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

• OBV/PTV/r/DSV with or without ribavirin is indicated for the treatment of HCV infection in both treatment-naïve and experienced patients, with genotype 1 and 4 infections
• In Romania, the treatment with OBV/PTV/r/DSV 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: to analyze the characteristics associated with the presence of adverse events (AE) in patients receiving OBV/PTV/r/DSV, with or without ribavirin

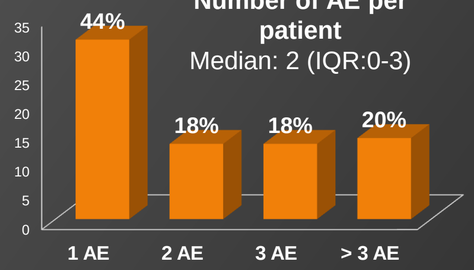
Methods

• Prospective cohort study of adults with HCV infection, stage 3 or 4 of liver fibrosis, genotype 1b
• Treatment with OBV/PTV/r/DSV, with or without ribavirin, for 12 weeks, between December 2015-November 2016, in a tertiary-care hospital
• Definition of AE:
➢ **Mild** = the patient accused a transient discomfort (<48 hours), with no medical intervention required
➢ **Moderate** = with moderate limitation in activity without or with minimal therapy required
➢ **Severe** = with marked limitation in activity, with medical intervention required and possible hospitalization

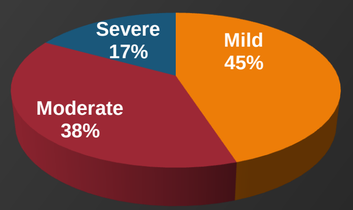
Results

• **95 patients** → F3 = 6
→ F4 = 89
• Male sex: 49 (52%)
• Age median: 64 ani (IQR: 58-69)
• Charlson comorbidiy index median: 3 (IQR: 2-4)
• Median VHC-RNA at initiation: 1.020.000 IU/ml
• Previous antiviral treatment: 63 patients → Non-responder: 35
→ Relapser: 28
• **155 AE** recorded in **71 (75%) patients**

Number of AE per patient
Median: 2 (IQR:0-3)



Severity of AE



Most frequent AE:

• pruritus (14%)
• hyperbilirubinemia (14%)
• anemia (10%)
• insomnia (10%)
• asthenia (8%)

• **42 (27%)** episodes required medical intervention
• **89 (59%)** episodes – rapidly resolution
• **60 (39%)** episodes – persistence of AE after the end of treatment

	Patients with adverse events N=71 N(%) or Median(IQR)	Patients without adverse events N=24 N(%) or Median(IQR)	p OR (95% CI)
Male sex	35 (49)	14 (58)	0.4 0.7 (0.2-1.7)
Age in years	63 (58-68)	65 (56-70)	0.9
ARN-VHC, IU/L	1.094.579 (481.750-2.146.158)	785.000 (236.750-1.100.000)	0.3
Comorbidities	45 (63)	19 (79)	0.1 0.4 (0.1-1.3)
Co-medication	38 (54)	16 (67)	0.2 0.5 (0.2-1.5)
Esophageal varices*	19 (27)	4 (17)	0.4 1.6 (0.4-6.05)
Albumin value, g/L	4.2 (3.8-4.5)	4.2 (3.9-4.6)	0.9
Platelet count, cells/dL	137.000 (95.000-194.000)	122.000 (96.000-159.000)	0.1
Alpha fetoprotein level, ng/mL	11.6 (7.4-30.79)	13.2 (8.4-22.6)	0.3

* 65 patients were evaluated

Conclusion

• Most of the AE were mild or moderate
• One third of the AE required medical intervention
• The presence of AE was not associated with patients baseline characteristics

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