Sofosbuvir-Based HCV Treatment Experience of AN/AI Persons Living in Alaska

The Alaska Hepatitis C Cohort (AK-HepC)

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OUR VISION:
Alaska Native people are the healthiest people in the world.
Background

• AN/AI persons have higher rates of death from hepatitis C than other ethnic groups in the U.S.
• Those disproportionately affected by HCV are underrepresented in clinical trials.
• Rates are unknown in AN/AI persons
  • Direct Acting Antiviral (DAA) side effects
  • Sustained Virologic Response (SVR)
• Treatment Discontinuation
Methods

- Non-controlled observational clinical study of sofosbuvir-based treatment (n=228).
  - Sofosbuvir (SOF) + Ribavirin (RBV)
  - Ledipasvir (LED)/Sofosbuvir (SOF)
  - LED + SOF + RBV
- SVR defined as non-detection of HCV RNA ≥ 12 weeks after treatment completion
- FibroScan® used to evaluate liver fibrosis prior to treatment and ≥ 12 weeks after treatment completion
Methods, Continued

- *Self-reported* symptoms inventory of 32 potential adverse events completed by participants at week 0 prior to treatment and monthly while on treatment.
- Frequency of adverse events at week 0 and 12 compared using logistic regression with generalized estimating equations.
Characteristics of Participants

- 43% female
- Median age 53 years
- Mean Body Mass Index 29.7
Characteristics of Participants

– Genotype 1a 68%, 1b 14%, 2 13%, 3 5%
– 29.6% advanced fibrosis; 20.4% cirrhosis
Characteristics of Participants

– 10% treatment experienced
– 46% IL28b CC
– 24% reported PPI use during treatment
Results

228 Participants

12 / 228 Discontinued
- 7 Relapse
- 5 SVR

216 Completed Treatment
- 6 Relapse
- 206 Responders
- 4 Reinfection
Results – Intent to Treat Analysis

SOF + RIBA (N=42)
- SVR: 93%
- NO SVR: 7%

LED + SOF (N=178)
- SVR: 94%
- NO SVR: 6%
Results – Completed Treatment Analysis

SOF + RIBA (N=37)
- SVR: 97%
- NO SVR: 3%

LED + SOF (N=171)
- SVR: 97%
- NO SVR: 3%
Results

• All treatment failures due to relapse

• Overall discontinuation rate was 5% (12 / 228)
Results

LED/SOF Adverse Events

n = 178

Statistically significant increase in chills (p value 0.049) and hair loss (p = 0.045), and decrease in joint pain (p = 0.01) reported from baseline to week 12 of treatment.
Results  SOF + RBV  Adverse Events

n = 42

Statistically significant increase in diarrhea (p = 0.02), dizziness (p = 0.04), and decrease in joint pain (p = 0.001) and back pain (p = 0.02) between weeks 0 and 12.

Hemoglobin drop below 10g/d in 11.9% and below 8.5 g/dl in 2.4%

2 patients discontinued due to AEs
1 Grade 3 AE related to anemia
Results

Among all persons who achieved SVR (either regimen), FibroScan® score dropped significantly for Metavir F2-F4 (p ≤ 0.0009).
Conclusion

• AN/AI persons represented in the AK-HepC Cohort tolerated *sofosbuvir*-based direct acting antiviral treatment for hepatitis C infection with few adverse events.

• Efficacy was on par with real world sustained virologic response rates of other ethnic groups.
Acknowledgements

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