



## Comparison of Novel LC-MS and EMIT Methods for Therapeutic Monitoring of Phenytoin in Epilepsy Patients and its Clinical Applications

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**SUMMARY.** The purpose of this study is to compare the correlation between liquid chromatography-mass spectrometry (LC-MS) and enzyme-multiplied immunoassay technique (EMIT) for the measurement of phenytoin (PHT) concentration in human plasma and to offer guide for clinical and pathological laboratories in clinical settings. The blood samples of 27 epilepsy patients were collected for analysis of PHT and compared through two methods. The calibration curves were linear within the range of 0.2-20 µg/mL for LC-MS and 2.5-40 µg/mL for EMIT, respectively. The inter- and intra-day RSDs were less than 10%. The correlation of the two methods was good ( $r^2 = 0.921$ ). Phenytoin plasma concentration determined by EMIT was 3.5 µg/mL lower than LC-MS. There was 95% confidence interval which is -21.4~14.3 µg/mL. There were no statistically significant differences between the two methods ( $P > 0.05$ ). Both of the methods were suitable for determining phenytoin concentration. The correlation between the two methods was very good but phenytoin concentration determined by LC-MS was higher than EMIT. However, its clinical significance needs further evaluation.

**RESUMEN.** El propósito de este estudio es comparar la correlación entre la cromatografía líquida con espectrometría de masa (LC-MS) y la técnica de inmunoensayo multiplicado por enzimas (EMIT) para la medición de la concentración de fenitoína (PHT) en plasma humano y ofrecer una guía para estudios clínicos y laboratorios patológicos en entornos clínicos. Las muestras de sangre de 27 pacientes de epilepsia se recogieron para el análisis de PHT y se compararon a través de dos métodos. Las curvas de calibración fueron lineales en el intervalo de 0,2-20 µg/mL para LC-MS y 2,5-40 µg/mL para EMIT, respectivamente. Las RSD intra- e intra-día fueron inferiores al 10%. La correlación de los dos métodos fue buena ( $r^2 = 0,921$ ). La concentración plasmática de fenitoína determinada por EMIT fue 3,5 µg/mL menor que LC-MS. Hubo un intervalo de confianza del 95% que es de -21,4~14,3 µg/mL. No hubo diferencias estadísticamente significativas entre los dos métodos ( $P > 0,05$ ). Ambos métodos resultan adecuados para determinar las concentraciones de fenitoína. La correlación entre los dos métodos fue muy buena, pero la concentración de fenitoína determinada por LC-MS fue mayor que EMIT. Sin embargo, su significado clínico necesita una evaluación adicional.

**KEY WORDS:** antiepileptic drugs, comparison of LC-MS and EMIT, phenytoin

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