Interferon Intolerant, Unwilling, or Ineligible

Sofosbuvir in HCV Genotype 2, 3 (PEG not an Option)
POSITRON

*Note: Published in tandem with **FUSION** Trial (GT 2,3 and prior failure with PEG)

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

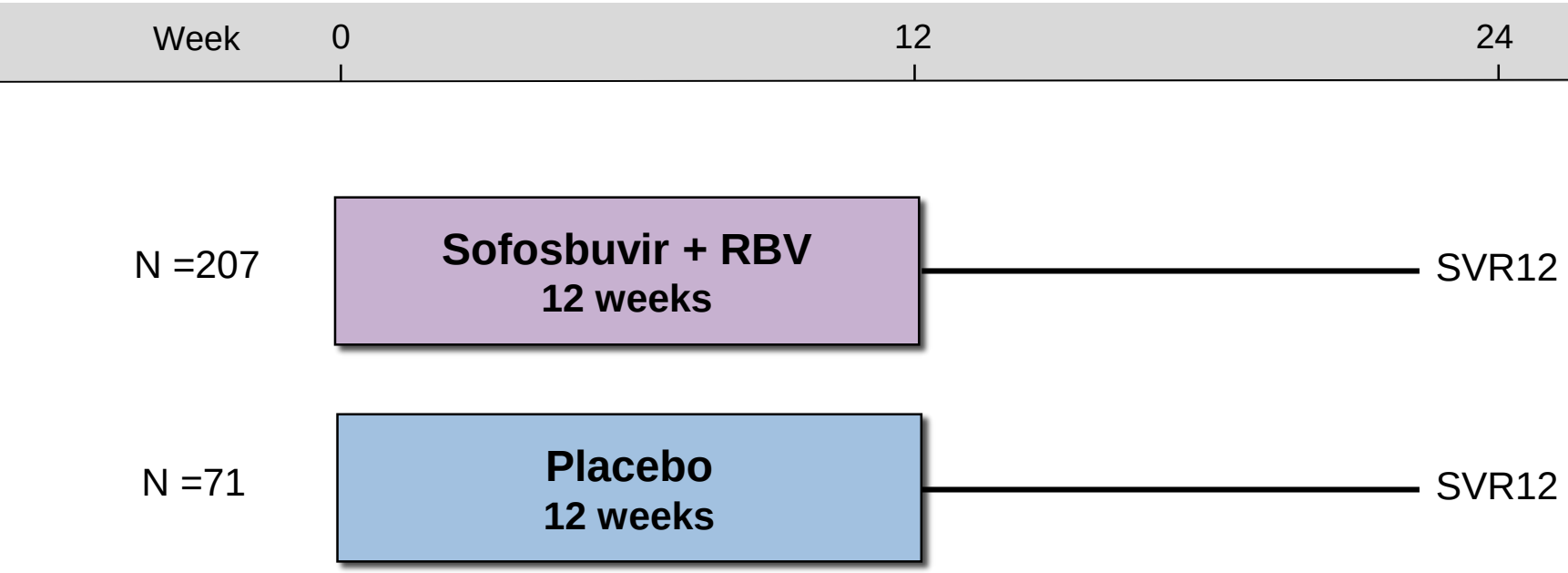
Sofosbuvir + Ribavirin for HCV GT 2 or 3 (PEG not an option)
POSITRON Trial: Design

POSITRON: Study Features

- **Design**: Randomized, double-blind, placebo-controlled, phase 3 trial of sofosbuvir + ribavirin versus placebo in patients with HCV GT 2 or 3
- **Setting**: 63 sites in US, Canada, Australia, New Zealand, enrolled March-May 2012
- **Entry Criteria**
  - Interferon intolerant with prior treatment, ineligible, or unwilling
- **Patient Characteristics**
  - N = 278 HCV-monoinfected patients
  - HCV Genotype: 2 (51%), 3 (49%)
  - IL28B Genotype: 55% non-CC
  - Age and Sex: 52 (range 21-75); 54% male
  - Race: 91% white; 5% black
  - Liver disease: 16% had cirrhosis
- **Primary End-Point**: SVR12

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

Sofosbuvir + Ribavirin for HCV GT 2 or 3 (PEG not an option)
POSITRON Trial: Design



Drug Dosing

Sofosbuvir: 400 mg once daily

Weight-Based Ribavirin (in 2 divided doses): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

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

Sofosbuvir + Ribavirin for HCV GT 2 or 3 (PEG not an option)
POSITRON Trial: Reasons for Interferon Ineligibility

Interferon Category	**Sofosbuvir + RBV** (n=207)	**Placebo** (n=71)
Ineligible	43%	46%
Intolerant	8%	11%
Unwilling	49%	42%

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

Hepatitis web study

Sofosbuvir + Ribavirin for HCV GT 2 or 3 (PEG not an option)
POSITRON Trial: Duration on Prior Interferon

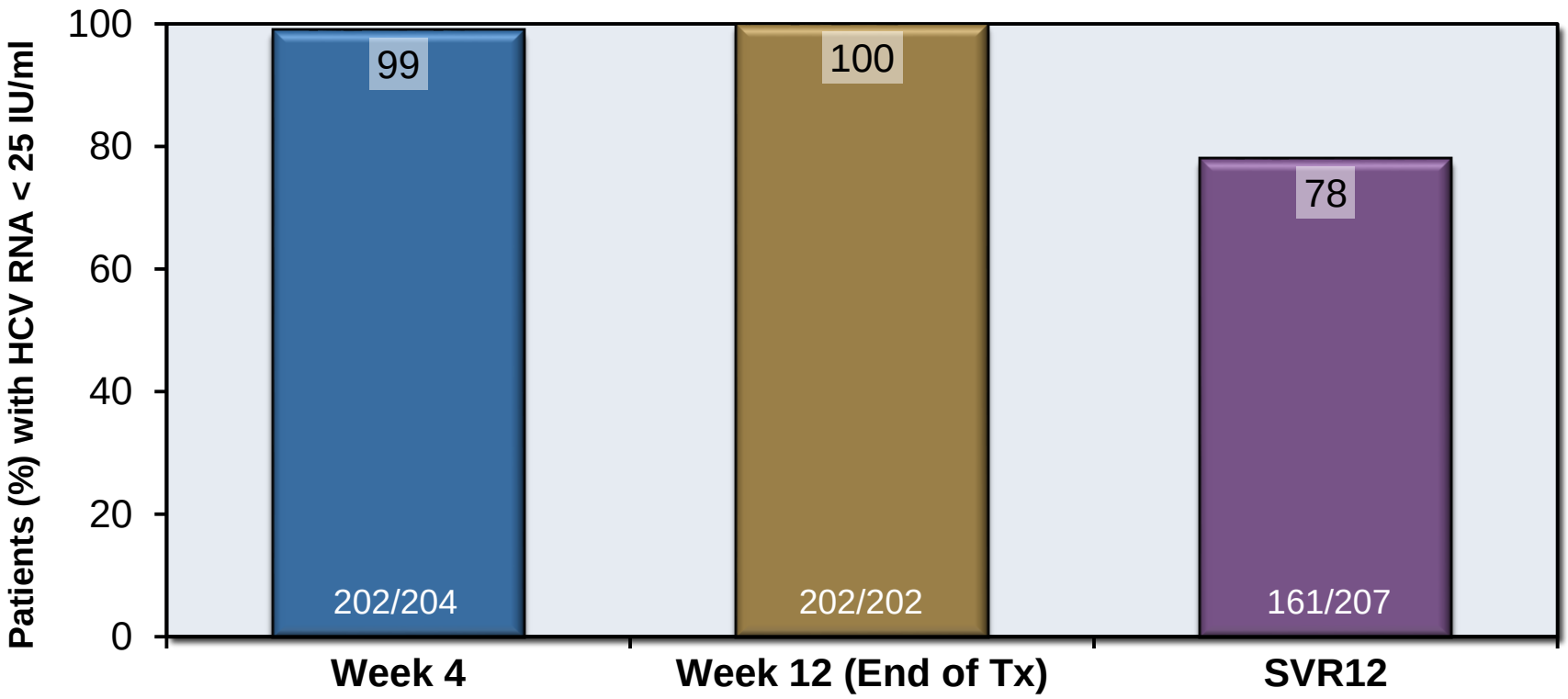
Interferon Category	**Sofosbuvir + RBV** (n=207)	**Placebo** (n=71)
None	82%	79%
≤ 12 weeks	10%	11%
> 12 weeks	8%	10%

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

Hepatitis web study

Sofosbuvir for HCV Infection GT 2,3 (PEG not an option)
POSITRON: Results with Sofosbuvir + Ribavirin

POSITRON: Patients with HCV RNA <25 IU/ml by Study Timepoint

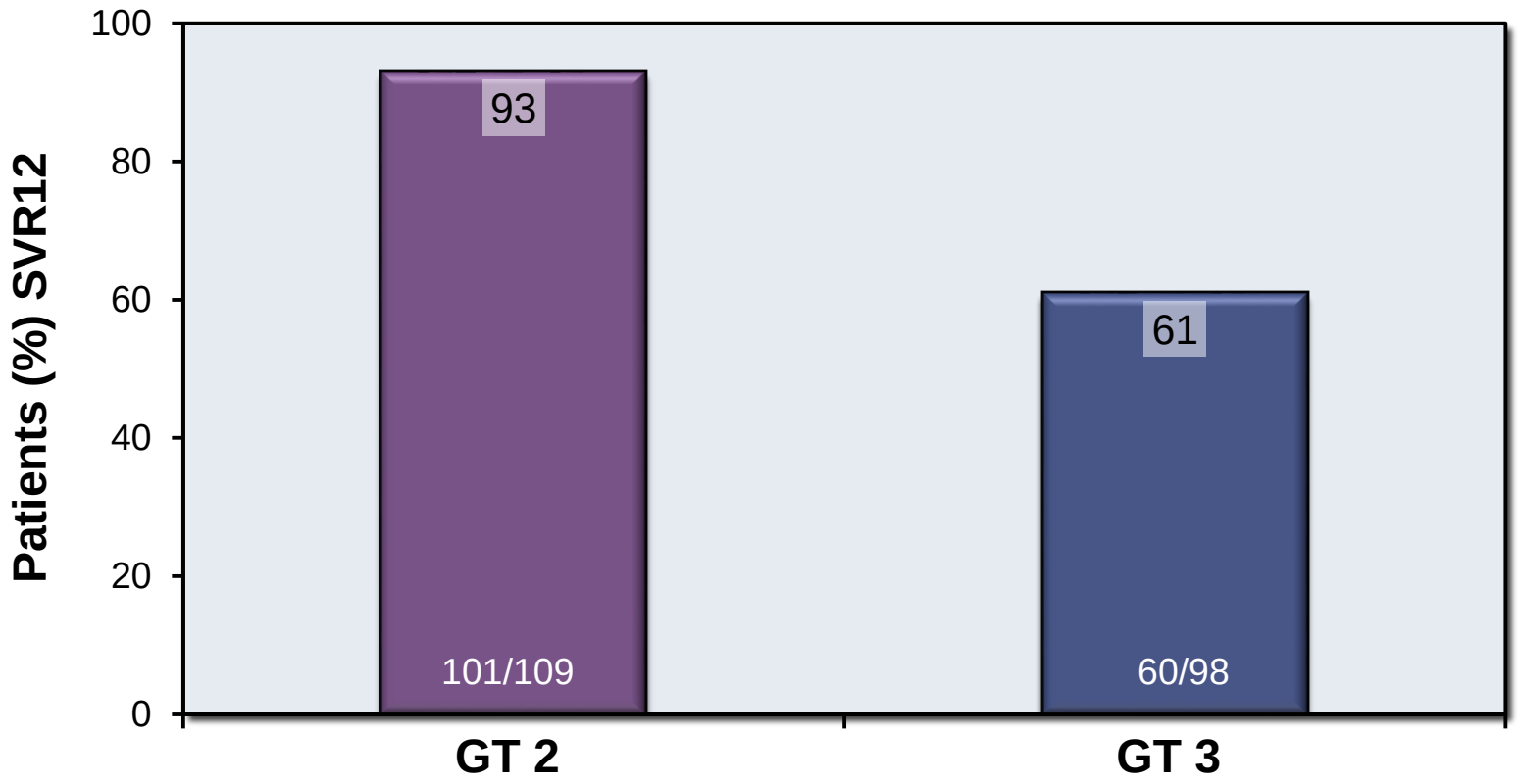


Placebo arm: 0% for each timepoint
Abbreviations: SOF = sofosbuvir; RBV = ribavirin

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

Sofosbuvir + Ribavirin for HCV GT 2,3 (PEG not an option)
POSITRON: Results with Sofosbuvir + Ribavirin

POSITRON: SVR12 by HCV Genotype

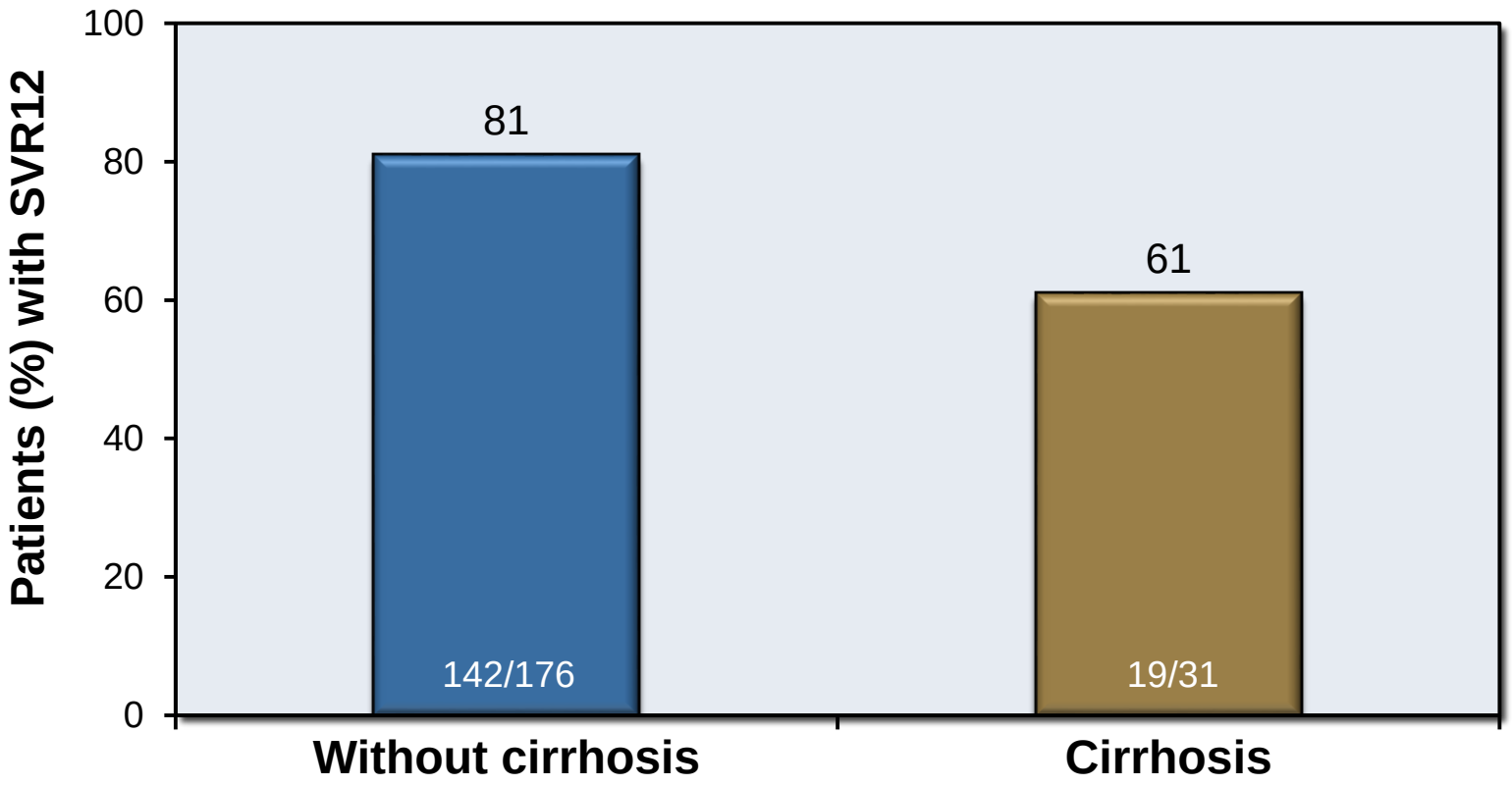


Placebo arm: 0% for each timepoint

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

Sofosbuvir + Ribavirin for HCV GT 2,3 (PEG not an option)
POSITRON: Results with Sofosbuvir + Ribavirin

POSITRON: SVR12 by Liver Disease

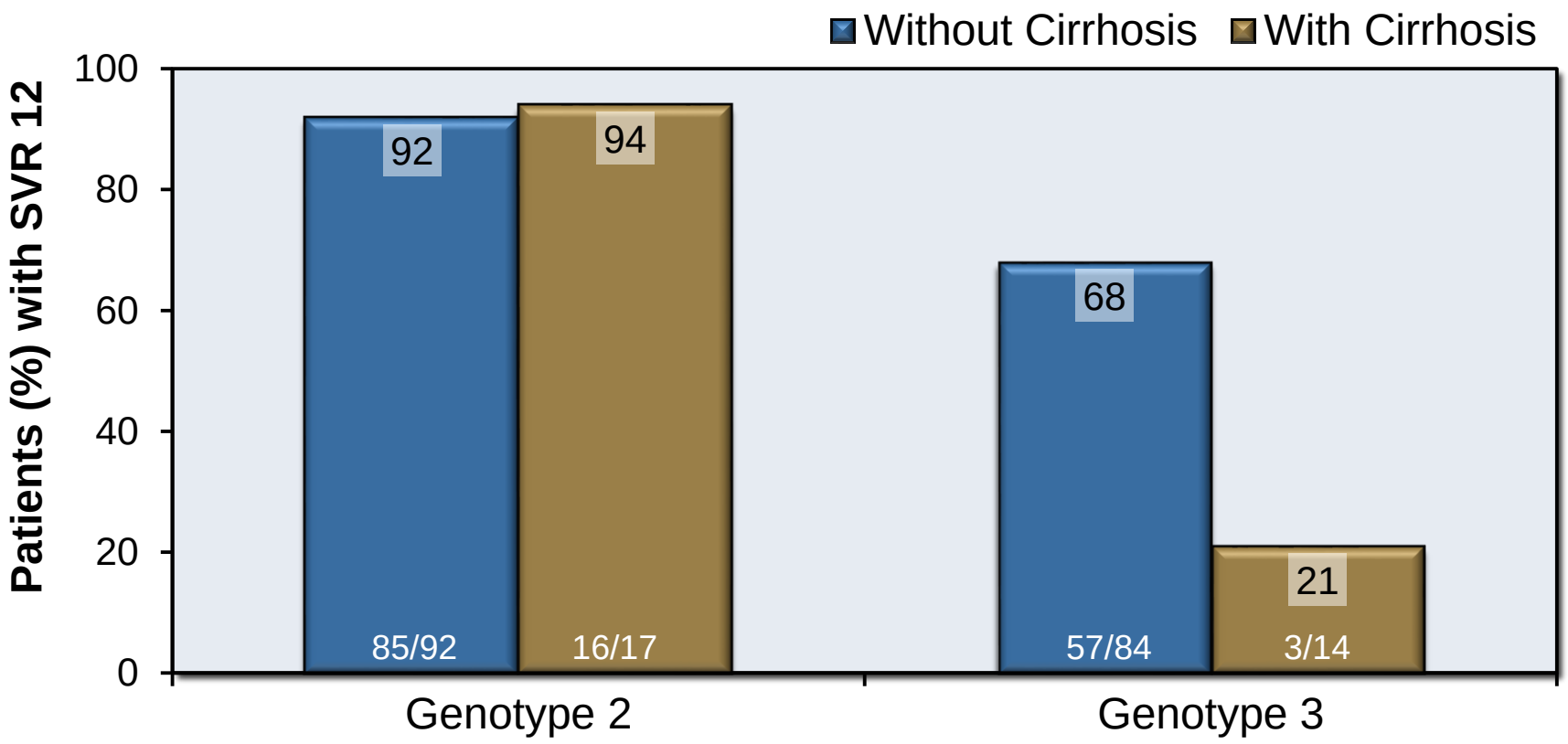


Placebo arm: 0% for each timepoint

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

Sofosbuvir + Ribavirin for HCV GT 2,3 (PEG not an option)
POSITRON: Results with Sofosbuvir + Ribavirin

POSITRON: SVR12 by Liver Disease and Genotype



Placebo arm: 0% for each timepoint

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

Sofosbuvir + Ribavirin for HCV GT 2,3 (PEG not an option) POSITRON Trial: Conclusions

Conclusion*: “In patients with HCV genotype 2 or 3 infection for whom treatment with peginterferon and ribavirin was not an option, 12 [or 16] weeks of treatment with sofosbuvir and ribavirin was effective. Efficacy was increased among patients with HCV genotype 2 infection and those without cirrhosis.”

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

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

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