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Characteristics associated with adverse events in patients with chronic C virus hepatitis treated with ombitasvir/paritaprevir/ritonavir and dasabuvir and ribavirin

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Background: In our country, the national program for hepatitis C virus (HCV) treatment with ombitasvir/paritaprevir/ritonavir and dasabuvir (OBV/PTV/r/DSV), with/without ribavirin was approved for patients with stage 4 of liver fibrosis and stage 3 associated with type 1 diabetes mellitus, autoimmune diseases and severe depression. **Objective:** Our aim was to analyze the characteristics associated with the presence of adverse events (AE) in patients receiving OBV/PTV/r/DSV, with ribavirin for cirrhosis patients.

Material/methods: Prospective cohort study of adults with HCV infection, stage 3 or 4 of liver fibrosis, treated for 12 weeks, between December 2015-November 2016, in a tertiary-care hospital. We defined the AE as 1) mild if the patient accused a transient discomfort (<48 hours), with no medical intervention required, 2) moderate if the AE implied moderate limitation in activity without or with minimal therapy required and 3) severe if the AE implied marked limitation in activity, with medical intervention required and possible hospitalization.

Results: We included 95 patients, 89 patients with fibrosis stage 4 and 6 patients with fibrosis stage 3. Forty-nine (52%) were male and the median age was 64 years (IQR: 58-69). All patients had genotype 1b and the median viral load was 1.020.000 UI/mL. Sixty-three (66%) patients had previous antiviral treatment. At the end of current treatment, 93(98%) had undetectable viral load. The median Charlson comorbidity index was 3(IQR: 2-4). We recorded 155 episodes of AE in 71(75%) patients. The median number of AE per patient was 2(IQR: 0-3), with 31(44%) patients with one AE, 13(18%) two AE, 13(18%) three AE and 14(20%) more than three AE. The most frequently reported AE were: pruritus (14%), hyperbilirubinemia (14%), anemia (10%), insomnia (10%) and asthenia (8%). The intensity of AE was classified as mild in 45%, moderate in 38% and severe in 17% patients. Forty-two (27%) episodes of AE required medical intervention. The AE outcome was favorable in 89(59%) episodes and in 60(39%) cases the AE persisted after the end of treatment. One patient died during the therapy (severe respiratory sepsis) and one patient interrupted the treatment after 2 weeks for an unrelated to treatment cause. The AE were more frequent in patients with vs without: esophageal varices 19(83%) vs 4(17%), comorbidities 45(70%) vs 19(30%), co-medication 38(70%) vs 16(30%), age over 70 years 13(62%) vs 8(38%), albumin value less than 4g/L 20 (74%) vs 7 (26%), platelet count less than 90000/dL 13(76%) vs 4(24%) and alpha-fetoprotein level more than 20ng/mL 16(76%) vs 5(24%), but without statistical significance.

Conclusions: Although a high number of patients reported AE, most of them were mild or moderate. One third of the patients with AE required medical intervention. The AE persisted after the end of antiviral treatment in one quarter of patients.