Comparative study of the adverse event profile of hydroxychloroquine before and during the Sars-CoV2 pandemic

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Abstract

Aims At the beginning of the Sars-CoV2 pandemic, there were no clinically-tested medications for the effective treatment of coronavirus disease. In this context, on 5 March 2020, the French Public Health Council issued several recommendations for the therapeutic management of this new disease, including the use of hydroxychloroquine (HCQ). An unexpected cardiovascular safety signal was quickly identified as being more frequent than expected thanks to the reports of adverse drug reactions (ADRs) submitted to French regional pharmacovigilance centres (RPVC). The objective of this study was to compare all ADRs reported with HCQ used in its usual indication, collected before the pandemic period (1985 to 31 December, 2019) with those reported with the COVID-19 indication (1 January to 21 July, 2020). Methods For this purpose, reports were extracted from the French pharmacovigilance database and analysed for these two periods. Results Our study showed a different safety profile in COVID-19 patients with more cardiac disorders (57% of ADRs versus 5% before the pandemic period), especially QT interval prolongation, resulting from an interaction with azithromycin in more than 20% of cases. Hepatobiliary disorders were also significantly more frequent. Conclusions These observations could be associated with the effect of the virus itself on the various organs, the profile of the patients treated, and concomitant drug treatments.

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