Treatment Naïve, Chronic HCV

WINR Study
Flat versus Weight-Based Ribavirin Dosing

Conclusion: “Peginterferon alfa-2b plus weight-based ribavirin is more effective than flat-dose ribavirin, particularly in genotype 1 patients, providing equivalent efficacy across all weight groups. Ribavirin 1400 mg/day is appropriate for patients 105 to 125 kg. For genotype 2/3 patients, 24 weeks of treatment with flat-dose ribavirin is adequate; no evidence of additional benefit of extending treatment to 48 weeks was demonstrated.”

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](http://www.hepatitisc.uw.edu)

**Hepatitis Web Study**

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Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose) WIN-R Study: Design

- **Study**
  - Prospective, randomized, open-label trial

- **Subjects**
  - N = 5027 with chronic hepatitis C (4913 analyzed)
  - Treatment naïve adult patients (Age 18-70)

- **Treatment Regimens**
  - Peginterferon alfa-2b: 1.5 µg/kg/wk + Wt-based* Ribavirin: 800-1400 mg/d
  - Peginterferon alfa-2b: 1.5 µg/kg/wk + Flat-dose Ribavirin: 800 mg/d

- **Treatment Duration**
  - Genotypes 1, 4, 5, 6: duration of 48 weeks
  - Genotypes 2, 3: duration of 24 or 48 weeks

- **Primary Endpoint**
  - Undetectable serum HCV RNA at end of treatment (ETR)
  - Undetectable serum HCV RNA 24 weeks after cessation of treatment (SVR)

*Weight-based ribavirin dosing: < 65 kg: 800 mg/d; 65-85 kg: 1000 mg/d; >85-105 kg: 1200 mg/d; >105 kg: 1400 mg/d

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Design

**Week 0**
- GT 1-6
  - PEG + Ribavirin (weight-based) (n = 2111)
  - SVR24

**Week 24**
- GT 1-6
  - PEG + Ribavirin (weight-based) (n = 2111)
  - SVR24

**Week 48**
- GT 1-6
  - PEG + Ribavirin (weight-based) (n = 2111)
  - SVR24

**Week 72**
- GT 1-6
  - PEG + Ribavirin (weight-based) (n = 2111)
  - SVR24

**Drug Dosing**
- Peginterferon alfa-2b: 180 μg once weekly
- Weight-based Ribavirin (in 2 divided doses):
  - 800 mg/d if < 65 kg; 1000 mg/d if 65-85 kg; 1200 mg/d if >85-105 kg; 1400 mg/d if >105 kg
- Flat-dose Ribavirin (in 2 divided doses): 800 mg/day

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose) WIN-R Study: Results

SVR 24, by Genotype and Treatment Regimen

- **All**:
  - Weight-Based Ribavirin: 44/938/2121
  - Flat Dose Ribavirin: 41/852/2121
  - P = .008

- **GT-1**:
  - Weight-Based Ribavirin: 34/447/1313
  - Flat Dose Ribavirin: 29/377/1305
  - P = .005

- **GT-2,3**:
  - Weight-Based Ribavirin: 62/479/775
  - Flat Dose Ribavirin: 60/462/777
  - P = .252

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose) WIN-R Study: Results

All Treated: SVR24 by Weight Distribution

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Results

Genotype 1: SVR24 by Weight Distribution

Peginterferon alfa-2b & Weight-based or Flat-dose Ribavirin
WIN-R Study: Results

Genotypes 2,3: SVR24 by Weight Distribution

Peginterferon alfa-2b + Ribavirin (weight-based or flat-dose)
WIN-R Study: Results

Sustained Virologic Response (SVR) by Weight Distribution

African American Genotype 1

Peginterferon alfa-2b & Weight-based or Flat-dose Ribavirin
WIN-R Study: Results

Relapse Rates among Patients who Achieved End-of-Treatment Responses

- Weight-Based Ribavirin
- Flat-Dose Ribavirin

- All Treated: 15.3%, 19.0%
- Genotype 1: 23.0%, 29.6%
- Genotypes 2 & 3: 7.0%, 8.3%