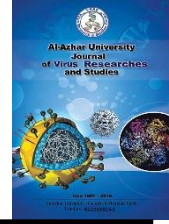




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Impact of COVID-19 Vaccines on Cirrhotic Egyptian Patients: A Prospective Cohort Study

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Abstract

All SARS-CoV strains have the capacity to lead to life-threatening pneumonia. Patients with chronic liver illness are more prone than the general population to experience deleterious effects from SARS-CoV-2 infection. Acute liver failure occurs more commonly in patients with SARS-CoV-2. Aim of the work: to evaluate impact of COVID-19 vaccines on cirrhotic Egyptian patients. Patients and Methods: This is prospective study, was carried out on 250 patients over 6 months duration. Patients were selected from those visiting the hepato-gastroenterology and infectious diseases outpatient clinics at El-Husseini and Bab-Elshaaria University hospitals, Faculty of Medicine, Al-Azhar University. Five equal groups of patients were formed: Group (1): 50 patients cirrhotic liver Child-Pugh score A, Group (2): 50 patients cirrhotic liver Child-Pugh score B, Group (3): 50 patients cirrhotic liver Child-Pugh score C, Group (4): 50 patients chronic liver disease without liver cirrhosis, Group (5): 50 healthy persons without chronic liver disease. All studied patients subjected to the followings: Full medical history, Clinical examination, Laboratory investigations (CBC, liver and kidney functions, fasting and postprandial blood glucose) and Pelviabdominal ultrasound. These procedures were done three times: One week before receiving vaccine, one to two weeks after receiving first dose of vaccine and one to two weeks after receiving second dose of vaccine (vaccines were administrated: Sinopharm, Sinovac, AstraZeneca, Pfizer and Johnson). Results: There were no significant changes as regard clinical, laboratory and imaging before, after the first dose, and after the second dose of the COVID-19 vaccines in the five groups. Conclusion: In conclusion, it was discovered that COVID-19 vaccination safe for persons with cirrhosis or without cirrhosis who have chronic liver disease. To identify risk factors of adverse events, additional comparison studies with bigger sample sizes and longer follow-up are required.

Keywords: COVID-19, Vaccine, Cirrhotic.

1. Introduction

During the most current pneumonia epidemic in January 2020, the severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) was found in Wuhan,

Hubei Province, China [1,2]. By March 11, 2020, the virus had spread throughout the entire world and was classified as a pandemic by the World Health

Organization. SARS-CoV-2 infected 647,972,911 individuals worldwide [3]. Middle East respiratory syndrome Coronavirus (MERS-CoV), SARS-CoV, and SARS-CoV-2 all cause severe pneumonia with death rates of 36%, 9.6%, and 2.9%, respectively [4,5]. Chronic liver disease patients are more likely than the general public to face the negative consequences of SARS-CoV-2 infection. Acute liver failure has a higher rate of short-term fatalities than chronic liver failure because of its fundamental characteristics, was present in 50% of the patients who had decompensated after contracting SARS-CoV-2 [6]. The COVID-19 vaccinations have advanced at a rate that is unheard of in the history of vaccines. There are now 104 candidate vaccines in the clinical stages of development and 184 candidate vaccines in preclinical stages [3]. According to recent data, 18 COVID-19 vaccines have been licensed and are now being used worldwide [7]. The COVID-19 vaccines are divided into four main groups employing various platforms: The severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) is used in whole virus vaccines as a weaker (attenuated) or inactivated form to encourage protective immunity. The virus used in live attenuated vaccinations can still grow and multiply but does not cause sickness [8]. Viruses in inactivated vaccines have had their genetic material altered by heat, chemicals, or radiation so they can no longer replicate in cells but can still elicit an immune response [9]. 16 inactivated and two live attenuated candidate SARS-CoV-2 vaccines are currently being developed in clinical trials [3]. Subunit vaccines and vaccines against virus-like particles are the two types of protein-based immunizations available [10]. For protein subunit vaccinations, viral antigenic fragments are produced using recombinant protein methods [11]. Currently, 33 potential vaccines against SARS-CoV-2 protein subunits and five

vaccines against virus-like particles are in clinical development [3]. The genetic coding for the SARS-CoV-2 antigens is inserted into the cell via the viral vector in viral vector vaccines. It has been chemically weakened to prevent disease transmission by the virus used as a vector. This makes it possible for the body to mount an immune response without running the risk of the disease spreading [12, 13]. Currently, 16 viral vectors do not replicate whereas only 2 viral vectors do. The SARS-CoV-2 vaccines are being investigated in clinical settings [3]. SARS-CoV-2 nucleic acid vaccines deliver genetic instructions in the form of deoxyribonucleic acid (DNA) or ribonucleic acid to produce a SARS-CoV-2 protein that activates the immune system (RNA). Before COVID-19, this platform was not inspected because no authorized vaccinations were being given [13, 14]. There are now at least 10 DNA and 18 RNA vaccine candidates being tested on humans [3]. For usage abroad, a number of SARS-CoV-2 mRNA vaccines have been approved [7]. The aim of this study was to evaluate impact of COVID-19 vaccines on cirrhotic Egyptian.

2. Patients and Methods

2.1. Study design and setting

This was a prospective cohort study that involved patients from those visiting the hepato-gastroenterology and infectious diseases outpatient clinics at El-Hussein and Bab-Elshaaria University hospitals, Al-Azhar University's Faculty of medicine, between February and July 2022.

2.2. Study sample

Five equal groups were created by dividing the study populations to: Group (1): 50 patients cirrhotic liver Child-Pugh score A. Group (2): 50 patients cirrhotic liver Child-Pugh score B. Group (3): 50

patients cirrhotic liver Child-Pugh score C. Group (4): 50 patients chronic liver disease without liver cirrhosis. Group (5): 50 healthy persons without chronic liver disease. Patients with liver cancer, long-term immune-suppressing conditions such diabetes mellitus, chronic kidney disease, HIV, pregnancy, and lactation, as well as patients younger than 18 years old, were excluded from the study.

2.3. Study tools

All studied patients subjected to the followings: Full medical history: name, age, sex, residence, occupation, special habits, marital state, detailed history of the liver illness, and another related history of medical importance, Clinical examination: general and abdominal examination with stress on the manifestations of chronic liver illness. Laboratory investigations: CBC, ALT, AST, bilirubin (total and direct), serum albumin, coagulation profile (PT, PTT, INR), alpha-fetoprotein, viral markers, fasting and postprandial blood glucose, blood urea and creatinine. Imaging: Pelviabdominal ultrasound to evaluate liver size, liver echogenicity, portal and splenic vein diameters, spleen size, degree of ascites if present. These procedures were done three times: One week before receiving vaccine, one to two weeks after receiving first dose of vaccine and one to two weeks after receiving second dose of vaccine. Type of vaccines were administrated: Sinopharm (85 cases), Sinovac (49 cases), AstraZeneca (74 cases), Pfizer (29 cases) and Johnson (13 cases).

2.4. Statistical analysis

Using Microsoft Excel software, data gathered throughout time, basic clinical examinations, laboratory investigations, and outcome measures were coded, recorded, and analysed. Following that, data were added to the statistical analysis

program Statistical Package for the Social Sciences (SPSS version 26.0).

3. Results

3.1. Comparison of the researched groups' demographic information.

Age and sex did not significantly differ across the groups under study (P-values = 0.132 and 0.143, respectively) Smoking showed a highly significant difference (P-value 0.001) with 82% of cases in group (1) being nonsmokers, 38% of cases in group (2) were smokers, 80% of cases in group (3) were x-smokers, 50% of cases in group (4) were smokers and 58% of cases in group (5) were nonsmokers (Table 1)

3.2. Type of vaccine among the studied five groups.

We found a highly significant difference between the studied five groups according to type of vaccine (P-value<0.001). Sinopharm was significantly higher in groups (1) and (3), AstraZeneca was significantly higher in group (4), Sinovac was significantly higher in group (2), and both AstraZeneca and Pfizer were significantly higher in group (5) (Table 2).

3.3. Clinical, laboratory and ultrasonography findings in the studied five groups.

Clinical and laboratory results show a highly significant difference between five groups (P-value<0.001). Pallor was a highly significant in groups (2&3). Jaundice, edema, ascites and splenomegaly were significantly higher in group (3). Hepatomegaly was a highly significant in group (4). Hemoglobin, platelet and albumin were significantly lower in group (3). PT, PTT, INR, bilirubin total and direct were a highly significant in group (3). Ultrasonography show ascites and splenomegaly higher in group (3) compared to other groups (Table 3).

3.4. Clinical, laboratory and ultrasonography findings in group (1).

There were no significant changes before, after 1st dose and after 2nd dose of vaccine in group (1) (Table 4).

3.5. Clinical, laboratory and ultrasonography findings in group (2).

There were no significant changes before, after 1st dose and after 2nd dose of vaccine in group (2) (Table 5).

3.6. Clinical, laboratory and ultrasonography findings in group (3).

There were no significant changes before, after 1st dose and after 2nd dose of vaccine in group (3) (Table 6).

3.7. Clinical, laboratory and ultrasonography findings in group (4).

There were no significant changes before, after 1st dose and after 2nd dose of vaccine in group (4) (Table 7).

3.8. Clinical, laboratory and ultrasonography findings in group (5).

There were no significant changes before, after 1st dose and after 2nd dose of vaccine in group (5) (Table 8).

Table (1): Comparison of the researched groups' demographic information.

	Group (1) (n = 50)	Group (2) (n = 50)	Group (3) (n = 50)	Group (4) (n = 50)	Group (5) (n = 50)	P-value
Sex						
Male (n (%))	27 (54%)	32 (64%)	38 (76%)	35 (70%)	29 (58%)	0.143
Female (n (%))	23 (46%)	18 (36%)	12 (24%)	15 (30%)	21 (42%)	
Age						
Mean \pm SD	50.07 \pm 11.5	54.8 \pm 10.3	55 \pm 11.38	52.07 \pm 9.25	51.42 \pm 11.5	0.132
Smoking						
Smoker (n %)	5 (10%)	19 (38%)	0 (0%)	25 (50%)	17 (34%)	<0.001
X-smoker (n %)	4 (8%)	13 (26%)	40 (80%)	13 (26%)	4 (8%)	
Non-smoker (n %)	41 (82%)	18 (36%)	10 (20%)	12 (24%)	29 (58%)	

Table (2): Type of vaccine among the studied five groups.

Type of vaccine	Group 1 (n = 50)	Group 2 (n = 50)	Group 3 (n = 50)	Group 4 (n = 50)	Group 5 (n = 50)	P-value
AstraZeneca (n (%))	9 (18%)	0 (0%)	10 (20%)	38 (76%)	17 (34%)	<0.001
Johnson (n (%))	5 (10%)	0 (0%)	0 (0%)	0 (0%)	8 (16%)	
Pfizer (n (%))	0 (0%)	0 (0%)	0 (0%)	12 (24%)	17 (34%)	
Sinopharm (n (%))	27 (54%)	24 (48%)	30 (60%)	0 (0%)	4 (8%)	
Sinovac (n (%))	9 (18%)	26 (52%)	10 (20%)	0 (0%)	4 (8%)	

Table (3): Clinical, laboratory and ultrasonography findings in the studied five groups.

	Group 1 (n = 50)	Group 2 (n = 50)	Group 3 (n = 50)	Group 4 (n = 50)	Group 5 (n = 50)	P-value
Clinical Examination						
Pallor n (%)	14 (28%)	50 (100%)	50 (100%)	0 (0%)	0 (0%)	<0.001
Jaundice n (%)	0 (0%)	28 (56%)	50 (100%)	0 (0%)	0 (0%)	<0.001
Edema n (%)	0 (0%)	13 (26%)	50 (100%)	0 (0%)	0 (0%)	<0.001
Ascites n (%)	0 (0%)	23 (46%)	50 (100%)	0 (0%)	0 (0%)	<0.001
Hepatomegaly n (%)	9 (18%)	6 (12%)	2 (4%)	21 (42%)	0 (0%)	<0.001
Splenomegaly n (%)	12 (24%)	37 (74%)	43 (86%)	5 (10%)	0 (0%)	<0.001
Lab Data						
Hemoglobin, Mean \pm SD.	11.06 \pm 1.33	9.23 \pm 1.32	8.93 \pm 0.41	12.2 \pm 0.43	12.56 \pm 0.77	<0.001
Platelet count, Mean \pm SD.	321.12 \pm 87.47	130.96 \pm 28.71	90.09 \pm 3.78	334.15 \pm 88.96	409.54 \pm 77.55	<0.001
WBCs, Mean \pm SD.	4.6 \pm 0.5	6.1 \pm 0.7	7.8 \pm 1.4	7.9 \pm 1.2	8.2 \pm 0.9	0.0017
Postprandial Blood Glucose (PPBG), Mean \pm SD.	151.32 \pm 10.63	149.6 \pm 15.42	148.75 \pm 12.23	155.12 \pm 14.31	146.81 \pm 13.38	0.665
Fasting blood Glucose (FBG), Mean \pm SD.	97.88 \pm 9.23	104.32 \pm 11.16	99.25 \pm 4.3	102 \pm 12.74	99.62 \pm 9.21	0.002
Serum creatinine, Mean \pm SD.	0.92 \pm 0.28	1.01 \pm 0.2	1.3 \pm 0.35	0.87 \pm 0.21	0.88 \pm 0.34	0.012
Urea, Mean \pm SD.	24.5 \pm 5.32	29 \pm 8.67	35.31 \pm 10.93	22.46 \pm 4.33	27.59 \pm 11.14	0.019
Liver Function						
INR, Mean \pm SD.	1.09 \pm 0.08	1.32 \pm 0.1	1.85 \pm 0.15	1.05 \pm 0.05	1.03 \pm 0.07	<0.001
PTT, Mean \pm SD.	29.87 \pm 2.37	37.72 \pm 4.07	47.78 \pm 1.81	30.46 \pm 0.86	29.3 \pm 3.12	<0.001
PT, Mean \pm SD.	13.41 \pm 2.23	15.64 \pm 1.65	20.12 \pm 3.13	11.77 \pm 1.07	13.81 \pm 2.83	<0.001
AST, Mean \pm SD.	43.94 \pm 20.35	47.34 \pm 23.84	59.12 \pm 31.73	37.92 \pm 11.26	37.12 \pm 6.09	0.013
ALT, Mean \pm SD.	35.75 \pm 18.26	43.34 \pm 20.88	53.34 \pm 26.44	30.5 \pm 5.67	31.7 \pm 6.02	0.012
Direct bilirubin, Mean \pm SD.	0.6 \pm 0.1	1.8 \pm 0.3	1.9 \pm 0.1	0.7 \pm 0.1	0.5 \pm 0.2	<0.001
Total bilirubin, Mean \pm SD.	1.1 \pm 0.2	2.7 \pm 0.2	3.5 \pm 0.1	1.1 \pm 0.1	1.0 \pm 0.2	<0.001
Albumin, Mean \pm SD.	4.48 \pm 0.2	3.1 \pm 0.1	2.1 \pm 0.4	4.1 \pm 0.3	4.6 \pm 0.5	<0.001
Pelviabdominal Ultrasonography						
Ascites n (%)	0 (0%)	29 (58%)	50 (100%)	0 (0%)	0 (0%)	<0.001
Cirrhotic liver n (%)	50 (100%)	50 (100%)	50 (100%)	0 (0%)	0 (0%)	<0.001
Splenomegaly n (%)	12 (24%)	37 (74%)	43 (86%)	5 (10%)	0 (0%)	<0.001

Table (4): Clinical, laboratory and ultrasonography findings in group (1).

	Before vaccine	After 1st dose	After 2nd dose	P-value
Clinical Examination				
Pallor n (%)	14 (28%)	14 (28%)	14 (28%)	1
Jaundice n (%)	0 (0%)	0 (0%)	0 (0%)	--
Edema n (%)	0 (0%)	0 (0%)	0 (0%)	--
Ascites n (%)	0 (0%)	0 (0%)	0 (0%)	--
Hepatomegaly n (%)	9 (18%)	9 (18%)	9 (18%)	1
Splenomegaly n (%)	12 (24%)	12 (24%)	12 (24%)	1
Lab Data				
Hemoglobin, Mean \pm SD.	11.06 \pm 1.33	10.35 \pm 0.77	10.02 \pm 0.53	0.662
Platelet count, Mean \pm SD.	321.12 \pm 87.47	340.54 \pm 5.8	314.78 \pm 5.97	0.504
WBCs, Mean \pm SD.	4.6 \pm 0.5	4.7 \pm 0.5	4.9 \pm 0.6	0.453
PPBG, Mean \pm SD.	151.32 \pm 10.63	162.4 \pm 9.56	158 \pm 8.31	0.449
FBG, Mean \pm SD.	97.88 \pm 9.23	99 \pm 10.7	98 \pm 7.07	0.801
Serum creatinine, Mean \pm SD.	0.92 \pm 0.28	0.86 \pm 0.38	0.87 \pm 0.34	1
Urea, Mean \pm SD.	24.5 \pm 5.32	25.8 \pm 12.01	26.8 \pm 11.26	0.444
Liver Function				
INR, Mean \pm SD.	1.09 \pm 0.08	1.06 \pm 0.1	1.05 \pm 0.05	0.249
PTT, Mean \pm SD.	29.87 \pm 2.37	29 \pm 2.8	30.2 \pm 4.4	0.292
PT, Mean \pm SD.	13.41 \pm 2.23	13.5 \pm 2.63	14.2 \pm 2.6	0.807
AST, Mean \pm SD.	43.94 \pm 20.35	40.77 \pm 7.11	40.9 \pm 10.9	0.424
ALT, Mean \pm SD.	35.75 \pm 18.26	34.9 \pm 7.8	35 \pm 9.9	0.368
Direct bilirubin, Mean \pm SD.	0.6 \pm 0.1	0.6 \pm 0.1	0.54 \pm 0.1	0.535
Total bilirubin, Mean \pm SD.	1.1 \pm 0.2	1.1 \pm 0.2	1.07 \pm 0.2	0.535
Albumin, Mean \pm SD.	4.48 \pm 0.2	4.53 \pm 0.0	4.52 \pm 0.1	0.812
Pelviabdominal Ultrasonography				
Ascites n (%)	0 (0%)	0 (0%)	0 (0%)	--
Cirrhotic liver n (%)	50 (100%)	50 (100%)	50 (100%)	1
Splenomegaly n (%)	12 (24%)	12 (24%)	12 (24%)	1

Table (5): Clinical, laboratory and ultrasonography findings in group (2).

	Before vaccine	After 1st dose	After 2nd dose	P. Value
Clinical Examination				
Pallor n (%)	50 (100%)	50 (100%)	50 (100%)	1
Jaundice n (%)	28 (56%)	28 (56%)	28 (56%)	1
Edema n (%)	13 (26%)	13 (26%)	13 (26%)	1
Ascites n (%)	23 (46%)	23 (46%)	23 (46%)	1
Hepatomegaly n (%)	6 (12%)	6 (12%)	6 (12%)	1
Splenomegaly n (%)	37 (74%)	37 (74%)	37 (74%)	1
Lab Data				
Hemoglobin, Mean±SD	9.23 ± 1.32	9.07 ± 1.51	8.75 ± 0.51	0.381
Platelet count, Mean ± SD.	130.96 ± 28.71	132.8 ± 31.03	130.9 ± 32.5	0.964
WBCs, Mean ± SD.	6.1 ± 0.7	6.5 ± 1.1	5.9 ± 0.8	0.234
PPBG, Mean ± SD.	149.6 ± 15.42	154.5 ± 11.14	149 ± 7.29	0.368
FBG, Mean ± SD.	104.32 ± 11.16	99.25 ± 6.11	97.25 ± 4.86	0.159
Serum creatinine, Mean ± SD.	1.01 ± 0.2	0.99 ± 0.2	0.98 ± 0.12	0.819
Urea, Mean ± SD.	29 ± 8.67	28.8 ± 9.08	30 ± 8.64	0.097
Liver Function				
INR, Mean ± SD.	1.32 ± 0.1	1.33 ± 0.18	1.32 ± 0.13	0.959
PTT, Mean ± SD.	37.72 ± 4.07	37.88 ± 4.22	38.0 ± 4.7	0.717
PT, Mean ± SD.	15.64 ± 1.65	16.3 ± 2.25	15.6 ± 2.97	0.607
AST, Mean ± SD.	47.34 ± 23.84	47.54 ± 24.5	46 ± 21.5	0.926
ALT, Mean ± SD.	43.34 ± 20.88	49.5 ± 22.3	44.1 ± 19.8	0.076
Direct bilirubin, Mean ± SD.	1.8 ± 0.3	1.8 ± 0.2	1.7 ± 0.3	0.954
Total bilirubin, Mean ± SD.	2.7 ± 0.2	2.72 ± 0.2	2.79 ± 0.3	0.18
Albumin, Mean ± SD.	3.1 ± 0.1	3.06 ± 0.1	3.01 ± 0.1	0.639
Pelviabdominal Ultrasonography				
Ascites n (%)	29 (58%)	29 (58%)	29 (58%)	1
Cirrhotic liver n (%)	50 (100%)	50 (100%)	50 (100%)	1
Splenomegaly n (%)	37 (74%)	37 (74%)	37 (74%)	1

Table (6): Clinical, laboratory and ultrasonography findings in group (3).

	Before vaccine	After 1st dose	After 2nd dose	P. Value
Clinical Examination				
Pallor n (%)	50 (100%)	50 (100%)	50 (100%)	1
Jaundice n (%)	50 (100%)	50 (100%)	50 (100%)	1
Edema n (%)	50 (100%)	50 (100%)	50 (100%)	1
Ascites n (%)	50 (100%)	50 (100%)	50 (100%)	1
Hepatomegaly n (%)	2 (4%)	2 (4%)	2 (4%)	1
Splenomegaly n (%)	43 (86%)	43 (86%)	43 (86%)	1
Lab Data				
Hemoglobin, Mean \pm SD.	8.93 \pm 0.41	8.8 \pm 1.55	8.8 \pm 1.29	0.975
Platelet count, Mean \pm SD.	90.09 \pm 3.78	89.5 \pm 86.4	89.3 \pm 79.9	0.452
WBCs, Mean \pm SD.	7.8 \pm 1.4	7.7 \pm 1.0	7.9 \pm 1.2	0.304
PPBG, Mean \pm SD.	148.75 \pm 12.23	147.1 \pm 17.04	148.8 \pm 14.5	0.803
FBG, Mean \pm SD.	99.25 \pm 4.3	93 \pm 6.5	93.5 \pm 6.6	0.975
Serum creatinine, Mean \pm SD.	1.3 \pm 0.35	1.3 \pm 0.23	1.3 \pm 0.22	0.401
Urea, Mean \pm SD.	35.31 \pm 10.93	34.5 \pm 9.3	36.8 \pm 4.7	0.465
Liver Function				
INR, Mean \pm SD.	1.85 \pm 0.15	1.87 \pm 0.1	1.89 \pm 0.1	0.707
PTT, Mean \pm SD.	47.78 \pm 1.81	48.3 \pm 2.5	49.1 \pm 2.5	0.368
PT, Mean \pm SD.	20.12 \pm 3.13	22.1 \pm 1.8	22.5 \pm 2.06	0.097
AST, Mean \pm SD.	59.12 \pm 31.73	54.4 \pm 20.3	56.2 \pm 14.7	0.343
ALT, Mean \pm SD.	53.34 \pm 26.44	55.8 \pm 27.9	55.8 \pm 19.88	0.227
Direct bilirubin, Mean \pm SD.	1.9 \pm 0.1	1.9 \pm 0.1	1.86 \pm 0.2	0.983
Total bilirubin, Mean \pm SD.	3.5 \pm 0.1	3.6 \pm 0.1	3.5 \pm 0.3	0.982
Albumin, Mean \pm SD.	2.1 \pm 0.4	2.1 \pm 0.4	2.06 \pm 0.4	0.765
Pelviabdominal Ultrasonography				
Ascites n (%)	50 (100%)	50 (100%)	50 (100%)	1
Cirrhotic liver n (%)	50 (100%)	50 (100%)	50 (100%)	1
Splenomegaly n (%)	43 (86%)	43 (86%)	43 (86%)	1

Table (7): Clinical, laboratory and ultrasonography findings in group (4).

	Before vaccine	After 1st dose	After 2nd dose	P. Value
Clinical Examination				
Pallor n (%)	0 (0%)	0 (0%)	0 (0%)	--
Jaundice n (%)	0 (0%)	0 (0%)	0 (0%)	--
Edema n (%)	0 (0%)	0 (0%)	0 (0%)	--
Ascites n (%)	0 (0%)	0 (0%)	0 (0%)	--
Hepatomegaly n (%)	21 (42%)	21 (42%)	21 (42%)	1
Splenomegaly n (%)	5 (10%)	5 (10%)	5 (10%)	1
Lab Data				
Hemoglobin, Mean \pm SD.	12.2 \pm 0.43	12.1 \pm 0.51	12.3 \pm 0.61	0.061
Platelet count, Mean \pm SD.	334.15 \pm 88.96	322 \pm 124	311.3 \pm 110.5	0.761
WBCs, Mean \pm SD.	7.9 \pm 1.2	7.9 \pm 1.2	7.9 \pm 1.2	1
PPBG, Mean \pm SD.	155.12 \pm 14.31	153.7 \pm 13.3	144 \pm 7.81	0.441
FBG, Mean \pm SD.	102 \pm 12.74	93.7 \pm 6.4	96.3 \pm 5.7	0.67
Serum creatinine, Mean \pm SD.	0.87 \pm 0.21	0.77 \pm 0.15	0.83 \pm 0.15	0.809
Urea, Mean \pm SD.	22.46 \pm 4.33	22.33 \pm 6.5	24.3 \pm 3.2	0.607
Liver Function				
INR, Mean \pm SD.	1.05 \pm 0.05	1.15 \pm 0.1	1.23 \pm 0.15	0.06
PTT, Mean \pm SD.	30.46 \pm 0.86	33.72 \pm 4.07	34.78 \pm 1.81	0.223
PT, Mean \pm SD.	11.77 \pm 1.07	14.64 \pm 1.65	13.12 \pm 3.13	0.05
AST, Mean \pm SD.	37.92 \pm 11.26	39.04 \pm 11.47	31.28 \pm 8.36	0.135
ALT, Mean \pm SD.	30.5 \pm 5.67	35.28 \pm 4.56	30.9 \pm 5.43	0.097
Direct bilirubin, Mean \pm SD.	0.7 \pm 0.1	0.6 \pm 0.0	0.7 \pm 0.1	0.342
Total bilirubin, Mean \pm SD.	1.1 \pm 0.1	1.0 \pm 0.1	1.2 \pm 0.1	0.432
Albumin, Mean \pm SD.	4.1 \pm 0.3	4.3 \pm 0.4	4.1 \pm 0.3	0.147
Pelviabdominal Ultrasonography				
Ascites n (%)	0 (0%)	0 (0%)	0 (0%)	--
Cirrhotic liver n (%)	0 (0%)	0 (0%)	0 (0%)	--
Splenomegaly n (%)	5 (10%)	5 (10%)	5 (10%)	1

Table (8): Clinical, laboratory and ultrasonography findings in group (5).

	Before vaccine	After 1st dose	After 2nd dose	P. Value
Clinical Examination				
Pallor n (%)	0 (0%)	0 (0%)	0 (0%)	-
Jaundice n (%)	0 (0%)	0 (0%)	0 (0%)	-
Edema n (%)	0 (0%)	0 (0%)	0 (0%)	--
Ascites n (%)	0 (0%)	0 (0%)	0 (0%)	---
Hepatomegaly n (%)	0 (0%)	0 (0%)	0 (0%)	---
Splenomegaly n (%)	0 (0%)	0 (0%)	0 (0%)	1
Lab Data				
Hemoglobin, Mean \pm SD.	12.56 \pm 0.77	12.48 \pm 0.79	12.53 \pm 0.84	0.486
Platelet count, Mean \pm SD.	409.54 \pm 77.55	411.5 \pm 77.1	413.3 \pm 77	0.132
WBCs, Mean \pm SD.	8.2 \pm 0.9	7.8 \pm 0.6	8.1 \pm 0.8	0.456
PPBG, Mean \pm SD.	146.81 \pm 13.38	144.5 \pm 12.7	140.8 \pm 11.9	0.125
FBG, Mean \pm SD.	99.62 \pm 9.21	95.2 \pm 9.2	97.7 \pm 11	0.574
Serum creatinine, Mean \pm SD.	0.88 \pm 0.34	0.9 \pm 0.26	0.87 \pm 0.36	0.905
Urea, Mean \pm SD.	27.59 \pm 11.14	27.5 \pm 9.8	30.2 \pm 10.4	0.186
Liver Function				
INR, Mean \pm SD.	1.03 \pm 0.07	1.09 \pm 0.1	1.12 \pm 0.15	0.368
PTT, Mean \pm SD.	29.3 \pm 3.12	32.72 \pm 4.07	33.78 \pm 1.81	0.124
PT, Mean \pm SD.	13.81 \pm 2.83	14.64 \pm 1.65	15.12 \pm 3.13	0.076
AST, Mean \pm SD.	37.12 \pm 6.09	39.46 \pm 6.21	42.14 \pm 9.72	0.21
ALT, Mean \pm SD.	31.7 \pm 6.02	34.38 \pm 7.43	34.72 \pm 9.75	0.055
Direct bilirubin, Mean \pm SD.	0.5 \pm 0.2	0.5 \pm 0.2	0.5 \pm 0.2	0.331
Total bilirubin, Mean \pm SD.	1.0 \pm 0.2	1.0 \pm 0.2	1.0 \pm 0.2	0.081
Albumin, Mean \pm SD.	4.6 \pm 0.5	4.6 \pm 0.5	4.6 \pm 0.5	0.905
Pelviabdominal Ultrasonography				
Ascites n (%)	0 (0%)	0 (0%)	(0%)	---
Cirrhotic liver n (%)	0 (0%)	0 (0%)	(0%)	---
Splenomegaly n (%)	0 (0%)	0 (0%)	(0%)	--

4. Discussion

Regarding the five groups' special habits, there was a highly significant difference, with 82% of cases in group (1) being nonsmokers, 38% of cases in group (2) were smokers, 80% of cases in group (3) were x-smokers, 50% of cases in group (4) were smokers and 58% of cases in group (5) were nonsmokers. Smoking suspension is enthusiastically suggested for patients getting coronavirus inoculation. In regard to kind of immunization, Sinopharm was more prevalent in groups (1 and 3), Sinovac was more prevalent in group (2), AstraZeneca was more prevalent in group (4), both AstraZeneca and Pfizer were more prevalent in group (5) and there was an exceptionally huge contrast between the five groups ($p < 0.001$) [5]. Regarding examination findings among the studied groups there was a highly significant difference between the five groups regarding pallor as it was significantly higher in groups (2&3). Jaundice, edema, ascites and splenomegaly there were a highly significant difference between the five groups as they were significantly higher in group (3). Hepatomegaly, there was a highly significant difference between the five groups as it was significantly higher in group (4). As regard laboratory data among the studied groups: regarding Hemoglobin (HB) and platelet count there were a highly significant difference between the five groups as they were significantly lower in group (3) compared to other groups. Regarding WBCs, fasting blood glucose (FBG), postprandial blood glucose (PPBG), ALT, AST, urea and creatinine, there was no significant difference between the five groups. Regarding PT, PTT, INR, bilirubin total and direct there were significant difference between the five groups as they were higher in group (3) compared to other groups. Regarding albumin there was significant difference between the five groups as it was significantly lower in group (3) compared to other groups. As

regard ultrasonography findings among the studied groups there were a highly significant difference the five groups as there were liver cirrhosis in groups (1, 2 and 3) and normal liver in group (4 and 5). Ascites and splenomegaly were highly significant in group (3) compared to other groups. Our results were supported by Scheiner et al., [15] who found that Anemia was associated with hepatic decompensation. Our results were supported by Peng et al., [16] who revealed that as the Child-Pugh score increased, total bilirubin, and INR gradually elevated, whilst albumin and platelet count gradually decreased. Regarding the examination results prior to, following 1st dose, and following 2nd dose of the vaccine in group (1): the findings revealed that pallor, jaundice, edoema, ascites, hepatomegaly, and splenomegaly did not significantly change prior to, following, and following the second dose of the vaccine in group (1). Also, in group (2): there was no significant change in pallor, Jaundice, edema, ascites, hepatomegaly, as well as splenomegaly before, after 1st dose and after 2nd dose of vaccine. As well, in group (3): there was no significant change in pallor, Jaundice, edema, ascites, hepatomegaly, as well as splenomegaly before, after 1st dose and after 2nd dose of vaccine. Similarly in group (4): we observed that there was not a massive change in pallor, Jaundice, edema, ascites, hepatomegaly, as well as splenomegaly previously, after first dosage and after second dosage of vaccine. Finally, in group (5): we observed that there was not a massive change in pallor, Jaundice, edema, ascites, hepatomegaly, as well as splenomegaly previously, after first dosage and after second dosage of vaccine. In this way, the current study showed that the coronavirus vaccination brought about no change in the examination results in any case the seriousness of liver illness. With respect to laboratory results (CBC, ALT, AST, bilirubin total and direct, serum

albumin, PT, PTT, INR, blood urea, serum creatinine, fasting and postprandial blood glucose) The current study exhibited that lab results in group (1) didn't mainly change before, following the first and second dosages of the vaccine. The ongoing investigation discovered that in group (2), lab results didn't altogether adjust previously, after the first dose of the immunization, or after the second dose. The current investigation also revealed that there was no significant difference in any laboratory parameters in groups (3, 4 and 5) before, after the first dose, and after the second dose of the vaccination. Regarding pelviabdominal ultrasonography results before, after 1st dose and after 2nd dose of vaccine, the current study showed that there was no-statistically significant difference in ascites, cirrhotic liver, as well as splenomegaly before, after 1st dose and after 2nd dose of vaccine in all of the studied groups .Overall, it was discovered that both patients with chronic conditions and those without them experienced no major liver effects from the COVID-19 vaccine. These findings agree with Wang et al., [17] who evaluated the immunogenicity and safety of SARS-CoV-2 vaccinations in 533 Chinese patients, together with 388 and a hundred sixty-five patients with compensated (C-cirrhosis) and decompensated (D-cirrhosis) liver cirrhosis of the liver, respectively. The major frequent effects in each the C-cirrhosis and D-cirrhosis teams were injection site pain (23/388 [5.9%] vs. 9/165 [5.5%]) and fatigue (5/388 [1.3%] vs. 3/165 [1.8%]). Severally, 4.4% (16/363) and zero.3% (1/363) of the patients, showed ALT elevations of grades two and three (ALT > two upper limit of normal [ULN] but \leq five ULN and ALT > five ULN, respectively). The chances of groups with C- and D-cirrhosis that tested positive for coronavirus neutralizing antibodies were seventy-one.6% (278/388) and sixty-six.1% (109/165), respectively. It ought to be highlighted that every Child-Pugh B and C score painted a possible risk issue for

negative neutralizing antibodies. So, they concluded that inactivated coronavirus vaccinations are safe with fair immunogenicity in cirrhotic patients, and Child– Pugh score of B and C levels is associated with low response to coronavirus vaccination. Besides, Ai et al., [18] evaluated the immunogenicity and security of inactivated coronavirus vaccines in individuals with constant liver sicknesses (CLD). The review had 581 people (437 patients with CLD and a hundred and forty-four healthy people). the principal side effect was pain at the infusion site (n [36; eight.2%]). Three cases had grade 3 ALT elevation (defined as ALT > 5 ULN) after the second dosage of inactivated coronavirus vaccination, and only one of them had severe adverse effects potentially related to coronavirus vaccination. Positive frequencies of coronavirus neutralizing antibodies were found inside the non-cirrhotic CLD group at 76.8%, the compensated cirrhotic group at 78.9%, the decompensated cirrhotic group at 76.7%, and consequently the healthy administration group at 90.3% (P [.894 for CLD subgroups) (P [.008 versus CLD group). They showed up to the end that inactivated coronavirus vaccines are unhazardous for patients with CLD. Also, Cao et al., [19] examined the adverse events following the immunization against the coronavirus in individuals with decompensated cirrhosis of the liver. Moreover, it was discovered that 75.3% of patients had no unfavorable incidents, 23.6% had mild reactions (20% infusion site pain, 1.2% tiredness, and 2.4% rash), and 1.2% had a significant incident (improvement of intense decompensation requiring hospitalization). Ivashkinet al.,[20] assessed the clinical adequacy and security of the coronavirus vaccinating specialist in patients with liver cirrhosis. Inside the examination, 148 patients were not taking the vaccine, while 89 were take the vaccine. They presumed that coronavirus vaccination is both viable and secure for cirrhotic people. The vaccination

was effective on 69.5% against symptomatic cases of coronavirus and 100% against severe cases.

5. Conclusion

Vaccination against COVID-19 in people with and without cirrhosis of the liver is secure. Additional comparison studies are required, with larger sample sizes and longer follow-up, to assist identify the risk factors for unfavorable outcomes.

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