

レセプトデータを用いた安全性監視活動の将来展望： セルトラリン製造販売後調査結果とレセプトデータの比較

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A Perspective of Pharmacovigilance Using the Healthcare Claim Database,
Based on Comparison with Sertraline Post Marketing Surveillance

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Summary

In Japan, most new drugs or drugs approved for additional indications are required to conduct post marketing surveillance (PMS). In addition to conventional PMS, pharmacoepidemiological studies have attracted attention recently as a means of evaluating the efficacy and safety of drugs in clinical practice. In Japan, however, few large-scale databases are available for pharmacoepidemiological studies.

Therefore, we examined the feasibility of using the large-scale health insurance claim database as a tool for pharmacovigilance in Japan by comparing the data for patients prescribed sertraline with the sertraline PMS results. We also explored the possibility of detecting safety signals in the claim database by means of sequence symmetry analysis (SSA), which is a self-controlled study design.

Most characteristics of the patients were not so different between the claim database and the PMS, and the differences that were found could be explained in terms of the characteristics of each data source. When the possibility of detecting safety signals from the claim database was explored for diabetes mellitus, hyperlipidemia and hyperthyroidism, we found no tendency for elevated risk of these events after exposure to sertraline, in accordance with the PMS data and sertraline's known safety profile.

We expect that the safety of other drugs could be examined similarly. It seems worthwhile to explore more thoroughly how database research could contribute to pharmacovigilance in Japan.

Key words

Sertraline, Database research, Pharmacovigilance, Post marketing surveillance, Healthcare claim