



How Successful are We in the Elimination of HCV Infection in the Alcohol and Substance-Dependent Population?

Alkol ve Madde Bağımlı Popülasyonda HCV Eliminasyonunda Ne Kadar Başarılıyız?

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ABSTRACT

Introduction: This study aimed to assess the prevalence of anti-hepatitis C virus positivity among individuals monitored for alcohol and drug addiction at the Alcohol and Substance Dependency Research, Treatment, and Education Center (AMATEM) outpatient clinic of a tertiary healthcare institution. The factors associated with referral rates to the infectious diseases (ID) clinic were evaluated.

Materials and Methods: This single-center, retrospective, observational study retrospectively evaluated the data of cases monitored for alcohol and drug addiction at the AMATEM outpatient clinic of a tertiary healthcare institution between January 1, 2021, and December 31, 2021, using the hospital information system.

Results: A total of 9974 cases visited the AMATEM clinic, but anti-HCV testing was requested for only 495 (4.96%) of these cases. Among them, 53 (10.7%) tested positive for anti-HCV. It was observed that consultation with the ID department was requested for 24 (45.28%) of the 53 patients, but only 10 (18.86%) presented to the ID outpatient clinic. Among the referred cases, four individuals (40%) were found to be HCV RNA positive, and only one of these patients completed an eight-week course of glecaprevir-pibrentasvir treatment and achieved sustained virological response. The referral rate to the ID outpatient clinic was significantly higher in cases where a formal ID consultation was requested compared to those where no consultation was requested. Using a logistic regression prediction model, it was estimated that if all 53 patients who tested positive for anti-HCV had presented to the ID clinic, the number of patients receiving treatment would have been tenfold higher.

Conclusion: Enhancing the awareness and knowledge of AMATEM clinicians regarding HCV and facilitating patient referrals to the ID department are crucial. Establishing specialized units to monitor HCV treatment adherence in this high-risk, challenging population and, when necessary, administering treatment under direct supervision will accelerate progress toward national HCV elimination goals.

Key Words: HCV; Elimination; Substance users

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ÖZ

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Giriş: Bu çalışmada üçüncü basamak sağlık kurumunun Alkol ve Uyuşturucu Madde Bağımlıları Tedavi ve Araştırma Merkezi (AMATEM) polikliniğinde alkol ve madde bağımlılığı nedeniyle izlenen bireyler arasında anti-hepatit C virüs (HCV) pozitiflik oranı belirlenerek pozitif bulunan hastaların enfeksiyon hastalıkları polikliniğine başvurusunu etkileyen faktörlerin belirlenmesi amaçlanmıştır.

Materyal ve Metod: Bu tek merkezli, retrospektif, gözlemsel çalışmada, 1 Ocak 2021 ile 31 Aralık 2021 tarihleri arasında üçüncü basamak sağlık kurumunun AMATEM polikliniğinde alkol ve madde bağımlılığı için izlenen olguların verileri, hasta kayıt sistemi üzerinden retrospektif olarak değerlendirildi.

Bulgular: Bir yıllık süre boyunca AMATEM polikliniğine 9974 olgu başvurmuştur. Bu olgulardan yalnızca 495 (%4.96)'inde anti-HCV testi istenmiş olup bunların 53 (%10.7)'ünde anti-HCV pozitif bulunmuştur. Elli üç olgunun 24 (%45.28)'ünden enfeksiyon hastalıkları konsültasyonu istenmiş, bunlardan yalnızca 10 olgu (%18.86) enfeksiyon hastalıkları polikliniğine başvurmuştur. Başvuran olgulardan dördü (%40) HCV RNA pozitif saptanmış ve bunlardan yalnızca biri sekiz haftalık glekaprevir-pibrentasvir tedavi sürecini tamamlayarak kalıcı virolojik yanıt elde etmiştir. Enfeksiyon hastalıkları polikliniği başvurusu olan ve olmayan olgular, sosyodemografik özellikler, madde kullanımı ve ilişkili faktörler açısından karşılaştırıldığında, enfeksiyon hastalıkları konsültasyonu istenen olgularda enfeksiyon hastalıkları polikliniğine başvuru oranının anlamlı derecede daha yüksek olduğu tespit edilmiştir. Lojistik regresyon analizi yapıldığında, anti-HCV pozitif olan 53 hastanın tümünün enfeksiyon hastalıkları polikliniğine başvurması halinde, tedavi alan olgu sayısının 10 kat artacağı öngörülmüştür.

Sonuç: Alkol ve Uyuşturucu Madde Bağımlıları Tedavi ve Araştırma Merkezi polikliniğinde çalışan hekimlerin HCV ile ilgili farkındalıklarının artırılması ve anti-HCV pozitif olduğu saptanan bireylerin enfeksiyon hastalıkları birimine yönlendirilmesi hayati önem taşır. Hepatit C virüsü tedavisine uyumun gözlenmesi için özellikli ünitelerin geliştirilmesi ve özellikle riskli gruplarda direkt gözlem altında tedavi uygulanması, ulusal HCV eliminasyon hedeflerine hızlı ulaşılmasını sağlayacaktır.

Anahtar Kelimeler: HCV; Eliminasyon; Madde kullanıcıları

INTRODUCTION

The use of substances continues to increase worldwide. According to the United Nations' World Drug Report 2023, there has been a 23% increase in substance use over the past 10 years. In 2011, the number of people using substances was 240 million, and by 2021, this figure had risen to 296 million. The same report states that in 2021, one in every 17 individuals aged 15-64 had used drugs at least once in the past 12 months, with over 11 million reported to have used intravenous drugs. New data indicates that an estimated 13.2 million people globally used intravenous drugs in 2021, reflecting an 18% increase from the 2020 figures of 11.2 million individuals^[1]. Intravenous drug use is one of the most significant factors contributing to the ongoing global epidemic of hepatitis C virus (HCV) infection. The World

Health Organization (WHO) reports that 23% of new HCV infections worldwide are attributed to unsafe intravenous drug use^[2]. According to 2024 data from the Ministry of Health, Public Health General Directorate in Türkiye, among 1262 individuals who used intravenous drugs, 41.7% (n= 526) had HCV, 3.3% (n= 42) had hepatitis B virus, and 3% (n= 16) had human immunodeficiency virus infection^[3]. Additionally, data from the Türkiye Hepatitis C Diagnosis and Treatment Guideline indicate that the prevalence of HCV among individuals receiving treatment at addiction treatment centers who use intravenous drugs is 50%^[4].

Direct-acting antivirals (DAAs) are used to inhibit the HCV replication cycle, facilitate viral elimination and cure, have minimal side effects, are well tolerated, and can shorten the treatment duration to 8-12 weeks. However, no vaccine has

been developed for the prevention of the disease to date^[5,6]. WHO aims to reduce HCV infections by 90% by 2030. To achieve this goal, priority groups identified for screening and treatment include individuals who share non-sterile medical equipment, undergo blood transfusions, receive hemodialysis, or use intravenous drugs. The aim is to ensure that 80% of this group has access to treatment. Expanding HCV screening is crucial for these at-risk populations^[2,7].

The detection and treatment of HCV infection, which is significantly more prevalent among individuals with alcohol and substance dependence than in the general population, are of paramount importance for both individual and public health. Although access to direct-acting antiviral treatments that completely eradicate HCV infection has been available in Türkiye since 2016, studies reporting the extent of access to this treatment among a key population for HCV elimination-individuals with alcohol and substance dependence-remain limited. This study aims to investigate the epidemiology and monitoring of HCV infection among individuals with alcohol and substance use. The primary endpoint is to determine the rate of anti-HCV positivity among patients monitored at the Alcohol and Substance Dependency Research, Treatment, and Education Center (AMATEM) clinic. The secondary endpoint is to identify factors associated with the referral rate to the infectious diseases (ID) outpatient clinic for patients who tested positive for anti-HCV at the AMATEM clinic.

MATERIALS and METHODS

This observational, single-center, and retrospective study designed and conducted by ID and AMATEM clinics included cases monitored at the AMATEM clinic of a tertiary healthcare facility between January 1, 2021, and December 31, 2021. All patients aged 18 and above were included in the study. Patient information was accessed through the hospital information management system and patient records. The number of cases with reactive anti-HCV ELISA test results conducted for screening purposes within the past year was identified, and these cases were included for further analysis. A standardized data collection form was used to record information on age, gender, education

level, reasons for admission to the AMATEM clinic, and types and routes of substance for all cases. The hospital information system was utilized to determine the number of patients referred to the infectious diseases clinic for consultation, the number who presented to the ID outpatient clinic for evaluation, the number tested for plasma HCV RNA using polymerase chain reaction, and the number who received antiviral treatment.

Statistical Analysis

Statistical Package for the Social Sciences 15.0 (Chicago, Illinois) software was utilized for the analysis of the obtained data. The distribution of the data was assessed using the Shapiro-Wilk test, and Fisher's exact test was employed for comparing categorical variables. The distribution of the data was assessed using the Shapiro-Wilk test. The Chi-square test was used for comparing categorical variables, and the independent samples t-test was used for comparing numerical data. A p-value of <0.05 was considered statistically significant in the analyses. A logistic regression prediction model was applied to determine how many of the 53 patients who tested positive for anti-HCV would have received treatment if all had presented to the ID clinic. The prediction model was developed based on the demographic and clinical characteristics of the patients. Missing data for numerical variables were imputed using the median, while categorical variables were imputed using the mode. A logistic regression prediction model was applied to estimate how many patients who tested positive for anti-HCV would have received treatment if all had presented to the ID clinic. A backward stepwise method was used for model optimization, including only significant variables to prevent overfitting and enhance interpretability. The dataset was randomly divided into training (80%) and testing (20%) subgroups for model development and evaluation. Model performance was assessed using the receiver operating characteristic (ROC) curve and area under the curve (AUC) value, and the Youden index. All analyses were conducted using R (version 2024.04.1+748), utilizing the "stats", "compareGroups" and "pROC" packages.

All procedures were conducted in accordance with the Helsinki Declaration, and ethical approval for the study was obtained from İzmir

Katip Çelebi University Faculty of Medicine Ethics Committee on November 24, 2022, with approval number 0538.

RESULTS

During the one-year follow-up period, 9974 cases visited the AMATEM clinic, but an anti-HCV test was requested for only 495 (4.96%) of these cases. Among those tested, 53 (10.7%) were anti-HCV positive. Anti-HCV positive cases were predominantly male (n= 49, 92.5%) with

a mean age of 31.2 ± 8.55 years (standard deviation). Among the 53 anti-HCV positive cases, 33 (62.3%) were in the 25-34 age group. Intravenous drug use was identified in 46 (86.8%), multiple substance use in 25 (47.2%), opioid use in 23 (43.4%), alcohol and multiple substance use in three (5.6%), and only alcohol use in two (3.8%) of the cases. The educational status of anti-HCV positive patients who presented and did not present to the infectious diseases outpatient clinic was similar (Table 1).

Table 1. A comparison of sociodemographic characteristics and substance use between cases with and without infectious diseases outpatient clinic admissions

	Admission to the Infectious Diseases Outpatient Clinic			p
	Overall (n= 53)	With (n= 10)	Without (n= 43)	
Gender				1.000
Female	4 (7.5%)	0 (0.00%)	4 (100%)	
Male	49 (92.5%)	10 (20.4%)	39 (79.6%)	
Age, year, mean (SD)	31.2 (8.55)	33.0 (9.52)	30.7 (8.37)	0.499
Age				0.447
18-24	8 (15.1%)	1 (10.0%)	7 (16.3%)	
25-34	33 (62.3%)	5 (50.0%)	28 (65.1%)	
35-44	4 (7.5%)	2 (20.0%)	2 (4.6%)	
45-54	7 (13.2%)	2 (20.0%)	5 (11.7%)	
55-64	1 (1.9%)	0 (0.0%)	1 (2.3%)	
Marital Status				0.442
Single	38 (71.7%)	6 (15.8%)	32 (84.2%)	
Married	15 (28.3%)	4 (26.7%)	11 (73.3%)	
Education				0.378
Not literate	1 (1.9%)	0 (0.00%)	1 (100%)	
Primary school	4 (7.5%)	1 (25.0%)	3 (75.0%)	
Secondary school	30 (56.6%)	4 (13.3%)	26 (86.7%)	
High school	14 (26.5%)	5 (35.7%)	9 (64.3%)	
University	4 (7.5%)	0 (0.00%)	4 (100%)	
Drug initiation age, year,mean (SD)	16.9 (3.54)	17.0 (4.45)	16.9 (3.36)	0.964
Intravenous Drug Use				0.114
Yes	46 (86.8%)	7 (15.2%)	39 (84.8%)	
No	7 (13.2%)	3 (42.9%)	4 (57.1%)	
Cirrhosis				0.481
Noncirrhotic	20 (90.9%)	10 (50.0%)	10 (50.0%)	
Cirrhotic	2 (9.1%)	0 (0.00%)	2 (100%)	
Substance				0.055
Opioid	23 (43.4%)	5 (21.7%)	18 (78.3%)	
Multiple drugs	25 (47.2%)	3 (12.0%)	22 (88.0%)	
Alcohol and drug	3 (5.6%)	0 (0.00%)	3 (100%)	
Alcohol	2 (3.8%)	2 (100%)	0 (0.00%)	
Prior Antiviral Treatment Experience				0.604
Yes	7 (13.2%)	2 (28.6%)	5 (71.4%)	
No	46 (86.8%)	8 (17.4%)	38 (82.6%)	
Infectious Diseases Consultation				<0.001
Yes	24 (45.3%)	10 (41.7%)	14 (58.3%)	
No	29 (54.7%)	0 (0.00%)	29 (100%)	

SD: Standart deviation.

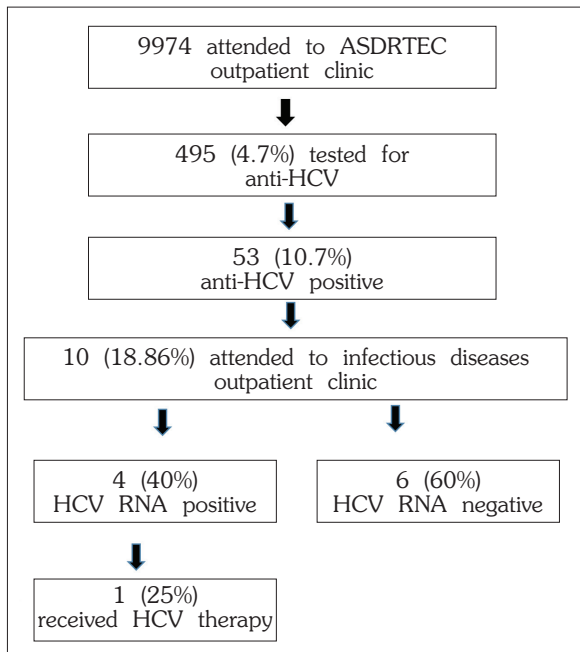


Figure 1. Evaluation of patients presenting to the ASDRTEC outpatient clinic for HCV infection.

A total of 53 anti-HCV positive patients were recruited for further analysis. A formal infectious diseases (ID) consultation was requested by the primary physician for 24 cases (45.3%), and only 10 cases (18.86%) were referred to the ID outpatient clinic for consultation. However, none of the remaining 29 anti-HCV positive cases for whom a formal consultation was not requested attended the ID outpatient clinic. Among the 10 anti-HCV positive cases who presented to the ID outpatient clinic, HCV RNA was negative in six cases and positive in four. Only one of the four cases with detectable HCV RNA in plasma regularly attended ID follow-up visits, completed

an eight-week course of glecaprevir-pibrentasvir treatment, and achieved a sustained virological response (Figure 1).

Referral by the primary care physician for formal ID consultation ($p < 0.001$) and alcohol use as a form of substance use ($p = 0.017$) were the only factors associated with presenting to the ID outpatient clinic among the anti-HCV positive cases. Sociodemographic characteristics, substance use other than alcohol, and the route of substance use did not affect the admission to the ID outpatient clinic (Table 1).

According to the logistic regression prediction model (AUC= 0.769, specificity= 70%, sensitivity= 86%, Youden index= 0.56), assuming that all 53 anti-HCV positive patients presented to the ID Clinic, the expected number of patients who would receive treatment was calculated to be 10 (Figure 2).

DISCUSSION

To achieve the WHO's goal of HCV elimination both globally and at the country level, rational interventions are essential. The most crucial among these is the need to increase awareness of this issue, particularly by expanding screenings in high-risk groups and ensuring access to diagnosis and treatment for positive cases.

In this study, the rate of requesting anti-HCV tests for cases followed up at the AMATEM outpatient clinic, a tertiary healthcare institution for alcohol and substance addiction, was found to be very low (4.9%). The study also demonstrated that both the referral rate to the ID outpatient clinic (18.86%) and the HCV elimination rate

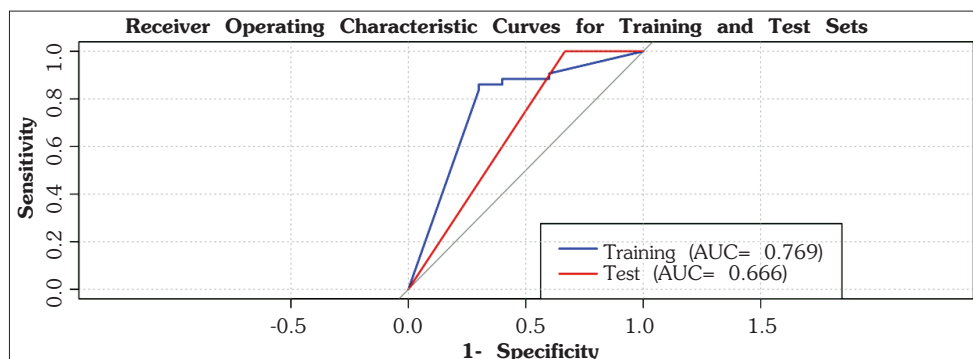


Figure 2. Comparison of receiver operating characteristic curves for training and test models.

(25%) were low. When evaluating the factors associated with referral to the ID outpatient clinic, it was observed that the referral rate was significantly higher among cases for which a formal ID consultation was requested.

In a meta-analysis of 15 studies from various centers in Australia and Europe, the prevalence of anti-HCV positivity among intravenous drug users presenting to general practitioners was found to be 46%^[8]. In a substance dependence outpatient treatment center in Northern Italy, among 636 applicants, 244 tested positive for anti-HCV, and of these, 99% had a history of intravenous drug use. It was reported that 68% of the anti-HCV positive cases were also positive for HCV RNA^[9]. In a study conducted in 2016 at an AMATEM clinic in Türkiye, the prevalence of anti-HCV positivity was 1.4%; however, only 0.7% of these cases had a history of intravenous drug use^[10]. In another study conducted between 2013 and 2017 on patients presenting with substance dependence, the prevalence of HCV in individuals without intravenous drug dependence was similar to that of the general population (0.6%), whereas among those with a history of intravenous drug use, the prevalence was 17.6%^[11]. In a study conducted on inpatient opioid-dependent patients at the AMATEM clinic between 2017 and 2018, the prevalence of anti-HCV positivity was 10.9%^[12]. Additionally, another study conducted between 2021 and 2022, which included 427 patients followed up on both an outpatient and inpatient basis at the AMATEM clinic (73.8% of whom reported intravenous drug use), reported an anti-HCV positivity prevalence of 12%^[13]. In another study examining the changing epidemiology of chronic hepatitis C infection in our country, intravenous drug use was identified as the most common transmission route (40.3%). The rate of intravenous drug use was found to be 46.3% between 2013 and 2017 and increased to 68.3% between 2018 and 2022^[14]. In our study, the prevalence of anti-HCV positivity was 10.7%, with 86.79% of cases reporting intravenous drug use. Although the prevalence rate in our study was slightly lower than the global prevalence, it was comparable to other studies conducted in

Türkiye on similar populations. The prevalence of HCV among intravenous drug users remains high both globally and in Türkiye, highlighting the need to overcome certain barriers to achieving the WHO elimination targets. An article on the micro-elimination approach to addressing hepatitis C in Türkiye emphasized that providing freely accessible treatment for HCV in people who inject drugs can help prevent HCV transmission to uninfected individuals and reduce the risk of reinfection among those who have been treated^[15]. A review published in 2023, which assessed opportunities and barriers on the path to HCV elimination, reported the availability of pan-genotypic treatments for HCV infection and their adoption by many countries as an opportunity. However, it also noted that numerous barriers to elimination persist, requiring organized national and local efforts to overcome them. The review emphasized the need to enhance accessibility to diagnostic tests for high-risk groups, ensure easy access to treatment, and implement effective follow-up strategies. It has been stated that the most critical factor in achieving these goals is the provision of resources and personnel by health authorities, along with efforts to increase awareness. Reports indicate that countries implementing national campaigns for HCV screening and treatment have achieved success in HCV elimination, whereas countries without such campaigns continue to face a high burden of HCV^[16]. Despite the availability of curative treatments in our country over the years, the rate of anti-HCV positivity has not decreased among individuals who use intravenous drugs, and the burden of HCV remains significantly high in this high-risk group. In an outpatient treatment center for drug users in Italy between 2020 and 2022, it was reported that 70% of referred cases completed treatment, and among those treated with direct-acting antiviral agents, 99% achieved a sustained virological response^[9]. A study conducted in the United States developed a methadone provision program designed to facilitate the simultaneous treatment of HCV and opioid use disorder. In this study, HCV infection was detected in 190 patients, of whom 88.9% initiated treatment and 62.7% completed it. Additionally, 68.9% of patients

received their treatment under direct observation alongside methadone therapy, and 96.2% of them achieved a sustained virological response. The authors suggested that implementing such a program could help reduce the burden of HCV and potentially break the HCV transmission cycle in this high-risk population^[5].

In a study conducted at the AMATEM clinic between 2021 and 2022 in our country, it was reported that out of 50 patients identified as anti-HCV positive, only 20 (38.46%) presented for further investigation and treatment. Among these patients, 12 (60%) tested positive for HCV RNA, while eight tested negative. The study indicated that the glecaprevir/pibrentasvir combination was the predominant treatment choice; however, clear information regarding treatment responses was not provided^[13]. In another study conducted at the AMATEM clinic in Türkiye between 2017 and 2018, the referral rate to the ID outpatient clinic was 31%, with 44.4% of those who presented receiving treatment with direct-acting antivirals. The same study found no significant differences in sociodemographic characteristics or substance use between those who applied to the ID outpatient clinic and those who did not^[12]. In our study, only 18.86% of cases identified as anti-HCV positive presented to the ID outpatient clinic. When examining factors potentially influencing outpatient clinic referrals, similar to the aforementioned study, it was observed that sociodemographic characteristics of the cases did not affect admission to the ID outpatient clinic. When evaluated based on substance use, it was found that only cases with alcohol use had significantly higher rates of admission to the ID outpatient clinic. However, due to the low number of alcohol users, this finding was not considered statistically significant. Consequently, it was concluded that the type of substance used did not affect the likelihood of presenting to the ID outpatient clinic. It was observed that a request for an ID consultation by AMATEM clinic physicians significantly influenced the rate of referral to the ID outpatient clinic. In our study, the rates of follow-up and treatment initiation for cases identified as anti-HCV positive were lower compared to rates reported in other

studies conducted in Türkiye and globally. This is believed to be due to the heavy workload at our hospital's AMATEM outpatient clinic, which may have limited physicians' ability to allocate sufficient time to address patients' additional health concerns. Additionally, it is believed that the physicians at this clinic may have insufficient knowledge and awareness regarding HCV infection. It has been concluded that educating physicians working in this clinic on the importance of HCV screening and the availability of curative treatments is essential. If all 53 patients who tested positive for anti-HCV presented to the ID clinic, the expected number of patients receiving treatment would have been 10 times higher. In this context, such an increase would represent a significant step towards achieving the goals of the global HCV eradication program. In this patient group, it has been observed that requesting an ID consultation and explaining its importance to the patient can increase their awareness. However, due to the challenges associated with adherence in this patient population, many patients who attend an initial outpatient visit do not return for follow-up appointments and treatment. It has been concluded that, to achieve success in the path to HCV eradication, specialized units should be established to monitor this high-risk patient group.

In conclusion, rational interventions within the national healthcare system are essential to achieve the WHO's goals for HCV elimination. Success in this endeavor requires health authorities to allocate sufficient resources for the widespread implementation of screenings. Collaboration with communication channels, such as media and telemedicine, is crucial for raising awareness within the community. Additionally, it is necessary to educate healthcare personnel who provide services to high-risk groups, including prisoners, intravenous drug users, and migrants, about HCV infection.

It has been concluded that establishing specialized units to monitor treatment adherence in this challenging, high-risk group and, if possible, ensuring that this population receives treatment under direct supervision will contribute significantly to national success in HCV elimination.

ETHICS COMMITTEE APPROVAL

This study was approved by the İzmir Katip Çelebi University Non-Interventional Clinical Studies Institutional Review Board (Decision no: 0538, Date: 24.11.2022).

CONFLICT of INTEREST

The authors have no conflicts of interest to declare that are relevant to the content of this article.

AUTHORSHIP CONTRIBUTIONS

Concept and Design: NT, HBAA

Analysis/Interpretation: NT, BK, FK, ÖEK

Data Collection or Processing: BB, HBAA

Writing: NT, BK, BÖ

Review and Correction: FK, NT, BÖ

Final Approval: NT, FK, BK, BB, HBAA

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