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Recapture of patients with an incomplete diagnosis of hepatitis C virus infection

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ABSTRACT

Background: hepatitis C virus (HCV) antibody tests have been performed since the 90s, although HCV-RNA (viral load) determination was not always performed. Some of these patients may be actively infected and not be aware of it. Here, we describe a procedure to capture these subjects and complete their diagnosis.

Methods: the historical laboratory results of Navarra were reviewed and individuals who were positive for antibodies against HCV (anti-HCV) and had not undergone HCV-RNA testing were identified. In September 2018, each general practitioner (GP) was informed about their patients and given precise instructions for completing the diagnosis. The procedure was assessed until December 2019.

Results: two hundred and eighty-nine anti-HCV positive patients were detected for whom active infection had not been discarded. Two were HIV-positive and six had already died. GPs were asked to assess the remaining 281 subjects. By the end of 2019, a new blood test had been performed in 187 (67 %) patients, 5 % decided not to do it, 4

% were living outside of Navarra, 3 % could not be contacted and the GP considered that it was not justified in 2 % of cases. Thus, 19 % remained to be contacted. From the 187 assessed patients, active infection was confirmed in 52 (28 %) individuals, 40 % were false positives and HCV-RNA was undetectable in 31 %. Regarding the 52 actively infected subjects, 34 had already initiated antiviral therapy and three were hospitalized due to decompensated cirrhosis, from which one patient died.

Conclusions: the strategy to recapture individuals with an incomplete HCV infection diagnosis was effective to detect active infections and subsequent initiation of antiviral therapy.

Keywords: Hepatitis C virus. Direct-acting antivirals. Sustained virological response. Eradication strategy. Undiagnosed infection.

INTRODUCTION

Chronic hepatitis C virus (HCV) infection is a public health problem. The high efficacy and good tolerance showed by novel direct-acting antivirals (DAAs) has led the World Health Organization (WHO) to set the target of eradicating the virus by 2030 (1-7).

During the 90s, the prevalence of HCV infection in Spain was higher than in other surrounding countries, mostly due to the transmission between intravenous drug users (8,9). However, with the spreading of DAAs, the basic conditions to eliminate HCV are being fulfilled. This is due to the low incidence rate and universal access to novel DAAs, which induce viral clearance in almost all treated patients (2). Local eradication must be achieved first to accomplish the objective proposed by the WHO. For this, screening for antibodies against HCV (anti-HCV) in potentially affected populations must be performed. Next, HCV-RNA (viral load) should be tested in positive cases to identify active infections. Finally, patients with an active infection should be treated and monitored until a sustained virological response (SVR) occurs.

Before the approval of DAAs, the management of patients in whom HCV antibodies were detected was not systematic, as it was based on clinical manifestations. Besides, available treatments had a modest efficacy and frequent adverse events (10-13). Thus, many patients did not complete the diagnostic procedure or abandoned medical

follow-up before reaching SVR. In some patients, the diagnosis of anti-HCV was not confirmed by a subsequent test. However, other patients had anti-HVC positive results but HCV-RNA was not determined, and it was therefore not possible to know if they had active infection or they were cured. In addition, follow-up of some patients was interrupted as there was no appropriate therapeutic alternative, despite having a positive diagnosis of infection. Currently, the completion of diagnosis is indicated in these patients and treatment with the novel DAAs must be prescribed in cases of active infection.

This study aimed to describe and assess the procedure performed in Navarra (Spain) regarding the active search of patients who were anti-HCV positive at any time but with no evidence of a subsequently confirmed or discarded active infection. This would complete their diagnosis and treatment could be prescribed in cases of an active infection.

MATERIAL AND METHODS

Study population and design

The population covered by the Healthcare Service of Navarra up to June 2018 was considered for the study. The primary source of information was the HCV infection serological diagnosis database. The information included in this database has been collected since HCV testing became available in Navarra during the 90s. Demographic data, anti-HCV and HCV-RNA results, confirmatory tests and the determination of HCV genotypes were obtained. Initially, anti-HCV positive patients, weakly positive or with a result classified as “doubtful” or “pending” without an additional determination were selected from the database. For patients with multiple determinations, the last one was taken as the valid test. Subsequent antibody and confirmatory tests, HCV viral load and HCV genotype results were incorporated from microbiology databases and information on antiviral therapy obtained from the hospital Pharmacy Service was added.

This was a prospective descriptive study of the steps taken in the healthcare procedure. Patients with an anti-HCV test that was later determined to be negative, a negative confirmatory test, positive or negative HCV-RNA determinations, determination of an HCV genotype or HCV antiviral therapy were excluded via automatic database

verification. Subjects who did not live in Navarra or were deceased when this study was performed were also excluded. The validation of cases was completed via a review of doubtful cases and possible errors.

Description of the procedure

The work team for the control of HCV infection in Navarra was made up of the main health specialties involved. They agreed on a plan of action to complete the diagnosis of subjects with positive or doubtful anti-HCV results, in whom the presence of HCV-RNA had not been discarded. The main patient association approved the strategy. In HIV-positive cases, the patients' infectious diseases specialist was directly informed and a recommendation was made to examine possible infection by HCV.

A pilot test was performed in June 2018, and in September, a list of candidates who may have required completion of their HCV study was sent to their general practitioner (GP) (through the director of the healthcare center), along with precise instructions on how to proceed. Each GP had to contact their group of patients and inform them on their incomplete HCV diagnosis. In a first step, these subjects had a blood test identified as "HCV program", which included anti-HCV determination. In positive cases, the HCV-RNA and HCV genotype were determined via a single blood sample (SBS) strategy. The laboratory ruled out active infection in negative anti-HCV cases or positive cases with an undetectable viral load. The patient was informed of the result and the diagnosis was considered as completed. On the other hand, in subjects with a positive viral load, the GP had to consider referring the patient to the Hepatology Unit for study completion. Furthermore, they also assessed starting a treatment with novel DAAs. In patients with a positive viral load, the liver disease stage was evaluated by elastography (Fibroscan®) and the METAVIR scoring system was used to classify the fibrosis. Various criteria have been proposed for selecting the cut-off point for the elastography. We used that reported by Castera et al., as follows: < 7.5 kPa = no fibrosis or mild fibrosis (F0-F1); 7.5-9.4 kPa = moderate fibrosis (F2); 9.5-12.4 kPa = advanced fibrosis (F3); and ≥ 12.5 kPa = cirrhosis (F4) (14-16).

The situation of the patients was reassessed four months after the first visit to the GPs. A personalized reminder was sent to the GP in cases where the blood test had still not

been performed (Fig. 1). At the end of 2019, whether the indicated blood tests had been performed, whether the request for a new blood tests came from the procedure identified as the "HCV program", whether referral to the hepatology specialist had been performed and if treatment with DAAs had been initiated were assessed.

Continuous variables are presented as medians and ranges and comparisons were performed using the Wilcoxon test. Absolute and relative frequencies were used for categorical variables and the Chi-squared and Fisher's exact tests were applied for these comparisons. A *p*-value of < 0.05 was considered as statistically significant.

Ethical considerations

The evaluative component of this study is part of the EIPT-HCV project, which was approved by the Navarra Clinical Research Ethics Committee, and informed consent of the patients was not required. Access to personal data was exclusively performed by the patients' health professional, following the procedures established by the Regional Health Department.

RESULTS

Identification of the target population for the procedure

In June 2018, the plan of action was started to recapture 289 patients who were identified through automatic database verification as anti-HCV positive or with a doubtful HCV result for whom active infection had not been discarded. This involved around 44 cases per 100,000 inhabitants. An in-depth review revealed that two patients were HIV-positive and were being followed-up by the Infectious Diseases Service. This service was informed and put in charge of discarding HCV infection, without the intervention of Primary Care services. Six patients were discarded because they had died before the plan of action began.

Diagnostic procedure in Primary Care

By December 2019, 205 (73 %) were contacted and 187 (67 %) had undergone a new blood test from the 281 patients contacted by their respective GPs. The analysis request was made because of our intervention for 178 (95 %) of the patients and due

to other healthcare issues for the remaining nine patients. From the 281 individuals that were contacted, the study was not performed in 14 % (n = 39) for different reasons: patients' decision (5 %, n = 13), moved to another region or country (4 %, n = 11), no contact details of the patient (4 %, n = 10) and not considered justified by the GP (2 %, n = 5). By the time this assessment was performed, 19 % remained to be contacted, as the procedure had still not ended (Table 1).

With regard to the 187 assessed patients, 40 % were anti-HCV false positives, no viral load was detected in 31 %, an active HCV infection was confirmed in 28 % and two patients (1 %) were waiting for the results of viral load (Fig. 2). No statistically significant differences were observed in response to the intervention between the subjects with a known (54 %, 51/95) and unknown (67 %; 101/186) risk exposure (p = 0.900). The response was slightly worse in males (61 %; 93/150) in comparison to females (72 %, 94/131; p = 0.100) and median age was somewhat higher in subjects who repeated the test (58 *vs* 54 years; p = 0.066), although there were no statistically significant differences.

Regarding the 52 patients with an HCV active infection, 56 % were male and the median age was 53 years (range 20-91). The possible mechanisms of infection were: intravenous drug use in 22 (42 %) cases, six (12 %) had a history of blood transfusion performed before 1991, two had undergone surgical interventions a long time ago and one had a tattoo performed by a non-professional tattooist. The potential causes of infection were not identified in 21 (40 %) cases (Table 2).

Among the 185 patients for whom blood analyses were completed, the presence of a detectable viral load was not significantly associated with median age (56 *vs* 58 years; p = 0.480) nor with gender (males: 32 %, 29/91; females: 24 %, 23/94; p = 0.327). Although it was associated with subjects who referred known risk exposures (36 %, 31/85) in comparison to the rest (21 %, 21/100) (p = 0.022).

Specialized care for patients with active infection

There were 52 cases of active infection from which 42 (81 %) had been referred to a specialist. Five were not referred for different reasons (institutionalized patients, with comorbidities, aged or patients' decision) and five were pending to be referred.

The stage of fibrosis was determined in 33 patients and 36 % had liver cirrhosis (F4). From the 42 patients with active infection who had been referred to the specialist, 34 (80 %) had received treatment with DAAs. The following drugs were prescribed: sofosbuvir/velpatasvir (n = 16), glecaprevir/pibrentasvir (n = 14), elbasvir/grazoprevir (n = 2) and sofosbuvir/ledipasvir (n = 1). One patient had started therapy in another region. At the time this analysis was performed, 19 patients had reached SVR and the rest of the subjects had not reached post-treatment week 12. Three patients with a diagnosis of an active infection were hospitalized for liver decompensation by ascites. One died and the other two had started treatment with DAAs.

DISCUSSION

The method described in this study and implemented by the Navarra Health Department has recovered undiagnosed HCV-infected subjects. Early detection, followed by treatment with the new DAAs prevents the progression to more advanced stages of the disease, which may be accompanied by complications such as cirrhosis and hepatocarcinoma. These are associated with a high mortality and potential need for a liver transplant (17,18). Until December 2019, 73 % of the initially detected patients had received information on the advantages of having a clear HCV infection diagnosis. Two thirds had undergone a new blood test and 14 % had not due to justified reasons.

The procedure described here was aimed at patients who had not attended the healthcare service on their own initiative, despite diffusion on HCV-infection treatment advances through the media. Furthermore, their GPs did not suspect that their patients were infected. Amongst HCV-positive patients, there were no known risk factors in 40 % of the cases, which probably reduced any suspicion of being infected or interest to complete the diagnosis.

The prevalence of an active infection was 28 %, which justified the priority of the procedure. These patients would had developed hidden infections, requiring more expensive and less efficient interventions for their detection had they not been recovered. Forty per cent of the assessed patients were anti-HCV-negative and had erroneously been classified as anti-HCV positive in their medical record. Possible

explanations for this may be the lower specificity of previous diagnostic techniques, unconfirmed results and subjects who had not returned to complete the study, had no clinical or epidemiological suspicion of an active infection or had doubtful, weakly positive or inconclusive results.

Among the patients with an active infection for whom the stage of liver fibrosis was measured, 36 % had liver cirrhosis (F4). It would be expected that most patients have a low degree of fibrosis, as they had not consulted their GPs regarding symptoms that would have led to the completion of an HCV active infection diagnosis. Nevertheless, the high percentage of subjects with advanced fibrosis or cirrhosis is outstanding, three of which had decompensated cirrhosis, which implies a high risk of death (19).

This procedure was possible due to the collaboration between Primary and Specialized Care. In addition, it has facilitated the entry of these patients into the healthcare system, the rapid intervention of the hepatologist and performance of complementary tests. Furthermore, patients have been able to start a therapy with less difficulties and further delay.

The Microbiology Laboratory was in charge of the SBS (20), which consists of performing all the necessary determinations to obtain a definitive diagnosis of hepatitis C virus infection using a single blood sample (21). The SBS, followed by an effective communication of the results, facilitates rapid access to treatment for all diagnosed patients, simplifies the process of receiving healthcare, reduces the possibilities of loss to follow-up and has been shown to be cost effective in comparison to the common clinical practice (22-24). The SBS cannot be used in certain cases due to insufficient samples or low antibody titers. HCV-RNA determination has not been performed in two patients.

The procedure described in this study had not finished by the end of 2019 and SVR had been reported for 19 patients. The target date for assessing SVR had not been reached for the rest of the subjects (12 weeks after completing therapy). The procedure is complemented with other strategies, such as micro-elimination in prisons and centers that provide care to drug users, as capturing subjects in these environments from Primary Care is more complicated (25).

On the other hand, other complementary strategies are also being used for detecting hidden HCV infections for which there are no previous positive results, similar to those proposed by other Spanish healthcare services (25,26). To achieve this, HCV awareness campaigns are performed, access to HCV testing is made available and more information is given to health professionals to increase their suspicion when attending a patient. Moreover, the possible usefulness of screening strategies in specific population groups are being studied (27-29).

This study had a reduced sample size and was limited to one region. Therefore, the results may not be valid for other regions or countries with different epidemiological characteristics or healthcare structure. Although an improvement in the response has been accomplished, as was the initial purpose of the procedure, an additional reminder to GPs is being considered. Our healthcare network offers high-quality services. However, the response to this procedure may have been affected by work overload, the rotation of the personnel or other similar factors.

In conclusion, we show that a strategy aimed to recapture subjects with an incomplete diagnosis of HCV infection is highly efficient to detect active infections and aid HCV eradication strategies. During this process, we found pockets of patients that may be infected, but decided against further analysis or their GPs did not consider it as a priority.

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Table 1. Characteristics of hepatitis C virus positive (antibodies) patients included in the procedure and the results for reassessed patients

	n (%)
Number of patients to be reassessed	*281 (100 %)*
Gender	
Male	150 (53 %)
Female	131 (47 %)
Age in years, median (range)	54 (20-99)
Year of anti-HCV detection, median (range)	2007 (1997-2018)
Result of the procedure	
Captured and reassessed	187 (67 %)
Moved to another region or country	11 (4 %)
Patient's decision not to be assessed	13 (5 %)
Not considered justified by the patients' general practitioner	5 (2 %)
Contacting the patient was impossible	10 (4 %)
Had not been contacted yet	55 (19 %)
Results for reassessed patients	
Negative anti-HCV (false positives in the previous test)	75/187 (40 %)
Positive anti-HCV	112/187 (60 %)
Positive HCV-RNA	58/112 (52 %)
Negative HCV-RNA	52/112 (46 %)
Pending HCV-RNA	2/112 (2 %)

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Table 2. Characteristics of the patients with a confirmed hepatitis C virus active infection by December 2019

	n (%)
Number of patients with active infection	*52 (100 %)*
Gender	
Male	29 (56 %)
Female	23 (44 %)
Age in years, median (range)	53 (20-91)
Year of anti-HCV detection, median (range)	2004 (2000-2018)
Mechanism of probable infection	
Intravenous drug use	22 (42 %)
Unknown	21 (40 %)
Blood transfusion	6 (12 %)
Surgical intervention	2 (4 %)
Tattoo performed by a non-professional tattooist	1 (2 %)
Stage of fibrosis (% among tested)	
No fibrosis or mild, F0-F1	17/33 (52 %)
Moderate, F2	3/33 (9 %)
Advanced, F3	1/33 (3 %)
Cirrhosis, F4	12/33 (36 %)
Pending	19
Genotype (% among tested)	
1a	13/39 (33 %)
1b	9/39 (23 %)
2	3/39 (8 %)
3a	8/39 (21 %)
4	6/39 (15 %)
Pending	8
Study not justified (the patient is not a candidate for the study or therapy)	5

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Fig. 1. Scheme of the steps taken to prepare and execute the strategy for the eradication of hepatitis C virus in Navarra.

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Fig. 2. Activity diagram for completing the hepatitis C virus diagnoses in patients with an incomplete diagnosis. Anti-HCV: antibodies against hepatitis C virus; HCV: hepatitis C virus; HCV-RNA: viral load; GP: general practitioner.