EFFICACY AND SAFETY OF SIMEPREVIR-CONTAINING HEPATITIS C THERAPY IN PATIENTS ON OPIATE SUBSTITUTION THERAPY

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Background:
Simeprevir (SMV) is an HCV protease inhibitor approved in combination with pegylated-interferon/ribavirin (PR) or sofosbuvir. SMV has no or no expected drug-drug interactions with common opiate substitution therapy (OST) medications. We investigated if efficacy, safety, and concomitant medication needs differed in SMV-treated patients on OST vs. not on OST.

Methods:
We report a post-hoc pooled analysis of the efficacy and safety of SMV-containing regimens in patients on OST (N=83) vs. not on OST (NOST; N=2356). Concomitant medications and medical history of patients participating in 11 phase 2/3 studies and 1 US observational phase 4 study were reviewed.

Results:
OST patients were more frequently male (73% vs. 63%), infected with GT1a (75% vs. 49%), HIV-infected (8.4% vs. 5.1%) and treatment-naïve (70% vs. 58%) compared to NOST patients; 26% of OST and 21% of NOST patients had cirrhosis.
SVR12 rates were similar in OST and NOST patients (SMV+PR: 70% vs. 71%; interferon-free SMV 84% vs. 87%). Overall, OST patients more frequently received concomitant medications at baseline than NOST patients, including benzodiazepines, antidepressants and non-OST opioids (47% vs. 24%). Concomitant medications use increased both in OST and NOST patients during treatment; this increase was more pronounced with PR-containing therapy. Non-OST opioid use remained stable in OST patients; 8.4% (7/83) of OST patients either changed the OST dose or stopped OST permanently. The safety profile during the first 12 weeks of SMV therapy was similar in OST and NOST patients. Three OST patients discontinued SMV due to an AE, which occurred under SMV+PR treatment; One of them (rash) was considered SMV-related. In OST patients, none of 6 reported serious AEs was deemed SMV-related.

Conclusion:
Simeprevir-containing regimens in OST patients using a substantial number of concomitant medications were well tolerated and resulted in SVR rates similar to those in the general HCV population.

Disclosure of Interest

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