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# 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 receive treatment from either a:
  - nurse practitioner (NP),
  - primary care physician (PCP), or
  - specialist (BC/BE Infectious Disease or Hepatology)
- Providers underwent uniform 3-hour training on IDSA-AASLD 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

| Characteristic | Total Cohort (n=600) | Treating Provider | | |
|---|---|---|---|---|
| | | NP (n=150) | PCP (n=156) | Specialist (n=294) |
| Age | 58.7 | 58.2 | 59 | 58.7 |
| Male (%) | 416 (69.3) | 109 (72.7) | 114 (73.1) | 193 (65.7) |
| Race (%) | | | | |
| Black* | 578 (96.3) | 140 (93.3) | 156 (100) | 282 (95.9) |
| White | 20 (3.3) | 9 (6.0) | 0 | 11 (3.7) |
| Other | 2 (0.3) | 1 (0.2) | 0 | 1 (0.2) |
| Infection Status | | | | |
| HCV | 458 (76.3) | 127 (84.7) | 109 (69.9) | 222 (75.5) |
| HIV/HCV* | 142 (23.7) | 23 (15.3) | 47 (30.1) | 72 (24.5) |
| Genotype | | | | |
| 1a | 431 (71.8) | 104 (69.3) | 113 (72.4) | 214 (72.8) |
| 1b | 169 (28.2) | 46 (30.7) | 43 (27.7) | 80 (27.2) |
| Fibrosis | | | | |
| 0 | 80 (13.3) | 22 (14.7) | 20 (12.8) | 38 (12.9) |
| 1 | 90 (15) | 23 (15.3) | 29 (18.6) | 39 (12.9) |
| 2 | 212 (35.3) | 54 (36.0) | 50 (32.1) | 108 (36.7) |
| 3 | 97 (16.2) | 22 (14.7) | 29 (18.6) | 46 (15.7) |
| 4 | 121 (20.2) | 29 (19.3) | 28 (18.0) | 64 (21.8) |
| Previous Treatment (%) | | | | |
| Experienced | 106 (17.7) | 29 (19.3) | 27 (17.3) | 50 (17.0) |
| Naive | 494 (82.3) | 121 (82.7) | 129 (80.7) | 244 (82.9) |
| HCV Viral Load | | | | |
| Baseline (IU/mL) | 3.61m | 3.22m | 3.93m | 3.64m |
| < 6 million | 484 (80.7) | 125 (83.3) | 124 (79.5) | 235 (79.9) |
| > 6 million | 116 (19.3) | 25 (16.7) | 32 (20.5) | 59 (20.1) |
| Treatment Duration | | | | |
| 8 weeks | 29 (4.9) | 7 (4.7) | 3 (1.9) | 19 (6.5) |
| 12 weeks | 537 (89.8) | 136 (90.7) | 148 (94.9) | 253 (86.6) |
| 24 weeks | 32 (5.4) | 7 (4.7) | 5 (3.2) | 20 (6.9) |

**Table 1.** Baseline and Treatment Characteristics of Total Cohort and Patients by Provider Type. Provider cohorts were comparable with significant differences in race and HIV status (p=.01).

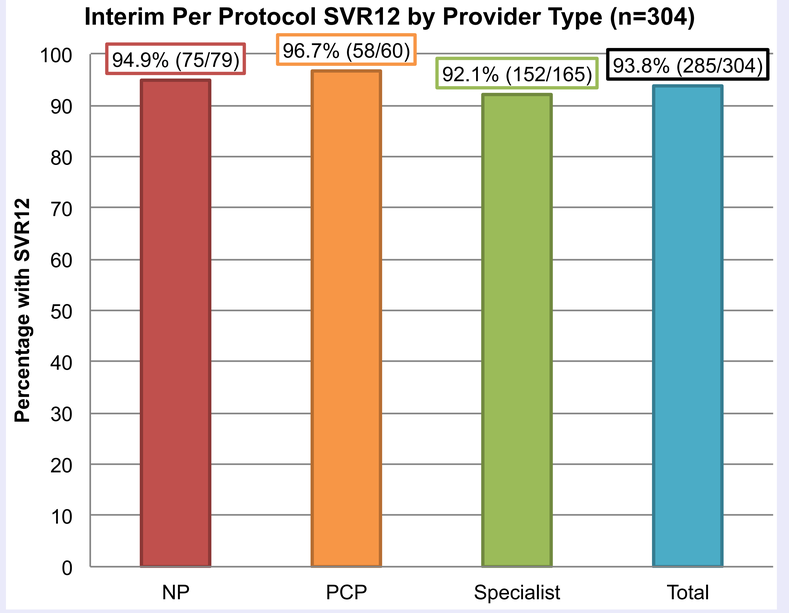


**Figure 1.** Interim Per Protocol SVR12 by Provider Type. Of 304 patients with available SVR12 results, 93.8% achieved SVR12. There was no significant difference in SVR12 between patients treated by NPs, PCPs, and specialist physicians

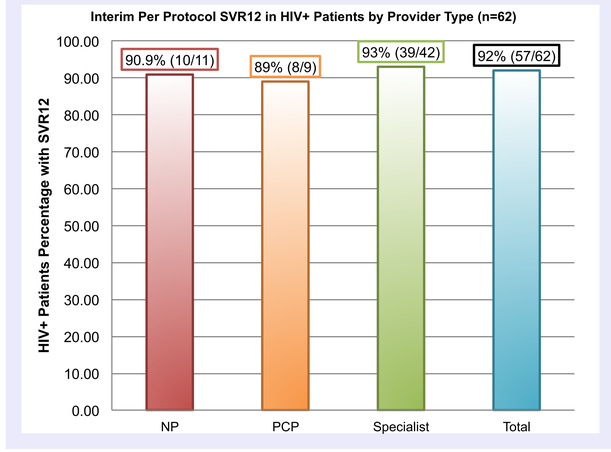


**Figure 2.** SVR12 by Provider in HIV+. There was no significant effect of provider on SVR12 in HIV+ patients

| Baseline Characteristics | SVR12 (n=285) | Non-SVR12 (n=19) | p-value |
|---|---|---|---|
| Male | 196/285 (68.8) | 13/19 (68.4) | 0.97 |
| Black Race | 275/285 (96.5) | 18/19 (94.7) | 0.51 |
| Non-Hispanic | 280/285 (98.2) | 18/19 (94.7) | 0.32 |
| HIV/HCV Coinfection | 58/285 (20.4) | 5/19 (26.3) | 0.56 |
| GT-1a | 198/285 (69.5) | 19/19 (100) | 0.003* |
| Cirrhosis | 53/285 (18.60) | 15/19 (21.1) | 0.76 |
| Treatment Experienced | 46/285 (16.1) | 4/19 (21.1) | 0.53 |
| HCV VL > 6 million | 51/285 (17.9) | 5/19 (26.3) | 0.36 |
| Treatment Duration | | | 0.47 |
| 8 weeks | 14/285 (4.9) | 2/19 (10.5) | |
| 12 weeks | 266/285 (93.3) | 17/19 (89.5) | |
| 24 weeks | 6/285 (1.8) | 0/19 (0) | |
| Provider Type | | | 0.48 |
| NP | 75/285 (26.3) | 4/19 (21.1) | |
| PCP | 58/285 (20.4) | 2/19 (10.5) | |
| Specialist | 152/285 (53.3) | 13/19 (68.4) | |

**Table 2.** Baseline and Treatment Characteristics Associated with SVR12 (n=304)

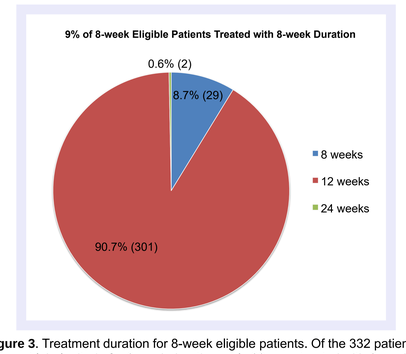


**Figure 3.** Treatment duration for 8-week eligible patients. Of the 332 patients who met label criteria for 8 week duration, only 29 were treated with 8 weeks.

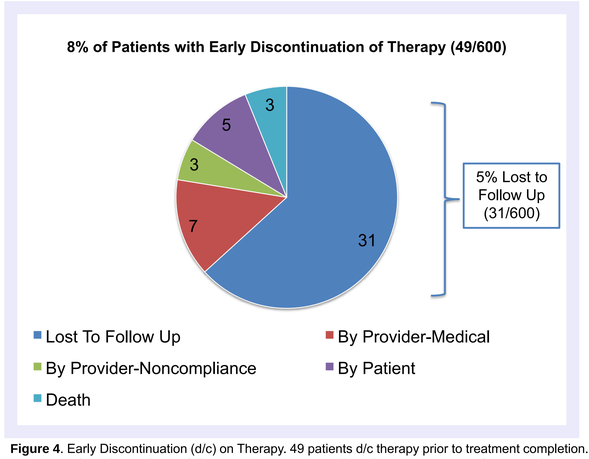


**Figure 4.** Early Discontinuation (d/c) on Therapy. 49 patients d/c therapy prior to treatment completion. The majority (n=31) were lost to follow up. 7 patients were d/c early by their provider for medical reasons.

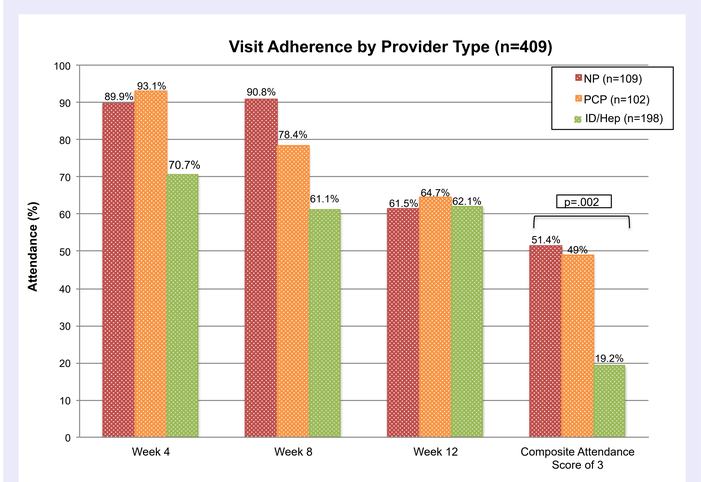


**Figure 5.** Adherence to visits by provider type in 409 patients who completed 12-week treatment. Composite Attendance Score of 3 was defined by attendance at all three visits (week 4, 8, and 12) with a window of -7 to +14 days per visit.

## 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.