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# Efficacy and safety of Paritaprevir/Ritonavir + Ombitasvir ± Dasabuvir ± Ribavirin in chronic hepatitis C patients with chronic renal failure

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**INTRODUCTION:** Chronic hepatitis C (CHC) is common in patients with chronic kidney disease who are on hemodialysis. Because sofosbuvir is eliminated mainly by kidney, sofosbuvir-based regimens are not recommended in patients with estimated glomerular filtration rate (eGFR) < 30 ml/dak/1,73 m². In the present study, we aimed to evaluate the efficacy and safety of paritaprevir/ritonavir+ombitasvir+dasabuvir (PrOD) or paritaprevir/ritonavir+ombitasvir (PrO) in CHC patients with chronic renal failure (CRF) who were on hemodialysis.

**METHODS:** We retrospectively reviewed our data of CHC patients with CRF who received PrOD or PrO ± ribavirin. Patients who completed therapy and came to follow up 12 weeks after therapy were included in the study. Baseline patient characteristics, and serum HCV RNA and ALT values at week 4, at the end of therapy and at 12 week after therapy were recorded.

**FINDINGS:** Thirteen patients were included in the study. Nine (69,2%) of them were female and the mean age was 56,4±13,2 years. At baseline, the mean serum HCV RNA level was 3.139.139±3.962.729 IU/mL (range, 8.297-13.918.459 IU/mL) and the mean ALT level was 28,5±19,6 IU/L. Nine patients had genotype 1b, 2 patients had genotype 1a and 2 patients had genotype 4a infections. Three patients had compansated cirrhosis. Nine patients were treatment naive and 4 patients were pegylated interferon-α experienced. Of them, 9 patients with HCV genotype 1b infection (2 patients had compansated cirrhosis) received PrOD for 12 weeks, 1 patient with HCV genotype 1a infection received PrOD+ribavirin for 12 weeks, 1 patient with HCV genotype 1a infection (with compansated cirrhosis) received PrOD+ribavirin for 24 weeks and 2 patients with HCV genotype 4a infection received PrO+ribavirin. All patients completed the scheduled therapy regimen. At week 4 and at the end of therapy, HCV RNA were negative in all patients and ALT were normal/normalized in all patients. At 12 week after therapy, HCV RNA were negative in all patients (SVR12 100%) and ALT were normal/normalized in all patients. The most common adverse event was anemia (6 patients, 46,2%). Grade 1 anemia developed in 3 patients and grade 2 anemia developed in 3 patients, while grade 3 anemia did not develop in any patient. The mean reduction in haemoglobin level was 1,4 g/dL. However, treatment was not discontinued in any patient. Erythrocyte transfusion was required in only 1 patient.

**CONCLUSION:** All chronic hepatitis C patients with CRF who were on hemodialysis in our cohort achieved SVR12 after PrOD±ribavirin or PrO+ribavirin therapy for 12/24 weeks. Treatment was well tolerated in all patients. The most common adverse event was anemia.

**Keywords:** HCV, CRF, paritaprevir/ritonavir+ombitasvir±dasabuvir±ribavirin, SVR12

| **Table 1: Baseline patient characteristics** | |
|---|---|
| Age (years) | 56,4±13,2 |
| Gender (female) | 9 (69,2%) |
| HCV RNA (IU/mL) | 3.139.139 ± 3.962.729 |
| Genotype (1a / 1b / 4a) | 2 / 9 / 2 |
| Creatinin (mg/dL) | 5,92±1,33 |
| AST (IU/L) | 24,23±13,83 |
| ALT (IU/L) | 28,54±19,61 |
| ALP (IU/L) | 156,00±71,84 |
| GGT (IU/L) | 60,38±50,26 |
| Albumin (g/dL) | 3,95±0,37 |
| Bilurubin (mg/dL) | 0,68±0,30 |
| INR | 1,06±0,09 |
| Hemoglobin (g/dL) | 12,71±2,36 |
| Platelet (x1.000) | 176,75±63,46 |
| Cirrhosis | 3 (23,1%) |

| **Table 2: Laboratory parameters at follow up** | | | |
|---|---|---|---|
| | Week 4 | End of therapy | Week 12 after therapy |
| Undetectable HCV RNA | 100% | 100% | 100% |
| Creatinin (mg/dL) | 5,01±1,02 | 5,21±1,80 | 5,81±1,62 |
| AST (IU/L) | 12,83±5,32 | 13,77±5,85 | 12,75±5,02 |
| ALT (IU/L) | 10,25±2,52 | 11,77±6,93 | 10,17±3,95 |
| ALP (IU/L) | 156,75±72,57 | 142,17±41,47 | 141,64±55,39 |
| GGT (IU/L) | 31,00±20,63 | 22,83±9,79 | 24,91±17,23 |
| Albumin (g/dL) | 3,70±0,22 | 4,06±0,41 | 4,21±0,23 |
| Bilurubin (mg/dL) | 1,02±0,50 | 0,70±0,25 | 0,71±0,23 |
| INR | 1,08±0,05 | 1,07±0,07 | 1,09±0,10 |
| Hemoglobin (g/dL) | 11,27±1,32 | 11,09±2,02 | 13,23±1,08 |
| Platelet (x1.000) | 204,98±70,17 | 220,70±88,62 | 198,18±66,65 |