

Treatment Experienced

Sofosbuvir in Genotype 2 or 3 FUSION Trial

*Note: Published in NEJM in tandem with POSITRON Trial (GT 2,3 Unable to receive PEG)

Jacobson I, et al. N Engl J Med. 2013;368:1867-77.

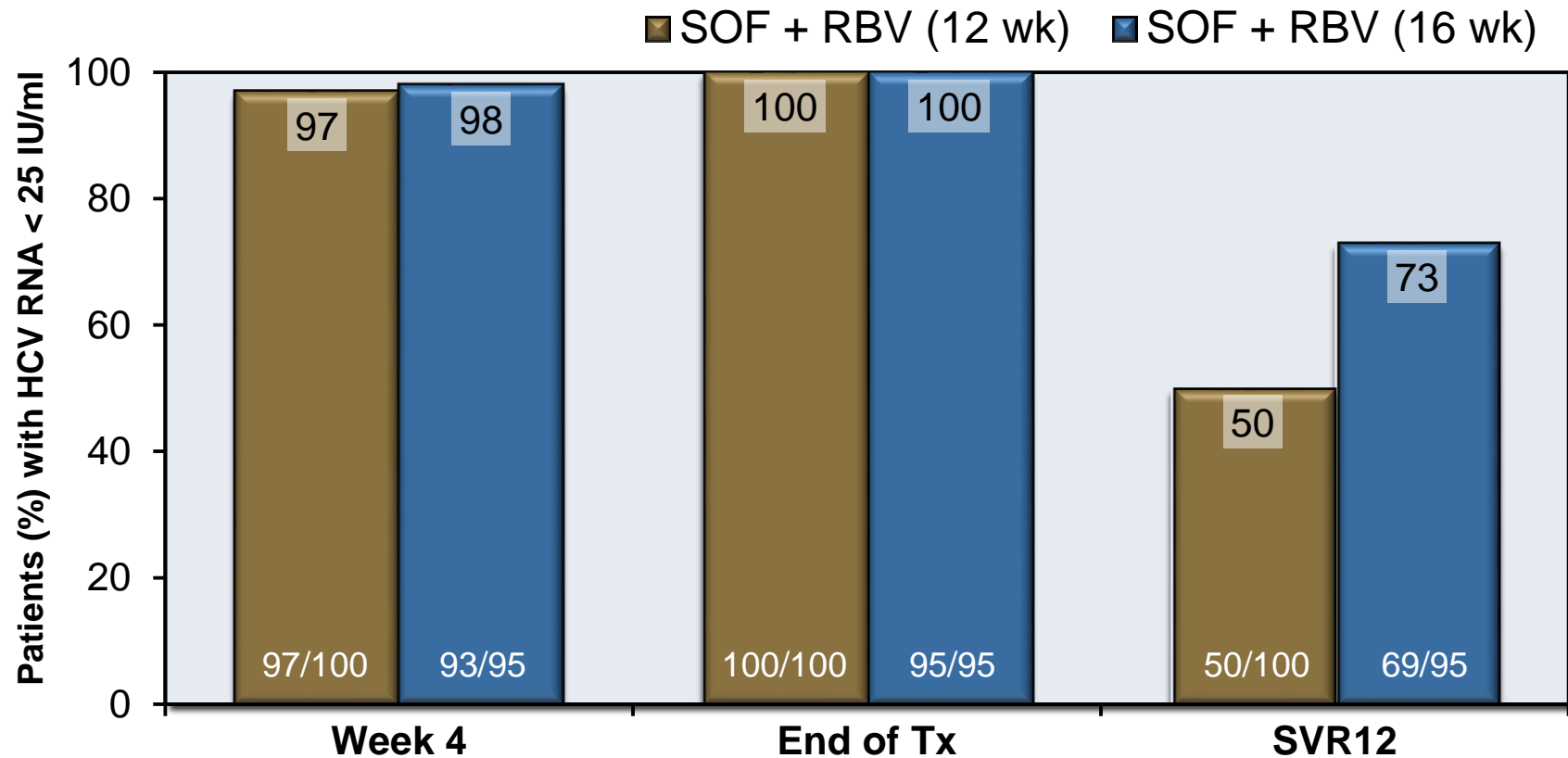
Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Features

FUSION Trial: Features

- **Design:** Randomized, controlled, blinded phase 3 trial comparing 12 and 16 weeks of sofosbuvir + ribavirin in treatment-experienced HCV GT 2 or 3
- **Setting:** 67 sites in US, Canada, New Zealand, enrolled May-July 2012
- **Entry Criteria**
 - Treatment-experienced (failed prior interferon-based therapy)
 - HCV RNA \geq 10,000 IU/ml
- **Patient Characteristics**
 - N = 201 HCV-monoinfected patients
 - HCV genotype: 2 (34%); 3 (63%)
 - IL28B genotype: 70% non-CC
 - Prior treatment failure: 75% relapse; 25% nonresponse
 - Age and sex: mean age 54 (range 24-70); 70% male
 - Race: 87% white; 3% black
 - Liver disease: 34% had cirrhosis
- **Primary End-Point:** SVR12

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Results

FUSION: HCV RNA <25 IU/ml by Study Timepoint

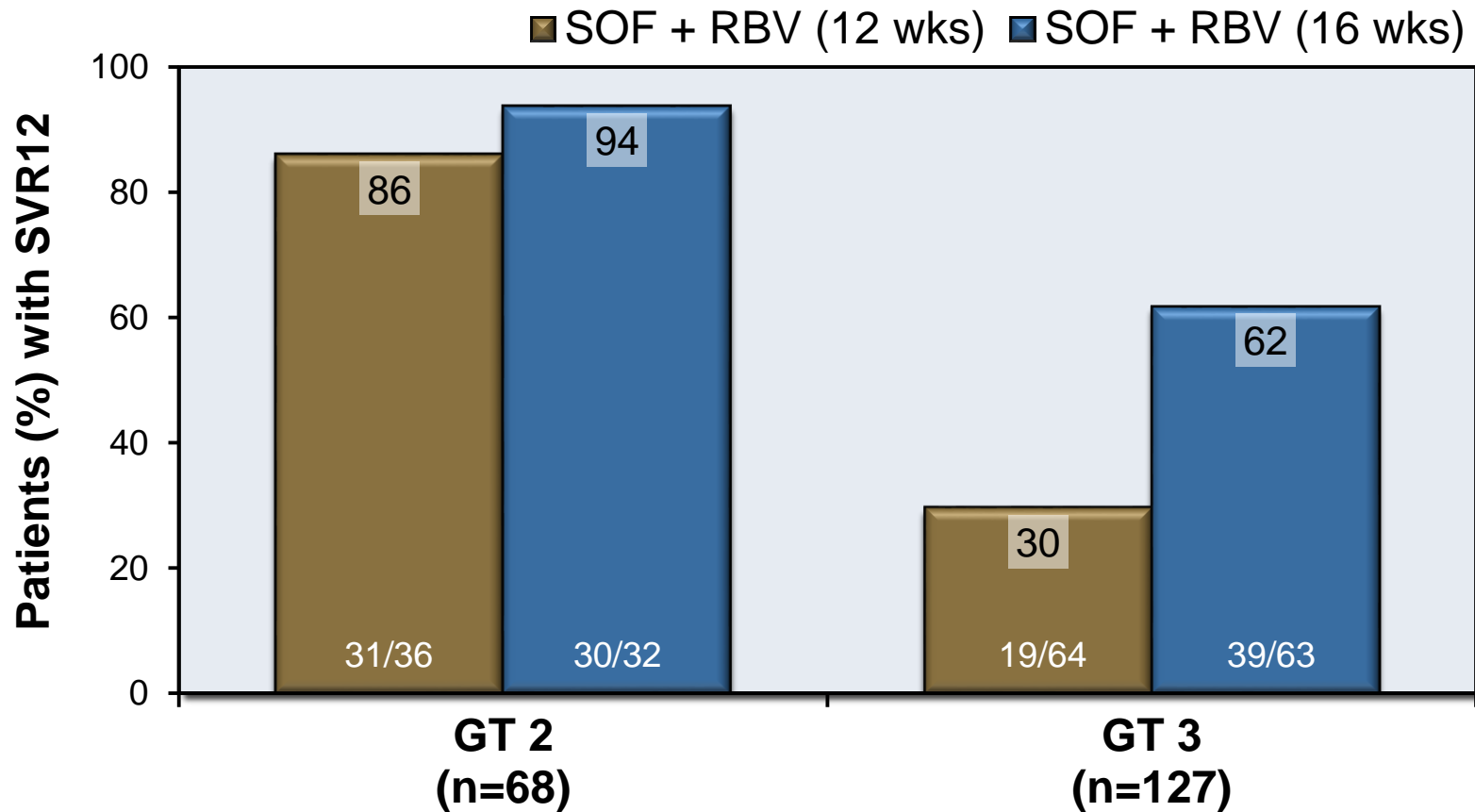


SOF= Sofosbuvir; RBV = Ribavirin

Source: Jacobson I, et al. N Engl J Med. 2013;368:1867-77.

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Results

FUSION: SVR12 by Genotype and Treatment Duration

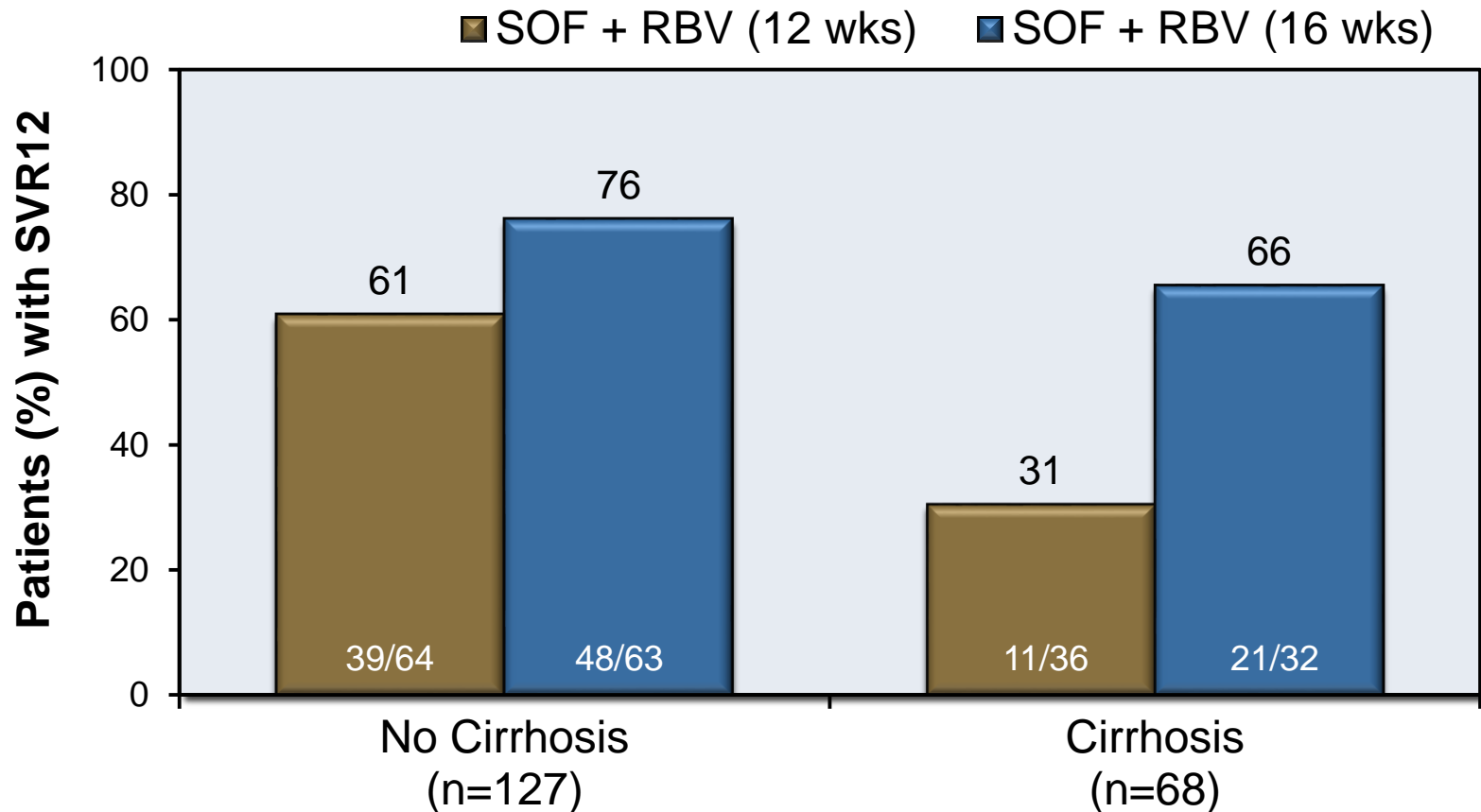


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Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Results

FUSION: SVR12 by Liver Disease

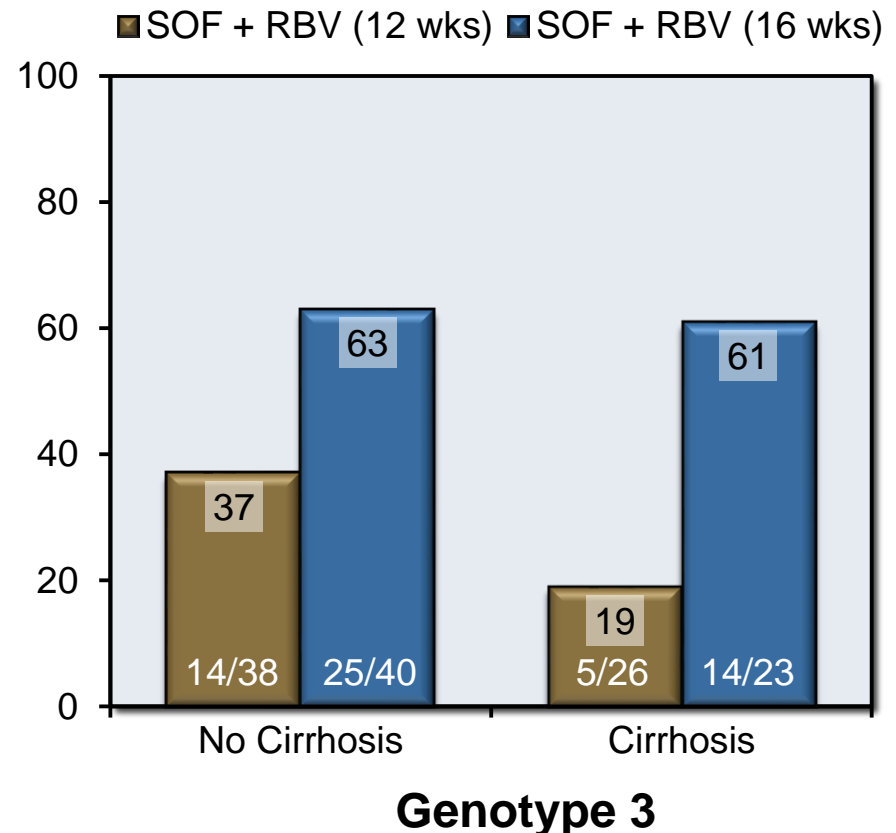
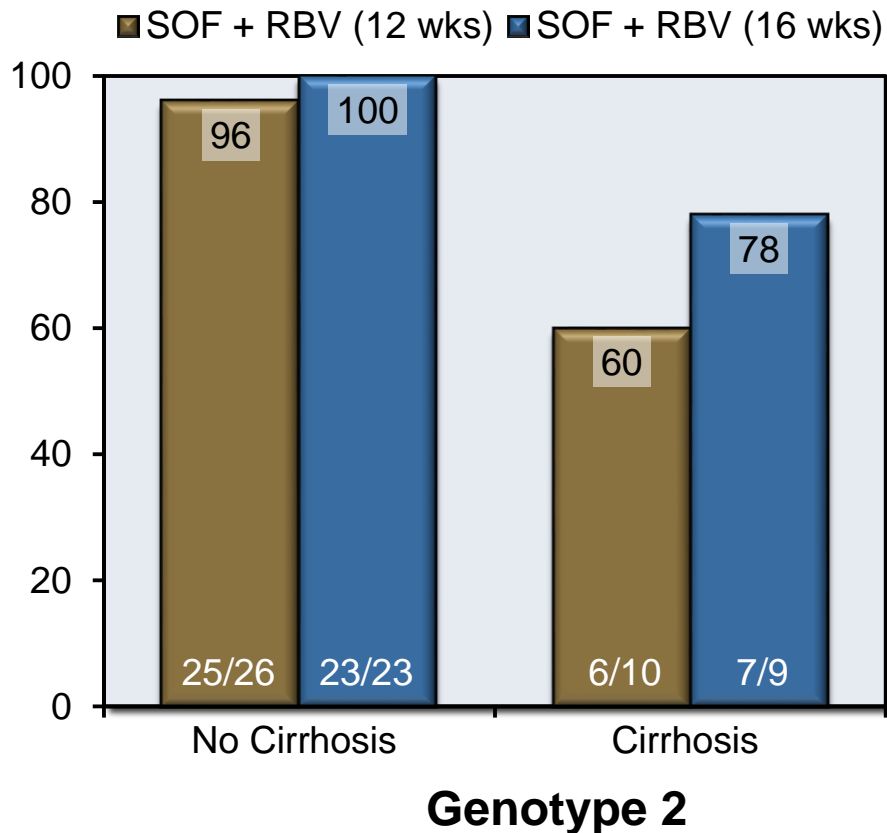


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Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Results

FUSION: SVR12 by Genotype, Cirrhosis, and Duration of Therapy



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Source: Jacobson I, et al. N Engl J Med. 2013;368:1867-77.

Sofosbuvir + RBV in Treatment-Experienced HCV GT 2 or 3 FUSION Trial: Conclusions

Conclusions: “Our findings suggest that 12 weeks of treatment with sofosbuvir and ribavirin can be an effective option for patients with HCV genotype 2 infection. However, for patients with genotype 3 infection, particularly those who have cirrhosis or who have not had a response to prior treatment with interferon, extending the duration of treatment to 16 weeks may provide an additional benefit.”

*Note: This conclusion pertains to both the **FUSION** and **POSITRON** trials, which were published in tandem

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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