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RESEARCH ARTICLE

Efficacy and Safety of Sofosbuvir-Based Regimens in Patients with Viral Hepatitis C and Stage 4 and 5 Chronic Kidney Disease: The Cameroon Experience

Martial Tsiazok Dongmo[1*], Mathurin Pierre Kowo[2], Aristide Eric Nono Tomta[3], Hermine Danielle Fouda Menye[4], Maïmouna Mahamat[5], Dorothe Soh Mankong[6], Linda Njonkam Toukep[7], Larissa Mbomena Tabene[8] and François JérômeKaze Folefack[2]

[1]*Bafoussam Regional Hospital, Cameroon*

[2]*Faculty of Medicine and Biomedical Sciences of Yaounde, Yaounde University Teaching Hospital, Cameroon*

[3]*Yaounde General Hospital, Cameroon*

[4]*Faculty of Medicine and Biomedical Sciences of Yaounde, Douala General Hospital, Cameroon*

[5]*Faculty of Medicine and Biomedical Sciences of Yaounde, Yaounde General Hospital, Cameroon*

[6]*Faculty of Medicine and Biomedical Sciences of Garoua, Garoua Regional Hospital, Cameroon*

[7]*Douala General Hospital, Cameroon*

[8]*Bertoua Regional Hospital, Cameroon*

***Corresponding author:** *Martial Tsiazok Dongmo, Bafoussam Regional Hospital, Cameroon, Tel: 00237-697-015-962*

Abstract

Background and objectives: Treatment of viral hepatitis C in chronic kidney disease patients with glomerular filtration rate < 30 ml/min/1.73 m^2 remains a challenge in countries with combinations containing only sofosbuvir. We investigated the efficacy and safety of sofosbuvir based regimens in patients infected with hepatitis C virus and stage 4 and 5 chronic kidney disease.

Methods: We conducted a multicentric, retrospective study of patients records treated for viral hepatitis C and chronic kidney disease. We collected data on adverse events, renal function during and after treatment, and virological response during and after treatment.

Results: We recruited 28 patients, including 13 patients on maintenance haemodialysis and 17 men. The mean age was 60.68 ± 13.00 years. Cirrhosis was found in 12 (43%) patients. The genotypes found were 1, 2 and 4. There were 27 (96.4%) treatment-naïve patients. The different combinations found were: Sofosbuvir 400 mg twice a week + ribavirin 200 mg daily (3.6%, n = 1), sofosbuvir 400 mg + daclatasvir 60 mg daily (21.6%, n = 6), sofosbuvir 400 mg + ledipasvir 90 mg daily in two patients, twice a week in 9 patients and three times a week in one patient (43.2%, n = 12), sofosbuvir 400 mg + velpatasvir 100 mg daily in 6 patients, twice weekly in three patients (32.4%, n = 9). The sustained virological response rate was 100% in the 21 patients who did viral load after treatment. The main adverse events were nausea (10.7%), vomiting (10.7%), dizziness (7.1%), headache (7.1%) and pruritus (7.1%). The glomerular filtration rate was 22.3 ± 5.7 ml/min/1.73 m^2 at the start of treatment, 17.7 ± 4 ml/min/1.73 m^2 at the end of treatment and 20.7 ± 5.3 ml/min/1.73 m^2 three months after treatment.

Conclusion: Treatment with sofosbuvir-containing regimens is effective and well tolerated in patients infected with hepatitis C virus and stage 4 and 5 chronic kidney disease.

Keywords

Sofosbuvir, Chronic kidney disease, Efficacy, Safety

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Background

Hepatitis C virus (HCV) infection is a public health problem worldwide, affecting 1% of the population [1]. It is associated with high morbidity and mortality due to the hepatic and extra-hepatic complications it causes. In patients with Chronic Kidney Disease (CKD), the problem arises more acutely. Indeed, it affects 9.9% of patients in this population [2] and is an independent factor of morbidity and mortality in this population [3-5]. In addition to being a factor in the progression of CKD [6,7], it is responsible for an increase in cardiovascular risk and an impairment in quality of life among chronic dialysis patients [3,8]. In kidney transplant recipients, HCV infection is associated with a higher risk of all-cause mortality and graft loss [9,10]. Therefore, patients with CKD should be considered as a priority for the treatment of HCV infection.

Treatment of HCV infection remains a challenge in patients with CKD with glomerular filtration rate (GFR) < 30 ml/min/1.73 m^2. For these patients, the combination therapies approved by the Kidney Disease Improving Global Outcomes (KDIGO) are: Ritonavir-boosted paritaprevir in combination with ombitasvir with or without dasabuvir, grazoprevir in combination with elbasvir and glecaprevir in combination with pribentasvir [11]. Sofosbuvir is currently the central molecule in the treatment of chronic viral hepatitis C worldwide [12]. It is an HCV NS5B polymerase inhibitor nucleotide analogue with pan-genotypic activity, strong resistance barrier, good safety profile and minimal drug interactions [12]. Unlike other direct-acting antivirals (DAAs), GS-331007, the main metabolite of sofosbuvir, is predominantly eliminated renally [13] and greater degradation of renal function has been reported in patients with CKD [14,15]. As a result, safe and effective doses in people with a GFR < 30 ml/min/1.73 m^2 have not been established.

In Cameroon, DAAs have been available since 2016; these are sofosbuvir-based combinations. To the best of our knowledge, we do not have data on the efficacy and safety of sofosbuvir-based regimens in patients with severe CKD in Cameroon. The aim of this study was to describe the efficacy and safety of treatment regimens containing sofosbuvir in patients' with grade 4 and 5 chronic kidney disease.

Materials and Methods

Patients and study design

We conducted a retrospective study from January 1st, 2016 to July 31st, 2021. The patients were recruited at the Yaounde General Hospitalof (YGH), the Yaounde University teaching Hospital (YUTH), the Cathedral medical center (CMC) and the Douala General Hospital (DGH). All patients treated for chronic viral hepatitis C with a combination containing sofosbuvir and with chronic kidney disease with GFR < 30 ml/min/1.73 m^2 were included. Patients lost to follow-up were excluded from the analysis.

Data collection

Data collected included: Socio-demographic data, medical history, clinical data, biological data including serum creatinine and hepatitis C viral load before, during, 12 weeks and 24 week after treatment, adverse effects, therapeutic regimens and treatment duration.

Statistical analyses and presentation of results

The data was captured and encoded by CS Pro 7.6.1 software and analyzed using IBM SPSS version 26 software. Qualitative variables were presented by numbers and frequencies. The quantitative variables were expressed as means ± standard deviations or the median and interquartile range where applicable.

Ethical considerations

This study was conducted in strict respect of ethics. The data was collected confidentially and treated in accordance with the privacy of the participants. We assigned codes to each file from the beginning of recruitment. An ethical authorization No. 0040/UY1/FMSB was obtained from the institutional committee for research and ethics of the Faculty of Medicine and Biomedical Sciences (FMSB) of the University of Yaoundel to conduct this study as well as administrative authorizations from the various health structures.

Operational definition of terms

- Undetectable viral load: Less than 15 IU/ml copy of HCV RNA.
- Sustained virological response or virological cure: Undetectable viral load three months after the end of HCV treatment.
- Rapid virological response (RVR), defined as an undetectable viral titre at the end of the fourth week of treatment.
- Relapse: It is characterized by an undetectable viral load during and at the end of treatment but the viral RNA becomes detectable again within 03 months of treatment.
- Major adverse reactions: Clinical or paraclinical events occurring after initiation of treatment and requiring discontinuation of treatment.
- Minor side effects: Clinical or paraclinical events occurring after initiation of treatment that do not require discontinuation of treatment.
- CKD staging was done using the KDIGO 2012 classification based on the glomerular filtration rate calculated by MDRD (modification of diet in renal disease) and using the last value of serum creatinine before the start of treatment.

Results

Socio-demographic and clinical characteristics

We recruited 28 patients including 13 patients with maintenance haemodialysis and 15 non-dialysis patients. The mean age of our participants was 60.68 ± 13.00 years. The most represented age group was 60-79 years with a male predominance (60.7%).The main comorbidities encountered were hypertension (92.9%) and diabetes (46.4%). Cirrhosis was common in our population with a percentage of 42.9%. Glomerular involvement (diabetic nephropathy and chronic glomerulonephritis) was the most common. The majority of the study population were naïve about HCV treatment (96.4%). Entry into dialysis was the mode of discovery of HCV infection in 7.7% of the dialysis population. An incidence of HCV infection was found in 76.9% of haemodialysis patients. The mean dialysis duration was 63.1 ± 37.71 months (Table 1).

Paraclinical characteristics of study population

The median viral load was 902425 IU/ml copy. The genotypes were foundwere 1, 2 and 4. Cirrhosis was found in 43% of patients (Table 2).

Treatment regimens and virological response

The most prescribed combination therapies were fixed combinations of SOF/LDV (400/90) and SOF/VEL (400/100). Patients on maintenance haemodialysis were given one tablet at the end of each dialysis session. Only two patients (15. 4%) on dialysis received the treatment daily. Non-dialysis patients received one

Table 1: Socio-demographic and clinical characteristics of study population.

Characteristics	Haemodialysis N = 13	Not on dialysis N = 15	Total (%) N = 28
Age (year)			
< 40	2	0	2(7.1)
[40-59]	6	2	8(28.6)
[60-79]	5	12	17(60.7)
≥ 80	0	1	1(3.6)
Gender			
Male	8	9	17(60.7)
Female	4	7	11(39.3)
Comorbidities			
HTA	12	14	26(92.9)
Diabetes	4	9	13(46.4)
HIV	1	1	2(7.1)
Cirrhosis	5	7	12(43)
Compensated	4	5	9(75)
Decompensated	1	2	3(25)
Baseline nephropathy			
Chronic tubulointerstitial nephritis	2	0	2(7.2)
Ischemic nephropathy	1	2	3(10.7)
Diabetic nephropathy	0	3	3(10.7)
Nephroangiosclerosis	3	1	4(14.3)
Chronic glomerulonephritis	4	3	7(25)
Indeterminate nephropathy	3	6	9(32.1)
HCV therapeutic status			
Naive	13	14	27(96.4)
Relapse (INF-Peg / RBV)	0	1	1(3.6)
Mean duration in haemodialysis (months)	63.1 ± 37.7	/	/
Virological status at dialysis initiation			
Positive	1(7.7)	/	/
Negative	10(76.9)	/	/
Unknown	2(15.4)	/	/
Median age of HCV diagnosis	/	/	6 [3-8.5]

HTA: Hypertension; HIV: Human Immunodeficiency Virus; INF-Peg: Pegylated interferon; RBV: ribavirin

tablet daily (n = 12) and one tablet twice weekly (n = 3) (Table 3). Two patients with cirrhosis were treated for 24 weeks with the combination of SOF 400/DCV 60. The rapid virological response was obtained in 83.3% and the cure rate (sustained virological response) was 100% in our population regardless of the treatment regimen (Table 4 and Table 5).

Adverse effects

The main adverse effects encountered were: Digestive (vomiting, diarrhoea), neurological (headache, dizziness) and cutaneous (pruritus). Treatment was discontinued for intolerance in a patient who was taking the drug daily. Patients on haemodialysis experienced

Table 2: Paraclinical characteristics of study population.

Characteristics	Haemodialysis N = 13	Not on dialysis N = 15	Total (%) N = 28
Median viral load (IU/ml)	/	/	902425 [195763-2208263]
Genotype			
4	5	7	12(42.9)
1	2	3	5(17.8)
2	2	1	3(10.7)
Undetermined	5	3	8(28.6)
Fibrosis			
F0/F1	3	2	5(17.8)
F2	1	4	5(17.8)
F3	1	2	3(10.7)
F4	5	7	12(43)
Undetermined	2	1	3(10.7)
Serum creatinine (mg/l)	/	34.3 ± 9.7	/
DFG according to MDRD (ml/min/1.73 m²)	/	22.3 ± 5.7	/
ALT (UI/ml)	/	/	39.79 ± 22.70
ASAT (UI/ml)	/	/	38.94 ± 20.91

Table 3: Therapeutic regimens of study population.

Combination Antiviral		Dosage			
		1 tablet per day	1 tablet x 2 per week	1 tablet x 3 per week	Total (%) N = 28
SOF 400/RBV 200*	Haemodialysis	0	1	0	1 (3.6)
SOF 400/DCV 60**	Not on dialysis	6	0	0	6 (21.6)
SOF/VEL (400/100)***	Haemodialysis	1	2	0	9 (32.4)
	Not on dialysis	5	1	0	
SOF/LDV (400/90)***	Haemodialysis	1	7	1	12 (43.2)
	Not on dialysis	1	2	0	

SOF: Sofosbuvir; RBV: Ribavirin; DCV: Daclatasvir; LDV: Ledipasvir; VEL: Velpatasvir

*RBV was taken daily; **daily intake of both molecules;comp: tablet; ***fixed suit.

Table 4: Virological response.

Virological response	Haemodialysis patients	Not on dialysis patients	Total (%)
RVR (n = 12)	5	5	10(83.3)
SVR12 (n = 21)	9	12	21(100)
SVR24 (n = 16)	7	9	16(100)

RVR: Rapid Virological Response; SVR12: Sustained Virological Response at week12; SVR24: Sustained Virological Response at week 24.

Table 5: Virological response according to the treatment regimen.

	SOF/DCV	SOF/LDV			SOF/VEL		SOF/RBV	Actual
	1 tab/d (n = 5)	1 tab/d (n = 2)	2 tab/week (n = 4)	3 tab/week (n = 1)	1 tab/d (n = 3)	2 tabs/week (n = 5)	2 tabs/week (n = 1)	
RVR	4(80)	0(0)	4(100)	/	1(100)	1(100)	/	10(81.8)
SVR12	5(100)	2(100)	4(100)	1(100)	3(100)	5(100)	1(100)	21(100)

RVR: Rapid Virological Response; SVR12: Sustained Virological Response at week 12; 1 tab/d: One tablet per day; 2 tabs/week: One tablet twice a week; 3 tabs/week: One tablet three times a week.

Table 6: Adverse effects by dialysis status or not.

	Not on dialysis		Haemodialysis		Total (%)
	1 tab day	**1 tab × 2 per week**	**1 tab per day**	**1 tab × 2 per week**	
Vomiting	1	1	1	0	3(10.7)
Nausea	1	1	1	0	3(10.7)
Headache	1	1	0	0	2(7.1)
Dizziness	1	1	0	0	2(7.1)
Pruritus	1	0	0	1	2(7.1)
Diarrhoea	0	1	0	0	1(3.6)
Anaemia*	0	0	0	1	1(3.6)
Stopping treatment	1	0	0	0	1(3.6)

*In patients taking ribavirin.

Table 7: Adverse effects by combination.

	SOF/DCV (400/60)	**SOF/LDV (400/90)**		**SOF/VEL (400/100)**		**SOF400/RBV 200***
	1 tab per day	**1 tab per day**	**1 tab × 2 per week**	**1 tab per day**	**1 tab × 2 per week**	**1 tab × 2 per week**
Headache	0	0	0	1	1	0
Nausea	0	1	0	1	1	0
Diarrhoea	0	0	0	0	1	0
Dizziness	0	0	0	1	1	0
Vomiting	0	1	0	1	1	0
Pruritus	1	0	0	0	1	0
Anaemia	0	0	0	0	0	1
Stopping treatment	0	0	0	1	0	0

*RBV 200 mg was taken daily; tab: tablet; week: week; SOF: Sofosbuvir; DCV: Daclatasvir; LDV: Ledipasvir; VEL: Velpatasvir.

fewer adverse effects than non-dialysis patients (Table 6). Sofosbuvir + ledipasvir and sofosbuvir + daclatasvir were best tolerated in our population (Table 7).

Evolution of renal function in non-dialysis patients

Serum creatinine increased during treatment and then decreased when treatment was discontinued (Figure 1). At the same time, the glomerular filtration rate decreased during treatment and approached the initial value after discontinuation of treatment (Figure 2).

Discussion

This retrospective and observational study involving 28 patients enrolled at YGH, DGH, CMC, UTHY aimed to describe the efficacy and safety of treatment regimens containing sofosbuvir in patients with viral hepatitis C and chronic kidney disease grade 4 and 5. It appears that all combination therapies containing sofosbuvir were effective with a cure rate of 100%, the undesirable effects are minor and well tolerated. The mean age of our participants was 60.68 ± 13.00 years. The most represented age group was 60-79 years (60.7%). This is close to the results of other studies on viral hepatitis C in Cameroon suggesting a cohort effect [16,17]. Li, et al. in a multicentric study of 24,642 patients found a significant association between advanced age, male sex, HCV infection and CKD [18]. This is in line with our study where men were in the majority (60.7%). Cirrhosis was found in 43%. This is related to the insidious course of

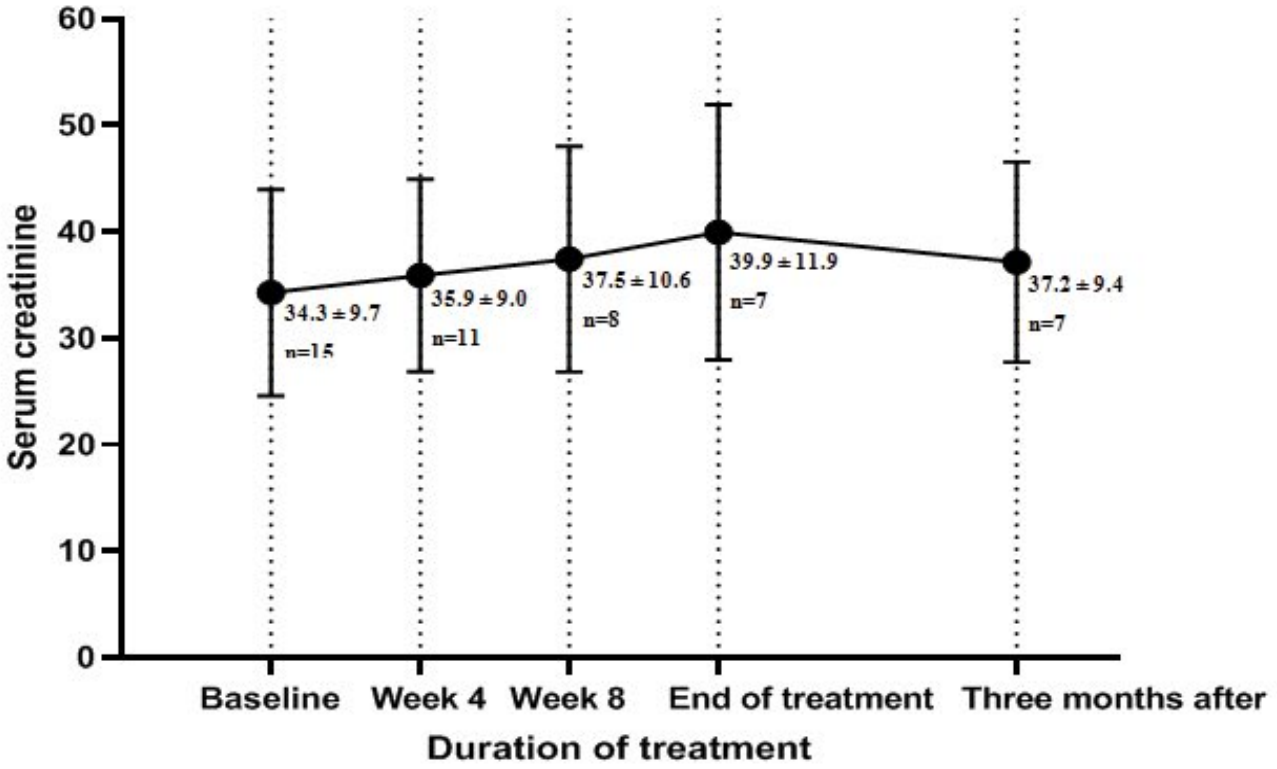

Figure 1: Evolution of serum creatinine during and after treatment.

infection, the diagnosis often made in the face of hepatic complications. The mean dialysis duration was 63.1 ± 37.7 months. An incidence of HCV infection of 76.9% was found in haemodialysis patients. This is a result of greater exposure to blood products, transmission of the disease from one patient to another in dialysis units, and dialysis duration [19,20]. The genotypes foundwere 1, 2 and 4. These three genotypes are those present in Cameroon with a predominance of genotypes 1 and 4 according to studies [21-24].

Our study population benefited from several treatment regimens. We achieved a RVR in 83.3%. Rates ranging from 88.3 to 100% have been reported in literature [25-29]. Historically, RVR has been a predictor of healing [30,31]. The different treatment regimens in our study did not affect the virological response. The SVR rate at week 12 was 100% in our population. The efficacy of full-dose sofosbuvir combinations has been demonstrated in several studies in patients with grade 4 and 5 chronic kidney disease with SVR rates greater than 90% [26,32-36]. This high level may be related to the observation that sofosbuvir produces similar concentrations of active intracellular metabolites independently of renal function [37]. Salim, et al. had a SVR rate of 82.6% [38], Lawitz, et al. in 10 patients receiving sofosbuvir 400 mg + ribavirin 200 mg per day achieved a SVR rate of 60% [39]. In the first case, 13% of patients relapsed to the SOF/RBV combination. In the second case the majority of patients were genotype 1 and adherence to treatment was poor due to adverse effects. The fear with the full dose of sofosbuvir in patients with CKD is the risk of worsening adverse reactions because of GS-331007, the main metabolite of sofosbuvir is eliminated 80% renally and the decrease in GFR leads to an increase in its plasma concentrations [13,37]. As a result, several studies have been conducted with reduced doses of sofosbuvir using either half daily doses or an alternating full dose. The combination of sofosbuvir 200 mg daily with daclatasvir 60 mg daily has been shown to be effective with cure rates of 90-100% [25,29,40,41]. Similarly, combinations with an alternating full dose of sofosbuvir were effective with cure rates of 82.3 to 100% [27,28,42]. These different results are in line with ours.

The adverse effects encountered in our study were mainly digestive (nausea and diarrhoea), neurological (headache, dizziness) and cutaneous (pruritus). The frequency of these events in literature was reported in a heterogeneous way according to various studies. Indeed, Surendra, et al. reported only neurological symptoms such as headache and dizziness in 5.2% of patients [28], Taneja, et al. reported headache in 3.9%, fatigue in 7.8% and nausea in 11.7% [36]. These rates are close to those we found in our study. Haemodialysis patients had fewer adverse effects than non-dialysis patients. This is probably related to the reduced treatment doses as only two haemodialysis patients (15.4%) took the treatment daily. The combinations of sofosbuvir + daclatasvir and sofosbuvir + ledipasvir were best tolerated. One patient discontinued treatment in our study. It was a patient with decompensated cirrhosis and hepatocellular carcinoma. Anaemia was found in the patient receiving

the combination of sofosbuvir plus ribavirin, which is an expected adverse effect with the use of ribavirin. Indeed, ribavirin is responsible for hemolytic anaemia and accumulates in case of renal failure [43].

In our study, there was a decrease in mean GFR upto 12 weeks. After discontinuation of treatment, the GFR approached the baseline value (Figure 2). Previous studies have reported similar results with respect to deterioration of kidney function. In Dumortier, et al, Taneja, et al, Cox-North, et al. the variations in GFR were respectively 29 ml/min/1.73 m^2 to 27 ml/min/1.73 m^2, 24.84 ± 3.93 to 24.39 ± 3.96 ml/min/1.73 m^2 and 22 ml/min/1.73 m^2 to 20 ml/min/1.73 m^2 respectively [33,41,44]. The pathophysiology of deterioration of renal function in patients receiving sofosbuviris not fully elucidated. Renal biopsy performed in a number of patients found tissue alterations consistent with acute interstitial nephritis [45]. After discontinuation of treatment, there is an improvement in GFR approaching baseline [46].

Limitations and Difficulties of the Study

The main limitations of the study were:

- Small sample size;
- Difficulty in linking the appearance of a symptom as adverse effects of sofosbuvir therapy since our patients were polymedicated and had with several comorbidities;
- Irregular follow-up, which may obscure some minor side effects since some patients were seen at the initiation of treatment and only at the end of it.

Strength of the Study

The strength of this study:

- Different treatment regimens used to treat patients;
- One of the few studies that used fixed combinations of DAAs at alternating doses

Conclusion

This study shows that:

- All antiviral combinations based on sofosbuvir are effective in treating patients with chronic viral hepatitis C and chronic kidney disease with glomerular filtration rate < 30 ml/min/1.73 m^2 or on dialysis.
- The combinations of sofosbuvir/daclatasvir and sofosbuvir/ledipasvir are well tolerated;
- Patients on haemodialysis have fewer adverse reactions than non-dialysed patients;
- Decrease in renal function is only observed during the treatment period.

Conflict of Interest

None.

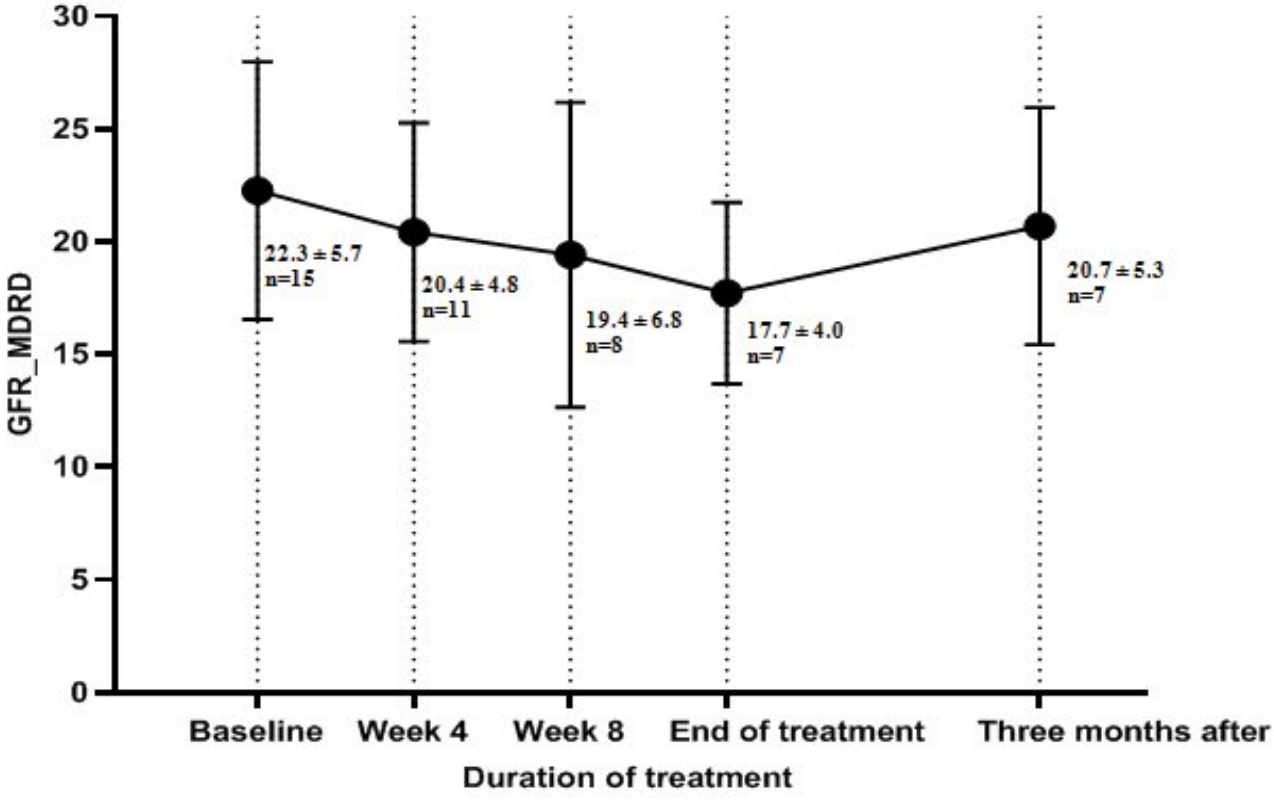

Figure 2: Evolution of GFR during and after treatment.

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Authors' Contribution

All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

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