ONLINE EXPERT POSTER REVIEW AND DISCUSSION

Advances in Chronic Hepatitis C Management and Treatment

Reporting From

THE 62ND AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES ANNUAL MEETING

(This coverage is not sanctioned by the conference organizers and is not an official part of the conference proceedings.)

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Predictors of Sustained Virologic Response Among Poor Interferon Responders When Boceprevir is Added to Peginterferon alfa-2b/Ribavirin

B. Bacon, S. Bruno, E. Schiff , P. Kwo, M. Buti, L. Pedicone, W. Deng, M. Burroughs, C. Brass, J. Albrecht, S. Flamm

Abstract 33

Background

- Pre-treatment predictors of SVR for IFN-based therapies include *IL-28*B, baseline VL, virus genotype, age, ethnicity, body weight and fibrosis stage
- In two phase 3 studies of BOC + PR, response to a 4 week PR lead-in was the strongest predictor of SVR
  - Poor IFN response (<1 log decline after lead-in) occurred in up to 28% of patients in SPRINT-2[1] and RESPOND-2[2]
  - Among patients receiving BOC, 28-38% of the poor IFN responders achieved SVR, compared with 0-4% of poor IFN responders in the PR control arm

BOC, boceprevir; IFN, interferon; PR, peginterferon alfa-2b plus ribavirin; SVR, sustained virologic response; VL, viral load.

1. Poordad F, et al. N Engl J Med. 2011;364:1195-206.
2. Bacon BR, et al. N Engl J Med. 2011;364:1207-17.

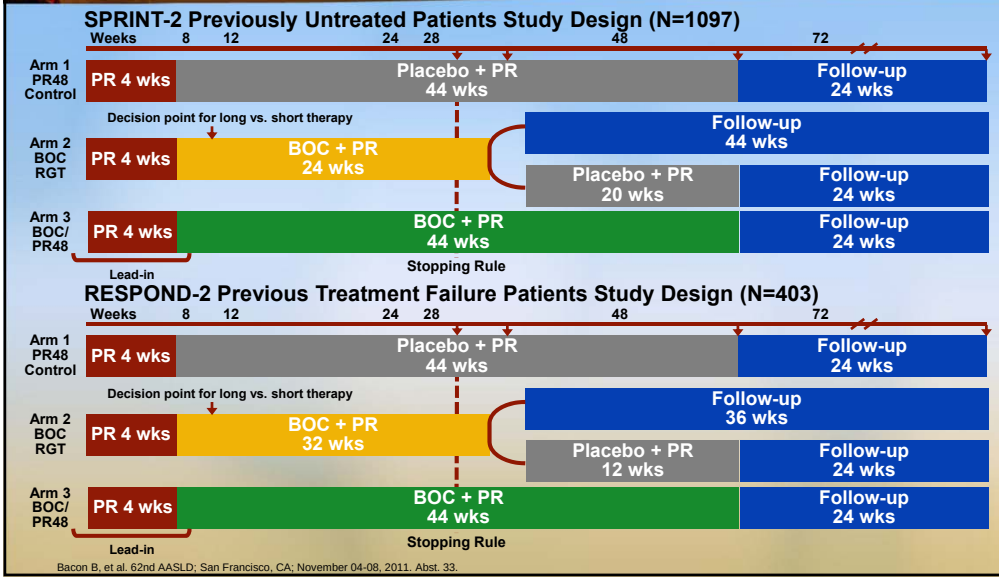
Objective

- To identify predictors of SVR in poor IFN responders (<1 log decline after 4 week PR lead-in) in patients with genotype 1 hepatitis C virus receiving BOC + PR

BOC, boceprevir; IFN, interferon; SVR, sustained virologic response.

Bacon B, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 33.

Study Designs



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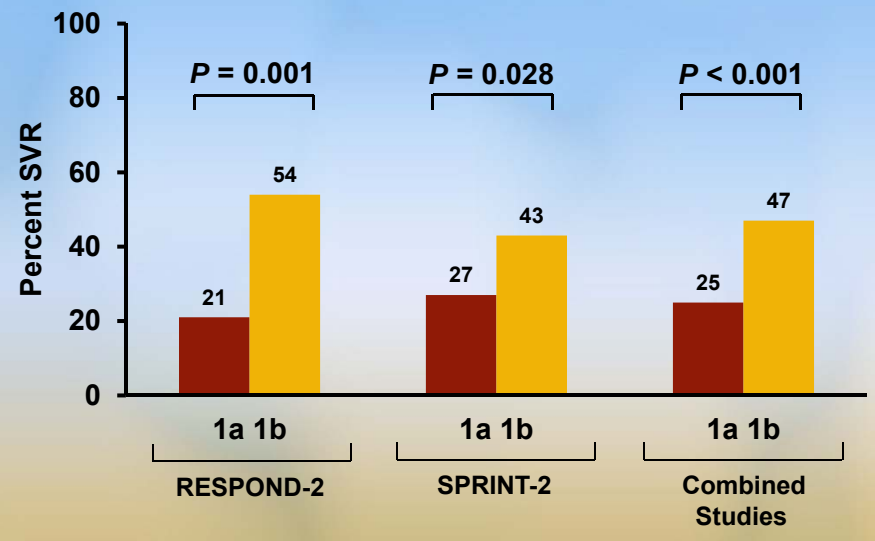
HCV G1 Subtype as a Predictor of SVR in Patients with Poor IFN Response (BOC Arms Combined)



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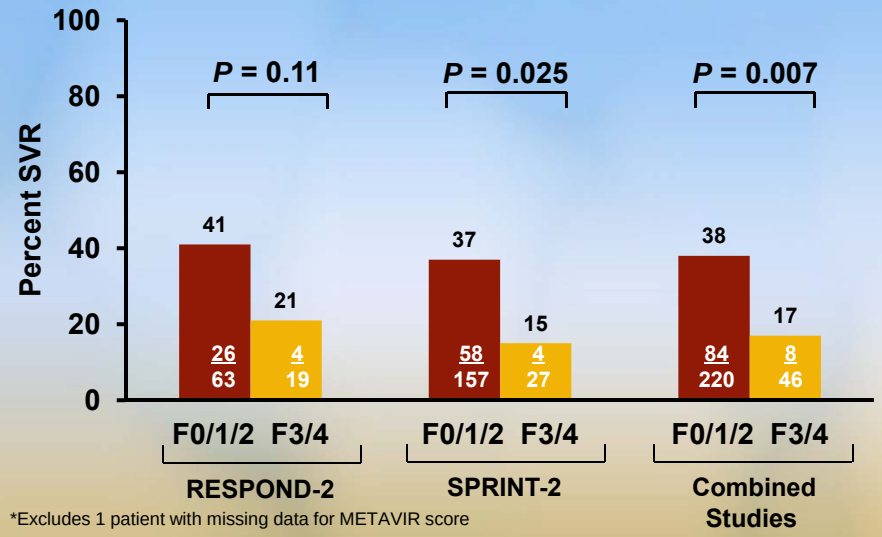
Baseline Fibrosis Score* as a Predictor of SVR in Patients with Poor IFN Response (BOC Arms Combined)



*Excludes 1 patient with missing data for METAVIR score

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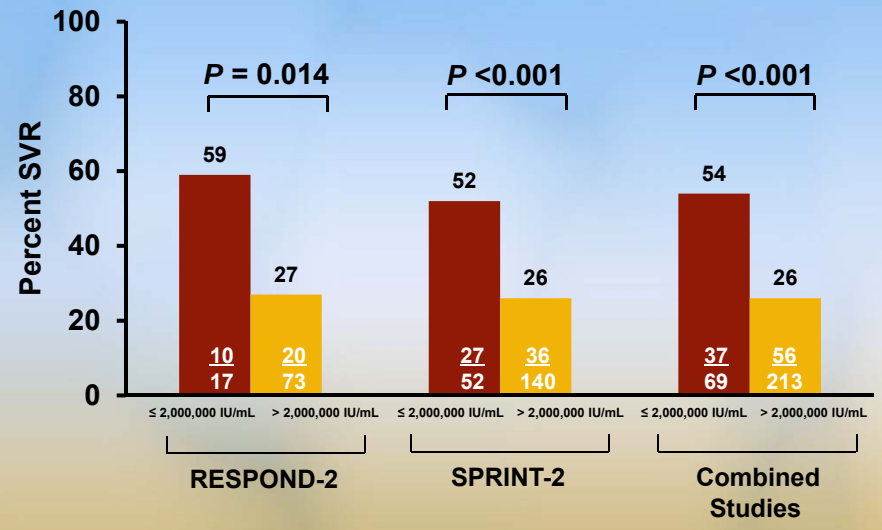
Baseline Viral Load as a Predictor of SVR in Patients with Poor IFN Response (BOC Arms Combined)



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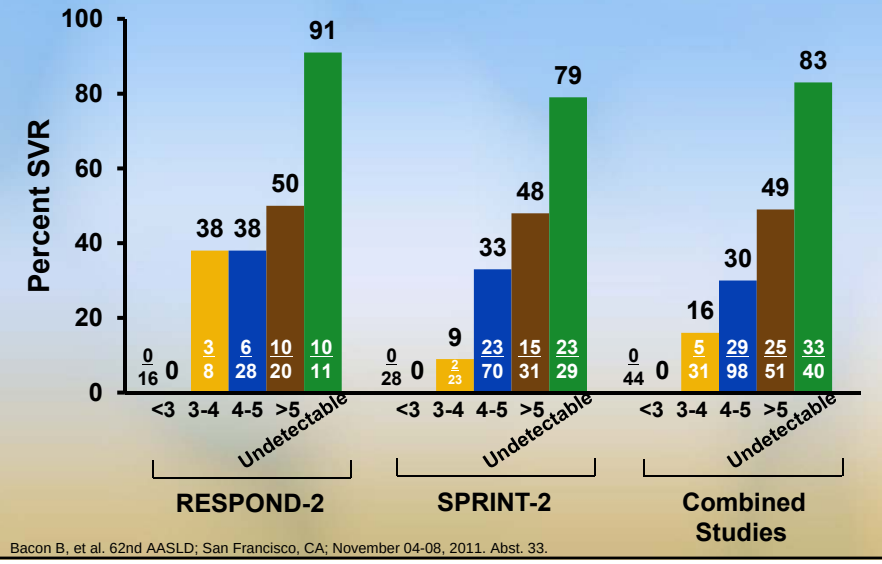
SVR in Poor IFN Responders Based on TW8 Response (Log Decline in VL Compared to BL VL) (BOC Arms Combined)



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Summary of Predictors of SVR in Poor IFN Responders

- TW8 virological response
  - No patient with <3 log decline at TW8 achieved SVR
  - Patients with undetectable HCV RNA at TW8 had best chance to achieve SVR
- Pre-treatment factors predictive of SVR
  - Genotype 1b
  - F0/1/2
  - BL viral load <2,000,000 IU/mL

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Efficacy of Boceprevir In Prior Null Responders to Peginterferon/Ribavirin: The PROVIDE Study

J. Vierling[1], S. Flamm[2], S. Gordon[3], E. Lawitz[4], J-P Bronowicki[5], M. Davis[6], E. Yoshida[7], L. D. Pedicone[8], W. Deng[8], M. Treitel[8], C. Brass[8], J. Albrecht[8], and I. Jacobson[9]

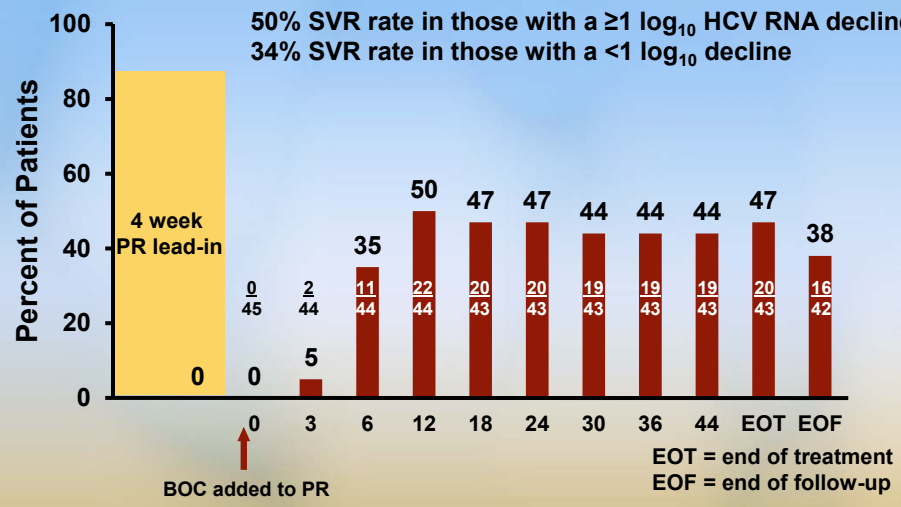
[1]Baylor College of Medicine, Houston, TX; [2]Northwestern Feinberg School of Medicine, Chicago, IL; [3]Henry Ford Hospital, Detroit, MI, USA; [4]Alamo Medical Research, San Antonio, TX; [5]University Henri Poincare of Nancy, Vandoeuvre-lès-Nancy, France; [6]South Florida Center of Gastroenterology, Wellington, FL; [7]University of British Columbia and Vancouver General Hospital, Vancouver, BC, Canada; [8]Merck Sharp & Dohme Corp., Whitehouse Station, NJ; [9]Weill Cornell Medical College, New York, NY

Methods: 48 Patients from SPRINT-2 and RESPOND-2 that were Classified as a Prior Null Responder to PR Therapy

- PROVIDE treatment regimen:
  - Boceprevir 800 mg orally TID
  - PEG2b 1.5 µg/kg s.c. once weekly
  - Ribavirin 600-1400 mg/day (based on weight) orally in 2 divided doses
- All patients in this sub-analysis received a 4-week PR lead-in prior to receiving BOC
  - Patients received BOC + PR for up to 44 weeks, with 24 weeks of post-treatment follow-up to determine SVR
- Futility stopping rule: Detectable HCV RNA at TW12
- Primary endpoint: SVR, undetectable HCV RNA 24 wks post therapy (Roche TaqMan, LLD = 9.3 IU/mL)

Vierling J, et al. 62nd AASLD; San Francisco, CA; November 04-08, 2011. Abst. 931.

Cumulative Achievement of Undetectable HCV RNA in Prior Null Responders*



*Of 48 prior Null Responders from SPRINT-2 and RESPOND-2, 3 discontinued during the lead-in phase, 2 are ongoing treatment (1 entering TW3, 1 entering TW18 of BOC/PR) and 1 is in follow-up phase

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