

Retrospective Study

Incidence and prevalence of hepatitis B and hepatitis C viruses in hemodialysis patients in Lebanon

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Informed consent statement: We performed a retrospective study using anonymous patients data collected through the ministry of public health which routinely compiles all HBsAg and HCV serology results from the affiliated HD centers across Lebanon on a monthly basis. Since then, no informed consent was required.

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Abstract

AIM: To determine the incidence and the prevalence of hepatitis B and C viral infections in patients on hemodialysis (HD) across Lebanon.

METHODS: We reviewed the data registry at the Lebanese Ministry of Public Health where records of monthly hepatitis B surface antigen (HBsAg) and hepatitis C virus (HCV) serology are reported from 60 affiliated HD centers across Lebanon. All patients who were on HD or who started HD between October 2010 and July 2012 were included in the study. Patients from seven HD centers were excluded due to inadequate and incomplete results reporting. During the selected

period, HBsAg and HCV serology were available for 3769 patients from 53 HD centers distributed at all Lebanese governorates. The prevalence was calculated by dividing the number of patients with positive HBsAg or HCV serology to the total number of patients. The Incidence was calculated by dividing the number of newly acquired infection to number of patients-years (p-y). Incidence rates at different governorates were compared to each other using two tailed *Z* test and a *P* value of < 0.05 was considered significant.

RESULTS: Sixty out of 3769 HD patients were found to have positive HBS Ag and 177 out of 3769 were positive for HCV Antibodies. The prevalence of hepatitis B virus (HBV) and HCV in HD patients across Lebanon was 1.6%, and 4.7%, respectively. The comparison of prevalence according to geographic distribution could not be done accurately due to the frequent shift of patients between dialysis centers at different governorates. The incidence rate was 0.27 per 100 p-y for HBV and 0.37 per 100 p-y for HCV. There was no significant difference concerning the incidence of HBV between HD centers at different governorates (all *P* values > 0.1), but this difference was highly significant concerning the incidence rates of HCV which occurred predominantly in the southern centers (1.47 per 100 p-y) with a *P* value of 0.00068 and 0.00374 when compared to Mount Lebanon (0.21 per 100 p-y) and the Northern centers (0.19 per 100 p-y), respectively.

CONCLUSION: The incidence rate of HBV and HCV is very low in the Lebanese HD centers and their prevalence is decreasing over the last two decades.

Key words: Hemodialysis; Prevalence; Hepatitis C virus; Incidence; Hepatitis B virus; Lebanon

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Core tip: This is the largest and most statistically significant study addressing the prevalence and the incidence of hepatitis B virus (HBV) and hepatitis C virus (HCV) in 3769 patients on hemodialysis (HD) through 88% of all HD centers across Lebanon over a period of 22 mo. The prevalence of HBV and HCV in the studied population was 1.6%, and 4.7%, respectively. The incidence rate was 0.27 per 100 p-y for HBV, and 0.37 per 100 p-y for HCV. These values are amongst the lowest rates reported in other countries, which is most probably related to good adherence to infection control standards in the Lebanese HD centers.

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INTRODUCTION

The susceptibility to acquire viral hepatitis during hemodialysis (HD) has several potential underlying reasons related to both the patient and the HD procedure. First, although the rate of blood products transfusions has decreased since the introduction of erythropoietin stimulating agents, HD dependent patients still subjects of recurrent transfusions. Second, HD machines and membranes are shared between different patients which increases the risk of direct blood cross contamination within one HD unit. Vaccination does not offer the same level of protection against HBV transmission in HD patients as in the general population and finally and once exposed to HBV or HCV, End stage renal disease (ESRD) patients are more prone to become chronic carriers compared to the general population^[1]. Acquiring an HBV and/or HCV infection has long-term impact on morbidity and mortality of HD patients. It has been suggested that HCV seropositivity is associated with all-cause as well as cardiovascular mortality in HD patients^[2]. In addition, HBV and/or HCV infection changes the clinical course and the prognosis after kidney transplantation. In Lebanon, HBV and HCV prevalence in HD patients has not been widely studied previously. The available studies were limited to few dialysis centers and date back to the late 1990's^[3-5]. Reassessing the extent of the problem for both viruses establishes the infection control protocols and the general means to prevent transmission of hepatitis infection in ESRD patients on HD.

The main objective of this study is to determine the incidence and the prevalence of HBV and HCV infections in ESRD patients on HD across Lebanon. The current common practice is that ESRD patients on HD should be screened for HBV and HCV infection before the initiation of HD and monitored monthly thereafter. This serology is reported to the ministry of public health (MOPH) on a monthly basis. Our goal is that by establishing the annual incidence of HBV and HCV infection in HD patients in the different centers in Lebanon, we will be able to document how extensive is the viral hepatitis in the Lebanese HD centers. In addition, a secondary objective is to compare the incidence and the prevalence between the different Lebanese regions in order to localize a potentially high risk center.

MATERIALS AND METHODS

Each dialysis center in Lebanon is required to report monthly serology for both HBV (HBsAg) and HCV (HCV antibody) for all its HD patients.

We reviewed the MOPH registry, which compiles all Lebanese dialysis centers data, for the period extending from October 2010 to July 2012. Using this data; we conducted an assessment of the prevalence and incidence of HBV and HCV in the HD population in Lebanon.

The study population included all the patients' who

Table 1 Distribution of hemodialysis centers across Lebanon

Governorates	No. of centers present	No. of centers with available data	No. of patients studied during this period
Beirut	6	6	559
Mount Lebanon	27	24	1632
Bekaa	7	5	394
South	6	5	339
North	11	11	757
Nabatieh	3	2	88
Total	60	53	3769

Table 2 Calculated total patient months for hepatitis B

Governorates	Total number of patients	Total patient-month	Patients with positive HBsAg	Newly acquired hepatitis B
Beirut	559	7232	8	2
Mount Lebanon	1632	23955	19	3
Bekaa	394	4026	9	2
South	339	4379	5	1
North	757	13014	18	4
Nabatieh	88	1120	1	0
Total	3769	53726	60	12

HBsAg: Hepatitis B surface antigen.

underwent HD during the period extending from October 2010 to July 2012 (*i.e.*, both already established ESRD and newly diagnosed ESRD initiated on HD). We only excluded dialysis units and patients who had incomplete, or did not report data for part or for the whole studied period (7 HD centers from a total of 60 HD centers).

Incidence analysis

Since we had monthly serology and the patients were starting or stopping dialysis at different date during the studied period, we calculated the incidence using a patient-month (p-m) unit. Each HD patient was represented in the incidence analysis by the total number of months spent undergoing HD (*i.e.*, if a patient was on dialysis only for 10 mo he will be counted in the analysis as 10 p-m).

In the incidence analysis, we excluded all the patients with positive serology at the start of the studied period. For the patients who did not seroconvert during the period they were receiving HD, we counted the total months during which the patient was on HD. For patients who eventually acquired hepatitis viral infection, we only counted the total months before the acquiring infection (the period during which the patient was at risk of acquiring an infection).

Incidence (per patient-month) = (Total number of acquired infection)/(Total patient|month)

At the end of the incidence calculation, we converted the unit p-m to patient-year (p-y) by dividing the final number by 12.

Incidence (per patient-year) = [(Total number of acquired infection)/(Total patient|month)]/12

We did the statistical analysis separately for HBV and HCV.

To compare the incidence between the different governorates and since the population is independent, we used a Z-test to compare head to head the incidence of acquiring hepatitis viral infection between the different Governorates. We used a $P < 0.05$ with a two-tailed Z-test to reject the null hypothesis with a 95 percent certainty. Since our sample size was large, our analysis did fulfill the requirement of a study power more than 80%.

Prevalence analysis

We divided the total number of patient with positive

serology for HBV and HCV separately by the total number of patients studied in this period of time.

Prevalence = (Total number of patients with positive serology)/(Total number of patients)

There are a total of 60 HD centers in Lebanon, fifty three (88.3%) had a complete data reporting and were included in the analysis. To evaluate the geographic differences in viral hepatitis in Lebanon, each dialysis unit was allocated to a Governorate based on its geographic location. Table 1 layout the geographic distribution of the HD units across Lebanon. The centers with missing data and not included in the analysis were 3 of 27 (11%) of the Governorate of Mount Lebanon (Haroun Hospital; Siblin Governmental Hospital and Serhal Hospital), 2 of 7 (28%) in the Bekaa (Hermel Governmental Hospital, Hraoui Governmental Hospital), 1 of 6 (16%) in South (Hammoud Hospital) and 1 of 3 (33%) in Nabatieh (Nabatieh Governmental Hospital).

RESULTS

Sixty out of 3769 HD patients studied during a 22-mo period from October 2010 to July 2012 were found to have positive HBsAg and 177 out of 3769 were positive for HCV Antibodies during anytime for this period. The Prevalence of HBV and HCV in HD patients across Lebanon was 1.6% and 4.7%, respectively.

The prevalence of HBV in HD units by governorate was distributed as follows: 1.43% for Beirut, 1.16% for Mount Lebanon, 2.28% for Bekaa, 1.47% for the South, 2.37% for the North and 1.13% for Nabatieh. The prevalence of HCV by Governorate was distributed as follows: 3.57% for Beirut, 4.47% for Mount Lebanon, 5.58% for Bekaa, 7.07% for the South, 5.01% for the North and 0% for Nabatieh. We did not analyze the difference in the prevalence between each Governorate since it is difficult to interpret such results due to the frequent shift of patient between dialysis units (*i.e.*, some patients switch HD center between seasons and relocate to Mount Lebanon or Beirut during the winter season). The geographical distribution is detailed in Tables 2 and 3.

The incidence of HBV in HD centers in Lebanon was 0.27 per 100 p-y, while for HCV it was 0.37 per 100 p-y (Table 4). No newly acquired infection for both HBV and

Table 3 Total patient-months distribution for hepatitis C

Governorates	Total number of patients	Total patient-month	Patients with positive HCV Abs	Newly acquired hepatitis C
Beirut	559	7055	20	3
Mount Lebanon	1632	22970	73	4
Bekaa	394	3797	22	2
South	339	4078	24	5
North	757	12597	38	2
Nabatieh	88	1142	0	0
Total	3769	51639	177	16

HCV: Hepatitis C virus.

HCV were observed in Nabatieh.

While comparing the incidence of HBV in HD units between different governorates in Lebanon, no statistically significant difference was found (with a *P*-value always higher than 0.05) (Table 5). In Contrast, a statistically significant difference was found between the incidence of HCV in the South (1.47 per 100 p-y) compared to Mount Lebanon (0.21 per 100 p-y) and the North (0.19 per 100 p-y) showing a higher incidence in the South with a *P*-value of 0.00068 and 0.00374 respectively (Tables 5 and 6 for a list of the different calculated *P*-values).

DISCUSSION

It is well known that HD patients are at high risk for HCV and HBV infections. In Lebanon three small studies were done concerning the prevalence of HCV in HD patients. Naman *et al*^[4] reported in 1996 that the prevalence of HCV among HD in Lebanon was 27% with a high variety between the 5 centers studied (10%-39%), Abdelnour *et al*^[3] reported in 1997 in various hospitals a prevalence of 16%, Abourached *et al*^[5] reported in 2006, a prevalence of 13% (2.2%-38%) in 17 HD centers in Lebanon.

In this epidemiologic study covering more than 88% of the HD centers in Lebanon, the prevalence of anti-HCV antibodies in ESRD patients undergoing HD was 4.7%, showing a decrease in the prevalence of HCV among HD patients in Lebanon over the last two decades. The lowest prevalence was in Beirut (3.5%) and the highest in the South (7%). We observed a high variability among the 53 different centers studied, ranging from as low as 0% to as high as 20%.

The reduction in HCV prevalence in HD patients is a common trend across several countries and it was mainly related to the reduction in the number of transfusions in HD patients and the improvement of the laboratory screening techniques for detection of anti-HCV antibodies in blood donors. The prevalence of HCV infection in patients on HD is highly variable but clearly much higher than in the general population of the respective countries. In phase one of the Dialysis Outcomes and Practice Patterns Study (DOPPS), a prospective observational study of adult HD patients

Table 4 Incidence of hepatitis B and hepatitis C among hemodialysis centers in Lebanon

Governorates	Incidence of HBV (per 100 p-y)	Incidence of HCV (per 100 p-y)
Beirut	0.33	0.51
Mount Lebanon	0.15	0.21
Bekaa	0.59	0.63
South	0.27	1.47
North	0.37	0.19
Nabatieh	0	0
Across Lebanon	0.27	0.37

HCV: Hepatitis C virus; HBV: Hepatitis B virus.

randomly selected from 308 representative dialysis facilities in France, Germany, Italy, Japan, Spain, the United Kingdom, and United States, an overall HCV prevalence of 13% was found in 8615 patients^[6].

Globally the prevalence of HCV among patients undergoing HD varies from as low as 6.1% in Germany in 2002^[7] to as high as 76% in Casablanca in 2005^[8]. In general, North Africa and the Middle East were cited as high prevalence areas, both in the general population and in HD patients, by the WHO in 1999^[9]. Previous studies from the region have reported a prevalence of anti-HCV antibodies in HD patients of 50% in Saudi Arabia in 2000^[10], 19.1% in Tunisia in 1994^[11], 20.2% in Turkey in 2006^[12] and 34.6% in Jordan in 2007^[13].

Concerning the prevalence of HBV, Abourached *et al*^[5] reported on 2007 a prevalence of 2.62% (0%-6.5%) of HBsAg in 17 HD centers in Lebanon, our study showed a decrease of the prevalence to 1.6%, ranging from 1.4% in Nabatieh and Bekaa, to 2.4% in the North. This prevalence is slightly elevated than that reported in different study In Lebanon concerning the general population^[14]. We observed a high variability among the 53 different centers, ranging from as low as 0% to as high as 15%. This observed prevalence is lower than that reported in the 2008 by the Saudi Centre for Organ Transplantation (SCOT) report, where HBV seropositivity was 4.6% in the Saudi HD population while among Jordanian HD patients it was 5.9%^[15]. It is also lower than that reported in HD patients in other regions including Europe (4.1%), Japan (2.2%) and the United States (2.4%) during the period extending from 1996 to 2002^[16]. A study sample from the DOPPS, which included 8615 adult HD patients from 308 dialysis facilities in Western Europe and the United States, reported prevalence rates for HBV infection ranging from 0% to 6.6%^[17]. Studies from less developed countries estimated that the proportion of HBsAg carriers in the HD population varies from 2% to 20%^[18,19].

Prospective follow up of seronegative HD patients enabled us to observe 12 newly acquired infection for HBV and 16 newly acquired infection for HCV during a twenty two months period. We observed a 0.37 per 100 p-y incidence of new HCV infections during the 22-mo observation period. The reported incidence of new HCV infections varies considerably between countries. A rate

Table 5 P-values for hepatitis B

HBV	Beirut	Mount Lebanon	Bekaa	South	North	Nabatieh
Beirut		<i>P</i> = 0.3759 NS	<i>P</i> = 0.5562 NS	<i>P</i> = 0.8702 NS	<i>P</i> = 0.8948 NS	<i>P</i> = 0.579
Mount Lebanon			<i>P</i> = 0.1059 NS	<i>P</i> = 0.6073 NS	<i>P</i> = 0.2208 NS	<i>P</i> = 0.7086 NS
Bekaa				<i>P</i> = 0.5038 NS	<i>P</i> = 0.5709 NS	<i>P</i> = 0.4578 NS
South					<i>P</i> = 0.778 NS	<i>P</i> = 0.6159 NS
North						<i>P</i> = 0.5547 NS
Nabatieh						

NS: Non-significant; HBV: Hepatitis B virus.

Table 6 P-values for hepatitis C

HCV	Beirut	Mount Lebanon	Bekaa	South	North	Nabatieh
Beirut		<i>P</i> = 0.229 NS	<i>P</i> = 0.8164 NS	<i>P</i> = 0.1274 NS	<i>P</i> = 0.2598 NS	<i>P</i> = 0.4854 NS
Mount Lebanon			<i>P</i> = 0.1822 NS	<i>P</i> = 0.00068	<i>P</i> = 0.9079 NS	<i>P</i> = 0.6548 NS
Bekaa				<i>P</i> = 0.2951 NS	<i>P</i> = 0.2036 NS	<i>P</i> = 0.438 NS
South					<i>P</i> = 0.00374	<i>P</i> = 0.2346 NS
North						<i>P</i> = 0.6707 NS
Nabatieh						

NS: Nonsignificant; HCV: Hepatitis C virus.

as low as 0.4% was observed in France from 1997 to 2000^[20] but higher rates have been reported from the Mediterranean region. According to the 2008 SCOT report, the annual rate of HCV sero-conversion in Saudi HD patients was 7%-9% while in Jordan it was 2.6%^[14]. The incidence rate of 0.27 per 100 p-y for HBsAg is slightly less than that reported in Europe, Japan and the United States (0.4-1.8 per 100 p-y)^[17]. While comparing the incidence of HBV infection among the different Governorates, no statistically significant difference was found. In contrast, a statistically significant difference in the incidence of HCV infection was found between the South and both Mount Lebanon and the North. This interestingly high incidence of HCV infection of 1.47 per 100 p-y found in the South need to be assessed further to be able to find a potential reason for this higher incidence.

In this study we collected data from 53 centers distributed across all the six Governorates of Lebanon from the total 60 centers reporting monthly serology to the MOPH, giving us a total of 3769 patients studied over a 22-mo period. This significantly increased the statistical power and the validity of the results.

In general, the prevalence and incidence of HBV and HCV infections in HD patients are directly related to the prevalence of these infections in the general population, the quality of healthcare services in a community and

the standards of infection control practices in HD units. In Lebanon, patients on maintenance HD were found to have a higher prevalence of HCV infection of 4.7% when compared to the general population since, according to available data, anti-HCV prevalence rate of 0.2% to 0.4% of the general population in Lebanon^[21], but we noted a significant decrease of this prevalence in this group of patients during the last 20 years. Also the prevalence of HBV was slightly higher than the general population 2.62% vs 2.2%.

This higher prevalence of HBV and HCV infection in HD compared to the general population has been confirmed by several reports from different countries^[22].

The incidence of HBV and HCV in HD centers in Lebanon is very low compared to others countries in the region, this can be due to the good applications of the standards of infection control practices in HD centers and the strict surveillance by the MOPH.

A notable result of this study was the significantly higher incidence of HCV found mainly in the South that may be due to variation in the degree of implementation of the universal precautions to prevent nosocomial transmission. In order to evaluate the reason for the variation between the different HD units, a more detailed evaluation of each dialysis patient should be done especially in the units with the lowest and the highest incidence for HBV or HCV. Such studies would assist in

guiding interventions aiming to reduce the occurrence of these infections and thus reduce the morbidity and mortality of the HD population in Lebanon.

Finally this study demonstrated a reduce in the prevalence of HBV and HCV infections in HD centers during the last 2 decades and a low incidence rate due to the good applications of the standards of infection controls practice.

COMMENTS

Background

End stage renal disease (ESRD) patients on hemodialysis (HD) are particularly at higher risk for acquiring hepatitis C virus (HCV) and hepatitis B virus (HBV) than the general population, due to the sharing of contaminated machines within the same center and the higher rates of blood transfusions. Such infections have a negative impact on the clinical course of ESRD causing higher rates of morbidity and mortality. Since then, it is essential to determine the prevalence and the incidence of HBV and HCV infections in HD patients in each country, then to decide accordingly about further interventions to control such infections.

Research frontiers

The prevalence of HCV and HBV in patients on HD in Lebanon was only addressed by small studies including few HD centers. This study will determine the prevalence and incidence of HCV and HBV in a significantly larger population including 3769 HD patients through 88% of all HD centers across Lebanon between October 2010 and July 2012.

Innovations and breakthroughs

Previous studies done on smaller sample sizes limited to some Lebanese HD centers reported a prevalence of 2.6% and 13%-27%, for HBV and HCV, respectively. No reports are yet available about their incidence rate. Although accurate comparison could not be done due to the different sample sizes, this study showed a reduction in HBV and HCV prevalence through HD patients in Lebanon (1.6% and 4.7%, respectively). On the other hand, their calculated prevalence and incidence rates were found to be among the lowest values reported in other countries, either in the Middle East, or in Europe and United States. Another notable result of this study was the significantly higher incidence rate of HCV in the Southern Lebanese HD centers.

Applications

This study reflects an appropriate adherence to standards of infection control in the Lebanese HD centers limiting the spread of HBV and HCV between HD patients. However, it emphasizes the need for further investigations to reestablish those standards in some centers having significantly higher incidence rate of HCV, located mainly in the South of Lebanon.

Peer-review

In this manuscript, the authors report on the prevalence and incidence of hepatitis B and hepatitis C among HD patients in Lebanon. This paper is clinically interesting.

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