High Efficacy of HCV Treatment by Primary Care Providers: The ASCEND Study

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BACKGROUND

- Limited access to specialists and lack of provider expertise in hepatitis C (HCV) treatment remain significant barriers in the hepatitis C care cascade.
- Given the advent of directly acting antiviral therapy, we conducted a longitudinal trial to evaluate the efficacy and safety of primary care driven HCV treatment.

METHODS

- Multi-center, open label, phase IV clinical trial of 600 patients, with follow up ongoing.
- HCV patients of three community health centers in Washington DC were identified by their providers, consented, and distributed in a non-randomized manner to treatment from either a: nurse practitioner (NP), primary care physician (PCP), or specialist (GI/GI Infectious Disease or Hepatology).
- Providers underwent uniform 3-hour training on IDSA-AAASLD therapeutic guidelines.
- Patients were treated with ledipasvir and sofosbuvir (LDV/SOF) as per FDA label.
- The primary outcome was defined as unquantifiable HCV RNA viral load 12 weeks after completion of therapy (SVR12).
- Adherence to visits at 4, 8, and 12 weeks (all >7 to >14 days), were categorized by a composite score of attendance.
- Statistical analysis included chi-squared or Fisher’s exact test and logistic regression using SAS, version 9.3.

RESULTS

- Interim Per Protocol SVR12 by Provider Type (n=304): 94.9% (75/79) for NPs, 96.7% (58/60) for PCPs, 92.1% (152/165) for specialists, 93.8% (285/304) for total.

CONCLUSION

The ASCEND investigation demonstrates that HCV treatment administered independently by PCPs and NPs is safe and equally effective as care observed with experienced specialists, inclusive of challenging subpopulations of the epidemic, and within the largest African-American cohort described to date.

The ASCEND model could increase the availability of community-based, non-specialist providers to significantly expand the scale of HCV therapy, and bridge existing gaps in the hepatitis C care cascade.