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The burden of HCV among prevalent hemodialysis patients after the National Egyptian HCV Eradication program

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Abstract

In the first phase of its treatment program, Egypt aimed to treat 250,000 people annually until 2020, thereby reducing the number of viremic patients and limiting hepatitis C virus (HCV) transmission. Egypt strives to eradicate HCV and HCV-associated morbidity by 2030. This study aimed to determine the prevalence of HCV infection among end-stage renal disease patients and the reasons for non-treatment among those offered free medication. This multi-center cross-sectional study was conducted during the period from November 2022 to April 2023. The study included 500 patients receiving hemodialysis (HD) sessions on a regular basis for more than three months in Dakahlia Governorate. According to patients` medical history, we found that 23.4% of patients had previous HCV infection. Of these, 12.6% received treatment, and 10.8% did not receive treatment due to a variety of reasons. For instance, some patients were unaware of the drug's availability, five patients (1%) feared side effects, 43 patients (8.6%) did not require treatment, and five patients (1%) had other causes as contraindications of drugs, noncompliance and deterioration of health status. In addition, 20.4% of patients were reported to have fully recovered, while 0.8% had a recurrence. After investigations, 1% of patients had positive hepatitis B surface antigen (HbsAg), 23.4% positive HCV Ab, and 4.2% positive HCV by the polymerase chain reaction. In conclusion, the low prevalence of HCV among HD patients confirms that HCV infection is not currently a significant health concern among patients on maintenance HD.

Keywords: Hepatitis C virus (HCV), Egypt, Hemodialysis

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Introduction

The hepatitis C virus (HCV) spreads predominantly through blood transfusions, medical injections and procedures, and the use of injectable medicines since it is a blood-borne virus.[1] According to estimates by the World Health Organization (WHO), more than 350,000 people die annually from liver disease caused by HCV, which affects 71 million people chronically worldwide.[2]

Antibody prevalence among adults aged 15-59 years was assessed by the Egyptian Demographic and Health Surveys (EDHS) as 14.7% in 2009 and 10.0% in 2015,[3] which is significantly higher than the global levels estimated by WHO to be 1.4%.[4] Antibody prevalence in Egypt was estimated to be 11.9%. There are currently 6 million chronically ill individuals in Egypt.[5]

In 2016, chronic kidney disease (CKD) impacted more than 275 million people worldwide, with an incidence of over 21 million new cases, over 1 million deaths, and over 35 million disability-adjusted life years (showing an increase in prevalence of 87.8% over the previous three decades).[6]

The prevalence of HCV infection among hemodialysis (HD) recipients varies by country as well as by facility within the same country. Egypt is one of the nations with the highest prevalence of HCV disease despite the existence of infection control program criteria. In Egypt, 50.7% of HD patients tested positive for HCV.[7]

Many patients have successfully maintained their health for twenty to thirty years while undergoing dialysis. Since numerous potential survivors last longer than 20 years, the public's conception of HD lifespan is relatively confusing. However, according to findings of a researcher study, some individuals have survived for longer than 35 years.[5]

Using contaminated medical equipment, such as endoscopy, angiography, and surgical instruments, resulted in nosocomial transmission. Due to the use of sterile devices, medical procedures such as gynecological and cardiology operations, angiography, endoscopy, and colonoscopy can increase the risk for HCV infection rates.[5] For instance, research conducted at the Ain Shams University-affiliated hospitals in Cairo revealed that 42% of patients had HCV antibodies, placing hospital staff at a high risk of contracting the virus.[8]

Egypt initiated a substantial treatment program to provide HCV therapies to Egyptians. The Egyptian National Committee for the Control of Viral Hepatitis provides a model of care in its fight against HCV that can be helpful to other countries with high HCV prevalence rates.[9]

In Assiut, the prevalence of HCV infection among HD patients was 34.8%. The seroconversion percentage was 13.2%. Significant risk factors for seroconversion were identified as a history of blood transfusion, the frequency of blood transfusion, medical staff handling of equipment and blood products, and the number of temporary dialysis catheters inserted.[10]

We believe that this is the first work to assess the prevalence of HCV patients with end-stage renal disease (ESRD) after the HCV eradication program. Therefore, this study aimed to determine the frequency rate of HCV infection among ESRD patients and identify the reasons for un-treatment among those offered the treatment free of charge.

Patients and Methods

This multi-center cross-sectional study included 500 patients receiving HD sessions on a regular basis for more than 3 months in Dakahlia Governorate. Sample size was calculated guided by previous study conducted in 2020.[10]

Patients were recruited during the period from November 2022 to April 2023. The study included patients aged ≥ 18 years receiving HD sessions on a regular basis for more than 3 months. Patients <18 years old, not willing to participate in the study, with hepatitis B virus (HBV) or the human immunodeficiency virus (HIV) infection, diagnosed with hepatocellular carcinoma (HCC) prior to treatment initiation, with a history of other malignant diseases, and liver transplant recipients were excluded from the study.

A structured questionnaire was distributed to all ESRD patients who consented to participate in the study. The questionnaire included sociodemographic data (such as age, gender, residence, education, and occupation), a history of illness, including the onset of renal disease and end-stage renal disease, and a history of HCV infection, including the onset of diagnosis and any treatment received, as well as any complications due to either the disease or the treatment, as well as reasons for not receiving HCV treatment.

Clinical examination and laboratory data were retrieved from patients' files, including viral markers (HCV by ELISA and the polymerase chain reaction (PCR), HBV), hepatitis B surface antigen (HBs Ag), serum creatinine, serum urea, and serum albumin. Radiological data were also retrieved from patients' files.

Statistical Analysis

Data analysis was performed utilizing the Statistical Program for Social Science (SPSS Inc., Chicago, IL, USA, Version 26). Quantitative variables were expressed as mean and standard deviation, whereas qualitative variables were expressed as numbers and percentages. The Student t-test was used to compare parametric quantitative variables between two groups. When frequencies were less than five, Chi-square (X^2) or Fisher's exact test was used to compare qualitative variables. For values with non-normal distribution, p-values <0.05 are considered significant.

Results

This multi-center cross-sectional study included 500 patients receiving HD sessions regularly for over three months. Table 1 depicts the basic demographic data of the studied patients. Participants had a mean age of 55.4±16 years, with male predominance (62.2%). In addition, 39% of the patients were illiterate, 79% had work, and 65.2% resident in rural areas. Most of them had comorbidities (78.4%), such as hypertension (HTN) (54%), diabetes mellitus (DM, 33.4%), cardiovascular diseases (CVD, 21.8%), autoimmune disease (3.2%), tumors (1.2%), and others (12.8%). Patients with a mean duration of renal dysfunction of 9±6 years ranged from 1 to 74 years, and a mean duration of renal dialysis of 6.2±4.7 years ranged from 1 to 23 years. Most patients (69.8%) received three renal dialysis sessions weekly.

Table 1. Basic sociodemographic data of the 500 study participants.

Studied parameter	Number (%)
Gender	
Male	311 (62.2%)
Female	189 (37.8%)
Age (years)	
mean±SD	55.4±16
Range	14-85
Educational level	
Illiterate	195 (39%)
Read and write	30 (6%)
Primary education	39 (7.8%)
Preparatory education	38 (7.6%)
Secondary education	131 (26.2%)
University education	64(12.8%)
Postgraduate	3 (0.6%)
Working status	
Working	395 (79%)
Not working	105 (21%)
Residence	
Urban	174 (34.8%)
Rural	326 (65.2%)
Comorbidities	
Yes	392 (78.4%)
No	108 (21.6%)
Comorbidities	
HTN	270 (54%)
DM	167 (33.4%)
CVD	109 (21.8%)
Autoimmune diseases	16 (3.2%)
Tumors	6 (1.2%)
Others	64 (12.8%)
Duration of renal dysfunction (years)	
mean±SD	9±6
Range	9 (1-74 years)
Duration of renal dialysis (years)	
mean±SD	6.2±4.7
Range	4 (1-23 years)
Sessions of renal dialysis (week)	
Two	151 (30.2%)
Three	349 (69.8%)

HTN: hypertension; DM: diabetes mellitus; CVD: cardiovascular diseases.

1% of study patients had a history of HBV infection, while 98.6% received HBV vaccination. In addition, 23.4% of patients had a history of HCV infection lasting for an average of 6.73.8 years. Among patients with previous HCV infection, 12.6% received treatment and 10.8% did not receive treatment for a variety of reasons. These included one patient's ignorance of the drug's availability, five patients feared of side effects, 43 patients lacked their need for treatment, and five patients had contraindication to drugs, noncompliance, and deterioration in health status. Of the treated patients, 11.2% received oral treatment while 1.4% received injection treatment. Moreover, 20.4% of patients were reported to have fully recovered, while 0.8% had a recurrence, (Table 2).

Table 2. History of hepatitis C virus (HCV) infection among the 500 study participants.

Studied parameter	Number (%)
Previous HBV infection	
Yes	5 (1%)
No	495 (99%)
Previous HBV vaccination	
Yes	490 (98.6%)
No	7 (1.4%)
Previous HCV infection	
Yes	117 (23.4%)
No	383 (76.6%)
Onset of HCV Infection	
Before or in 2019	96 (82.1%)
After 2019	21 (17.9%)
Duration of HCV infection (years)	
mean±SD	6.7±3.8
Range	12 (1-18 years)
Receiving HCV treatment	
Yes	63 (53.8%)
No	54 (46.2%)
Causes of not receiving HCV treatment	
Do not know about treatment availability	1 (0.2%)
Occurrence of side effects	5 (1%)
No need for treatment	43 (8.6%)
Others	5 (1%)
Type of HCV treatment	
Oral	56 (11.2%)
Injection	7 (1.4%)
Complete HCV recovery	
Yes	102 (20.4%)
No	15 (3%)
Recurrence	
Yes	4 (0.8%)
No	113 (22.6%)

HBV: hepatitis B virus

1% of patients had positive hepatitis B surface antigen (HbsAg), 23.4% had positive HCV Ab, and 4.2% had positive HCV PCR with a mean of 131666±70571 IU/L, (Table 3).

Table 3. Virology status of the 500 study participants.

Studied parameter	Number (%)
HbsAg	
Positive	5 (1%)
Negative	495 (99%)
HCV Ab	
Positive	117 (23.4%)
Negative	383 (76.6%)
HCV PCR	
Positive	21 (4.2%)
Negative	479 (95.8%)
HCV PCR (IU/L)	
mean±SD	131666±70571
Range	0-220000

According to PCR results, patients were grouped into HCV PCR positive and negative groups. Patients with positive HCV PCR had significantly lower educational levels than the negative group (p=0.007). In contrast, age, gender, working status, residence, and comorbidities showed no statistically insignificant differences between groups, (Table 4).

Table 4. Comparison between HCV positive and negative patients regarding the basic demographic data.

	HCV positive N=21	HCV negative N=479	*p*-value	OR	95% C.I.
Gender (n, %)					
Male	15 (71.4%)	296 (61.8%)	NS	1.5	0.6-4.1
Female	6 (28.6%)	183 (38.2%)			
Age (years)					
mean±SD	56±15.7	55.4±16	NS		
Educational level (n, %)					
-Illiterate	10 (47.6%)	185 (38.6%)			
-Read and write	4 (19%)	26 (5.5%)			
-Primary education	1 (4.8%)	38 (7.9%)			
-Preparatory education	1 (4.8%)	37 (7.7%)			
-Secondary education	2 (9.6%)	129 (26.9%)			
-University education	3 (14.2%)	61(12.7%)			
-Post graduate	0 (0%)	3 (0.7%)	0.007		
Working status (n, %)					
Working	14 (66.7%)	381(79.5%)	NS	1.11	0.9-3.8
Not working	7 (33.3%)	98 (20.5%)			
Residence (n, %)					
Urban	6 (28.4%)	168 (34.9%)	NS	1.01	0.4-4.5
Rural	15 (71.6%)	311 (65.1%)			
Comorbidities (n, %)					
Yes	15 (71.6%)	377 (78.7%)	NS	1.05	0.6-4.2
No	6 (28.4%)	102 (21.3%)			

$p > 0.05$ is not significant (NS).

Patients with positive HCV results had a significantly longer mean duration of renal dysfunction, renal dialysis, and a higher percentage of weekly sessions than the negative group, ($p<0.05$), (Table 5).

Table 5. Comparison between HCV positive and negative patients regarding kidney disease history.

	HCV positive N=21	HCV negative N=479	**p*-value
Duration of renal disease (years) (mean±SD)	11.6±6.5	8.9±6	0.022
Duration of hemodialysis sessions (years) (mean±SD)	8±5.6	6.1±4.6	0.033
Frequency of hemodialysis Sessions / week			
Twice weekly	2 (9.5%)	149 (31.1%)	0.035
Thrice weekly	19 (90.5%)	330 (68.9%)	

*$p \leq 0.05$ is significant.

All patients with positive HCV results had previous HCV infection ($p<0.001$). Also, receiving treatment, recovery and recurrence showed statistically significant difference between groups, (Table 6).

Table 6. Comparison between HCV positive and negative patients regarding infection history.

Infection	HCV positive N=21 n (%)	HCV negative N=479 n (%)	*p*-value	OR	95%± CI
HBV infection	0 (0%)	5 (1%)	NS	0.958	0.9-1.1
HBV vaccination (n,%)	21(100%)	469(97.9%)	NS	1.044	1.0-1.08
Previous HCV infection	21(100%)	96(20%)	<0.001	1.3	1.1-1.4
Duration of HCV infection (years) mean±SD	7.6±5.2	6.5±3.4	NS	---	---
Receiving HCV treatment	10(47.6%)	53(11.1%)	<0.001	0.7	0.5-0.8
Causes of not receiving HCV treatment					
-Don`t know about treatment availability	1 (4.8%)	0 (0%)			
-Occurrence of side effects	5 (23.8%)	0 (0%)			
-No need for treatment	0 (0%)	43 (9%)			
-Others	5 (23.8%)	0 (0%)	<0.001		
Type of HCV treatment					
-Oral	4 (19%)	52 (10.9%)	NS	0.9	0.5-4.3
-Injection	6 (28.6%)	1 (0.2%)			
Complete HCV recovery					
Yes	6 (28.6%)	96 (20%)	<0.001	--	--
No	15 (71.4%)	0 (0%)			
Recurrence	2 (9.5%)	2 (0.4%)	<0.001	--	--

p > 0.05 is not significant (NS).

Discussion

The Egyptian Demographic Health Survey (EDHS), conducted in 2008 on a sizable nationally representative sample, estimated the prevalence of HCV antibodies and HCV-RNA among the 15- to 59-year-old age group to be 14.7 and 9.8%, respectively. Egypt has the highest prevalence rate of HCV in the world.[3]

HD patients have, on average, a significantly higher prevalence of HCV infection than the general population, owing to a cellular immune impairment that renders them more susceptible to infection. Patients with HD are also susceptible to prolonged intravenous access, contaminated equipment, and human handling. In addition, HD patients required blood transfusions, frequent hospitalizations, and surgery, which increased their susceptibility to nosocomial infections.[11]

Since 2014, Egypt's treatment program has focused on the early diagnosis and treatment of HCV patients to reduce the virus's prevalence to less than 2% in ten years. In addition, Egypt has set a goal to treat 250,000 patients annually through the year 2020 as part of the first phase of its treatment program, which aims to reduce the number of viremic patients and halt the spread of HCV. According to Omran et al., 2018,[12] Egypt attempts to eradicate HCV and HCV-related morbidity by 2030.

Therefore, this study aimed to assess the prevalence of HCV infection among ESRD patients and to determine the reasons for non-treatment among patients offered free treatment. This multi-center, cross-sectional study included 500 patients who had been receiving regular hemodialysis treatments for at least three months. It was found that 23.4% of the patients had a history of HCV infection; 12.6% received treatment, 20.4% were informed that they were fully recovered, and 0.8% had relapsed disease. Furthermore, 4.2% of patients had positive HCV PCR, 23.4% had positive HCV Ab, and 1% had positive HBsAg.

The study by Zahran et al., 2014, reported a prevalence of 49.6% for HCV in the governorate of Menufia, Egypt, which is inconsistent with the current study's low prevalence. Moreover,

259 of the 514 patients surveyed tested negative for HCV, whereas 255 were positive.[13]

Additionally, the prevalence in our study is lower than that reported in Cairo, Egypt by the study of Sarhan & Kamel, 2015 which enrolled 987 individuals from 22 HD centers and found that the incidence rate of seroconversion was 10.7% and that the prevalence of HCV antibody at the commencement of dialysis was 45.2%.[14]

According to a follow-up research study by Khodir et al., 2012, involved 2351 patients in eight towns of the Al Gharbiyah governorate, 35% of patients were initially anti-HCV reactive, and then the seroconversion rate reached 11% by the end of treatment.[15] Another retrospective study comprised 1600 patients (2005–2009) and acquired the registration data from the Nephrology Department of Ain Shams University Adult Hospital during a period of 5 years. According to their findings, 25.8% of patients had positive HCV antibodies.[16] The study by Zabadi et al., 2015, reported an HCV prevalence of 7.4% among patients receiving HD in West Bank hospitals in Palestine.[17] Their study enrolled 868 hemodialysis patients from nine hemodialysis hospitals.

In the present study, there were numerous variables for this high incidence of HCV infection. The propagation of the HCV infection is significantly influenced by blood transfusion. The patients in the current study were predominantly male (62.2%) and had a mean age of 55.4 16 years. They were employed at a rate of 79%, lived in rural areas at a rate of 79%, and were illiterate at a rate of 65.2%. The majority (78.1%) had comorbidities, including malignancies (1.2%), autoimmune disease (3.2%), CVD (21.8%), HTN (54%), and DM (33.4%). Patients with positive HCV PCR results had significantly lower educational levels than the negative group, (p=0.007). Age, gender, employment status, place of residence, and comorbidities demonstrated non-significant differences among the HCV PCR positive and negative groups.

According to an Egyptian study, HCV was the most prevalent in the lower socioeconomic strata of the population.[18] The prevalence of HCV was higher in rural regions (12%) than in cities (7%), and it also increased with affluence, with 12% of cases in the lowest quintile of wealth and 7% in the highest. With an income of less than $1.60 per day, 26% of Egyptians live below the national poverty threshold [19]. Hepatitis C infection can therefore be categorized as a socioeconomic condition.

The study by Anwar et al., 2021,[8] reported that the prevalence of HCV was significantly lower among individuals with a high school diploma or higher than among those without one (14.0% vs. 29.17%, respectively).

In the present study, the prevalence of anti-HCV was highest among health care workers (HCWs) living in older rental apartments. They were nine times more likely to test positive for anti-HCV (OR=8.837, p=0.002). This correlation may be explained by the increased exposure to unsafe environments experienced by individuals with flexible housing. In addition to being associated with negative health outcomes, flexible housing conditions also increase the demand for hospital and emergency department services. Those who lived in rural areas had significantly higher anti-HCV positive rates than those who lived in urban areas (22.5% vs 6.1% and 24.0% vs 10.5%, respectively). Rural residents were approximately three to four times more likely to test HCV positive than urban residents (OR=2.679, p=0.019; OR=4.442, p=0.004, respectively).[5]

The study by Anwar et al., 2021,[8] of patients and HCWs at Ain Shams University Hospitals in Cairo, found similar observation that patients and HCWs living in rural areas outside of Cairo had more significant proportions of HCV antibodies (11.11% vs. 7.32%, p=0.5, and 30.54% vs. 14.41%).

All patients in the current study who assessed HCV positive had prior HCV infections. They were treated and there were statistically significant differences between the groups in recovery and recurrence. Patients with positive HCV test results had statistically significant differences between groups (p= 0.05) in terms of the mean duration of renal impairment, renal dialysis, and the proportion of weekly sessions.

Our findings are consistent with those of another study, demonstrated a correlation between anti-HCV positive and hepatitis risk

factors, including sociodemographic, occupational, and other factors.[5] That study found that anti-HCV was significantly more prevalent in older age groups (17.3% vs. 6.6%, *p*=0.029) than in younger age groups. Regarding gender, 10% of females and 7% of males were anti-HCV positive. A higher percentage of married HCWs (10.4% vs. 3.3%, respectively) tested positive for anti-HCV than unmarried HCWs.[5]

In addition, it was demonstrated that the prevalence of anti-HCV antibodies increased significantly with decreasing HCW education levels. Anti-HCV positivity was also found to be significantly associated with living in elderly rental apartments and rural areas. HCWs residing in old rental apartments had a nearly nine-fold increased risk of having HCV antibodies (OR=8.837, *p*=0.002), whereas those residing in rural areas had a nearly four-fold increased risk (OR=4.442, *p*=0.004). Additionally, previous hospital admissions (13.5% vs. 6.1%), history of surgical or dental procedures (9.9% vs. 4.8%), history of blood transfusions (16.7% vs. 7.5%), and receiving any medicine by injection or infusion (11.4% vs. 4.8%) were all associated with higher anti-HCV positive rates.[5]

Regarding the history of prior blood transfusions, another investigation reported a statistically significant difference between HCV seroconverted and HCV seronegative patients (*p*= 0.000).[10]

Our findings agreed with the results of an Iranian study by Jabbari et al., 2005[21] which suggested a strong correlation between surgical procedures and HCV antibody positivity. The Iranian research was a descriptive-analytical study, included 93 HD patients from all hospitals affiliated with Golestan University of Medical Sciences were screened for HCV antibodies. In addition, findings of the study by Surendra Kumar et al., 2011 which included 145 patients supported our findings, as their research demonstrated that previous surgery contributed to the development of HCV in these patients.[22] Furthermore, the study of Zarkoon et al., 2008, included 97 participants, revealed that surgical procedures were a risk factor for HCV seroconversion in HD patients.[23] Moreover, a study involving 514 patients conducted in the Menufia Governorate (Egypt) by Zahran et al., 2014, found that the duration of dialysis and a positive family history of HCV infections were significantly different among the study groups, consistent with our findings.[13]

The study by Mohamed et al., 2010, in Saudi Arabia, conducted over 5 years and enrolled 36 participants, agreed with our findings that HCV transmission within HD units can be prevented by isolating HCV-positive patients, limiting blood transfusions, and strictly adhering to infection control regulations.[24]

Our findings were supported by results of a retrospective research study of 189 patient records by Saxena et al. 2002.[25] They found that vascular access contributed to the spread of HCV and that patients with arteriovenous fistulas and synthetic grafts were more prone to nosocomial infections than those with permanent catheters. This may result from repeated punctures and cannulations of arteriovenous fistulas (AVF) and polytetrafluoroethylene (PTFE) to perform HD in a unit with a high HCV prevalence at baseline, which may have compromised standard infection control procedures.

In the study by Brakat et al., 2021, HD patients had an anti-HCV positivity rate of 55.6% compared to 17.0% of non-HD patients (*p*=0.013). HD patients had a six-times greater probability of having HCV-positive than other patients (OR=6.094, *p*=0.013). In addition, 32.7% of the HCV-positive patients were associated with prior hospitalization, compared to 13.4% of individuals who had not previously been admitted. Patients who had previously been hospitalized had a threefold increased risk compared to those who had not (OR=3.149, *p*=0.002). Nosocomial HCV transmission has been implicated in HCV outbreaks caused by medical procedures.[5]

In 2011, the study by Lavanchy found that the mean prevalence of anti-HCV antibodies was 7.5% and 2% the annual risk associated with dialysis. The prevalence of HCV among HD patients worldwide ranged from 1% to 90%.[26] In a retrospective epidemiological investigation, hospitalization 73 (67%) was the most significant risk factor. The remaining 16 patients

underwent an invasive diagnostic or therapeutic procedure, 33 had surgery, and 24 were admitted to a hospital ward or emergency room.[27]

In conclusion, the low prevalence of HCV in HD patients indicated that HCV infection does not pose a significant health risk to patients on maintenance HD. HCV transmission in HD units is multifactorial and includes modifiable factors. The study revealed that previous HCV infection, treatment, recovery, mean duration of renal dysfunction, renal dialysis, and weekly dialysis sessions were the most significant risk factors for HCV acquisition. The prevalence of HCV highlights the consequences of HCV acquisition in this setting, which should be targeted by preventive programs.

Author Contributions

The study's principal investigators were IIS, MME, MME and KG proposed the topic of this research and designed the study. DMTH collected the data. All authors contributed to preparing the final draft of the manuscript, revised the manuscript, and critically reviewed the intellectual contents. In addition, they have all read and approved the final manuscript and are responsible for it's accuracy and integrity.

Declaration of Conflicting Interests

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Ethical approval

The study protocol was reviewed and approved by the Research Ethics Committee of the Faculty of Medicine, Ain Shams University (FMASU MS 824/2022).

Informed consent

A signed consent form was obtained from each study participant.

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