

THE PREVAIL STUDY: INTENSIVE MODELS OF HCV CARE FOR PEOPLE WHO INJECT DRUGS

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Background:

People who inject drugs (PWID) are the main drivers of hepatitis C virus (HCV) infection yet many PWID are denied treatment. Optimal models of care for promoting sustained virologic response (SVR) in PWID have not been studied.

Methods:

PREVAIL is a randomized controlled trial that enrolled HCV-infected (genotype 1) PWID maintained on OAT, including those actively using drugs. Participants were randomized to one of three models of HCV care delivered on-site in an OAT program: 1) directly observed treatment (DOT), 2) group medical visit (Group), or 3) individual treatment as usual (TAU). Participants received DAAs according to AASLD guidelines: telaprevir/pegylated interferon/ribavirin (TVR/PEG/RBV), sofosbuvir/ribavirin (SOF/RBV), sofosbuvir/pegylated interferon/ribavirin (SOF/PEG/RBV), sofosbuvir/simeprevir (SOF/SMV), or sofosbuvir/ledipasvir (SOF/LDV). The primary outcome was SVR12 and secondary outcomes were end of treatment response (ETR) and SVR12. Drug use (opiates, cocaine, and benzodiazepines) was assessed through urine screens. Differences by arm were tested by a Fisher exact test, and the 95% confidence interval (CI) for virological outcomes were determined by the Clopper-Pearson method.

Results:

158 prospective trial participants were enrolled and randomized, and 150 initiated treatment: DOT (n=51), Group (n=48), and TAU (n=51). Participant characteristics include: mean age 51.2 (\pm 10.6); male, 65%; Latino, 56%; African-American, 27%; cirrhotic, 27%; HIV-infected, 14%; and depression, 25%. 65% used illicit drugs within 6 months of treatment and 51% had positive baseline urine screens. Overall, 96% (144/150) achieved ETR and 94% (95% CI 89% - 97%; 141/150) achieved SVR12: TVR/PEG/RBV (n=3, SVR12=100%); SOF/RBV (n=17, SVR12=88%); SOF/PEG/RBV (n=15, SVR12=93%); SOF/SMV (n=11, SVR12=100%); and SOF/LDV (n=104, SVR12=94%) with no significant differences among arms (p=0.24): DOT 98%, Group 94%, and TAU 90%.

Conclusion:

HCV care delivered on-site in an OAT program resulted in high rates of SVR among PWID despite ongoing drug use. Intensive models of care (DOT and Group) were more likely to result in SVR than TAU, but these differences were not significant.