Randomized Clinical Trial to Test E-health Interventions to Improve Adherence to a Once-daily Single-tablet Regimen in Patients with Chronic Hepatitis C Virus Infection

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Background: Interventions to promote hepatitis C virus (HCV) medication adherence in challenging populations are needed. The HepCure toolkit is a mobile application for patients and a provider web dashboard developed to increase patient engagement in HCV treatment.

Methods: Seventy-one patients initiating single-tablet treatment were recruited at an academic hospital. Patients used AdhereTech smart wireless pill bottles, which provided real-time data on bottle opening. 33 patients received no intervention (Arm 1). In the second phase, 38 patients were randomized to one of two interventions [Arm 2 -HepCure toolkit alone (n=19) or Arm 3 - HepCure toolkit + AdhereTech medication reminders (n=19)]. Adherence was examined over the 84 days immediately following treatment initiation in terms of Dosing Adherence (DA= percentage of days that bottle was opened at least once).

Results: Sixty-eight patients (Arm 1= 32; Arm 2 = 18; Arm 3 =18) had usable adherence data (male, 66.2%; black, 35.3%; Hispanic, 29.4%, mean age, 51.3±13.3). 89.7% were treatment naïve. 66.2% were on medication assisted therapy for opioid use disorder.

The mean DA was 92.3% (±11.8%). 55 patients achieved SVR12; 2 relapsed (both in Arm 1, treatment-naïve, genotype 1b, noncirrhotic) and 11 had unknown statuses due to loss to follow-up (2 in Arm 1; 4 in Arm 2 and 5 in Arm 3). There was no significant difference in adherence across patients in the study arms [Arm 1 mean=94.7% (±6.4); Arm 2 mean = 90.4% (±15.9%); Arm 3 mean = 89.9% (±14.2) p=0.28]. Adherence was lower in those who were lost to follow-up as compared to those with confirmed SVR statuses (DA Means = 94.5 vs. 81.0; p=0.03). Mean DA was above 90% in both patients who relapsed.

Conclusion: There was no indication that these e-health interventions improved adherence in this older sample. Interventions to improve retention to reach SVR12 monitoring are needed.