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Hepatitis C diagnosis slowdown in high-prevalence groups and using decentralised diagnostic strategies during the COVID-19 pandemic

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Abbreviations: HCV: hepatitis C virus, WHO: World Health Organisation, DBS: dried blood spot test

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Authors' contribution

D.M.A contributed to data collection, database generation, statistical analysis, writing and editing of the manuscript. F.B.Z assisted with data collection and database generation. F.D.F assisted with data collection from the laboratory and sample analysis. M.J.M.A, L.G.S and V.P.P. contributed to the screening and sample collection from the drug treatment centres. F.G.N collaborated with the analysis of the samples. M.H.G. contributed to the project design, coordination and final review and manuscript approval.

Abstract

Introduction: The COVID-19 pandemic has had a major impact on hepatitis C virus (HCV) diagnosis by hindering the path to elimination, although probably in an uneven manner depending on the risk group and diagnostic strategy.

Methods: We recorded the requests of antibodies/RNA by venipuncture at the hospital and primary care centres (centralised), as well as the requests via venipuncture or dried blood spot test at prison and drug treatment centres referred for central processing (integrated decentralised), for one year before and after the onset of the COVID-19 health alarm.

Results: A total of 20,600 tests (51% male, 47.9 ± 15.8 years) were recorded. Among them, 96.5% of the cases came from centralised and 3.5% from decentralised settings, with an active infection rate of 0.2% and 2.3% ($p < 0.001$), respectively. There was a 31.3% decrease in the number of requests during the pandemic compared to the pre-pandemic period, which was more pronounced in decentralised diagnosis than centralised (60 vs. 30%, $p < 0.001$). In addition, there was a 31.5% decline in screening and an 18.2% decrease in the diagnosis of new cases of active infection, showing a statistically significant decrease in decentralised compared to centralised diagnosis.

Conclusions: During the COVID-19 pandemic, a decline in HCV diagnostic effort has been observed, especially in decentralised strategies with a higher prevalence of infection. Our results suggest a diagnostic delay that will prevent Spain from reaching the elimination target in 2023, and therefore the reactivation of strategies particularly targeting the priority groups is urgently required.

Introduction

Hepatitis C virus (HCV) infection is one of the leading causes of liver disease in the world (1). Nevertheless, direct-acting antivirals cure the infection by slowing the progression to liver cirrhosis and its subsequent complications (2). Therefore, the World Health Organisation (WHO) has set 2030 as the target date for global elimination by promoting elimination projects (3). In Spain, regulatory authorities encouraged HCV elimination through the national HCV elimination plan (4), supported by different scientific societies which promote initiatives such as diagnostic decentralisation, particularly in high-risk groups (5), positioning Spain among the first countries to achieve the elimination by 2023 (6).

On 11 March 2020, the WHO declared COVID-19 a global pandemic, and as a result, numerous measures were implemented to prevent transmission (7). These changes limited face-to-face care in consultations and non-urgent outpatient medical examinations, and options such as telemedicine emerged (8) which, nonetheless, have not prevented diagnostic delays in many pathologies (9).

In terms of HCV infection, the COVID-19 pandemic is likely to have significantly impacted diagnostic efforts, thus hindering the path to HCV elimination. A recent study by Sperring H. *et al*, in Boston, showed a decline of 71.9% in screenings and 63.3% in new diagnoses, at 3.5 months after the pandemic (10). Similarly, Kaufman H.W. *et al*,

in New Jersey and Georgia, demonstrated a 1-month decrease of 59% in screening and 62% in new diagnoses (11), with no published studies available so far concerning Spain. Being aware of these data is relevant as a delayed diagnosis will increase cases of hepatocarcinoma and liver disease-related death in the next 10 years (12). Likewise, a Markov model with Spanish data has estimated the same results (13). Furthermore, the pandemic has likely led to an uneven diagnostic delay across risk groups and diagnostic strategies (centralised vs. decentralised), that must be corrected accordingly.

Therefore, this study aimed to assess the impact of the COVID-19 pandemic on HCV screening and diagnosis in our setting. In particular, we evaluated the diagnostic strategy and repercussions on risk groups, providing relevant information to set targets to improve and reinforce HCV elimination strategies.

Material and methods

Study design

HCV antibody and RNA test requests and their result were recorded using laboratory records from the health area of the Hospital Universitario de Canarias covering 400,000 inhabitants. The present study included requests during the period of one year before (pre-pandemic: 1st June 2019 – 15th March 2020) and after the beginning of the COVID-19 health alarm in Spain on the 16th of March 2020 (pandemic: 16th March 2020 – 31st December 2020). Any duplicate cases identified by matching history numbers were excluded.

According to the origin of the laboratory requests, they were classified into two groups: a) centralised (those performed by venipuncture in the hospital or the primary care centre) and b) integrated decentralised (those performed in prison by venipuncture or in drug treatment centres by dried blood spot test (DBS) referred for

processing to the hospital centre).

Since July 2018, our laboratory has incorporated reflex testing or one-step diagnosis in such a way that RNA is automatically tested after detecting HCV antibodies. As for diagnosis in DBS in drug treatment centres, RNA was determined directly given the high prevalence of infection in this group of patients, which is a technique that has been previously validated by our group (14) and has been part of the screening programme since January 2017. Direct RNA identification has been performed since August 2018 (15).

Statistical analysis

The Chi-square test was used to compare qualitative variables. For continuous variables comparison, the t-Student or U-Mann Whitney t-test was used depending on whether the variables met the normality criteria or not, respectively. Changes in the request for diagnostic tests were analysed by comparing percentages and absolute changes. A value of $p < 0.05$ was considered statistically significant.

Ethical aspects

The present study followed the ethical principles of the Declaration of Helsinki of October 2013 and obtained the approval of the Ethics Committee of the Hospital Universitario de Canarias (Code CHUC_2020_116, approved on 14/01/2021).

Results

HCV determinations

A total of 20,600 requests (51% male, 47.9 ± 15.8 years) were identified after excluding 13,097 duplicate cases during the study period (Figure 1). A total of 19,874 (96.5%) determinations were performed centrally (54.5% primary care, 42% hospital specialties), and 724 (3.5%) decentralised (1.7% prisons, 1.8% drug treatment centres). There was a higher percentage of men (85% vs. 47.7%, $p < 0.001$) and younger people

(46.2 ± 12.3 vs. 48.9 ± 17.4 years, $p=0.002$) in the decentralised diagnostic group compared to the centralised one.

Considering the type of test, we recorded 19,818 (96.2%) anti-HCV, 402 (2%) RNA and 380 (1.8%) DBS. According to the origin, 98.2% anti-HCV and 1.8% RNA were centralised, while 42.7% anti-HCV, 5.1% RNA and 52.2% DBS were decentralised.

During the pre-pandemic period, a total of 12,212 determinations were recorded (50.3% male, 46.4 ± 16.1 years), while 8,388 determinations were recorded during the pandemic period (47.1% male, 52.2 ± 14.1 years), with a total decrease of 31.3% in the number of determinations. There was a 30% reduction in the centralised approach (pre-pandemic 11,694 vs. pandemic 8,180) compared to 60% in the decentralised one (pre-pandemic 518 vs. pandemic 208) (Figure 2). Regarding the centralised diagnosis, there was a 41% decrease in primary care (pre-pandemic 7,061 vs. pandemic 4,167) and a 13.3% reduction in-hospital specialities (pre-pandemic 4,633 vs. pandemic 4,015; $p<0.001$). According to the type of test, there was a decrease in DBS tests of 55.5% (pre-pandemic 263 vs. pandemic 117), followed by anti-HCV determination of 31% (pre-pandemic 11,726 vs. pandemic 8,092) and RNA determination of 19.7% (pre-pandemic 223 vs. pandemic 119).

In terms of screening (anti-HCV and DBS requests for RNA identification in drug treatment centres), there was an overall decrease of 31.5%, with a higher decrease observed in those requested from the decentralised origin (60.8% vs. 30.5%, $p<0.001$).

HCV determination results

Regarding the results of the determinations, there was a lower percentage of patients testing positive in the pandemic period ($n=34$) compared to the pre-pandemic period ($n=48$), with a decrease of 29.2%; and a more pronounced reduction in decentralised compared to centralised diagnosis (41.7% vs. 25% respectively, $p=0.792$). A higher percentage of patients were found to be positive in the decentralised strategy compared to centralised (2.7% vs. 0.3% respectively, $p<0.001$), nevertheless, no

differences were found between pre-pandemic and pandemic periods (decentralised 2.3% vs. 3.4%, $p=0.442$; centralised 0.3% vs. 0.3%, $p=0.801$). Patients with a positive result from a decentralised diagnosis were younger ($p=0.004$) and had less comorbidity ($p<0.001$) compared to positive patients from the centralised diagnosis (Table 1).

Active HCV infection

Considering only new diagnoses of active infection or those with positive RNA ($n=60$), an 18.2% decrease was recorded during the pandemic period ($n=27$) compared to the pre-pandemic period ($n=33$), showing a higher percentage of positive patients in the decentralised approach compared to the centralised one (2.3% vs. 0.2% respectively, $p<0.001$). There was no difference in the percentage of patients with an active infection between the pre-pandemic and pandemic periods (decentralised 2.1% vs. 2.9%, $p=0.540$; centralised 0.2% vs. 0.3%, $p=0.306$), although there was a smaller decrease in the detection of active infection in the decentralised compared to the centralised strategy (4.5% vs. 45.4% respectively, $p=0.399$). RNA-positive patients identified through decentralised diagnosis compared to centralised diagnosis, were more frequently male ($p=0.046$) and had less comorbidity ($p=0.002$) (Table 2).

Discussion

The COVID-19 pandemic has negatively affected the path towards the elimination of HCV infection. This study found a sharp decline in the diagnosis of new cases, extended up to one year after the declaration of the state of alarm, and a significant two-fold decline in high-prevalence and therefore priority groups.

The reduction in non-urgent healthcare, after the state of alarm declaration in Spain, had a negative impact on hospital waiting lists and delayed diagnosis for many diseases. Regarding hepatitis C, this pandemic has slowed down and even stopped many micro-elimination programmes affecting all steps of the care cascade (16) and the harm reduction programmes (17).

Our data are consistent with those published in the United States of America, where the decrease in the screening of around 50% in the hospital setting, and 70% in the outpatient setting; and a 42-63% decrease in the diagnosis of new cases were reported (10, 11). The greater decrease in the published data in comparison with our study, especially regarding new diagnoses, might be due to the longer follow-up time after the declaration of the alarm state, which in our case is one year, whereas in both published studies was 3.5 months (10) and 1 month (11). Our study provides significant evidence of the greater decrease in screening through integrated decentralised diagnosis from prisons and drug treatment centres. Despite facilitating diagnosis, is in these risk groups where the pandemic has had the greatest impact. It is also noteworthy that DBS was the most affected diagnostic method. Patients from risk groups were younger and had little comorbidity, therefore this group should be prioritised in the future reactivation of diagnostic efforts after the impact of this pandemic.

The loss of diagnostic opportunity due to the slowing down of screening programmes even estimating a diagnostic delay of only 3 months, will lead to an increase in new, unassessed cases and the associated consequences resulting from the untreated infection. This will directly hinder the elimination targets initially proposed by WHO (12). The impact of such a delay and the importance of reactivating and prioritising elimination efforts have also been highlighted by many national studies (13, 18).

It has been proposed to incorporate different diagnostic options into care circuits during the pandemic, along with measures to prevent the spread of COVID-19 (19). In this regard, HCV screening has been promoted in conjunction with COVID-19 diagnostic tests or with routine vaccination (20), such as the experience published in Italy by Giacomelli A. *et al*, in patients over 50 years of age with a participation rate close to 50% (21); or even considering a more simplified circuit using the DBS for joint screening (22). Additionally, given the least impact achieved at the hospital as opposed to the primary level during the pandemic, promoting diagnosis at the primary care level should be considered (23, 24). However, telemedicine, which in previous studies has proven its effectiveness in facilitating access to the health system for difficult-to-treat populations (25, 26), and despite its increased use after the pandemic, it has yet to show its ability to effectively improve the diagnosis rate, since some authors postulate it as a barrier in itself (10). According to our study, the greatest impact of the pandemic took place in drug treatment centres and prisons, despite the obvious benefits of telemedicine in those settings (15, 25).

Some limitations arise from this study. First, it is a single-centre study, although it covers a broad health area, which should enable the extrapolation of these data to other regions of the country. In addition, pandemic measures were implemented homogeneously throughout the entire country (8). Second, extending our study period to one year after the declaration of the state of alarm may have underestimated the initial impact. However, extending the study period gives a more global and steady view of the impact, leaving the implementation and effectiveness of recovery strategies to be assessed later. Third, HCV treatment provision was not recorded as

another estimate of impact. However, new diagnoses of active infection were assessed as an indirect measure of treatment rate.

In conclusion, the present study shows the impact of the COVID-19 pandemic on the diagnostic delay of HCV infection in Spain. Our data suggest a greater impact on integrated decentralised diagnostic strategies that are precisely targeting hard-to-treat groups. Therefore, public health policies that prioritise diagnostic algorithms and programmes targeting those high-prevalence populations that have been the hardest hit during the pandemic are needed.

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Table 1. Characteristics of patients with positive results according to decentralised and centralised diagnosis.

	Decentralised n=19	Centralised n=63	p
Age (years, mean \pm SD)	49,5 \pm 14,8	54 \pm 12,1	0,178
Gender (male, %)	94,7	60,3	0,004
Anti-HCV previous positive (%)	26,7	45,2	0,239
Time from 1 st positive anti-VHC (years, mean \pm SD)	5,4 \pm 6,2	5,3 \pm 6,6	0,944
ARN previous positive (%)	20	19	1,000
Time from 1 st positive ARN (years, mean \pm DS)	3,5 \pm 5,1	5,5 \pm 7	0,294
Transaminase elevation (%)	46,7	27,3	0,206
FIB-4 (\geq F3, %)	7,7	15,6	0,656
Charlson Index (\geq 2, %)	0	47,6	<0,001
Psychiatric disorder (%)	13,3	7,1	0,599
Alcohol use history (%)	20	28,6	0,735
Drugs use history (%)	33,3	23,8	0,507
Social environment (bad, %)	13,3	2,4	0,166
Decompensated liver cirrhosis (%)	0	0	-

HCV: hepatitis C virus, SD: standard deviation

Table 2. Characteristics of RNA-positive patients according to decentralised versus centralised diagnosis.

	Decentralised n=17	Centralised n=43	p
Age (years, mean \pm SD)	51,2 \pm 14,7	54,1 \pm 11,9	0,430
Gender (male, %)	94,1	67,4	0,046
Anti-HCV previous positive (%)	30,8	50	0,315
Time from 1 st positive anti-VHC (years, mean \pm SD)	6,9 \pm 6,4	4,5 \pm 5,4	0,351
ARN previous positive (%)	23,1	16,7	0,678
Time from 1 st positive ARN (years, mean \pm DS)	3,9 \pm 5,3	4,1 \pm 6,4	0,933
Transaminase elevation (%)	38,5	33,3	1,000
FIB-4 (\geq F3, %)	9,1	23,5	0,619
Charlson Index (\geq 2, %)	0	50	0,002
Psychiatric disorder (%)	15,4	8,3	0,602
Alcohol use history (%)	23,1	29,2	1,000
Drugs use history (%)	38,5	25	0,465
Social environment (bad, %)	15,4	4,2	0,278
Decompensated liver cirrhosis (%)	0	0	-

HCV: hepatitis C virus, SD: standard deviation

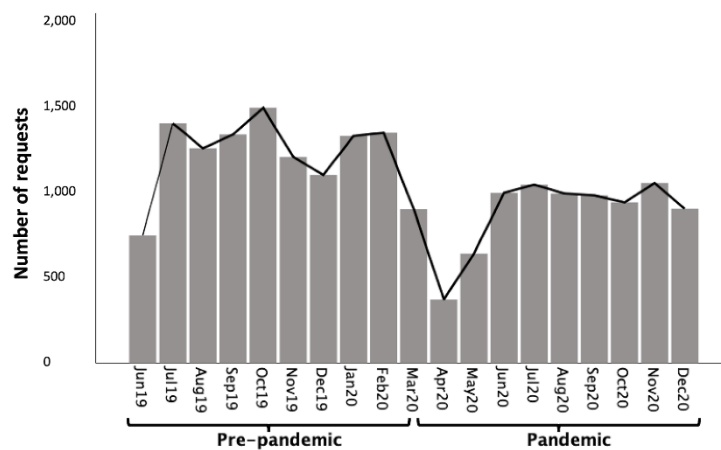


Figure 1. The absolute number of hepatitis C requests according to the category during the study period (COVID-19 pre-pandemic and pandemic).

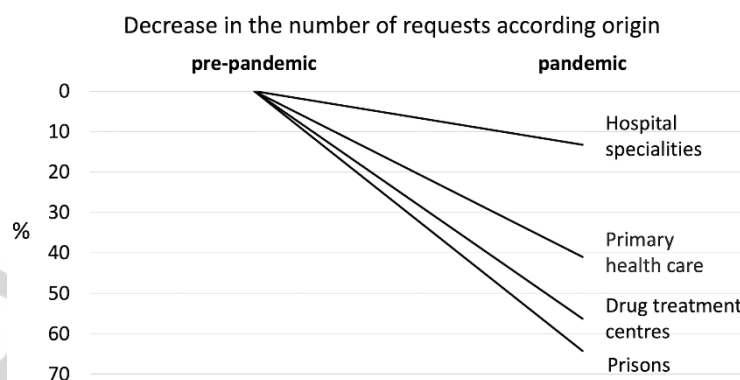


Figure 2. Decrease in hepatitis C test requests within the COVID-19 pandemic compared to the pre-pandemic period according to the origin of the request.