

Treatment Naïve, Chronic HCV

Peginterferon alfa-2b + Ribavirin
versus
Interferon alfa-2b + Ribavirin

Manns MP, et. al. Lancet. 2001;358:958-65

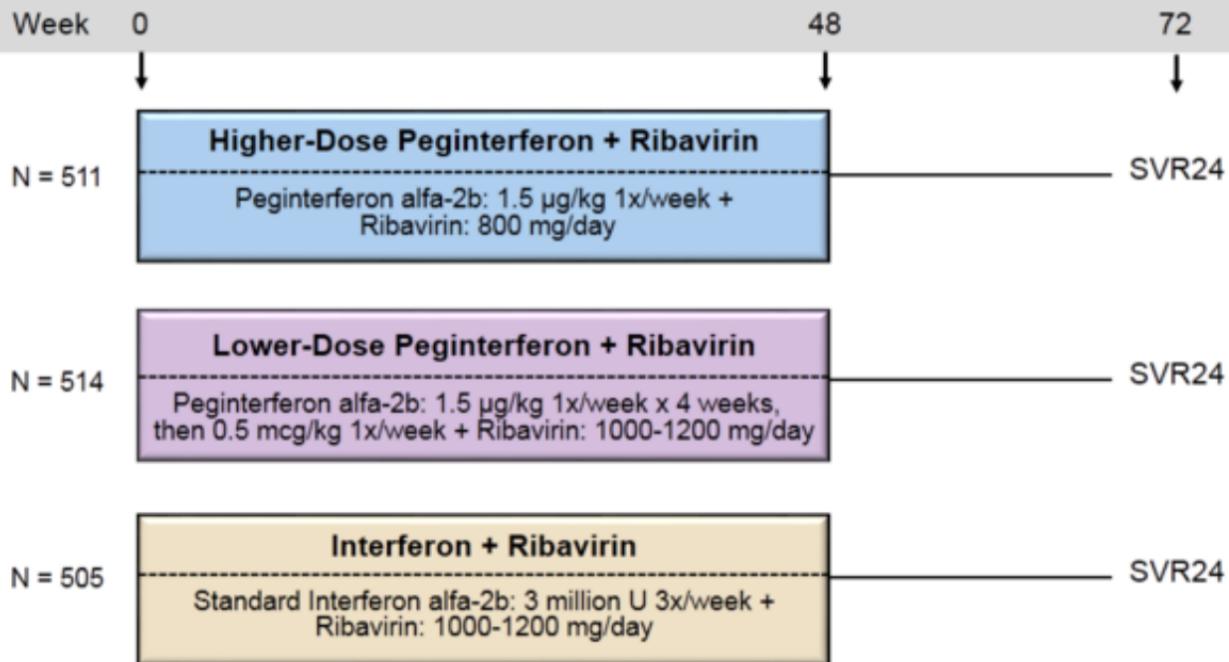
Peginterferon alfa-2b + Ribavirin versus Interferon alfa-2b + Ribavirin Study Design

- **Study**
 - Open-label, randomized controlled trial
 - 62 sites in Europe, North America, & Argentina
- **Subjects**
 - N = 1530 with chronic hepatitis C
 - Treatment naïve
 - Genotype 1: 68%; Genotype 2 or 3: 29%; Genotype 4,5, or 6: 3%
 - Serum ALT >34 IU/L for women, >43 IU/L for men
- **Regimens**
 - Higher Dose Peginterferon alfa-2b: 1.5 µg/kg 1x/week + ribavirin 800 mg/day
 - Lower Dose Peginterferon alfa-2b: 1.5 µg/kg 1x/week x 4 weeks then 0.5 µg/kg 1x/week + ribavirin 1000-1200 mg/day*
 - Standard interferon alfa-2b: 3 million U 3x/week + ribavirin 1000-1200 mg/day*
- **Primary Endpoint (Sustained Virologic Response [SVR])**
 - SVR = Undetectable serum HCV RNA 24 weeks after 48-week treatments

*Ribavirin dosing: <75 kg: 1000 mg/day; ≥75 kg: 1200 mg/day

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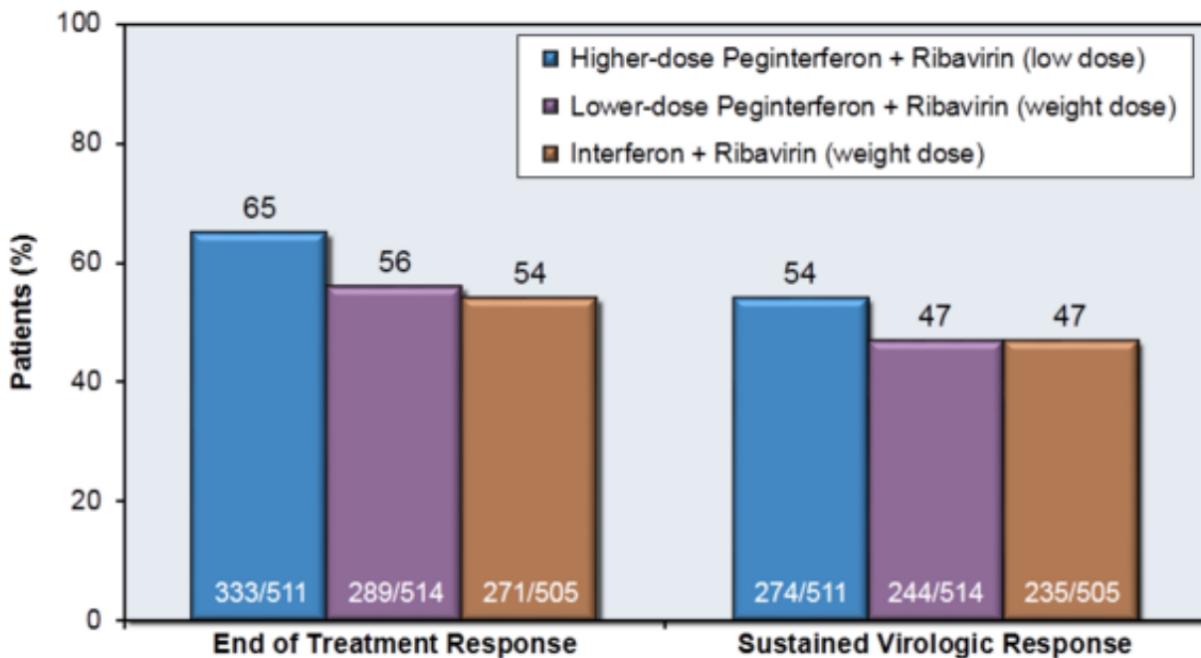
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Peginterferon alfa-2b + Ribavirin versus Interferon alfa-2b + Ribavirin Results

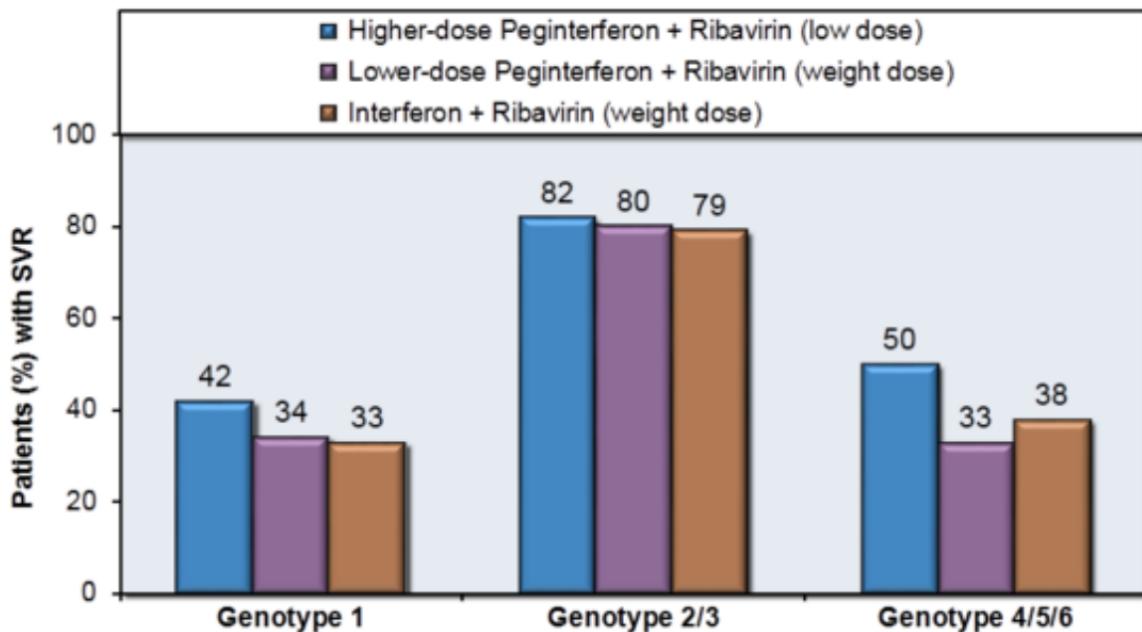
Response after 48 Weeks of Treatment



Source: Manns MP, et. al. Lancet. 2001;358:958-65.

Peginterferon alfa-2b + Ribavirin versus Interferon alfa-2b + Ribavirin Results

SVR24, Based on Genotype



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Peginterferon alfa-2b + Ribavirin versus Interferon alfa-2b + Ribavirin IDEAL Study: Conclusions

Interpretation: "In patients with chronic hepatitis C, the most effective therapy is the combination of peginterferon alfa-2b 1.5 µg/kg per week plus ribavirin. The benefit is mostly achieved in patients with HCV genotype 1 infections."

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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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