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Real-world experience of the Lebanese haemodialysis patient infected with the hepatitis C virus and treated with direct-acting antiviral drugs

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Abstract
Objective: The introduction of direct-acting antivirals (DAAs) has the potential to make a substantial contribution to HCV eradication within dialysis centers. Our study seek assess effectiveness, safety of oral DAAs, both with and without ribavirin, in the Lebanese hemodialysis population afflicted with HCV.
Methods: Patient on hemodialysis infected with hepatitis C virus having either genotype 1 or 4 were treated with DAAs. We conducted an analysis of various data points, including age, gender, year of HCV diagnosis, method of infection, comorbidities, previous treatment history, fibrosis stage, current DAAs treatment. We evaluated the virological response at the end of treatment, and12 weeks after stopping treatment
Results: Twenty hemodialysis patients infected with HCV genotype 1 or 4 underwent DAA treatment. The gender ratio was 0.82, with an average age of 46.2 years. The mean duration between diagnosis and treatment was 5.7 years. Half of the patients contracted the virus in dialysis centers, 5% through blood transfusion, and in 45% of cases, the cause remained unknown. Comorbidities were present in 45% of cases, with 35% been treated with Ribavirin and Pegylated Interferon. Seventy percent of patients were genotype 1 (70% 1a, 15% 1b), while 25% had fibrosis <F2, 40% F2-F3, and 20% F4. Patients received Ombitasvir/Paritaprevir/Ritonavir +/- Ribavirin for genotype 4, and Ombitasvir/Paritaprevir/Ritonavir-Dasabuvir +/- Ribavirin for genotype 1. The sustained virological response (SVR) at 12 weeks was 95%, with one patient (5%) discontinuing treatment after 2 weeks due to poor tolerance. No significant differences in treatment response observed in the two genotypes, various fibrosis stages, or prior treatment history.
Conclusion: These findings represent the first Lebanese data on HCV treatment using DAAs in hemodialysis patients. The study demonstrates an impressive SVR12 rate of 95%, with only 5% of patients experiencing treatment intolerance. These results in real-life settings show the potential for the eradication of HCV in hemodialysis centers.

Keywords: Antiviral drugs, hepatitis C virus, haemodialysis, HCV

Introduction

Hepatitis C virus (HCV) infection is notably more prevalent among individuals undergoing hemodialysis than in the general population, regardless of whether they reside in developing or developed countries [1]. The prevalence of HCV in this context varies widely, ranging from 5% to as high as 60% in specific regions around the world [4-7].

In Lebanon, the general population reports a HCV prevalence of 0.21% [8]. However, within the hemodialysis population, this rate significantly increases to 4.7% [9]. This increase in prevalence highlights the heightened vulnerability of hemodialysis patients to HCV infection. Furthermore, HCV infection is established as a significant risk factor for chronic kidney disease (CKD) and the progression to end-stage renal disease (ESRD) [10-13]. Particularly in the hemodialysis population, the associated all-cause mortality is 1.35 times higher than in non-infected individuals [14]. The implications of HCV infection in CKD patients extend beyond health outcomes, leading to increased healthcare costs and utilization [15].

Several factors contribute to the elevated prevalence of HCV among hemodialysis patients, including extended periods of hemodialysis, male gender, black ethnicity, concurrent illnesses, and a history of alcohol or drug abuse [16].

The treatment of HCV infection in hemodialysis patients has shown a correlation with reduced mortality and a decreased risk of developing cirrhosis and hepatocellular carcinoma [17, 18]. Notably, these treatment benefits might also extend to improving cardiovascular and renal outcomes [19]. These compelling findings emphasize the significance of addressing HCV infection in hemodialysis patients.

Notably, certain antiviral drugs, including simeprevir, ledipasvir, daclatasvir, paritaprevir/ritonavir, ombitasvir, dasabuvir, grazoprevir, and elbasvir, do not require dose adjustments for patients undergoing hemodialysis, as they do not undergo renal elimination. In contrast, sofosbuvir exhibits significant renal elimination [14, 15].

Although accumulating evidence suggests that sustained virological response (SVR) rates exceeding 95% can be achieved in patients receiving renal replacement therapy, managing HCV-infected patients with compromised renal function remains a challenge, as real-world clinical outcomes may not always mirror those observed in clinical trials.

Objective

This study evaluate the real-world effectiveness of DAAs in HCV-infected Lebanese hemodialysis patients.

Materials and Methods

A retrospective cohort study was carried out, involving an examination of the medical records of hemodialysis patients having HCV infection, who had been treated with DAAs provided by the Lebanese Ministry of Public Health (MOPH) during the year 2017.

Information's from patients included: the age, gender, body mass index, comorbidities, year of HCV diagnosis, and the year when hemodialysis began, was collected. We also recorded how HCV was transmitted, virologic characteristics (Genotype and subtype), fibrosis stage assessed using elastography, and whether patients were new to treatment or had prior treatment. The duration of treatment varies from 12 weeks to 24 weeks, with or without ribavirin, depending on fibrosis stage and treatment history, following Lebanese guidelines. The primary objective was achieving Sustained Virological Response (SVR) at 12 weeks, as detailed in Table 1.

Our study was approved by the MOPH, and the requirement for informed consent was waived because of the study's retrospective nature and the utilization of de-identified patient data.

We used descriptive statistics, which involved reporting numbers and percentages for categorical variables and means with standard deviation (SD) for continuous variables. Additionally, we conducted multivariate logistic regression modeling, which included a pre-defined set of variables such as age, gender, and genotype.

Table 1: Patient's characteristics, and treatment protocols

Patient Details					Medical History			Treatment			
Sex	**Year Birth**	**Naïve/ experienced**	**Comorbidity**	**Date of Diagnosis**	**Mode of contamination**	**Genotype**	**Fibroscan Result**	**Treatment Duration**	**Ribavirin 200mg**	**Treatment adherence**	**SVR 12 Weeks**
M	1941	Naïve	Hypertension	2016	Unknown	1A	F4	24 weeks	1/DAY	100.00	PCR neg
F	1954	Naive		Unknown	Hemodialysis	4	Unknown	12 weeks	5/day	100.00	NA
F	1961	Naïve		2014	Unknown	1A	F0-F1	12 weeks	6/day	300.00	PCR neg
F	1975	Experienced	Diabetes	2007	Hemodialysis	1A	Unknown	12 weeks	1/DAY	100.00	PCR neg
M	1959			unknown	Unknown	1A	F3	12 weeks	6/day	100.00	PCR neg
M	1965	Experienced		1997	Unknown	4	F1	12 weeks	1/2days	100.00	PCR neg
F	1959	Experienced	Hypertension	2012	Hemodialysis	1A	Unknown	12 weeks	1/2days	100.00	PCR neg
M	1965	Naïve		2016	Hemodialysis	4	F2	12 weeks		100.00	PCR neg
M	1967	Naïve	Diabetes, hypertension	2014	Hemodialysis	1B	F2	12 weeks		100.00	PCR neg
M	1941	Naïve		2017	Hemodialysis	1A	F3-F4	24 weeks	1/DAY	100.00	PCR neg
M	1988	Naïve	Hypertension	2017	Unknown	1A	F0-F1	12 weeks	1/2days	73.81	PCR neg
M	1956	Experienced		2010	Hemodialysis	1	F2	12 weeks	1/DAY	100.00	PCR neg
F	1967	Experienced	Open Heart	2011	Blood Transfusion	1	F2	12 weeks		100.00	PCR neg
F	1976	Naïve		unknown	Hemodialysis	1A	F0-F1	12 weeks	1/DAY	100.00	PCR neg
F	1974	Naïve	Hypertension	2017	Hemodialysis	1A	F4	24 weeks		100.00	PCR neg
F	1959	Naïve	Diabetes, hypertension	unknown	Unknown	1B	F3	12 weeks		100.00	PCR neg
F	1961	Naïve		unknown	Hemodialysis	4	F3	12 weeks		100.00	PCR neg
F	1966	Experienced		2003	Unknown	1A	F0-F1	12 weeks	1/week	98.81	PCR neg
F	1951	Naïve	Hypertension	2016	Unknown	4A	F4	12 weeks	2/week	100.00	PCR neg
M	1959	Experienced	Kidney Transplant	2005	Unknown	4	F3	12 weeks	1/2days	100.00	PCR neg

Results

During 2017, 20 patients infected with HCV from different hemodialysis center in Bekaa district in Lebanon had been treated. Male/female ratio was 9/11, mean age was 46.2 years (range: 29 to 76), 70% had genotype 1 (1a: 70%, 1b:15%, untypable: 15%). Concerning fibrosis stage, 25% were <F2, while 40% had F2-F3 and 20% had F4.

The mean duration between the diagnosis and treatment was 5.7 years. 50% of patients acquired their infection from hemodialysis center, while 5% from previous blood transfusions, and 45% had undetermined way of transmission of the infection. At least one comorbidity such as hypertension, diabetes or heart failure was present in 45% of cases. 65% of patients were treatment naïve, whereas 35% had been treated with pegylated interferon and Ribavirine. For genotype 4 treatment included: Ombitasvir/Paritaprevir/ Ritonavir +/- Ribavirin, and for genotype 1: Ombitasvir/Paritaprevir/Ritonavir –Dasabuvir +/- Ribavirin. Duration of the treatment with both regimens was 12 and 24 weeks.Overall RBV with a dose of 100 mg to 1200 mg per day was used in 70% of cases. In 95% of patients we obtained a SVR12. Treatment was discontinued due to intolerance in only one patient (5%). No difference between the 2 genotypes in terms of fibrosis stage, previous

treatment, duration of the disease and response to treatment. SVR12 in genotype 1 was 100% while SVR12 in genotype 4 was 84%.

Discussion

Historically, the treatment of HCV in chronic kidney disease (CKD) patients, especially those undergoing hemodialysis, predominantly depended on combinations of pegylated interferon and ribavirin. Nevertheless, these treatments demonstrated limited effectiveness, with a success rate of approximately 40% in achieving Sustained Virological Response (SVR), and often caused adverse effects that led to treatment discontinuation in a substantial number of patients [20]. This reduced efficacy played a significant role in the globally low rates of HCV treatment in hemodialysis patients, even in cases where kidney transplantation was a viable option.

The introduction of DAAs marked a turning point in HCV therapy. These interferon-free options demonstrated significantly higher SVR rates (Up to 95%) with fewer side effects, making them a viable choice for patients undergoing renal replacement therapy, including hemodialysis [14, 15].

In Lebanon's general population, real-world DAA treatment for HCV achieved an impressive SVR rate of 94% [23]. Our study, focusing on Lebanese hemodialysis patients infected with HCV genotypes 1 or 4, reaffirmed these positive outcomes, demonstrating a notable SVR rate of 95%. It's worth mentioning that the only patient who didn't achieve SVR discontinued treatment after 4 weeks due to adverse events. Within this group, a significant portion had cirrhosis (20%), advanced fibrosis (40%), prior treatment experience (35%), and comorbidities (45%). Genotype-wise, SVR rates were 100% for genotype 1 and 84% for genotype 4. Notably, treatment response was consistent regardless of the presence of comorbidities (100% and 89%, respectively).

The scarcity of studies and real-world evidence on HCV treatment in hemodialysis patients is a notable challenge.

The C-Surfer study, which included 235 patients with advanced stage of chronic kidney disease (4 or 5), with approximately three-quarters of them undergoing hemodialysis, primarily focused on genotype 1 cases. Notably, only 6% of the participants had cirrhosis. The treatment regimen included grazoprevir at 100 mg/day and elbasvir at 50 mg/day, leading to an impressive SVR12 rate of 99.1%. While 98.9% of Hemodialysis patients achieved an SVR12 [21].

In a retrospective real-world study that involved grazoprevir/elbasvir, 99% of patients with advanced stage of chronic kidney disease (Achieved SVR12 (113 out of 114), making this protocol an FDA-approved option for the treatment of chronic HCV genotypes 1 and 4 in adults, including patients with end-stage renal disease on hemodialysis [24, 25].

Moreover, in two case series involving Japanese hemodialysis patients infected with genotype 1 HCV, daclatasvir/Asunaprevir was utilized. In both series, SVR rates exceeding 95% were observed, along with acceptable tolerability and low incidence of severe adverse events unrelated to the DAA regimen [26, 27].

In a multi-center nationwide analysis, involving a substantial cohort of hemodialysis patients (n = 123), the effectiveness and safety of combining daclatasvir/Asunaprevir therapy were prominently demonstrated, an overall SVR12 rate of 95.9% was obtained, very low discontinuation rate due to adverse events was noted (3.3% [28].

Gomez *et al*. documented a 100% sustainable virologic response in patients who received a treatment regimen involving Ombitasvir (OBV), ritonavir with Paritaprevir (PTV), and dasabuvir (DSV). Overall, the tolerance to this regimen was generally acceptable, some patients experienced drug interactions with antihypertensive medications, and a few individuals encountered worsened anemia, which did not require treatment discontinuation [29].

In another study involving 20 patients with chronic kidney disease (Stage 4 and 5) or on hemodialysis, who underwent a 12-week course of DAAs, they were split into two groups. The first group, with genotype 1a, received the PTV/ritonavir plus OBV, while the second group, with genotype 1b, received the PTV/ritonavir plus OBV plus ribavirin. The study reported a successful SVR12 rate of 90%, with only two patients not achieving SVR12, and, importantly, the overall treatment was well-tolerated [22].

Gane *et al*. attained a 94% SVR using the same approach for genotype 1 patients with stage 4 or 5 CKD [30].

Additionally, a real-world investigation examining effectiveness and safety of OBV/PTV in genotype 4, in conjunction with DSV in genotype 1-infected patients with severe CKD, yielded a remarkable SVR12 rate of 97% [31].

It's important to acknowledge that there is a scarcity of research on Sofosbuvir-based treatments for patients with advanced-stage CKD. Case series involving patients treated with Sofosbuvir/Simeprevir revealed a rate of 89% achieving SVR (8 out of 9) [32, 33].

In HCV-TARGET study, patients with diverse baseline renal function received regimen containing sofosbuvir. The SVR rate for those with an estimated glomerular filtration rate of 30 mL/min was 88% (15 out of 17). It's noteworthy that patients with impaired kidney function encountered more frequent cases of anemia, worsening renal function, and severe adverse events compared to those with normal kidney function [34].

These clinical trials have provided valuable insights into HCV treatment among hemodialysis patients. It's worth noting that these trials had limitations, including a low representation of patients with liver cirrhosis (0-6%) and the exclusion of individuals with a history of hepatocellular carcinoma (HCC), who often require immediate treatment.

Limitations of our study, it’s a retrospective design and the relatively small cohort of 20 patients with genotypes 1 and 4, representing over 80% of HCV cases, our findings emphasize the significance of treating all patients with severe renal impairment for HCV, irrespective of their dialysis status. Sofosbuvir-free regimens emerge as preferred choices. The remarkably high cure rates (95% SVR12), along with favorable tolerability and safety profiles, make these regimens highly promising.

Larger studies examining these or alternative regimens are crucial to further enhance our understanding and expand ttherapeutic options for HCV in hemodialysis patients.

Conflict of Interest

Not available

Financial Support

Not available

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