EFFECTIVENESS AND SAFETY OF SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR FOR RETREATMENT OF CHRONIC HEPATITIS C PATIENTS WITH A PREVIOUS FAILURE TO DIRECT-ACTING ANTIVIRALS: A REAL-LIFE STUDY FROM THE NAVIGATORE LOMBARDIA AND VENETO NETWORKS


BACKGROUND

Sofosbuvir/Velpatasvir/Voxilaprevir (SOF/VEL/VOX) is approved for retreatment of hepatitis C (HCV) patients with a previous failure to direct-acting antivirals (DAA), however real-life data are still limited.

OBJECTIVES

Aim of the study was to assess effectiveness and safety of SOF/VEL/VOX combination in an Italian real-life setting.

MATERIALS & METHODS

All consecutive HCV patients receiving SOF/VEL/VOX between May-October 2018 in 27 centers in Northern Italy were enrolled.

Bridging fibrosis and cirrhosis were diagnosed by liver stiffness measurement (LSM): >10 and >13 kPa for F3 and F4, respectively.

Sustained virological response (SVR) was defined as undetectable HCV-RNA 4 (SVR4) or 12 (SVR12) weeks after the end of treatment (EOT).

Resistance associated substitution (RAS) testing was performed by direct sequencing (threshold 15%).

RESULTS

Overall, 82% of patients carried resistance associated substitutions (RAS) in the NS3, NS5A or NS5B regions (Figure 1).

Patients received SOF/VEL/VOX for 12 weeks. Ribavirin (RBV) was added in 22% of treatment schedules.

Cirrhosis (p=0.03) and detectable HCV-RNA at treatment week 4 (p=0.03) were associated with treatment failure.

Most frequent adverse events included fatigue (7%), hyperbilirubinemia (6%) and anemia (3%).

CONCLUSIONS

SOF/VEL/VOX is an effective and safe retreatment for HCV patients failing a previous DAA course in a real-life setting.

REFERENCES

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