

Title:

Incidence and delayed diagnosis of hepatitis C: unexpected findings in times of elimination

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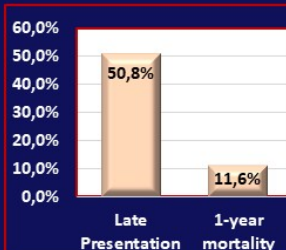
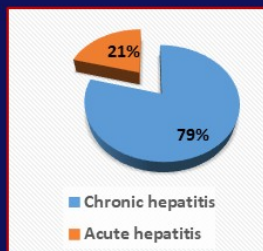
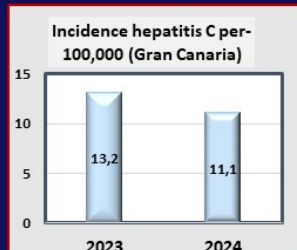
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Incidence and delayed diagnosis of hepatitis C in times of elimination

Results presentation



Acute hepatitis (n:18)	Late Presentation Chronic Hepatitis (n:33)	Non-Late Presentation Chronic Hepatitis (n:32)
➤ 88,9% in HIV-positive MSM ➤ 38,9% Reinfections ➤ Screening: main method of diagnosis ➤ Mainly Asymptomatic ➤ 94.4% cured in 1-year	➤ 39,4 % no identifiable risk factors ➤ 27,3% terminal illness ➤ 95,8% without terminal illness cured in 1-year	➤ 31,2 % no identifiable risk factors ➤ 84.4% cured in 1-year



- ☐ Incidence of new diagnoses exceeds the WHO elimination targets
- ☐ High proportion of late-stage diagnoses
- ☐ Significant active transmission among vulnerable population
- ☐ Over 30% of chronic cases lack identifiable risk factors
- ☐ Need to intensify screening strategies, optimize care coordination, and strengthen preventive

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Incidence and delayed diagnosis of hepatitis C: unexpected findings in times of elimination

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Ethical considerations: The study was approved by the Committee on Ethics in Research with Medicines (CEIm) of the Province of Las Palmas and has complied at all times with the Declaration of Helsinki (64th General Assembly, Fortaleza, Brazil, October 2013) and the Law on the Protection of Patients' Rights (Law 41/2002 on patient autonomy).

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Abbreviations list:

HCV: hepatitis C virus

DAA: direct-acting antiviral agent

PEAHC: Plan Estratégico para el Abordaje de la Hepatitis C (Strategic Plan for the Management of Hepatitis C)

WHO: World Health Organization

MSM: Men who have sex with men

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Lay summary

Hepatitis C is a viral infection that affects the liver and remains a significant public health problem. Although there are fewer cases in Spain than 10 years ago, many people still do not know they are infected, which makes it difficult to eliminate this disease.

In Gran Canaria, between 2023 and 2024, 87 new cases of hepatitis C were identified. This equates to approximately 12 people per 100,000 inhabitants per year. The majority (almost 80%) had had the infection for some time, and the rest were new cases or reinfections.

More than half had significant liver damage when diagnosed, and approximately 1 in 10 patients died within the first year after learning they had the disease. One-third of cases were detected through screening tests, which help find the infection before it causes symptoms. More than 30% of those diagnosed had no clear risk factors, which means that the virus may be hidden in the population.

Recent cases were particularly concentrated among HIV-positive men who have sex with men. Thanks to a good laboratory monitoring system, most patients were able to start treatment on time.

In summary, to eliminate this disease, screening tests must be improved, medical care must be better coordinated, and prevention must be strengthened to prevent the virus from continuing to spread, thereby controlling and eliminating hepatitis C.

Abstract

Introduction: Chronic hepatitis C virus (HCV) infection remains a public health concern. Late diagnosis and barriers to treatment hinder progress toward elimination goals. In Spain, although prevalence has declined, a hidden burden of infection persists. This study analyzes the incidence of newly diagnosed HCV cases in a region of Gran Canaria during 2023–2024, the frequency of late presentation, and access to antiviral treatment.

Patients and Methods: Clinical-epidemiological, observational, descriptive, and retrospective study of newly diagnosed hepatitis C patients, whether identified through clinical request or opportunistic screening. “Late presentation” was defined as fibrosis $\geq$ F3.

Results: A total of 87 cases were diagnosed (13.2 and 11.1 per-100,000 people in 2023 and 2024, respectively): 69 chronic cases (79.3%) and 18 acute cases (20.7%, with 38.9% reinfections). Among chronic hepatitis cases, 50.8% presented late, with a 1-year mortality of 11.6%. Screening led to diagnosis in 34.5% of cases, and more than 30% of chronic cases had no identifiable risk factors. Acute infections predominantly affected HIV-positive men who have sex with men (88.9%). Direct referral from the laboratory enabled most patients to access treatment within one year.

Conclusions: In this descriptive, and retrospective study, the incidence of new HCV diagnoses exceeds the WHO elimination targets, with a high proportion of late-stage diagnoses and active transmission amongst vulnerable populations. There is a need to intensify screening strategies, optimize care coordination, and strengthen preventive interventions.

Keywords: Hepatitis C. Epidemiology. Late diagnosis.

Introduction

Worldwide, an estimated 50 million people live with chronic hepatitis C virus (HCV) infection. In 2022, there were approximately one million new infections and around 221,000 deaths attributed to HCV, mainly due to complications from liver cirrhosis and

hepatocellular carcinoma (1).

The introduction of direct-acting antivirals (DAAs) revolutionized the treatment of HCV, with cure rates exceeding 95%. However, their therapeutic impact does not directly translate into disease control if not accompanied by effective early diagnosis strategies and equitable access to treatment. In this context, the detection of infection in advanced stages (2) is a critical barrier to global efforts to eliminate hepatitis C.

In Spain, the implementation of the Strategic Plan for the Management of Hepatitis C (PEAHC) in 2015 (3) contributed significantly to reducing HCV prevalence. However, a hidden burden of infection persists, especially in people over 40 years of age, in individuals with unrecognized risk factors, in migrants, in drug users, and in people in socially vulnerable situations (4). In addition, transmission continues to occur in sexually at-risk groups (5,6).

In our healthcare area, various strategies have been developed to improve the detection of hidden infection and recover patients lost to the system. Laboratory data recording has been available since 1995; one-step diagnosis was implemented in 2014; and referral from the laboratory to the specialist was implemented in 2022. Over the last decade, active search campaigns have been developed for patients without treatment since 1995, as well as for people with incomplete diagnoses since 2010 (positive serology without confirmation of viremia) (7). In addition, database cross-referencing and screening have been carried out in Drug Addiction Care Units and in hospitals (8,9).

The aim of this study was to estimate the incidence of new hepatitis C diagnoses in a health area on the island of Gran Canaria during the period 2023–2024, as well as to analyze the proportion of cases with advanced liver disease and the associated factors. Access to antiviral treatment in the identified cases was also reviewed in order to provide data for decision-making that will enable the elimination targets set by the World Health Organization (WHO) for 2030 to be met (10).

Patients and Methods

A clinical-epidemiological, observational, descriptive, and retrospective study was conducted based on a review of the medical records of patients with a new diagnosis of HCV infection in the northern part of the island of Gran Canaria between January 2023 and December 2024. This health area served a population of 354,600 and 358,938 people over the age of 14 in 2023 and 2024, respectively.

A new case was defined as a patient with no previous diagnosis of hepatitis C recorded in either the Canary Islands Health Service electronic medical records or the laboratory information system. Patients with a history of previous infection (even if they had been lost to follow-up or had no documented treatment) were classified as previously known cases and were not included in the study. Diagnoses were made at the request of the physician based on clinical suspicion or risk factors. In addition, since May 15, 2023, automated opportunistic screening has been implemented in the hospital setting for all requests for urine drug abuse testing, detection of sexually transmitted infections in genital samples, pneumococcal antigenuria, viral infection of the CNS in CSF, and specific serological profiles (9). In the event of a positive serology, a diagnosis was made using PCR and viral genotype detection. All patients were referred to a specialist through consultation by a microbiologist.

The diagnosis of acute primary infection was made by seroconversion. Reinfection was defined as the detection of HCV RNA after documented sustained viral response or after confirmed spontaneous clearance. To confirm previous negativity, all patients had at least one undetectable HCV RNA test in the previous 12 months. The minimum time interval between negativity and new positivity was 6 months. In patients at high risk of acute infection (for HIV and, since May 2024, for patients on pre-exposure prophylaxis for HIV), hepatitis C was monitored with check-ups every 6–12 months, depending on clinical follow-up.

Incidence rates were calculated based on the population treated each year, without adjustments for age or sex.

Antibody detection was performed using an Atellica IM (Siemens) analyzer, viral RNA detection using a Cobas 5800 system (Roche Diagnostic), and genotyping using the Abbott RealTime HCV Genotype II Amplification Reactive kit (Abbott Molecular).

Sociodemographic data, transmission risk factors (clinical survey conducted by hepatologists), diagnostic center (primary or specialized care), hepatic complications at diagnosis, antiviral treatment, and fibrosis status (assessment by elastography or FIB-4) were all collected.

Advanced liver disease was defined as the presence of fibrosis $\geq$ F3, and end-stage liver disease was defined as the presence of at least one symptom of decompensated cirrhosis and/or hepatocellular carcinoma at the time of diagnosis (2).

For statistical analysis, categorical variables were measured using absolute and relative frequencies, and quantitative variables were measured using mean ($\pm$ SD). Association tests (chi-squared or Student's t-test, as appropriate) were performed to explore factors associated with acute or chronic infection and advanced liver disease. Binary logistic regression analysis was also performed to identify factors associated with the presence of advanced liver disease. The results were expressed as odds ratios (OR) with 95% confidence intervals (95% CI). A p-value < 0.05 was considered statistically significant. The study was approved by the Clinical Research Ethics Committee of our hospital (Code CEIm 2025-335-1).

Results

From January 1995 to December 2022, 3,427 patients were diagnosed with hepatitis C infection in our area, of whom 74 (2.2%) remained uncured by early 2025. During the period 2023-2024, 87 new cases were diagnosed, 47 in 2023 and 40 in 2024, representing an incidence of diagnosed patients of 13.2 and 11.1 cases per 100,000 inhabitants, respectively. Of these, 69 (79.3%) had chronic hepatitis (four of them died within a short period of time from terminal causes unrelated to hepatitis, so the analysis was performed on 65 patients) and 18 (20.7%) had acute hepatitis (7-38.9% reinfections). Of the cases of acute infection, 9 occurred in 2023 and 9 in 2024, representing an incidence of 2.5 cases per 100,000 in each year.

Of the 87 patients, 28 (32.2%) were diagnosed in primary care clinics and 59 (67.8%) in hospitals, 30 (50.8%) of them through screening programs (14 by opportunistic hospital screening and 16 by screening of HIV patients undergoing follow-up or pre-exposure prophylaxis) and 29 (49.1%) at the express request of their physician. These

30 patients diagnosed in screening programs represent 34.5% of total diagnoses.

In patients with acute hepatitis (n=18), the cure rate with DAAs was 94.4%, with a single death from causes unrelated to the infection. Only one patient presented symptoms; the rest had asymptomatic infections. In 16 cases, hepatitis was diagnosed by annual screening of HIV patients, and in one case by screening during the follow-up of patients with pre-exposure prophylaxis for HIV.

In patients with chronic hepatitis, degree of fibrosis was assessed by elastography in 51 patients (78.5%) and by FIB-4 in the rest. Of these, 50.8% (n=33) had advanced liver disease, with 9 of these having end-stage disease (7 with hepatocellular carcinoma and 2 with decompensated cirrhosis). Of the 24 patients with advanced disease without terminal disease, 23 (95.8%) were cured with treatment and one refused it. Of the 9 patients with terminal disease, 8 died within one year of diagnosis due to hepatitis C complications (7 from hepatocellular carcinoma and one from decompensated cirrhosis), representing 11.6% of all patients with chronic hepatitis.

Among patients without advanced disease (n=32), 27 (84.4%) were cured, 2 (6.2%) started treatment, and one patient is awaiting treatment (3.1%). Two additional patients (6.2%) have not been treated — one refused treatment and one has repeatedly failed to attend appointments.

Table 1 describes the epidemiological characteristics of the patients. Statistically significant differences were observed in mean age, which was higher in patients with advanced disease (63.8 ± 8.8 years) compared to those without advanced disease (54.4 ± 8.6 years); the latter, in turn, had a higher mean age than patients with acute hepatitis (45.2 ± 10.3 years) ($p < 0.01$). Likewise, the proportion of migrant patients was significantly higher in the acute hepatitis group (33.3%) than in the chronic hepatitis group (13.8%) ($p < 0.05$). Statistically significant differences were also found in risk factors, with previous drug abuse being more common among patients with chronic infection than among patients with acute hepatitis, and transmission among men who have sex with men (MSM) being predominant in the latter group ($p < 0.01$). Among patients with chronic hepatitis, more than 30% had no known risk factors. No patients with chronic hepatitis were HIV-positive, while 88.9% (n=18) of patients with acute hepatitis were coinfecting with HIV ($p < 0.01$). Genotype 1b was predominant in

both patients with acute hepatitis (61.1%) and patients with chronic hepatitis (35.4%), with a statistically significant difference in percentage ($p < 0.05$).

In the multivariate analysis to identify predictive factors for late diagnosis, age remained an independent predictor (OR: 1.07; 95% CI: 1.02–1.13; $p < 0.01$), as did the presence of genotypes 1a (OR: 18.9; 95% CI: 1.2–1290; $p < 0.05$) and 3 (OR: 20.2; 95% CI: 1.1–345; $p < 0.05$). In contrast, the presence of a known risk factor showed a protective effect (OR: 0.35; 95% CI: 0.13–0.92; $p < 0.05$).

Discussion

The WHO has set a target for 2030 to diagnose 90% of people with chronic hepatitis C, with the aim of treating the majority of them and reducing mortality by 65% compared to 2015. Their objectives for eliminating hepatitis C as a public health problem also include reducing its incidence, with the aim of achieving a rate of less than 5 new cases per 100,000 inhabitants (10). To this end, the WHO proposes strengthening early diagnosis, improving access to antiviral treatments, expanding prevention programs in vulnerable populations, and ensuring universal access to health services.

In Spain, the PEAHC has now been in place for a decade. To evaluate its progress, it is essential to quantify the magnitude of the problem, to understand the clinical and epidemiological characteristics of newly diagnosed patients, and to analyze therapeutic interventions and their follow-up. This information is key to identifying possible areas for improvement and, if necessary, implementing measures to advance toward the established objectives.

In our study, conducted in 2023 and 2024, we observed that the incidence of new cases was 13.2 and 11.1 per 100,000 inhabitants, respectively, values that are higher than the threshold of 5 per 100,000 established by the WHO. It was also higher than that reported in the community of Murcia (7.9/100,000) (11) and the European average of cases reported to the ECDC in 2023 (7.4/100,000) (5). Our finding should be interpreted in the context that one-third of patients were identified through opportunistic screening, which was implemented in mid-2023. This introduces a possible diagnostic bias, as the increased detection rate resulting from this strategy may have increased the incidence observed in our area compared to other regions

where such interventions are not available. In addition, more than 20% of the cases diagnosed corresponded to acute infections, of which almost 40% were reinfections, representing an incidence of acute infection of 2.5 cases/100,000 inhabitants. These cases were mainly concentrated among HIV-positive MSMs, a particularly vulnerable population group at high risk for HCV transmission (5,6). The high proportion of acute infections reflects active and sustained transmission in this community, indicating that current prevention measures are not sufficient to interrupt the chain of infection. The high prevalence of genotype 1b observed in cases of acute hepatitis is possibly associated with an epidemic outbreak caused by a single cluster documented in this health area since May 2022 (12). On the other hand, the high rate of reinfection, already described in different studies (13), shows that, despite access to effective treatments, continued exposure to the virus maintains the risk of infection, hindering epidemiological control. In a multicenter study conducted before and after the introduction of antivirals (13), the percentage of reinfection increased in some cohorts and remained stable or decreased in other cohorts. Because most reinfections are asymptomatic, these percentages depend largely on the frequency of screening of the at-risk population. These findings underscore the need to incorporate comprehensive and specific strategies that include not only diagnosis and treatment but also prevention and surveillance programs, which are key to advancing toward elimination goals, given that most of these cases are asymptomatic, meaning that this population can act as a reservoir for transmission, posing a significant challenge for public health policies. Systematic screening not only of HIV-positive patients but also of those with risk behaviors who receive pre-exposure prophylaxis will contribute to early diagnosis. This, together with early treatment, should be key to controlling the epidemic in this population group.

Our results show a worrying reality: half of new hepatitis C diagnoses correspond to late presentations, which impact patient prognosis as individuals present in advanced stages of the disease, when therapeutic options are more limited and less effective. Mortality attributed to hepatitis C during the first year of diagnosis in patients with chronic infection exceeded 10%, which is an indicator that significant deficiencies in diagnostic suspicion and early diagnosis still persist. In a multicenter study conducted

in our country, the percentage of patients with advanced liver disease represented a quarter of those attending a hepatology consultation for the first time (14). Although the study had a large number of cases due to its multicenter nature, one of its main limitations was variability in the quality of the data collected, but it was noted that the proportion of late presentations did not show a downward trend. The results of our study not only show a high burden of undiagnosed disease, but also underscore the urgency of establishing interventions aimed at reducing avoidable mortality. Despite therapeutic advances and the availability of highly effective DAAs, these benefits do not reach all patients when the diagnosis is made in advanced stages of the disease.

An additional relevant finding, which coincides with other studies (15), is that over 30% of chronic infections were diagnosed in patients with no known risk factors. This suggests that current screening policies (16), which focus on populations considered to be at risk, may be overlooking a significant portion of the infected population. This indicates that a selective screening approach may be insufficient to detect all cases, limiting the effectiveness of elimination programs. Furthermore, this situation may be influenced by a lack of knowledge of risk factors due to an absence of accurate information gathered during the clinical interview. In this context, it is a priority to improve healthcare personnel training in order to identify possible risks and promote a more comprehensive clinical interview. Likewise, coordination between primary and specialized care is essential, given that the high proportion of patients with advanced disease could be related to insufficient screening at the primary care level. The implementation of opportunistic screening programs—such as age-based screening or screening based on hypertransaminasemia—in combination with micro-elimination strategies, constitutes a complementary and synergistic approach aimed at achieving the goal of elimination.

A study conducted in our country showed that all hepatitis C screening strategies are cost-effective for early detection, also contributing to reducing associated mortality (17).

On a positive note, our results show that virtually all patients diagnosed were treated and cured within the first year, reflecting an effective healthcare model with rapid referral to specialists and access to treatment. Coordination between the Clinical

Microbiology Laboratory, the Hepatology Unit, and the Infectious Diseases Unit has been essential in achieving these results. Similar cure rates have been reported in well-organized cohorts with screening strategies and a comprehensive approach (18). This is important because it not only prevents progression but also reduces viral transmission.

In conclusion, to move towards the elimination of hepatitis C, the results of our cohort suggest that systematic screening could also be beneficial in populations without identified risk factors. In addition, coordination between primary and specialized care should be improved, prevention programs focused on vulnerable populations where transmission occurs should be established, awareness should be raised, healthcare professionals should be trained in early diagnosis, and barriers that hinder access to diagnosis and treatment should be eliminated.

Table 1. Epidemiological characteristics of 83 patients diagnosed with chronic (with and without advanced liver disease) and acute HCV infection

	Chronic Hepatitis (n: 65)		Acute Hepatitis (n: 18)
	Patients with advanced disease (n: 33)	Patients without advanced disease (n: 32)	
Sex, n (%)			
○ Male	23 (69.7)	23 (71.9)	17 (94.4)
○ Female	10 (30.3)	9 (28.1)	1 (5.6)
Year of birth, n (%)			
○ <1950	8 (24.3)	2 (6.2)	0 (0.0)
○ 1950-1959	4 (12.1)	2 (6.2)	1 (5.6)
○ 1960-1969	17 (51.5)	15 (46.9)	5 (27.8)
○ 1970-1979	4 (12.1)	8 (25.0)	4 (22.2)
○ 1980-1989	0 (0.0)	4 (12.5)	5 (27.8)
○ >1989	0 (0.0)	1 (3.1)	3 (16.7)
Mean Age ± SD (Range)	63.8 ± 8.8 (47-93)	54.4 ± 8.6 (32-83)	45.2 ± 10.3 (23-68)
Immigrants, n (%)	3* (9.1)	6** (18.7)	6*** (33.3)
Genotypes			
○ 1	1 (3.0)	3 (9.4)	1 (5.6)
○ 1a	10 (30.3)	9 (28.1)	4 (22.2)
○ 1b	10 (30.3)	13 (40.6)	11 (61.1)
○ 2	1 (3.0)	1 (3.1)	1 (5.6)
○ 3	6 (18.2)	2 (6.2)	0 (0.0)
○ 4	2 (6.1)	2 (6.2)	0 (0.0)
○ No genotype	3 (9.1)	2 (6.2)	1 (5.6)
Risk factor, n (%)			
○ Drug Use History	15 (45.4)	15 (46.9)	1 (5.6)
○ Transfusions <1990	3 (9.1)	3 (9.4)	0 (0.0)
○ MSM	0 (0.0)	1 (3.1)	16 (88.9)
○ Other	2 (6.1)	3 (9.4)	1 (5.6)
○ Unknown	13 (39.4)	10 (31.2)	0 (0.0)
HIV-positive, n (%)	0 (0.0)	0 (0.0)	16 (88.9)
Diagnostic Center, n (%)			
○ Primary Care	10 (30.3)	16 (50.0)	1 (5.6)
○ Hospital Care	23 (69.7)	16 (50.0)	17 (94.4)

* 1 Austria, 1 Finland, 1 Portugal. **2 Venezuela, 1 Cuba, 1 Nepal, 1 Ivory Coast, 1 Italy

***2 Colombia, 1 Brazil, 1 Venezuela, 1 Philippines, 1 Scotland

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