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Coronavirus Pandemic

Impact of COVID-19 pandemic on diagnosis and treatment access of patients with viral hepatitis in Turkey

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Abstract

Introduction: We aimed to evaluate access to diagnosis, treatment and follow-up in patients with viral hepatitis during the COVID-19 pandemic.
Methodology: Patients who started treatment for hepatitis B and hepatitis C were included in the study and analyzed in two periods: before-pandemic and during-pandemic. Indication for treatment and frequency of laboratory follow-up was obtained from hospital records. A telephone survey was administered to evaluate treatment access and compliance.
Results: Four centers with 258 patients were included in the study. Of these 161 (62.4%) were male, median age was 50 years. The number of patients, admitted to outpatient clinics was 134647 in the before-pandemic period and 106548 in the during-pandemic period. Number of patients who started treatment for hepatitis B were significantly high during-pandemic period compared with before-pandemic (78 (0.07%); 73 (0.05%) respectively; $p = 0.04$). The number who received treatment for hepatitis C was similar in both periods: 43 (0.04%); 64 (0.05%), respectively ($p = 0.25$). Prophylactic treatment for hepatitis B, due to immunosuppressive agents was significantly higher in during-pandemic period ($p = 0.001$). In the laboratory follow-ups at 4th, 12th and 24th weeks of treatment, worse adherence was detected in during-pandemic (for all $p < 0.05$). Access to treatment and compliance of all patients was over 90% and did not differ in the two periods.
Conclusions: During-pandemic, hepatitis patients' access to diagnosis, treatment initiation and follow-up had worsened in Turkey. The health policy implemented during the pandemic had a positive impact on patients' access to and compliance to treatment.

Key words: Hepatitis B; Hepatitis C; COVID-19; access; treatment.

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Introduction

The COVID-19 pandemic has adversely affected all stages of hepatitis elimination programs and patient follow-ups around the world [1-3]. Many countries have used the bulk of their health budgets for the COVID-19 pandemic, resulting in a lack of resources for the targets of viral hepatitis elimination programs. During the COVID-19 pandemic, minimizing contact between people, including patient-doctor relations, was determined as the most important preventive measure, except in emergencies [4,5]. Therefore, restrictions, and the closure of outpatient clinics negatively affected patients' access to diagnosis and treatment [1].

In 2012 there were only 17 countries which had viral hepatitis elimination programs whereas in 2019 this number went up to 124. The incidence of hepatitis B, hepatitis C and mortality due to hepatitis decreased in the last five years [1]. In the shadow of the COVID-19 pandemic, it was reported from regions with different epidemiological characteristics that there were disruptions in hepatitis elimination programs. It is estimated that a one-year delay in the diagnosis of hepatitis C patients alone will lead to more than 72000

deaths worldwide in 2030 [2,3]. The hepatitis elimination program in Turkey was started and implemented successfully in 2018, but its execution was affected by the COVID-19 pandemic, as in other regions of the world. During the COVID-19 period in Turkey, hepatitis B patients received their medicines directly from pharmacies, while the necessity of visiting a doctor in order to access the medicines of hepatitis C patients continued. We wanted to examine how drug access was impacted under these practices. Determining the impact of these changes is essential for appropriate interventions.

This study aimed to identify the impact of diagnosis and access to treatment, laboratory follow-ups and treatment compliance for hepatitis B and hepatitis C patients who were treated for the first time during the COVID-19 pandemic.

Methodology

The study was conducted as a multicenter retrospective observational study. Patients over the age of 18 years from outpatient clinics of study centers between March 1, 2019, and March 1, 2021, were screened. Regardless of the time of diagnosis, patients who initiated the antiviral treatment for the first time with the diagnosis of hepatitis B and patients who were started on direct-acting antivirals for hepatitis C for the first time were included in the study.

The patients were evaluated in two periods: before-pandemic and during-pandemic. The period between 1 March 2020 – 1 March 2021 was defined as during-pandemic in which there were closure and restrictions due to the COVID-19 pandemic. Dates between 1 March 2019 – 29 February 2020, which were one year before the during-pandemic period, were defined as before-pandemic, during which there were no restrictions to access outpatient clinics.

Age and gender of the patients were recorded as demographical data. For all patients, the date of initiation of treatment, and compliance with laboratory monitoring before and after treatment were obtained from the electronic records of each center. Antiviral initiation indication was recorded for hepatitis B patients. Indication of hepatitis B treatment was classified as: chronic hepatitis B infection, or prophylaxis in patients receiving immunosuppressive treatment.

In terms of evaluating the compliance of laboratory follow-ups; the laboratory tests at the beginning of the treatment and at the 4th, 12th, 24th, and 48th weeks were screened from the hospital records. Specifically, data for the tests for alanine aminotransferase (ALT), aspartate aminotransferase (AST), hepatitis B virus (HBV) DNA, hepatitis C virus (HCV) RNA, alpha-fetoprotein (AFP), platelet, International Normalized Ratio (INR) and hepatobiliary ultrasonography tests

Table 1. Telephone survey questions for patients with Hepatitis B/Hepatitis C.

0.	**Do you agree to participate in our research telephone survey?**
1.	**How were you diagnosed? / The reason for being tested for HBsAg/anti HCV?**
o	checked post exposure
o	checked due to family history
o	checked before surgery
o	checked before marriage
o	checked before immunosuppressive therapy
o	blood donor
o	other # #
2.	**How often did you go to outpatient clinic follow-up after starting treatment?**
o	Once in 3 months
o	Once in 6 months
o	At the beginning once monthly/in 3 months, didn't go/irregular after pandemic
3.	**How did you get your medicines? (Only for HBV patients)**
o	by getting a prescription at the hospital
o	directly from the pharmacy
4.	**Did you use your medication regularly?**
o	Yes
o	No
-	I didn't use it for a day once in a while
-	I took a break for 1 week
-	I took a break for 1 month
5.	**If you had gone for a doctor's visit, would your medication use be more regular?**
o	Yes
o	No

HBsAg: Hepatitis B surface antigen; anti HCV: Hepatitis C virus antibody; HBV: Hepatitis B; # #Drug user; tested for differential diagnosis or unknown.

were used to determine whether laboratory tests were performed or not.

Prior to the pandemic, patients who started treatment with the diagnosis of hepatitis B were able to receive their medications from pharmacies with doctor prescriptions. However, during the pandemic in Turkey, hepatitis B patients were allowed to receive their medications directly from pharmacies without consulting a hospital and without a doctor's follow-up. This was a targeted government policy for patients receiving treatments for long-term chronic diseases, to ensure these patients continue their treatments. Hepatitis C treatment is short-term and involves high-cost medication. Therefore, the policies applied for hepatitis B were not deemed appropriate for hepatitis C. Patients receiving treatment for hepatitis C, accessed their medicines only through hospital pharmacies after a hepatologist visit.

A short telephone survey was prepared to evaluate patients' access to diagnosis and treatment compliance. The patients were contacted by the principal investigator of the center. Survey questions were asked after receiving verbal approval and patient consent for participation in the study. Table 1 lists the questions used in the survey.

Ethical approval was provided by Ankara City Hospital Ethical Committee 1 with the approval number E1-21-1674.

Statistical analysis

Descriptive statistics were used to define continuous variables (mean, median, minimum,

Table 2. Change in access to diagnose and follow-up characteristics of hepatitis B and hepatitis C patients during the COVID-19 pandemic.

	All patients with HBV[1] n (%)	**Before pandemic HBV n (%)**	**During pandemic HBV n (%)**	***p***	**All patients with HCV n (%)**	**Before pandemic HCV n (%)**	**During pandemic HCV n (%)**	***p***
Patients	151	73 (43.8)	78 (51.6)	0.745	107	64 (59.8)	43 (40.1)	0.053
Age (median [IQR]) years	53 [44-62]				43 [27-61]			
Gender (male percent)	94 (62.3)				67 (62.6)			
Indication for treatment				**0.001**				
Chronic hepatitis	62 (41.1)	40 (54.8)	22 (28.2)		107 (100)			
Prophylactic	89 (58.9)	33 (45.2)	56 (71.8)		-			
Access to diagnoses				**0.016**				0.90
Checked post exposure		-	-		1 (0.9)	-	1 (2.3)	
Checked due to family history	25 (16.5)	17 (23.3)	8 (10.3)		3 (2.8)	2 (3.1)	1 (2.3)	
Checked before surgery	13 (8.6)	7 (9.6)	6 (7.7)		20 (18.6)	12 (18.8)	8 (18.6)	
Checked before marriage	-	-	-		2 (1.9)	1 (1.6)	1 (2.3)	
Checked before immunosuppressive therapy	82 (54.3)	29 (39.7)	53 (67.9)		2 (1.9)	2 (3.1)	-	
Blood donor	8 (5.2)	5 (6.8)	3 (3.8)		1 (0.9)	1 (1.6)	-	
Other	23 (15.2)	15 (20.5)	8 (10.3)		78 (72.9)	46 (71.9)	32 (74.4)	
How did you get your medicines? * (n = 130)				0.492				
By getting a prescription at the hospital			15 (21.4)					
Directly from the pharmacy			55 (78.6)					
How often did you go to outpatient clinic follow-up after starting treatment? #								
Once in 3 months			19 (24.3)				10 (23.2)	
Once in 6 months			14 (17.9)				12 (27.9)	
At the beginning once monthly/in 3 months, not gone/irregular after pandemic			45 (57.7)				21 (48.8)	
Did you use your medication regularly? (n = 138/104)				0.584				
No	13 (9.4)	5 (7.9)	8 (10.7)		-			
Yes	125 (90.6)	58 (92.1)	67 (89.3)		104 (100)			
If you had gone to a doctor's visit, would your medication use be more regular? (n = 81/75)				0.570				
No	53 (65.4)	30 (68.2)	23 (62.2)		54 (72)			
Yes	28 (34.6)	14 (31.8)	14 (37.8)		21 (28)			

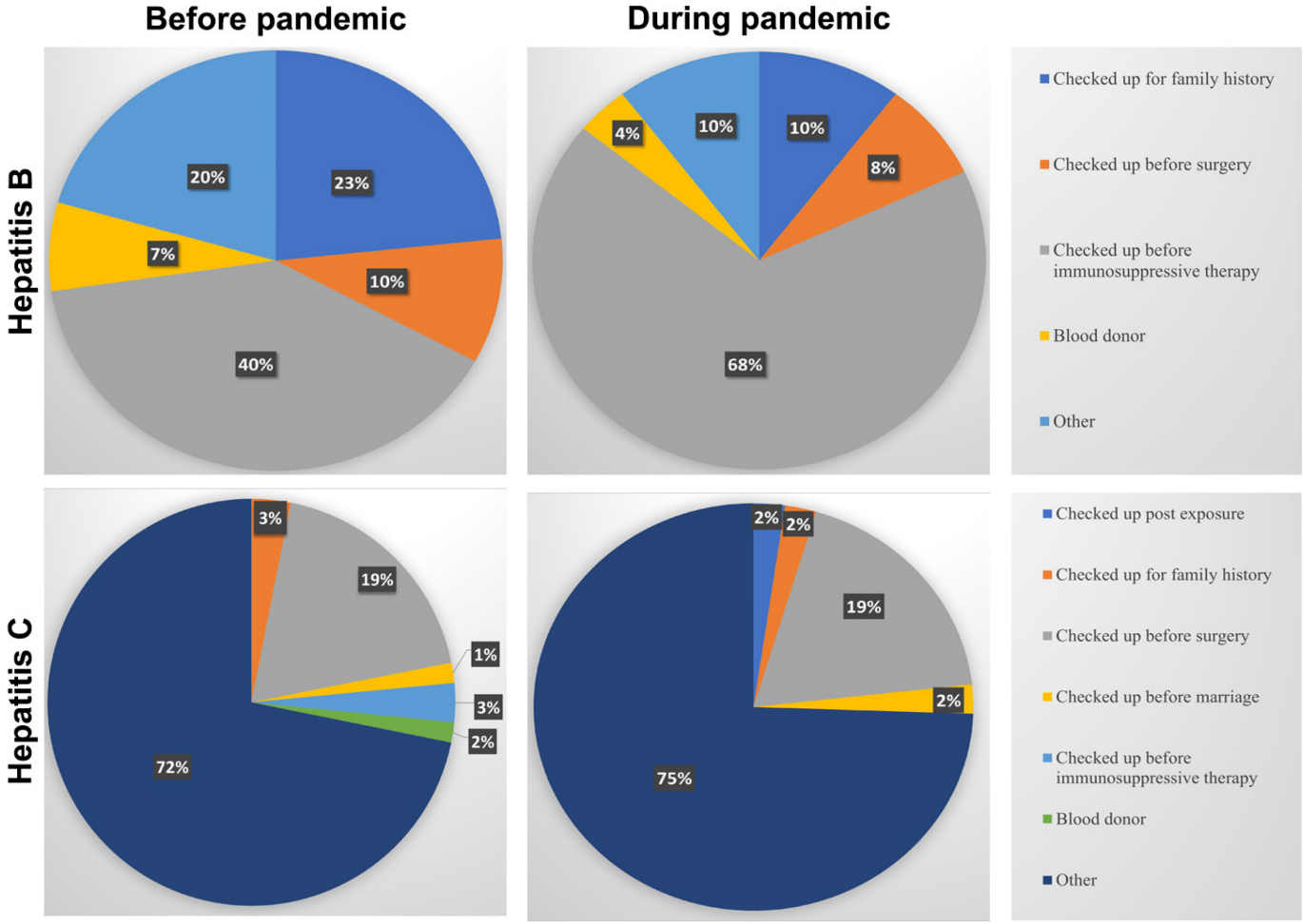
maximum) and frequency and percent for categorical variables. The relationship between categorical variables was analyzed with the Chi Square test. Fisher Exact test was used for comparing numerical data between independent groups. Statistical significance was regarded as a p value < 0.05 in overall comparisons. SPSS 25 (IBM Inc., Armonk, NY, USA) was used for statistical analyses.

Results

Four centers and 241195 outpatient clinic admissions were screened and 258 patients who started the treatment for the first time for viral hepatitis were included in the study. Of the patients 161 (62.4%) were male, median age was 50 (range: 36-62) years. The number of patients who admitted to outpatient clinics was 134647 patients in the before-pandemic and 106548 patients in the during-pandemic period. During the study period, hepatitis B treatment was started on 151 patients and hepatitis C treatment was started on 107 patients. Among outpatient clinics admissions, the number of patients who started the treatment for the first time for HBV in the before-pandemic and during-pandemic period was 73 (0.05%) and 78 (0.07%), respectively; the rate of HBV patients who started new treatment in the during-pandemic period was significantly higher than the before-pandemic period (p = 0.04). The number of patients who started direct-acting antivirals for HCV before and during-pandemic period was 64 (0.05%) and 43 (0.04%), respectively; there was no significant difference between the rate of HCV patients who started new treatment, in one year before and during the pandemic period (p = 0.25).

Patients with hepatitis B were evaluated in terms of treatment initiation indications (Table 2, Figure 1). In the before-pandemic period 40 (54.8%) patients and in the during-pandemic period 22 (28.2%) patients were initiated antiviral treatment for chronic hepatitis B. In the before-pandemic period 33 (45.2%) patients and in the during-pandemic period 56 (71.8%) patients were initiated antiviral treatment for prophylactic. The number of patients in whom prophylactic treatment was

Figure 1. Access to diagnosis in before-pandemic and during-pandemic periods for patients with hepatitis B and hepatitis C.



initiated due to immunosuppressive treatment was significantly higher in the during-pandemic period (p = 0.001).

Adherence to treatment in the 4th, 12th and 24th weeks of the treatment was higher in the before-pandemic period than in the during-pandemic period (p = 0.043, 0.002, 0.023respectively). Week 48 follow-up was not evaluated as it was incomplete for all patients included (Table 3).

The telephone survey evaluated access to diagnosis and compliance with treatment and follow up. In terms of the reasons for access to diagnosis for hepatitis B patients, there was a significant difference between the before-pandemic and during-pandemic periods; while the patients with hepatitis B were frequently diagnosed due to family history and other reasons during the before-pandemic period, they were mostly diagnosed during the examinations performed before immunosuppressive therapy during-pandemic period (p = 0.016). Reasons for access to diagnosis were not different for hepatitis C patients in before-pandemic and during-pandemic periods (p = 0.90) (Table 2, Figure 1). The responses for evaluating compliance with treatment and using medication regularly without doctor visit are listed in Table 2.

Discussion

During the COVID-19 pandemic, there were significant disruptions in the stages of diagnosis, access to treatment and follow-up of patients with viral hepatitis [6,7]. This study highlights these effects for Turkey. It was determined that the diagnosis and treatment of chronic hepatitis B and C patients in Turkey were adversely affected during the pandemic, and there were delays in the follow up visits of the patients under treatment. In addition, when the indication for treatment initiation was evaluated in hepatitis B patients, it was determined that prophylactic antiviral use was relatively increased due to the use of immunosuppressive agents during the pandemic period.

The four centers included in the study were hospitals in regions with different epidemiological characteristics. However, during the pandemic period healthcare personnel in all centers were directed to the health services of COVID-19 patients, and the number of patient admissions to outpatient clinics decreased due to restrictions. Therefore, in order to evaluate the change in the number of hepatitis B and hepatitis C patients for whom new treatment was initiated, we compared the ratio of the number of patients who were newly treated or admitted during the period before and during the pandemic. The number of patients who were started on medication for hepatitis B was significantly higher during the COVID period. This increase was evaluated as the effect and success of the hepatitis elimination program, which was implemented in Turkey in 2018 and was carried out quite successfully until the COVID-19 pandemic restrictions. The rate of patients who started new treatment for hepatitis C was statistically similar during the pandemic period; this indicates that the treatment of patients was delayed for one more year in 2020, when we aimed to reach more patients within the hepatitis elimination program compared to the previous year. However, the number of patients who started hepatitis C treatment had not decreased. In Turkey, the prevalence of HCV in the general population is 3-6 per thousand [8,9], while the prevalence in risk groups varies between 3.8-7.6%, and it reaches 50% in intravenous (IV) drug users [10,11]. In the presence of these epidemiological characteristics, it is necessary to develop micro elimination strategies in addition to the hepatitis elimination program.

During the COVID-19 pandemic, minimizing the contact between patients was the main precaution procedure to reduce the risk of transmission. It was recommended that the face-to-face visits of the patients with chronic hepatitis, except urgent liver conditions all invasive procedures, including liver biopsies should be postponed [4,5,7]. One hundred twenty-three of 131 (94%) civil society organizations reported that the effect of the COVID-19 pandemic altered their activities on countries elimination programs [12]. These interventions have resulted in fewer diagnoses of people living with viral hepatitis during the COVID-19 pandemic. [12,13]. In a multicenter study conducted in USA, Japan and Singapore; it was reported that there

Table 3. Laboratory follow ups of the patients with viral hepatitis before and during COVID-19 pandemic.

Week of treatment	**Week 4, n (%)**		**Week 12, n (%)**		**Week 24, n (%)**	
Period	**before-pandemic**	**during-pandemic**	**before-pandemic**	**during-pandemic**	**before-pandemic**	**during-pandemic**
At least one of the laboratory parameters*						
None	53 (38.7)	62 (51.2)	70 (51.1)	85 (70.2)	75 (54.7)	83 (68.6)
Tested	84 (61.3)	59 (48.8)	67 (48.9)	36 (29.8)	62 (45.3)	38 (31.4)
p	0.043		0.002		0.023	

*alanine aminotransferase, aspartate aminotransferase, Hepatitis B virus DNA polymerase chain reaction (PCR), Hepatitis C virus RNA PCR, alpha-fetoprotein, platelet, INR and hepatobiliary ultrasonography.

was a significant decrease in patients admitted to liver disease clinics between 2018 and 2020 [14].

When the treatment indications in hepatitis B patients were evaluated, the number of patients who started treatment for chronic hepatitis B decreased, while the proportion of patients who started prophylactic hepatitis B treatment due to the use of immunosuppressive agents increased significantly during the COVID period. Restrictions and limited outpatient services delayed the access of chronic hepatitis B patients to treatment by at least one year. This has left many patients with chronic liver disease and the possibility of preventing the progression to cirrhosis and hepatocellular carcinoma. In this study, different from the current literature, the indications for starting treatment were evaluated, and there was no data evaluating treatment indications in the literature. In addition, the number of patients in whom prophylactic hepatitis B treatment was initiated due to the use of immunosuppressive agents increased during the pandemic period. This situation was interpreted as a result showing that the hepatologists' awareness on this topic had increased as a result of the hepatitis elimination program.

It was concluded that post-treatment laboratory follow-ups of the patients during the pandemic were 20% less than in the before-pandemic period. This result emerged in parallel with the fact that patients were not admitted to hospitals and less laboratory tests were performed. Hepatitis C patients whose treatment is normally 8-12 weeks in duration have to regularly come to a doctor's visit during drug use. It was interpreted that these results for hepatitis C patients included 12th and 24th week follow-ups. More studies are needed to evaluate results of the disruptions in laboratory follow-ups after treatment. During COVID-19, different restriction programs were implemented in countries to provide remote care. Due to these restrictions, there was a 63% decrease in laboratory tests and a 77% decrease in imaging in the World Health Organization (WHO) countries, mainly in underdeveloped countries [13].

Access to diagnosis, drug and compliance with treatment were evaluated through the telephone questionnaire. Among hepatitis B patients, access to diagnosis had shifted from being diagnosed because of family history to being investigated for immunosuppressive agent in parallel with the indication for treatment initiation. During the COVID-19 process, there were serious disruptions in access to hepatitis B and hepatitis C testing and treatment [2,15,16]. In a global survey in 32 countries performed by the World Hepatitis Alliance (WHA); two third of 132 responders reported that they were not able to access hepatitis testing during COVID-19 [12]. The World Hepatitis survey data showed that treatment access had significantly deteriorated due to COVID-19 in low-income and middle-income countries, and 15 (52%) of 29 respondents of World Hepatitis Alliance society from those countries described that the patients could not access treatments timely [17].

Treatment access and compliance of all patients was found over 90%, which is well above the worldwide data. Although one third of all patients said that if they went to a doctor's visit, their drug use would be more regular, the regular use of drugs by the patients was not different in the before-pandemic and during-pandemic periods. It is reported that one-third of the patients in non-US countries and approximately one-tenth of them in the USA could not access hepatitis medicine during the pandemic period [6,12]. It has also been reported that there was a 50% decrease in the follow-up of hepatitis patients in the lockdown situation, which took place without very rigid restrictions, and a significant drug supply problem had been reported in Egypt [2]. When compared with the current literature, it was determined that treatment access was successfully provided in Turkey.

Conclusions

During the COVID-19 pandemic, hepatitis patients' access to diagnosis, treatment and post-treatment follow-up were affected negatively. Although prophylactic antiviral initiation had increased proportionally due to the use of immunosuppressive agents, the treatment of a large group of patients with chronic hepatitis B was delayed. This demographical change should be taken into account when scheduling hepatitis elimination programs.

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