

Pharmacovigilance of paracetamol-induced Stevens–Johnson Syndrome and toxic epidermal necrolysis in the Indian population

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Abstract:

AIMS: Despite decades of proven safety of paracetamol, serious and rare reactions such as Stevens–Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) often occur in the Indian population. The current study aimed to understand the safety profile of this relatively safer drug, paracetamol, with respect to rare and serious adverse events, SJS/TEN, based on data collected from the Indian population through the Pharmacovigilance Programme of India.

METHODS: The collected, collated and analyzed all Individual Case Safety Reports with the use of paracetamol from the Indian population for the period January 1, 2010, to December 31, 2021, were reported to VigiBase and analyzed using the WHO database, VigiLyze.

RESULTS: Analysis of the reported data showed that 313 SJS/TEN adverse events were associated with the use of paracetamol. Disproportionality analysis of paracetamol-induced SJS/TEN reactions in the Indian population using the Proportional Reporting Ratio (PRR), reporting odds ratio, and the information component indicated higher risk of paracetamol in the Indian population.

CONCLUSIONS: The findings provide crucial insights into the extent of rare and infrequent SJS/TEN associated with the use of paracetamol in the Indian population. Owing to the seriousness of reaction and the widespread use of paracetamol for fever-like illness, the prescribing physicians, pharmacists, and other healthcare professionals should closely monitor patients administered paracetamol for this potential rare reaction, SJS/TEN.

Keywords:

Paracetamol, pharmacovigilance, Stevens–Johnson Syndrome, toxic epidermal necrolysis