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Real-life experience of hepatitis C treatment in a Spanish prison

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ABSTRACT

Background. Hepatitis C virus (HCV) infection is a major public health problem that causes multiple comorbidities. People in prisons who inject intravenous drugs are at increased risk of HCV infection, and HCV infection is 15-fold more prevalent among prisoners compared with the community. The objective of this study was to analyse the clinical and epidemiological characteristics of residents of a Spanish prison with HCV infection who received antiviral treatment.

Material and methods. An observational, descriptive and retrospective study was performed. All patients with HCV infection diagnosed or followed up in an Infectious Diseases attached to a penitentiary were included in this study.

Results. Of 81 patients analysed, sixty-nine (83.1%) patients were male. The mean age was 50.1 (SD8.8) years, and 70% of the inmates had a history of injection drug use. Coinfection with HIV was detected in 30%. In up to 25% of the sample, there were data on chronic liver disease in the degree of liver cirrhosis. The diagnosis of HCV infection had been made more than 15 years earlier in 28% of those studied. Decompensations from liver disease, hepatocellular carcinoma, or hospital admissions were exceptional. Most of the inmates with HCV accepted treatment, and approximately 94% of the patients who completed treatment achieved a sustained virological response without interactions or complications of interest.

Conclusions. The availability of direct-acting antivirals and their exceptional side effects constitute an opportunity to reduce the burden of HCV infection in Spain, particularly in these high-risk populations.

Keywords: Hepatitis C; liver cirrhosis; disease eradication; treatment; prisoners

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Tratamiento de la hepatitis C en un centro penitenciario Español

ABSTRACT

Introducción. La infección por el virus de la hepatitis C (VHC) es un importante problema de salud pública con una gran morbimortalidad. El consumo de drogas inyectables es la principal vía de transmisión, siendo la infección por VHC 15 veces más prevalente en las cárceles españolas respecto a la comunidad. El objetivo de este estudio fue analizar las características clínico-epidemiológicas de los residentes de un centro penitenciario con VHC que recibieron tratamiento.

Material y métodos. Estudio observacional, descriptivo y retrospectivo. Se incluyeron en este estudio todos los pacientes con infección por VHC diagnosticados o seguidos en una Unidad de Enfermedades Infecciosas adscrito a un centro penitenciario.

Resultados. De 81 pacientes analizados, sesenta y nueve (83,1%) pacientes eran varones. La edad media fue de 50,1 (DE 8,8) años y el 70% de los internos tenía antecedentes de consumo de drogas inyectables. Se detectó coinfección por VIH en 30%. En un 25% presentaban enfermedad hepática en grado de cirrosis. En el 28% de los internos el diagnóstico de VHC se había realizado hacia más de 15 años. Las descompensaciones por enfermedad hepática, carcinoma hepatocelular o ingreso hospitalario fueron excepcionales. El 94% de los pacientes que completaron el tratamiento lograron una respuesta virológica sostenida sin interacciones ni complicaciones de interés.

Conclusiones. La disponibilidad de antivirales de acción directa y sus excepcionales efectos secundarios constituyen una oportunidad para reducir la carga de infección por VHC en España, especialmente en estas poblaciones de alto riesgo.

Palabras clave: Hepatitis C; cirrosis hepática; erradicación de enfermedades; tratamiento; prisioneros.

INTRODUCTION

Hepatitis C virus (HCV) infection is a major public health concern globally with an estimated 71 million people infected worldwide [1]. When untreated, HCV can lead to cirrhosis, hepatocellular carcinoma and death [2]. Unsafe injecting drug use (IDU) is the main route of HCV transmission in developed countries with an estimated 20 million people who inject drugs infected [3].

In Spain, 1.6–2.6% of the population is infected with HCV, and IDU is the most common mode of HCV transmission [4,5]. People who inject drugs are overrepresented in prison populations and globally represent 20–55% of persons imprisoned. These individuals have higher levels of HCV infection than the general population [4,5]. HCV is 15-fold more prevalent among persons in Spain's prisons than in the community, and the HCV seroprevalence in Spanish prisons was 22.7% according to a survey performed in 2011 [6-8]. Therefore, prisons are HCV infection reservoirs.

This collective had some specific problems of the prison health care system, including excessive delays for specialized consultations, poor communication between specialists from reference hospitals and prisons doctors and health providers, missed appointments and logistical difficulties for inmate transfer to hospitals.

The Spanish Health Ministry Strategic Plan for hepatitis C infection highlighted intervention in prisons as a priority action. However, there are important barriers associated with specialized care provision to the penitentiary population [9,10].

With recent advances in treatment regimens, HCV is now a curable and preventable disease, and prisons provide an ideal opportunity to engage this hard-to-reach population [11,12].

Several recent studies have shown that treating prisoners in Spanish prisons with HCV using current direct-acting antiviral agents (DAAs) can be successful [13] and has a similar effectiveness to that observed in the nonincarcerated population [13]. Therefore, optimizing HCV treatment in prison inmates represents an opportunity to improve the health of these patients and has great epidemiological importance given the ability of this group to transmit the infection.

The objective of this study was to analyse the main clinical-epidemiological characteristics of residents of a Spanish prison with HCV infection who received antiviral treatment.

MATERIAL AND METHODS

Study design and participant selection. A retrospective, longitudinal, descriptive study was designed to review all patients diagnosed with HCV infection residing in Topas' Penitentiary Centre and assisted in Complejo Asistencial Universitario de Salamanca (CAUSA) between January 2015 and December 2021.

CAUSA is a tertiary care hospital. The internal medicine service of this hospital has approximately 130 beds allocated. The Infectious Diseases Unit attached to this service is organized based on general and monographic external consultations, serves as an area of hospitalization, and is a medical liaison with the penitentiary centre of the province.

Topas' Penitentiary Centre was opened in 1995 in the municipality of Topas in the province of Salamanca under the direction of the Ministry of the Interior, a department of the Government of Spain responsible for public security. The facility has the capacity to house 2,000 inmates.

Data collection. The clinical and epidemiological data were collected after a review of the medical records. All analysed data were anonymized. It was not necessary to contact any of the patients to perform this study. A review was performed according to the clinical protocol that included age, sex, nationality, province of residence, personal history of injecting drug use, type of sexual intercourse, transfusion of blood products, year of diagnosis, year of first evaluation in CAUSA, HCV genotype, stage of fibrosis by live elastography, MELD and CHILD index score, human immunodeficiency virus (HIV) coinfection, presence of liver disease and complications/hospital admissions, date of initiation of antiviral treatment, duration of treatment, medical follow-up, sustained virological response and reinfections.

Inclusion and exclusion Criteria: All patients over 18 years of age who were residents of Topas Prison and had a diagnosis of active HCV infection were included. Patients who did not meet these criteria or had missing data were excluded.

Definitions

MELD: The MELD (Model for End-stage Liver Disease) index is an objective and easily reproducible prognostic staging of mortality based on three simple analytical variables: bilirubin, serum creatinine, and the international normalized ratio of prothrombin time (INR). Various studies have shown that the MELD index estimates the mortality risk of patients on the transplant waiting list better than other prognostic indices [3]. Patients with a MELD greater than 18 points have a high risk of mortality and a median survival of less than 3 months [11].

CHILD: The Child–Pugh scale is a staging system used to assess the prognosis of chronic liver disease, mainly cirrhosis, and the need for liver transplantation. Each criterion is rated from 1-3, with a score of 3 indicating the most serious damage [2]. All the patients analysed had 5-6 points on the Child–Pugh scale, corresponding to class A, with a 2-year survival of 85% [14].

Portal Hypertension: Portal hypertension syndrome was noted if the patient had symptoms or signs usually associated with PH (including variceal haemorrhage, portal hypertensive gastropathy, ascites, and spontaneous bacterial peritonitis) and radiological signs on ultrasonography or tomography (such as ascites, splenomegaly, portal flow mean velocity < 12 cm/second, inversion of flow in the portal vein, portosystemic collaterals of a patent periumbilical vein or spleen-renal collaterals, dilated left and short gastric veins, portal vein diameter

0.13 mm, decreased or no respiratory variation in the diameter of the splenic and superior mesenteric veins, and portal, splenic, or superior mesenteric vein thrombosis). We also considered PH if liver stiffness was > 13.6 kPa as measured by FibroScan®.

Liver elastography: Ultrasound-based elastography is primarily used as an alternative to liver biopsy for the assessment of hepatic fibrosis. It is a type of ultrasound imaging that directs painless low-frequency vibrations into the liver to measure how quickly these vibrations move through it. A computer uses this information to create a visual map showing the stiffness of the liver. In patients with chronic hepatitis C, researchers [15] showed that liver stiffness measurements ranged from 2.4 to 75 kPa with a median value of 7.4 kPa. Based on the stiffness measurement distribution according to fibrosis stage and receiver operating characteristic (ROC) curves, we found that the cut-off value for cirrhosis was 12.5 kPa in patients with HCV infection.

Data analysis. To perform statistical analyses, descriptive analysis was conducted for each individual variable. For categorical variables, the results are expressed as absolute values (n), proportions (n/N), or percentages (%). For quantitative variables, the results are expressed as the mean and standard deviation (SD), median and interquartile range (minimum value–maximum value). The SPSS 26.0 (SPSS, IBM, Armonk, NY) statistical package was used.

Ethics statement. The study protocol (PI 2021 12 919) was approved by the Clinical Research Ethics Committee of Complejo Asistencial Universitario de Salamanca (Salamanca, Spain). All data analysed were anonymized. Exemption of informed consent was obtained from the University Assistance Complex of Salamanca Ethics Committee due to the retrospective nature of the study and the anonymized patient data. The procedures described here were performed in accordance with the ethical standards described in the revised Declaration of Helsinki in 2013.

RESULTS

Between 2015 and 2021, a total of 83 residents of the Topas Penitentiary Centre were candidates to receive antiviral treatment against HVC infection. Two patients finally refused the treatment. The main data of the 81 patients studied are shown in Table 1.

The mean age of the patients was 50.1 (SD 8.8) years, and 69 (83.1%) were male. Grouped by age, 9.6% were between 24 and 40 years old, 33.7% were between 41 and 50 years old, 45.8% were between 51 and 60 years old, and 10.9% were over 61 years old. Of the 83 patients studied, 57 (68.7%) were or had been injection drug users. Thirty-one percent of the patients were unaware of the method of transmission.

Sixteen (19.3%) of the patients had been diagnosed with HCV infection in the last 5 years. In 27.7% of the cases, the diagnosis had been made more than 15 years ago. Regarding complications, only one patient had required hospital admission due to oedema ascitic syndrome during the year prior to this study. None of the patients presented evidence of hepatic encephalopathy, upper gastrointestinal bleeding or hepatocellular carcinoma.

Table 1 Main epidemiological and clinical of prisoners with chronic hepatitis C virus infection

Variables	N= 83
Male gender (n, %)	69 (83.1)
Age, years (mean [SD])	50.1 (8.8)
Nationality (n, %)	
Spain	69 (83.1)
Other Western European country	2 (2.4)
Eastern Europe	4 (4.8)
Asia	2 (2.4)
Africa	3 (3.6)
Unknown	3 (3.6)
Comorbidities (n, %)	
HIV coinfection	25 (30.1)
Injecting drug users	57 (68.7)
Established liver disease (hepatic cirrhosis)	33 (39.8)
Stage F3	14 (16.9)
Stage F4	19 (22.9)
Portal hypertension	5 (6)
Hepatocarcinoma	0 (0)
Time from diagnosis to treatment (n, %)	
≤ 5 years	16 (19.3)
5-10 years	16 (19.3)
11-15 years	27 (32.5)
> 15 years	23 (27.7)
Unknown	1 (1.2)
Naïve patients (n, %)	64 (77.1)
Refusal of treatment (n, %)	2 (2.4)
Relevant complications of treatment (n, %)	0 (0)
Sustained virologic response (n, %)	76 (93.8)

Regarding characteristic data, two patients had been diagnosed with non-Hodgkin lymphoma when HCV infection was known; 7% were diabetic, and 20.5% had psychiatric illnesses, such as personality disorders, schizophrenia or bipolar disorder. In 25 (30.1%) patients, HCV infection coexisted with HIV infection.

The main analytical data related to HCV are shown in Table 2. Of the patients studied, 37% had mild hepatic cytolysis in the first follow-up test with a transaminase value less than 1.5 times the upper limit of normality without associated co-

Table 2 Main characteristics of HVC and liver disease in prisoners

Variables	N= 83
Child-Pugh (n, %)	
Child A	82 (98.8)
Child B	1 (1.2)
Child C	0 (0)
MELD (n, %)	
≤ 9	76 (91.6)
10-19	7 (8.4)
≥ 20	0 (0)
Genotype of HCV (n, %)	
1a	39 (47)
1b	5 (6.1)
2	2 (2.4)
3	16 (19.3)
4	13 (14.6)
1a/3a	2 (2.4)
Unknown	6 (7.2)
Fibrosis stages (sound bases electrography) (n, %)	
Stage F0	27 (32.5)
Stage F1	6 (7.2)
Stage F2	16 (19.3)
Stage F3	14 (18.9)
Stage F4	19 (22.9)
Unknown	1 (1.2)

MELD: Model for End-stage Liver Disease

agulopathy. Seven percent of inmates had mild thrombocytopenia with platelet counts greater than 100,000/µL.

A total of 33 patients (39.7%) with HCV infection had fibrosis score of F0 to F1 in the last liver elastography performed. Approximately 23% of the patients analysed had grade 4 fibrosis, indicating maximal fibrosis or cirrhosis. None of the patients analysed had a MELD index ≥ 19, so no case was registered in the pre-liver transplant programme.

Regarding the treatment, 17 (20.5%) patients had previously received interferon and ribavirin without achieving a sustained viral response. In addition, three patients had previously received treatment with interferon and ribavirin and a combination of direct-acting antivirals in other health centres. None of the patients had completed therapy, and the three patients maintained a detectable viral load.

The number of patients treated per year is shown in Figure 1. The combination of sofosbuvir and daclatasvir was used in patients with genotype 3; sofosbuvir and ledipasvir in genotypes 1 and 4; sofosbuvir and velpatasvir in genotypes 1, 3 and 4; and glecaprevir and pibrentasvir in genotypes 1-4. The prescribed direct-acting antivirals for HCV infection are detailed in Figure 1. Inmates' chronic medication was recorded prior to antiviral initiation to avoid drug interactions, especially with antiretroviral therapy against HIV. The duration of treatment varied between 8 and 24 weeks. Three patients were lost during the posttreatment follow-up due to transfer to other prisons, and two patients finally declined to start antiviral treatment. In total, 76 patients achieved a sustained viral response, representing 93.8% of those treated. The patients who remained in the province received follow-up by the Infectious Diseases Unit for at least six months without registering complications or notable interactions.

DISCUSSION

Our work, which involved greater than 80 inmates with multiple pathologies, coinfection with HIV and drug use who receive treatment with direct-acting antivirals against HCV, shows sustained viral response rates in greater than 93% of patients with few side effects.

The number of men in Spanish prisons exceeds that of women with a 12:1 ratio according to data from the Spanish Ministry of the Interior. The majority (83%) of the inmates studied were male, so the prevalence based on gender cannot be estimated without bias. It has been described in prevalence studies that HCV infection is more frequent in men between 50 and 59 years of age followed by the age group between 60 and 69 years [4]. In our study, half of the patients were between 51 and 60 years old.

On the other hand, greater than 80% of the inmates studied had Spanish nationality, so it is not possible to assess the prevalence of HCV infection or compare the genotypes of the virus with those of the foreign population.

Approximately one-third of the inmates with HCV infection studied had coinfection with HIV. This prevalence is slightly higher than that reported in other studies (approximately 26%) [16]. This subgroup had a mean age of 52 years (SD 8.8). The prevalence of HIV infection in prisoners in Spain is 10.8%. Those infected are usually injection drug users and over 40 years of age, and 85% are coinfected with HCV [16]. According to data from GeSIDA [17], the prevalence of HIV/HCV coinfection in Spain in 2018 was 3.7%, which represents a reduction of 83.3% compared to that observed in 2015 [18]. The increase in exposure to direct-acting antivirals against HCV was the cause of this drastic decline.

In parallel, approximately 70% of the analysed sample had a history of parenteral drug use. Injection drug users are a high-risk HCV infection group with a prevalence of up to 90% in Irish prisons [6,12], constituting the leading cause of infection in young adults. Other transmission methods, such as vertical transmission, transmission through blood products, sexual transmission or transmission due to piercing or tattoos, could not be estimated in our study due to the lack of data in

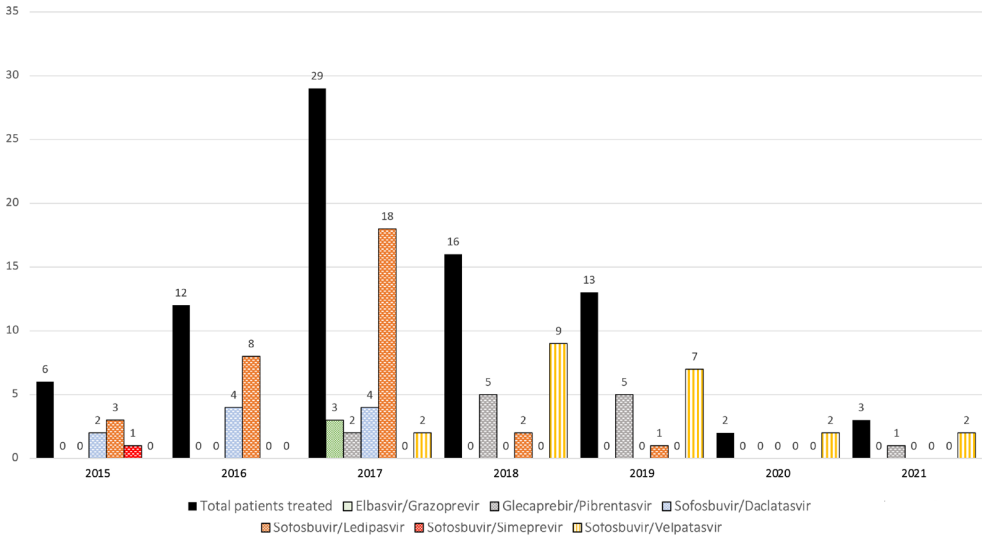

Figure 1 | **Direct-acting antiviral HCV prescribed to inmates of a penitentiary centre**

the medical records and the retrospective nature of this study.

In Spain, the most prevalent HCV genotype is genotype 1 with a predominance of 1a and 1b, which also coincides with the data obtained in our study [4]. In the group of foreigners, 62% also had genotype 1, 31% had genotype 3, and 8% had genotype 4.

Liver cirrhosis due to HCV is the main cause of chronic liver disease. Chronic inflammation of the liver can lead to liver fibrosis and eventually the development of cirrhosis. Approximately 25% of the patients analysed had grade 4 fibrosis estimated with non-invasive tests, although only a small percentage of patients presented decompensations or required hospital admission due to liver disease. No case of hepatocellular carcinoma was recorded.

Of note, 28% of those studied were infected with HCV for more than 15 years. It has been estimated that the risk of developing cirrhosis after 20 years of HCV infection without treatment ranges between 14 and 45%. In addition, once cirrhosis is established, the probability of developing decompensation or primary liver cancer is 20% at 5 years [19].

The efficacy of direct-acting antivirals for the treatment of HCV infection has been demonstrated in clinical trials, including in coinfected patients [19]. In our study, approximately 94% of treated inmates achieved sustained virological response. Spain started a pilot program to detect and treat HCV in prisons in 2016. The results of this study showed that a sustained viral response was achieved in greater than 95% of treated patients [7], and this result is consistent with our data. Toxicity and therapeutic abandonment were exceptional [20]. The COVID-19 pandemic is one of the main factors that explains the decrease in the number of cases treated in recent years.

Inmates in prisons have complex physical and psychological needs, which are not addressed by the primary health system. Different studies have shown that prisoners have better access to primary care and lower mortality when serving time in a prison compared to when they are released back to the community as a result of access to good nutrition, exercise, and a structured routine and the lack of stressors experienced [12]. Time in prison is an opportunity to treat hepatitis C. At the community level, these studies can make a great contribution to the country in controlling HCV infection.

The strategic plan of the Spanish Ministry of Health for HCV infection emphasized intervention in prisons as a key factor to address HCV infection. However, there are specific problems related to health care in prisons, including excessive delays in specialized consultations, poor communication between prisons and medical centres, a lack of providers and logistical difficulties in managing the transfer of inmates to hospitals [10].

In this sense, telemedicine offers a unique opportunity to eliminate geographic barriers, improve equity of access to specialized medical care, and guarantee continuity of care between hospitals and prisons.

Our study has methodological limitations derived from its retrospective nature and its inclusion of a small sample of inmates in a Spanish prison. The difficulty of accessing these patients and the interruption of follow-ups due to prison changes are other limitations of this work.

CONCLUSIONS

The wide acceptance and therapeutic adherence to antiviral treatment against HCV infection in a sample of inmates in a penitentiary centre with a high sustained virological re-

sponse rate and exceptional side effects is the main finding of our study. Antiviral treatment of patients with HCV infection is a priority, and it can be effectively provided in Spanish prisons with results equal to or better than those described in the community. Direct-acting antivirals have been shown to be safe and effective, even in coinfected patients. It is necessary to implement educational programs that highlight the benefits of these treatments in communities with limited access to the health system that are governed by the acceptance and reduction of stigma. Telemedicine has been employed in this environment to facilitate inmates' access to specialized care and as a comprehensive public health strategy.

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None to declare

CONFLICT OF INTEREST

All authors declare no conflicts of interest.

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