Comparison of adverse events associated with ribavirin in sofosbuvir treated chronic hepatitis C patients.
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Results

- Severe adverse events were observed in 16-54% of patients with ribavirin-inclusive treatment versus 5% in the ribavirin-free regimen of sofosbuvir and simeprevir (p=0.006, Figure 1)
- Sofosbuvir plus simeprevir reached similar SVR rates at week 12 post-therapy versus other ribavirin-inclusive treatments except for triple therapy in cohort 1.
- Cohort 1 with peginterferon, sofosbuvir and ribavirin had the most fatigue, headaches rash, and overall SAE compared to the other treatment arms (p=0.006-0.018).

Methods

- From December 2013 to July 2014, 128 chronic HCV patients received sofosbuvir based therapies including sofosbuvir, ribavirin and weekly peginterferon for 12 weeks (cohort 1), 12 or 24 weeks of sofosbuvir and ribavirin (cohorts 2 and 3) or sofosbuvir plus simeprevir for 12 weeks (cohort 4).
- All clinical and laboratory adverse events were recorded from baseline, through 12 or 24 weeks of treatment, and until attainment of SVR at week 12 or virologic relapse.

Acknowledgements: Many thanks to Mary Rappoport, Clinical Trial Coordinator and Tara Martini at the Huntington Medical Research Institute: Liver Center, all the amazing past summer students at the HMRI: Liver Center, and Dr. Kenneth Mitchell, Program Director of The DeBakey Scholars Program at Tulane University: School of Medicine.

References


Sponsorships

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Conclusion

- HCV Treatments with ribavirin increased SAEs leading to more treatment dropout and reduction of ribavirin dose.
- Newer sofosbuvir and simeprevir combination demonstrates high SVR at week 12 with the lowest SAE.
- Next step: Investigate in larger subpopulation if sofosbuvir with newer simeprevir, ledipasvir or daclatasvir combinations confer higher SVR 12 and lower SAE rates in Asian populations.

Figure 1. Cohorts 1–4 with respective percentages of severe adverse events and SVR at week 12 rates.