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Research Article

Off Trail Treatment of Hepatitis C with Hemodialysis Patients, Results of an Algerian Cohort

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Abstract

Introduction: There is a wild range in the prevalence of HCV infection among hemodialysis patients (HD) patients in different parts of the world, With constant growth in the number of hemodialysis patients associated to a prevalence of 23,8% of infection with hepatitis C 2, Algeria is confronted to a serious public health problem. With constant growth in the number of hemodialysis patients associated to a prevalence of 23,8% of infection with hepatitis C 2, Algeria is confronted to a serious public health problem.

Methods: We proceeded to a prospective descriptive study including all patients treated for (VHC) on dialysis over a period of one year (January 2017-January 2018) recruited from all hemodialysis centers of the Provence of Constantine. 29 patients were treated, all included in our study, the therapy was based on: Sofosbuvir 400 mg/Ledipasvir 90 mg +/- Ribavirin for 12 or 24 weeks depending on the liver fibrosis status, prescribed after each dialysis, (3 times a week for all our patients). A viral load was requested in pre-therapeutic (as a reference), at the end of treatment and 12 weeks after therefore defining a sustained viral response (SVR).

Results: A total of 29 patients were treated, all patients were subjected to a viral load in addition to another one performed 12weeks later confirming a 96% success rate (SVR). No patient had to stop the treatment for any side effects.

Conclusion: The renal clearance of Sofosbuvir makes it difficult to handle in patients with terminal chronic renal insufficiency, however our study shows that with close and strict monitoring we can get a sustained viral response in more than 95% of patients with no significant side effects.

Keywords: *Hemodialysis; HCV Infection; Sofosbuvir*

Introduction

There is a wild range in the prevalence of HCV infection among hemodialysis patients (HD) patients in different parts of the world, varying from 1% to 90%; In northern Europe the prevalence rate is less than 5%, in southern Europe and USA around 10% and in many countries of northern Africa Asia and south America ranges between 10% and 70% [1].

With constant growth in the number of hemodialysis patients associated to a prevalence of 23,8% of infection with hepatitis C [2], Algeria is confronted to a serious public health problem.

Evidence of outbreaks suggests that transmission of Hepatitis C virus (VHC) in dialysis facilities cannot be solely a function of machine contamination, but instead occurs through contamination of equipment, medications or other supplies like environmental surfaces, and/or healthcare worker hands as a result of poor infection control practices [3-5] putting the dialysis related risk at 2% per year [6].

Adapted drugs exist for this population as stated in the AASLD and the EASL guidelines [7] such as Grazoprevir, Elbasvir… unfortunately those treatments are quite expensive and not available in our country.

HD patients infected with HCV face a higher mortality and morbidity rate compared to their non HCV counterparts [6] with an HCV infection rate continually increasing with time the necessity to treat with the antiviral therapy at our disposal despite the lack of data and recommendation became clear.

The purpose of our study is to highlight the difficulties associated with the management of hemodialysis patients with viral hepatitis C (VHC), particularly with the unavailability of adapted drugs in some countries like Algeria and try to prove the effectiveness of current therapies outside consensual indications.

We had Concerns because of the substantially higher concentrations of sofosbuvir and, most importantly, of its renally excreted metabolite GS-331007 in patients with renal impairment compared to those without (+103% and +501% AUCT, respectively) [8].

Methods

We proceeded to a prospective descriptive study, including all patients treated for (VHC) on dialysis recruited from all hemodialysis centers of the Provence of Constantine over a period of one year (January 2017 - January 2018).

29 patients were treated, all included in our study, the therapy was based on: Sofosbuvir 400 mg/Ledipasvir 90 mg +/- Ribavirin for 12 or 24 weeks depending on the liver fibrosis status, prescribed after each dialysis (3 times a week for all our patients).

All members of the cohort received a complete clinical examination, a biological assessment (blood count, aminotransferases, Urea/Creatinine) with a genotype identification and an assessment of liver fibrosis (fibroscan/fibrotest) before the beginning of the treatment.

Our patients had a regular monitoring every 4 weeks with an appraisal of tolerance based on any reported side effects, as well as compliance confirming that there was no discontinuance of the treatment, transaminases and blood counts were also performed.

A viral load was requested in pre-therapeutic (as a reference), at the end of treatment and 12 weeks after therefore defining a sustained viral response (SVR).

Results

A total of 29 patients were treated, 28 of whom were naïve to any treatment, with an average age of 46 years old ± 20 years and a sex ratio close to 1.

The average pre-therapeutic viral load was 500 * 10^3/ml (4.7Log) all of which were Genotype 1b.

We had to treat 7 cirrhotic patients, 5 of which had a treatment duration of 24 weeks due to the hemoglobin level (< 10 g/dl) prohibiting the use of Ribavirin; the remaining two were treated in combination with Ribavirin for 12 weeks.

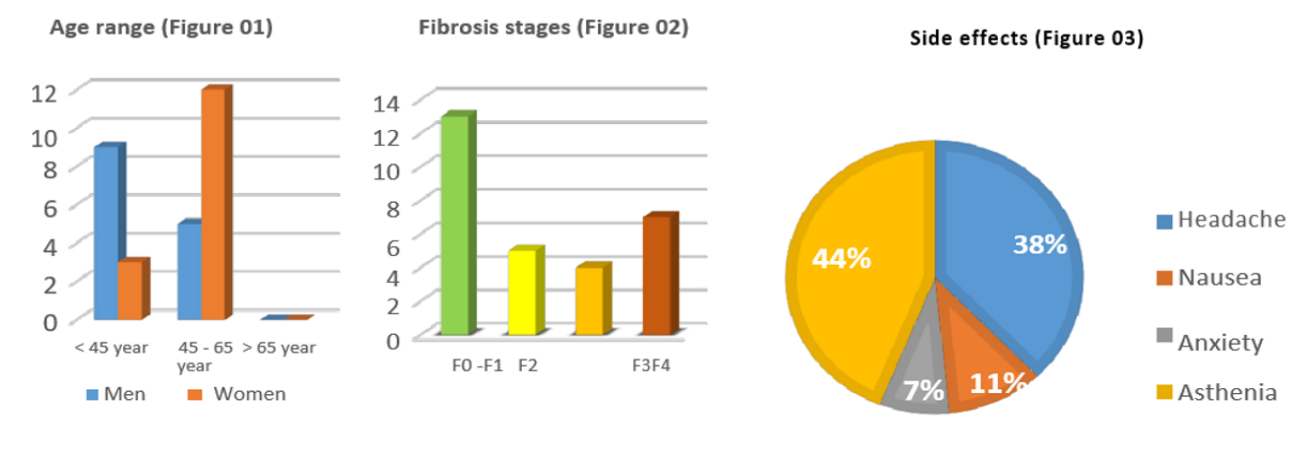
After completing the treatment all patients were subjected to a viral load in addition to another one performed 12weeks later confirming a 96% success rate (SVR).

Only one patient had a positive viral load at week 12 (naive non-cirrhotic patient).

Concerning side effects, complaints were mainly about headaches and asthenia. Only one case of severe anxiety was reported as shown in figure 3.

Due to a decrease in red blood cells count, all patients benefited from an optimization of Erythropoietin injections.

No patient had to stop the treatment.



Discussion

The inevitable question here is where is the rest of the patients? Counting only the 29 patients treated at our center, which represents the third largest hospital in the country, and with a prevalence of 23.8% of HD patients infected with Hepatitis C out of 17500 HD patients. Meaning that only a mere 1% of theoretical infected patients is being treated. Which brings our attention to the competence of the screenings conducted.

The efficiency of this drug (Sofosbuvir) with HD patients is real as proven by our work and the 96% success rate (SVR) obtained. As for the tolerance related to the medication, it was determined acceptable as the main side effect was mild headaches and no patient had to stop their treatment for any other cause.

About the unique patient refractive to the treatment there was no identifiable cause found.

However, no indicator concerning the presence and amount of the cumulative doses of the active substance for our cohort is available, that would have been interesting especially when the FDA pharmacokinetics data affirm that 1280% of the Sofosbuvir's metabolite is present in HD patients compared to non HD patients [9].

Studies suggest that genotype 1b is correlated with more severe liver disease and a more aggressive course [10] yet since all our patients were infected with the same genotype (1b) we couldn't confirm or deny any difference regarding the response to the treatment.

No short term complications were reported, nonetheless long term reactions are still to be assessed, even if no new symptoms have emerged since the completion of our study.

Conclusion

The renal clearance of Sofosbuvir makes it difficult to handle in patients with terminal chronic renal insufficiency, however our study shows that with close and strict monitoring we can get a sustained viral response in more than 95% of patients with no significant side effects.

However more exhaustive studies, with dosage of active metabolites should be conducted to support our results.

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