

# RENAL FUNCTION EVOLUTION IN PATIENTS INFECTED WITH HEPATITIS C VIRUS (HCV) AND BASELINE ESTIMATED GLOMERULAR FILTRATION RATE (eGFR) BETWEEN 30–60 ML/MIN/1,73 M<sup>2</sup> TREATED WITH OMBITASVIR/PARITAPREVIR/RITONAVIR AND DASABUVIR (3D) VS REGIMENS BASED ON SOFOSBUVIR (SOF).

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## INTRODUCTION

- Guidelines and recommendations of the IFN free regimens based on DAAs to treat chronic HCV infection according to the renal function of the patient, only takes into consideration the contraindication of SOF use in patients with a glomerular filtration rate (GFR) under 30 ml/min, due to its nephrotoxic effect and to the increase in the concentration of metabolites that increase side effects. However, there is no evidence of patients treated with SOF with a GFR between 30 – 60 ml/min, since this patient profile has not been studied in clinical development studies. On the other side, it has been studied with 3D but with limited evidence.

## OBJECTIVE

- To determine the change on eGFR on week 12 post-treatment in patients with a baseline eGFR between 30 – 60 ml/min treated with 3D with or without RBV or SOF-based regimens also with or without RBV.

## MATERIALS AND METHODS

- 43 HCV patients were studied with a baseline eGFR between 30 – 60 ml/min measured by the MDRD4 formula. 8 patients were treated with 3D (5 of them with RBV), 35 with SOF (31 with Harvoni, 1 with RBV and 3 with simeprevir). The eGFR was analyzed at week 12 post-treatment and so was the virological response

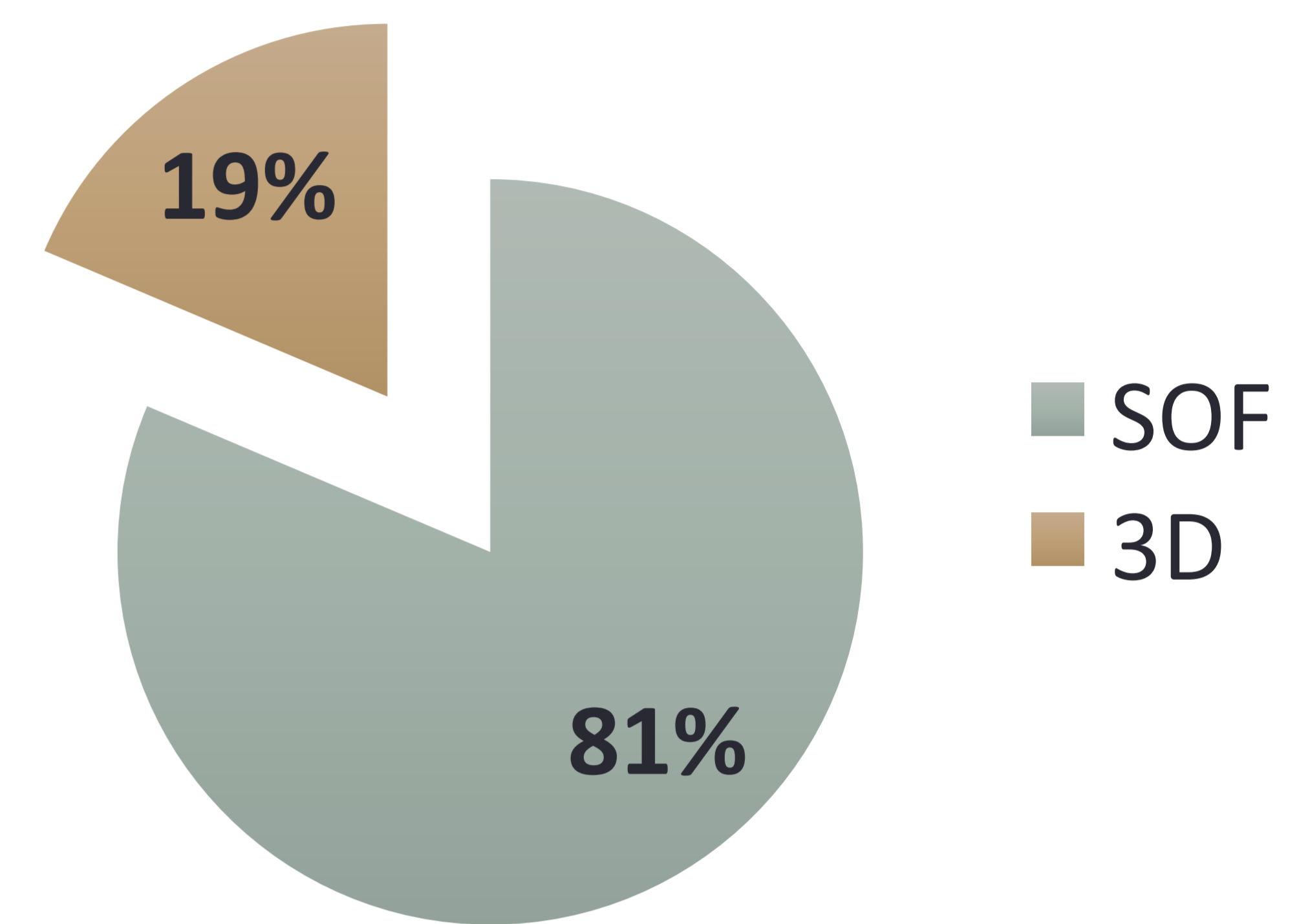


Figure 1. Number of patients and types of treatments used

## RESULTS

The change in eGFR with the 3D regimen (baseline vs 12w) was  $56.6 \pm 12.6$  vs  $51.7 \pm 13.1$  ml/min (ns), and with SOF  $57.8 \pm 14.7$  vs  $48.6 \pm 11.1$  ml/min ( $p=0.004$ ). None of the patients with a decrease over a 20% in eGFR vs baseline were treated with 3D and 12 of them (34.3%) were treated with SOF. Proteinuria was measured on 14 patients: 1 on 3D and 13 on SOF. Proteinuria decreased more than 20% in the patient treated with 3D and in 8 of 13 (61.5%) treated with SOF. Out of a total 26 patients, 10 patients showed a positive proteinuria that was not modified with the treatment; out of those only 3 had a proteinuria higher than 1 gr/mg. Only three patients showed hematuria.

|             | Baseline        | Post-treat      | p     |
|-------------|-----------------|-----------------|-------|
| OMB/PTV/DBV | $56.6 \pm 12.6$ | $51.7 \pm 13.1$ | ns    |
| SOF         | $57.8 \pm 14.7$ | $48.6 \pm 11.1$ | 0.004 |

Table 1. Change in eGFR (ml/min) according to type of treatment used

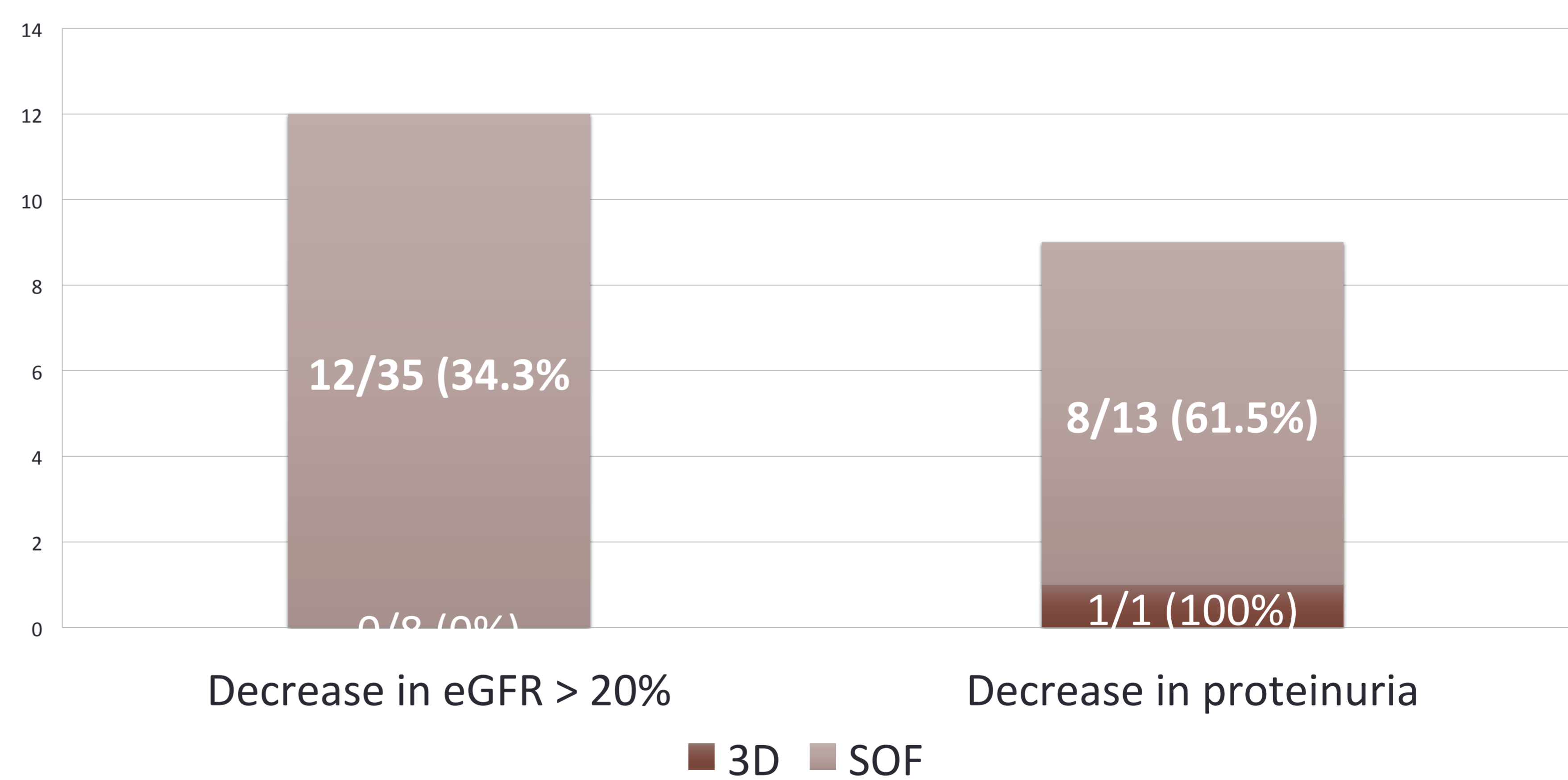


Figure 2. Decrease in eGFR (higher than 20%) and in proteinuria according to type of treatment used.

## CONCLUSIONS

- Renal function impairment has been observed on those patients with a baseline eGFR between 30-60 ml/min and treated with sofosbuvir-based therapies ( $p=0.004$ ) and not on those treated with 3D (ns).
- 34% of the patients treated with sofosbuvir had over a 20% decrease in the eGFR after treatment.
- Neither the proteinuria nor the hematuria were corrected post-treatment.