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Postmarketing Safety of Irinotecan and Association with Pharmacogenomic Studies: a Pharmacovigilance Study Based on FDA Adverse Event Reporting System (FAERS)

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SUMMARY. **In this study, we aimed to conduct a descriptive research based on FAERS, to comprehensively evaluate the post-marketing safety of irinotecan, and the impact of pharmacogenomics studies on it. We accessed all available reports from the FAERS public dashboard. Taking irinotecan, UGT1A1, and SLCO1B1 as keywords, searched all literatures in PubMed. A total of 18,294 cases were included in the final analysis. The 60-69 age group has the largest number of ADRs, Myelosuppression accounted for the largest proportion (17.60%), followed by diarrhea (12.82%). 17,933 cases (98.03%) are serious, and 3,293 (18.23%) led to death. The total and death ADRs began to decrease after 2018 (APC = -26.25) and 2014 (APC = -8.19), respectively. The pharmacogenetic studies ushered rapid growthand during 1998-2006, then remained relatively high (APC = -0.12). With the development of pharmacogenomics, the ADRs caused by irinotecan showed a downward trend, indicating the importance of personalized medicine.**

RESUMEN. En este estudio, nuestro objetivo fue realizar una investigación descriptiva basada en FAERS, para evaluar de manera integral la seguridad posterior a la comercialización de irinotecán y el impacto de los estudios de farmacogenómica en él. Accedimos a todos los informes disponibles desde el panel público de FAERS. Tomando irinotecán, UGT1A1 y SLCO1B1 como palabras clave, buscó toda la literatura en PubMed. En el análisis final se incluyeron un total de 18.294 casos. El grupo de edad de 60 a 69 años presenta el mayor número de RAM, la mielosupresión representó la mayor proporción (17,60 %), seguida de la diarrea (12,82 %). 17.933 casos (98,03%) son graves y 3.293 (18,23%) provocaron la muerte. Las RAM totales y de muerte comenzaron a disminuir después de 2018 (APC = -26,25) y 2014 (APC = -8,19), respectivamente. Los estudios farmacogenéticos marcaron el comienzo de un rápido crecimiento y durante 1998-2006, luego se mantuvieron relativamente altos (APC = -0.12). Con el desarrollo de la farmacogenómica, las RAM provocadas por el irinotecán mostraron una tendencia a la baja, lo que indica la importancia de la medicina personalizada.

KEY WORDS: FAERS, irinotecan, joinpoint regression, pharmacogenomics, postmarketing safety.

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