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BRIEF REPORT

Incident Use of Hydroxychloroquine for the Treatment of Rheumatoid Arthritis and Systemic Lupus Erythematosus During the COVID-19 Pandemic

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Objective. We studied whether the use of hydroxychloroquine (HCQ) for COVID-19 resulted in supply shortages for patients with rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).

Methods. We used US claims data (IQVIA PHARMETRICS® Plus for Academics [PHARMETRICS]) and hospital electronic records from Spain (Institut Municipal d'Assistència Sanitària Information System [IMASIS]) to estimate monthly rates of HCQ use between January 2019 and March 2022, in the general population and in patients with RA and SLE. Methotrexate (MTX) use was estimated as a control.

Results. More than 13.5 million individuals (13,311,811 PHARMETRICS, 207,646 IMASIS) were included in the general population cohort. RA and SLE cohorts enrolled 135,259 and 39,295 patients, respectively, in PHARMETRICS. Incidence of MTX and HCQ were stable before March 2020. On March 2020, the incidence of HCQ increased by 9- and 67-fold in PHARMETRICS and IMASIS, respectively, and decreased in May 2020. Usage rates of HCQ went back to prepandemic trends in Spain but remained high in the United States, mimicking waves of COVID-19. No significant changes in HCQ use were noted among patients with RA and SLE. MTX use rates decreased during HCQ approval period for COVID-19 treatment.

Conclusion. Use of HCQ increased dramatically in the general population in both Spain and the United States during March and April 2020. Whereas Spain returned to prepandemic rates after the first wave, use of HCQ remained high and followed waves of COVID-19 in the United States. However, we found no evidence of general shortages in the use of HCQ for both RA and SLE in the United States.

INTRODUCTION

At the onset of the COVID-19 pandemic, multiple repurposed medicines were taken despite a lack of trial evidence on their safety and effectiveness to treat and prevent SARS-CoV-2 infection.[1] Hydroxychloroquine (HCQ), a drug approved for the treatment of rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE), showed in vitro evidence of inhibiting virus

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SIGNIFICANCE & INNOVATIONS

- In the initial stages of the COVID-19 pandemic, a limited study suggested hydroxychloroquine (HCQ) as a potential treatment for SARS-CoV-2, leading to its emergency approval in the United States but not in Europe. However, approval in the United States was rescinded two months later due to evidence indicating that HCQ was neither effective nor safe against COVID-19.
- We found a substantial increase in incident use of HCQ at the onset of the COVID-19 pandemic, in both the United States (claims data) and Spain (hospital data). Within two months, HCQ usage returned to prepandemic levels in the Spanish hospital, whereas in the United States, it persistently remained elevated and correlated to COVID-19 waves. This suggests continued utilization of HCQ as a treatment for COVID-19 in the United States.
- Despite this substantial increase in HCQ usage, our findings did not indicate any evidence of shortages of this medicine for patients with rheumatoid arthritis and systemic lupus erythematosus.

replication.[2] Subsequently, on March 2020, a nonrandomized study with 36 patients suggested a possible benefit of HCQ in patients with SARS-CoV-2.[3] On March 16, 2020, the US Food and Drug Administration (FDA) authorized its use for the treatment of patients hospitalized with COVID-19.[4] However, HCQ is known to have serious side effects including cardiovascular events, particularly when used with macrolide antibiotics,[5] which led to warnings from international regulators.[6] Furthermore, randomized controlled trials showed that HCQ was not effective against COVID-19 disease.[7] Subsequently, the FDA revoked the approval of use for COVID-19 on June 15, 2020.[8]

Substantial media attention put on HCQ as the cure for COVID-19 raised concerns about a potential shortage of HCQ supplies for patients who relied on it.[9,10] Indeed, some small survey-based studies reported that patients had difficulties accessing HCQ during this time.[11,12] Therefore, we aimed to estimate the rates of use of HCQ in the general population and among patients with RA and SLE during the COVID-19 pandemic to better understand how the use of HCQ by individuals infected with COVID-19 impacted the drug supply for patients with RA and SLE. We hypothesized that in the presence of significant shortages, there would likely be a decrease in incident rates of HCQ among patients with RA and SLE.

MATERIALS AND METHODS

Data sources. We used US health claims data from IQVIA PHARMETRICS® Plus for Academics (PHARMETRICS) and the Spanish Hospital del Mar electronic health records from the Institut Municipal d'Assistència Sanitària Information System (IMASIS). The PHARMETRICS data set covers 34.8 million active patients in the United States and contains medical and pharmacy claims, including patient enrollment data. Data from IMASIS cover two general hospitals in Barcelona, which includes more than 500,000 active patients.

Both PHARMETRICS and IMASIS data sources were mapped to the Observational Medical Outcomes Partnership Common Data Model,[13] which allowed the execution of the same analytical code in both data sets. The analysis was executed locally, and aggregated results were shared. To adhere to privacy policies, events with fewer than five occurrences were clouded.

Study design and population. To determine whether there was a shortage of HCQ, we estimated monthly incidence of HCQ use in three cohorts: general population cohort (GPC), RA cohort (RAC), and SLE cohort (SLEC). For the GPC, we included people who had at least one year of previous follow-up in the database at the beginning of the study (January 1, 2019) or included them when they fulfilled this criterion in later dates. Previous follow-up refers to time since the registration date to the claims database (PHARMETRICS) or to the hospital system (IMASIS).

The RAC included patients with a diagnosis of RA and no previous or subsequent diagnosis of SARS-CoV-2 infection. Follow-up commenced on their diagnosis date (or start of the study if they were diagnosed before it began) for individuals with at least one year of prior observation; the rest entered the cohort when this requirement was fulfilled. The SLEC followed the same logic structure as the RAC, enrolling patients with a diagnosis of SLE. Additionally, we conducted sensitivity analyses without excluding individuals infected with SARS-CoV-2 from the RAC and SLEC. We used methotrexate (MTX) as a control in the study as we expected no impact of the COVID-19 pandemic on its

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initiation as a first-line treatment for RA other than through changes in health care resource use due to public health restrictions.

Statistical analysis. HCQ and MTX were identified from claims in PHARMETRICS and from dispensations and pharmacy orders in IMASIS. Continuous periods of drug use separated by less than 30 days were considered as a single exposure. Incident use was defined as a new HCQ (or MTX) exposure, or exposures starting at least one year after concluding the prior exposure. Cohort patients contributed time to the denominator until having a record of the exposure of interest (HCQ or MTX). Incidence rates were calculated monthly from January 2019 until March 2022 (study period) for each study cohort using the R package IncidencePrevalence.[14]

Additionally, we characterized new recipients of HCQ and MTX during the study period based on socio-demographics, comorbidities, and medications taken in the year before therapy initiation (baseline covariates). The new recipient cohort consisted of individuals who had no record of taking the drug for at least a year before entering the cohort. Subsequently, patients were stratified according to the potential drug indication: COVID-19 if they had a record of the virus in the past 21 days, RA or SLE if they had a record of these conditions any time previously, multiple indications if the participants had more than one, and none if they did not have any of records of COVID-19, RA and SLE.

The use of IMASIS was approved by the Hospital del Mar Ethics Committee (CEIm no. 2021-9987). PHARMETRICS needed no approval for use of pseudoanonymized secondary data. We conducted all analyses using R 4.2.3. Analytical code and code lists to identify conditions and medications can be found in the following GitHub repository: https://github.com/oxford-pharmacoepi/HydroxychloroquineSummerSchool2023. Patient-level data cannot be shared under General Data Protection Regulation regulation. Aggregated-level data are publicly available in the Shiny App interactive web interface (https://dpa-pde-oxford.shinyapps.io/HydroxychloroquineSummerSchool2023/).

RESULTS

Overall, the GPC cohort enrolled 13,311,811 people in PHARMETRICS and 207,646 in IMASIS, whereas RAC included 135,259 and SLEC 39,295 people for PHARMETRICS. RAC and SLEC enrolled less than 200 individuals for IMASIS; therefore we did not estimate use rates for these cohorts.

HCQ and MTX incidence. Figure 1 depicts incidence rates of HCQ and MTX initiation in both databases and weekly cases of SARS-CoV-2 infections in the underlying populations of the United States and Catalonia (Spain) based on official data. Table 1 presents the overall incidence rates for the study cohorts in three time windows within the study period: before HCQ approval for COVID-19 (January 1, 2019, to March 14, 2020), during the approval period (March 15, 2020, to June 16, 2020), and after approval withdrawal (June 17, 2020, to March 31, 2022).

Monthly rates of use of HCQ and MTX in the GPC before March 2020 were stable over time, with slightly higher incidence of MTX compared to HCQ; from January 1, 2019, to March 14, 2020, the overall MTX incidence rate for 100,000 person-years in the GPC was 124.39 (95% confidence interval 122.03–126.79) in PHARMETRICS and 304.10 (95% confidence interval 280.09–329.61) in IMASIS, compared to 112.76 (95% confidence interval 110.51–115.04) and 78.50 (95% confidence interval 66.56–91.98) for HCQ, respectively, for PHARMETRICS and IMASIS (see Table 1). In March 2020, there was an abrupt increase in the incidence of HCQ initiation in the GPC, with a 9-fold increase seen in PHARMETRICS and a 67-fold in IMASIS: monthly incidence (per 100,000 person-years) was 968.65 (95% confidence interval 943.76–994.03; PHARMETRICS) and 5,204.19 (95% confidence interval 4,822.53–5,608.03; IMASIS). After two months, we observed a sudden and pronounced drop in HCQ use for both databases. However, whereas in Barcelona (Spain) rates returned to prepandemic values, in the United States the use of HCQ remained higher than before March 2020, as depicted in Table 1 and Figure 1. In PHARMETRICS, subsequent monthly rates followed patterns mimicking COVID-19 waves nationally (refer to Figure 1). Despite this short and steep increase in the use of HCQ seen in the GPC, we did not observe a decrease in the trends of use of HCQ in the RAC and SLEC for PHARMETRICS.

Monthly rates of MTX initiation decreased during the HCQ approval period (March 15 to June 16, 2020) among the three denominator cohorts. Findings from sensitivity analyses were very similar; see Supplementary Figure 1 and Supplementary Table 1.

Characterization of new HCQ recipients. Among new recipients of HCQ with a previous indication of RA and SLE, the majority were female, accounting for approximately 80% in both databases. On the other hand, the distribution of sex was more balanced among those with a COVID-19 indication. In the PHARMETRICS database, new users of HCQ with a COVID-19 indication tended to be younger compared to those with an RA indication. However, the opposite trend was observed in the IMASIS database, likely due to association between age and COVID-19–related hospitalization. In both databases, new HCQ recipients with SLE indication represented the youngest group (median of 50 years). See Supplementary Tables 2 and 3.

DISCUSSION

Our findings show a substantial increase in the use of HCQ (but not MTX) in the general population during the first weeks of the COVID-19 pandemic in both Barcelona (Spain) hospital data

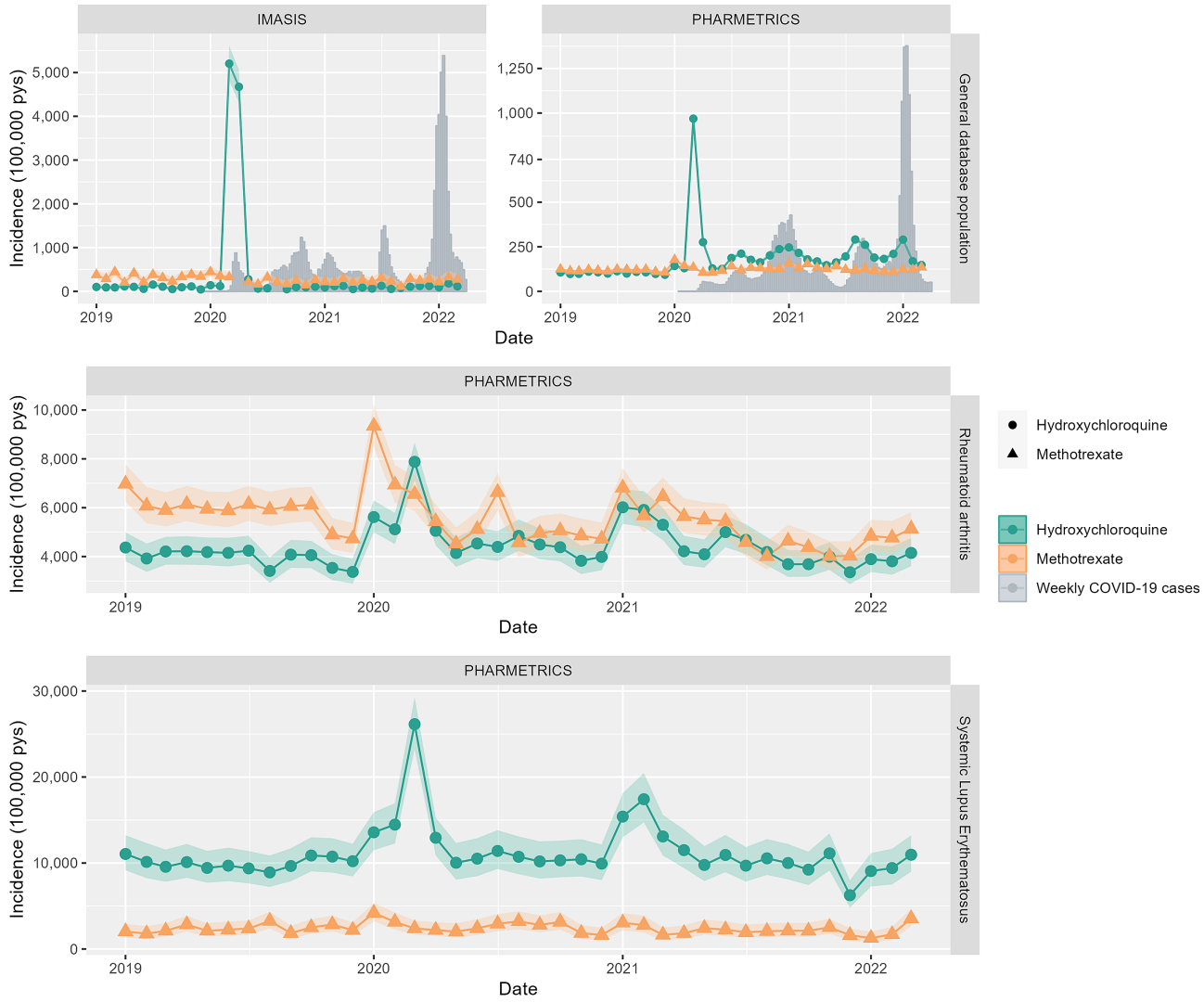

Figure 1. Incidence of hydroxychloroquine and methotrexate in the general population cohort for IQVIA PHARMETRICS Plus for Academics (PHARMETRICS) and Institut Municipal d'Assistència Sanitària Information System (IMASIS) databases and among patients with rheumatoid arthritis and systemic lupus erythematosus without COVID-19 for PHARMETRICS. Dots represent incidence estimates per 100,000 person-years, and shadowed lines represent the 95% confidence intervals. In the general population graphs, shadowed in gray is depicted the shape of the weekly COVID-19 cases in the Catalan region of Spain for IMASIS (source: https://analisi.transparenciacatalunya.cat/Salut/Vigil-ncia-sindr-mica-d-infeccions-a-Atenci-Prim-r/fa7i-d8gc/about_data), and in the United States for PHARMETRICS (source: https://data.cdc.gov/Case-Surveillance/Weekly-United-States-COVID-19-Cases-and-Deaths-by-/pwn4-m3yp).

and US claims data. Whereas rates of HCQ initiation then normalized and returned to prepandemic values for Spain, use rates remained higher than before March 2020 in the US, and waves of use seemed to follow those of national COVID-19 transmission.

A substantial shortage of HCQ affecting patients with RA and SLE would likely manifest in the data as a reduction of its incident use in the RAC and SLEC, in comparison to prepandemic rates. Despite the notable increase seen in use of HCQ for alternative indications, we did not observe a reduction in the incident use of HCQ in the RAC and SLEC for PHARMETRICS after the COVID-19 outbreak. These findings suggest that patients with RA and SLE in the United States did not suffer a severe shortage of this medicine during the pandemic. Although these results offer a reassuring general perspective, it is important to note that they may not reflect the experiences of individual patients or clinicians.

Findings from survey-based studies suggested potential HCQ shortages.[11,12] For instance, Mendel et al[11] asked Canadian rheumatologists in April 2020 whether they were concerned about HCQ shortages and if they had been contacted by pharmacies or patients regarding difficulties getting HCQ. Out of 134 responses (24% response rate), 100 (75%) expressed concern about potential shortages, and 81 (60%) reported difficulties in accessing or renewing HCQ.[11] However, these findings were

Table 1. Overall incidence estimates of HCQ and methotrexate across three time windows*

Database and denominator cohort	Outcome	Incidence per 100,000 person-years (95% confidence interval)		
		Before HCQ approval	During HCQ approval	After HCQ approval revocation
IMASIS				
General	HCQ	78.50 (66.56–91.98)	3,405.03 (3,222.77–3,594.90)	76.32 (65.96–87.85)
	Methotrexate	304.10 (280.09–329.61)	174.15 (134.97–221.17)	213.32 (195.77–232.03)
General	HCQ	112.76 (110.51–115.04)	473.15 (462.51–483.98)	197.98 (195.30–200.70)
	Methotrexate	124.39 (122.03–126.79)	108.64 (103.57–113.88)	128.21 (126.05–130.40)
PHARMETRICS				
Rheumatoid arthritis	HCQ	4,209.11 (4,059.65–4,362.66)	5,805.91 (5,422.99–6,208.73)	4,365.80 (4,239.92–4,494.46)
	Methotrexate	6,284.49 (6,096.65–6,476.65)	5,216.40 (4,845.30–5,608.37)	5,113.41 (4,974.59–5,255.12)
Systemic lupus erythematosus	HCQ	10,712.34 (10,198.55–11,245.31)	16,213.08 (14,797.79–17,727.21)	10,775.19 (10,329.49–11,235.18)
	Methotrexate	2,408.07 (2,199.55–2,631.04)	1,909.75 (1,507.15–2,386.86)	2,073.12 (1,910.14–2,246.30)

* Three time-windows: (1) the preapproval phase for HCQ as a COVID-19 treatment by the Food and Drug Administration (January 1, 2019, to March 14, 2020), (2) the approval period (March 15, 2020, to June 16, 2020), and (3) after approval withdrawal (June 17, 2020, to March 31, 2022). Estimates are presented in the general population cohort for PHARMETRICS and IMASIS databases, and among patients with rheumatoid arthritis and systemic lupus erythematosus for PHARMETRICS. HCQ, hydroxychloroquine; IMASIS, Institut Municipal d'Assistència Sanitària Information System; PHARMETRICS, IQVIA PHARMETRICS® Plus for Academics.

likely attributed to Canada's policies regarding HCQ access rather than actual supply shortages.

In another study, Mendel et al[12] distributed a survey among Systemic Lupus Erythematosus International Collaborating Clinics members: 20 out of 31 responses reported being contacted by pharmacies or patients indicating problems with HCQ supplies. Nevertheless, it is important to note that these findings were based on physicians from single tertiary centers and may not reflect the overall experience within a region or country.[12]

The COVID-19 Global Rheumatology Alliance conducted an online survey worldwide, collecting 9,393 responses, of which 3,872 were individuals taking antimalarial drugs. Among them, 230 (6%) reported being unable to continue taking their medications due to a lack of supply at their pharmacy.[15] However, it should be considered that survey-based studies are prone to bias because physicians and patients who were more concerned about HCQ access may have had a greater interest in participating. Therefore, these findings may not represent the overall experience of accessing HCQ during the pandemic.

Considering the evidence, our study findings suggest that the high increase in HCQ use due to its endorsement as COVID-19 treatment did not lead to significant shortages for patients with RA and SLE in the US, as feared at the beginning of the pandemic. However, our results provide a general overview, and there might have been punctual difficulties to access HCQ during the pandemic, as various health services suffered disruptions due to the COVID-19 outbreak.[16,17]

This study has several strengths: we used real world data and standardized analytical tools to provide objective evidence on the use of HCQ in the pandemic. Additionally, we used MTX as a control in the study and reproduced the analysis in two different databases. Nonetheless, there are also limitations in our study. First, although PHARMETRICS is a large data set, representative of the US population demographics (age, sex, and region), it may be not representative of the country's population socioeconomic level. However, we do not think this would change the study results, because severe HCQ shortages would have been captured among the insurance clients. Second, although in Spain, RA and SLE are treated in both hospital and primary care settings, the small number of patients with RA and SLE in the IMASIS database prevented a full assessment of the usage of HCQ among these patients in this database. Lastly, our study used data from two high-income northern hemisphere countries, whereas low- and middle-income countries may have been more exposed to possible HCQ shortages.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr Prieto-Alhambra had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Jödicke, Burn, Prieto-Alhambra, Català, Prats-Uribe.

Acquisition of data. Ramírez-Anguita, Mayer, Leis, Prieto-Alhambra.

Analysis and interpretation of data. Mercadé-Besora, Guo, Du, Li, Ramírez-Anguita, Moreno, Valente, Villalobos, Cheng, Carrasco-Ribelles, van Swieten, Merkelbach, Magoya, Lasalvia, Pulido, Berg, Bosco-Lévy, Lillini, Ribeiro, Bagga, Ramella, Khalid, Leis, Burn, Prieto-Alhambra, Català, Prats-Uribe.

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