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Original article

Efficacy and safety of direct-acting antivirals in the treatment of hepatitis C virus infection: Sub-Saharan context

Efficacité et tolérance des antiviraux à action directe dans le traitement de l'infection par le virus de l'hépatite C : Contexte subsaharien

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Résumé

Objectif : Évaluer le traitement de l'hépatite virale C avec des antiviraux à action directe

Méthodologie : Il s'agissait d'une étude descriptive et analytique. Elle comprenait une phase rétrospective de janvier 2018 à janvier 2020 et une phase prospective de février 2020 à décembre 2020.

Résultats : A la fin de notre étude, 35 patients ont été inclus. L'âge moyen de nos patients était de 56 ans ± 12,20 avec un sex-ratio de 1,5. Dans 37,1 % des cas, la découverte du VHC était accidentelle. Il y avait des antécédents de transfusion et de diabète chez respectivement 5,8 % et 20 % de nos patients. Les génotypes I et II du VHC étaient les plus fréquents, ce qui a motivé l'utilisation des schémas thérapeutiques Sofosbuvir + Ribavirine et Sofosbuvir + Velpatasvir chez 51,4 % et 37,1 % de nos patients, respectivement. La charge virale était indétectable chez 97,1 % des patients à la fin du traitement. Un patient non observant avait toujours une charge virale positive. La réponse virologique soutenue était de 100 %.

Dans 82,9 % de notre échantillon, aucun effet indésirable n'a été signalé.

Conclusion : L'infection par le VHC est grave par sa chronicité et ses complications. Les antiviraux, mieux tolérés et très efficaces, ont révolutionné sa prise en charge.

Mots-clés : Hépatite C, Traitement antiviral à action directe.

Abstract

Purpose: To evaluate the treatment of viral hepatitis C with direct-acting antivirals

Methodolody: This was a descriptive and analytical study. It included a retrospective phase from January 2018 to January 2020 and a prospective phase from February 2020 to December 2020

Results: At the end of our study, 35 patients were included. The average age of our patients was 56 years ± 12.20 with a sex ratio of 1.5. In 37.1% of cases, the discovery of HCV was accidental. There

was a history of transfusion and diabetes in 5.8% and 20% of our patients, respectively. HCV genotypes I and II were the most common, which motivated the use of the Sofosbuvir + Ribavirin and Sofosbuvir + Velpatasvir regimens in 51.4% and 37.1% of our patients, respectively. Viral load was undetectable in 97.1% of patients at the end of treatment. A non-compliant patient always had a positive viral load. The sustained virologic response was 100%.

In 82.9% of our sample, no adverse effects were reported.

Conclusion: HCV infection is serious in its chronicity and complications. Antivirals, which are better tolerated and highly effective, have revolutionized its management.

Keywords: Hepatitis C, Direct-acting antiviral treatment.

Introduction

Hepatitis C virus (HCV) infection is a major public health problem because its global prevalence is currently estimated at 100 million infected individuals [1,2]. Its role in the genesis of chronic liver disease makes it an important cause of morbidity and mortality.

Pegylated dual therapy had some efficacy but this was limited by adverse effects and the cost of medication, with fairly frequent failure rates [3]. The advent of direct-acting antivirals has been a real therapeutic revolution in HCV infection. Indeed, sustained virological response rates with these molecules are obtained in 90 to 100% of cases, at all stages of liver disease with excellent tolerance [1].

In Mali, anti-HCV antibodies were found in 3.5% of blood donors [4]. Two other studies reported a prevalence of HCV infection of 15.1% in chronic liver disease [5] and 10% in diabetics [6]. The first therapeutic attempts of this infection by pegylated dual therapy in our context were modest because of the inaccessibility and adverse effects of the molecules. Direct-acting anti-virals are increasingly available in Mali. We undertook this study to evaluate the efficacy and safety of these molecules in the management of HCV infection in our context.

Methodology

This was a descriptive and analytical study that took place in the hepato-gastroenterology department of the Gabriel Touré University Hospital in Bamako-Mali.

It had included a retrospective phase from January 2018 to January 2020 and a prospective phase from February 2020 to December 2020. Patients with HCV infection confirmed by the presence of its RNA were included. Patients were required to have an HCV viral load test at baseline and at 12 weeks after discontinuation of treatment.

For the retrospective period, data were collected from the department's records. During the prospective period, the data were recorded in real time. The study parameters collected were socio-demographic data, reasons for consultation, joint pain, signs of PH and hepatocellular insufficiency, adverse drug effects, and disease progression. All patients in the prospective phase were informed about the progress of the study and gave their verbal consent.

The data analysis was done on the statistical software Epi Info version 6.04. The chi² statistical test was used to compare our results with a significant cut-off for $p<$ at 0.05.

Results

At the end of our study, 35 patients met our inclusion criteria. The mean age was 56 years ± 12.20 years with extremes of 27 and 76 years. The 50-59 age group was the most represented with 31.4%. Men represented 60% of the sample with a sex ratio of 1.5. In 94% of cases our patients were married. Civil servants, shopkeepers and housewives accounted for 28.6%, 20% and 20% of our study, respectively. In 37.1% of cases, the discovery was fortuitous during a screening examination. Diabetes was the most

common history and blood transfusion was reported in two patients (Table I). The average viral load was . The genotypes encountered were: 18 (51.4%) cases of genotype II, 15 (42.8%) cases of genotype I, 3 (8.6%) cases of genotype IV with in one case a genotype I associated with a genotype IV. Treatment consisted mainly of the combination of Sofosbuvir + Ribavirin used in 51.4% of cases and the combination of Sofosbuvir + Velpatasvir in 37.1% of cases (Table II). Viral load was undetectable in 34 patients (97.1%) at 12 weeks of treatment and only one non-compliant patient was viremic. In all these patients with an undetectable viral load, the sustained virologic response was 100%. We found four minor adverse effects (headache, dizziness, diarrhoea, anaemia). In 82.9% of cases, no adverse effects were reported.

Table I: Medical History

Medical History	Actual	Percentage
Transfusion	2	5,7
Diabetes	7	20
HTA	2	5,7
Jaundice	2	5,7
None	27	77,1

Table II : Distribution according to the scheme used

Scheme	Actual	Percentage
Sofosbuvir+Ribavirin	18	51,4
Sofosbuvir+Velpatasvir	13	37,1
Sofosbuvir+Daclatasvir	3	8,6
Sofosbuvir+Ledipasvir	1	2,9
Total	35	100,0

Discussion

At the end of this study, 35 patients were collected. Our sample was limited by both the cost of the confirmatory test for HCV infection and antiviral drugs. However, this study is the first on the subject in our context. It allowed an analysis of the effectiveness of direct-acting antivirals in the treatment of HCV infection.

The average age of our patients, 56 ± 12.20 years, can be superimposed on that found by Mohamed [7] in Morocco, which was 60.7 years. Another study carried out in Algeria by Mohamed Amine [8] found an average age of less than 49 years.

Men were the most represented in our study with a sex ratio of 1.5, comparable to that reported by Mohamed in Morocco [7] which was 1.25. The frequency of HCV infection in this genre could be related to a greater drug addiction theoretically more common in the male population.

Civil servants, shopkeepers and housewives were the most represented in our study.

The discovery was fortuitous in 37.1% of cases. Mohamed Amine in Algeria [8] also reported 31% of HCV cases during screening. This finding confirms the asymptomatic or pauci symptomatic nature of the infection.

Diabetes was found in 20% of patients. Diarra et al [6] found HCV infection in 10% of diabetics. Both of these findings support the strong relationship between diabetes and HCV infection.

Genotype II was the most common with 51.4%. Previous studies in Mali [5,6] have already reported this predominance, while in Cameroon genotype I was the most common [9]. A predominance of genotype II in West Africa has already been reported [10].

The combination of Sofosbuvir + Ribavirin was the most commonly used regimen because genotype II, the most sensitive to this combination, was the most frequently encountered in our study. This regimen was also recommended, for genotype II, by the French Association for the Study of the Liver (AFEF) [11].

The sustained virologic response (at 12 weeks from the end of treatment) was 100% in all 34 patients who had a negative viral load at the end of treatment. This result is consistent with data from the literature for which the sustained virologic response rate is 90 to 100% at any stage of HCV infection [1]. Only

one non-compliant patient always had a detectable viral load. Poor adherence to treatment is classically reported to be a factor negatively influencing the outcome of this treatment [1]. In 82.9% of cases, no adverse effects were reported, thus confirming the proven tolerability of direct-acting antivirals [12]. The few very rare cases of adverse reactions were minor and did not interfere with treatment.

Conclusion

HCV infection is serious because of the frequency of its chronicity and the serious complications it causes. Direct-acting antivirals are well tolerated and more effective. A policy of informing and raising awareness among the population about this infection could promote its widespread detection and early management.

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