Treatment Naïve (unfavorable baseline treatment characteristics)

Sofosbuvir + Ribavirin in HCV Genotype 1

NIAID/NIH Trial

Osinusi A, et al. JAMA. 2013;310:804-11.

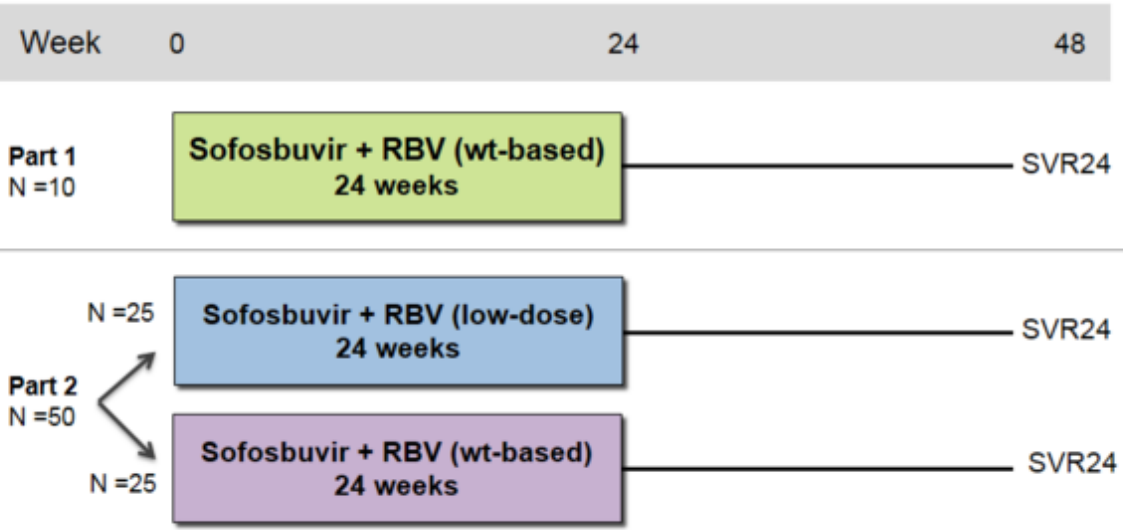
Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID/NIH Trial: Features

NIAID/NIH Trial: Features

- **Design**
  - Randomized, open-label, 2-part, phase 2 study of sofosbuvir and ribavirin
  - Part 1: "proof of concept"
  - Part 2: low dose versus weight-based dose of ribavirin in GT-1
- **Setting**: Single center: NIAID
- **Entry Criteria**: HCV genotype 1; treatment-naïve
- **Patient Characteristics**
  - N = 60 HCV-monoinfected patients
  - HCV Genotype: 1A (70%), 1B (30%)
  - IL28B Genotype: 81% non-CC
  - Age and Sex: median 54 (range 48-57); 62% male
  - Race: 83% black; 13% white
  - Liver disease: 23% had advanced fibrosis (F3-F4 by Knodell-HAI scoring)
- **Primary end-points**: Efficacy (SVR24) and safety

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID/NIH Trial: Design



Drug Dosing

Sofosbuvir: 400 mg once daily

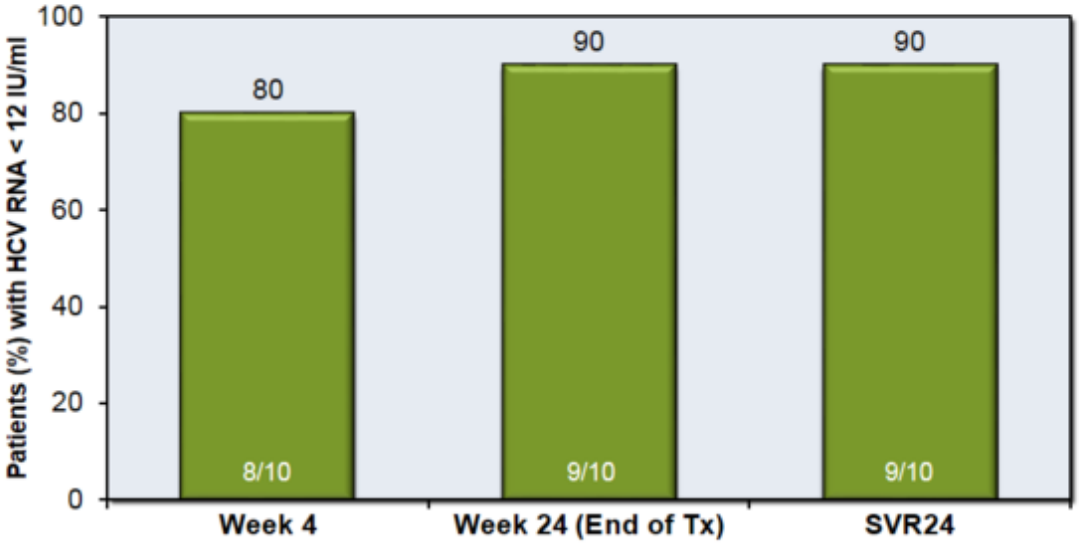
Low-dose Ribavirin (divided bid): 800 mg/day

Weight-based Ribavirin (divided bid): 1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID/NIH Study: Part 1 Results

NIAID Part 1: HCV <12 IU/ml by Study Timepoint

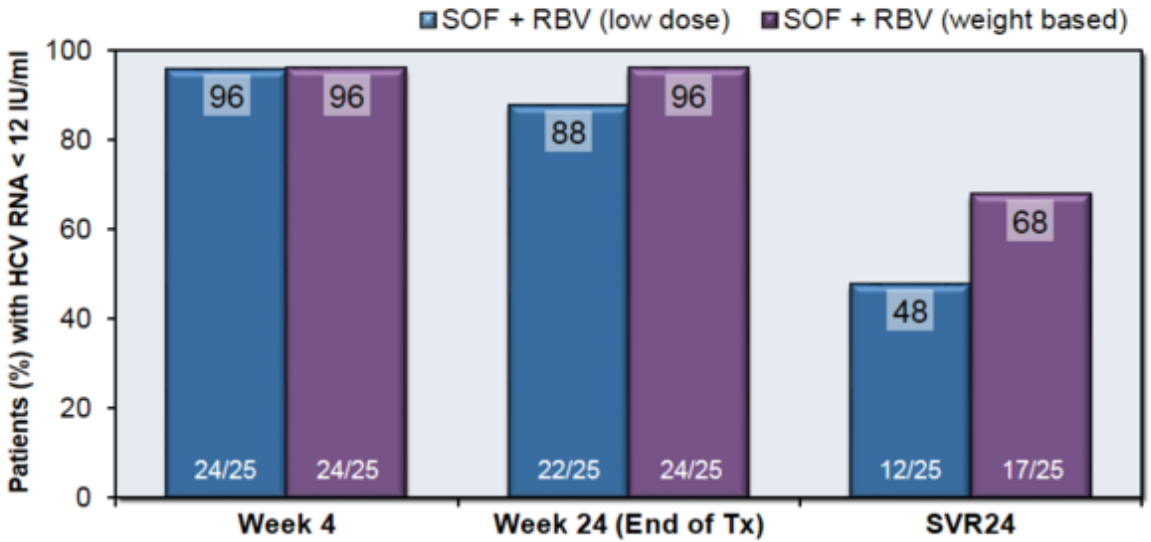


All 10 patients in Part 1 received sofosbuvir plus weight-based ribavirin

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID/NIH Study: Part 2 Results

NIAID/NIH Part 2: HCV RNA <12 IU/ml by Study Timepoint

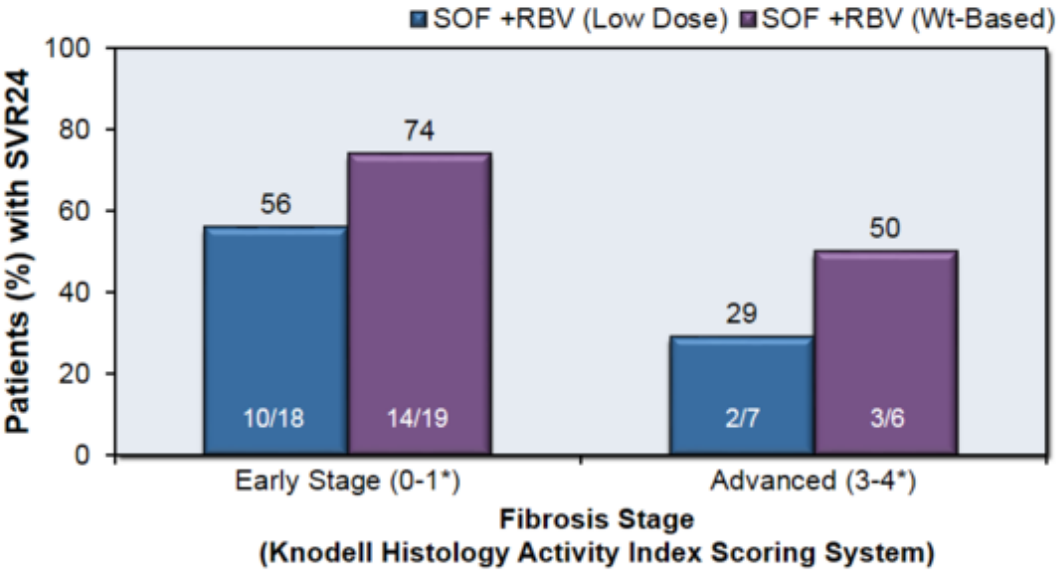


SOF = Sofosbuvir; RBV = Ribavirin

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID/NIH Study: Part 2 Results

NIAID/NIH Part 2: SVR24 by Fibrosis Stage



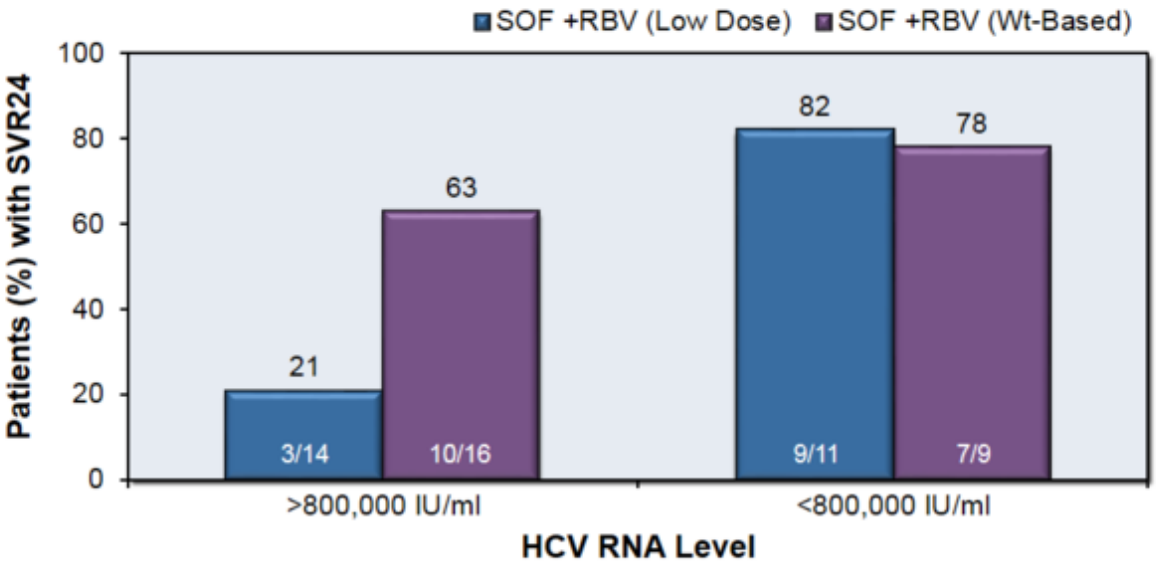
SOF = Sofosbuvir; RBV = Ribavirin

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Hepatitis web study

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID/NIH Study: Part 2 Results

NIAID/NIH Part 2: SVR24 by Baseline HCV RNA Level



SOF= Sofosbuvir; RBV = Ribavirin

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

Sofosbuvir and Ribavirin for Treatment-Naïve HCV GT 1 NIAID Trial: Conclusions

Conclusion: "In conclusion, treatment with a 24-week regimen of sofosbuvir and ribavirin resulted in an SVR rate of 68% in the weight-based ribavirin regimen and 48%in the low-dose ribavirin regimen among patients with chronic HCV and unfavorable traditional predictors of treatment response who are representative of the demographics of the US HCV epidemic."

Source: Osinusi A, et al. JAMA. 2013;310:804-11.

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online
www.hepatitisc.uw.edu

Hepatitis Web Study
http://depts.washington.edu/hepstudy/

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Hepatitis web study