EFFICACY AND SAFETY OF SOFOSBUVIR-BASED DIRECT-ACTING ANTIVIRAL (DAA) THERAPIES FOR HCV INFECTION IN PATIENTS RECEIVING OPIOID SUBSTITUTION THERAPY (OST)

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Background: HCV DAA therapy is effective among people receiving OST, but most studies are limited by small numbers of HCV non-genotype 1 (GT1) patients. Our aim was to evaluate treatment completion, adherence, sustained virologic response (SVR12), and safety of sofosbuvir-based therapies in HCV GT1-6 patients receiving and not receiving OST.

Methods: Phase 3 studies of sofosbuvir-based regimens included ION (ION-1, -2, -3; sofosbuvir/ledipasvir ± ribavirin for 8, 12, or 24 weeks in GT1), ASTRAL (ASTRAL-1, -2, -3; sofosbuvir/velpatasvir for 12 weeks in GT1-6), and POLARIS (POLARIS-1, -2, -3, -4; sofosbuvir/velpatasvir and sofosbuvir/velpatasvir/voxilaprevir in GT1-6). People with clinically significant drug use (within prior 12 months) or non-cannabinoids detected at screening by urine drug tests (not explained by prescriptions) were ineligible.

Results: Among 4743 patients, 4% (n=194) were receiving OST (buprenorphine, n=35; buprenorphine/naloxone, n=40; methadone; n=113; and other, n=6). Compared to those not receiving OST (n=4549), those receiving OST (n=194) were younger (mean age 48 vs. 54 years), and more often male (73% vs. 61%), GT3 (38% vs. 17%), treatment-naïve (78% vs. 66%), and cirrhotic (36% vs. 23%). Among those receiving and not receiving OST, there was no difference in treatment completion (97% vs. 99%; *P*=0.06), SVR12 (94% vs. 97%, *P*=0.06), relapse (0.5% vs. 2.1%, P=0.19), adverse events (78% vs. 77%, *P*=0.79), or serious adverse events (3.6% vs. 2.4%, *P*=0.24). SVR12 rates were high among those receiving methadone (95%) and buprenorphine or buprenorphine/naloxone (96%). Patients with cirrhosis who were receiving OST had a high SVR12 rate (99%) that was similar to those not receiving OST (95%; *P*=0.25). There was no difference in SVR12 among GT3 patients receiving and not receiving OST (95% vs. 95%, *P*=0.77). Minimal drug-drug interactions were observed between SOF-based regimens and commonly prescribed OST.

Conclusion: Sofosbuvir-based therapies are effective and safe in patients receiving stable OST.