

Sex differences in ADR reports for drugs used to treat COVID-19

Adverse drug reaction (ADR) reporting patterns for drugs used to treat COVID-19 appear to differ between men and women, according to findings of a study published in *Drug Safety*.

Data from VigiBase, the WHO global database of individual case safety reports (ICSRs), were used to investigate ADR reporting in male versus female patients receiving drugs for the treatment of COVID-19 (azithromycin, chloroquine, hydroxychloroquine, lopinavir/ritonavir, oseltamivir, remdesivir and tocilizumab) in over 130 countries, and to compare ADR reporting when these drugs were used for other indications.

Overall, 2573 ICSRs associated with drugs used to treat COVID-19 were submitted to VigiBase as of 7 June 2020, and 93% of these reports included azithromycin, chloroquine, hydroxychloroquine, lopinavir/ritonavir and/or remdesivir. Lopinavir/ritonavir was more frequently reported in men than in women (309 vs 160 ICSRs).

The most frequently reported ADRs in men (in order of frequency) were QT-interval prolongation, diarrhoea, nausea, hepatitis and vomiting, while the most frequently reported ADRs in women were diarrhoea, QT-interval prolongation, nausea, vomiting and upper abdominal pain. Liver enzyme abnormalities and acute kidney injury were also reported frequently in men but were not reported in women, while insomnia, headache, vertigo and blurred vision were reported in more frequently in women.

Reporting patterns in drugs used for COVID-19 differed from non-pandemic reporting patterns when the drugs were used in other indications. Of note, no heart, liver or renal disorders were among the most reported ADRs when the drugs were used for other indications.

"The increased risk for males of severe COVID-19 disease is reflected in a male predominance of ADR reports in drugs used in the COVID-19 indication. Notably, some hepatic and renal reactions and QT prolongation were more commonly observed in male reports," concluded the authors.