: Research involving human subjects complied with all relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration (as revised in 2013), and has been approved by the authors' institutional review board or equivalent committee.

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Supplementary Material

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