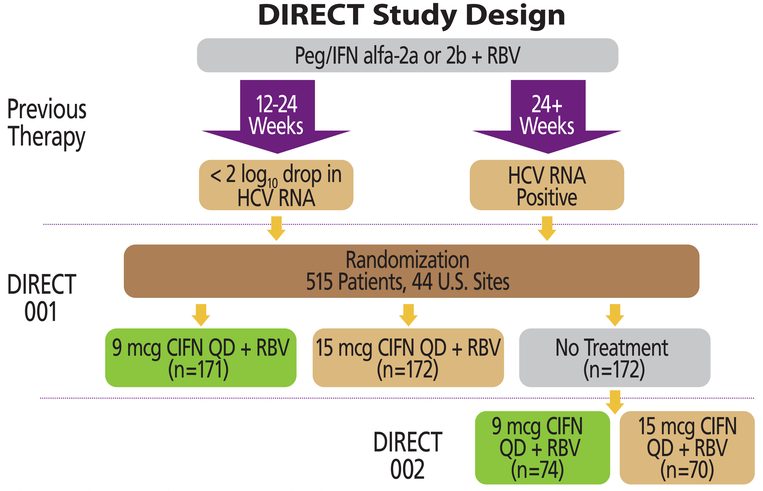
SUSTAINED VIROLOGICAL RESPONSE RATES IN PATIENTS ACHIEVING SLOW RESPONSE OR COMPLETE EARLY VIROLOGICAL RESPONSE (cEVR) WITH CONSENSUS INTERFERON (CIFN) AND RIBAVIRIN IN THE DIRECT TRIAL

Bruce R. Bacon[1]; Mitchell L. Shiffman[2]; Flavia Mendes[3]; Reem Ghalib[4]; Tarek Hassanein[5]; Giuseppe Morelli[6]; Shobha Joshi[7]; Kenneth Rothstein[8]; Paul Kwo[9]; Norman Gitlin[10]

[1]Saint Louis University Liver Center, Saint Louis University School of Medicine, St. Louis, MO, USA; [2] Hepatology Section, Virginia Commonwealth University Medical Center, Richmond, VA, USA; [3] University of Miami Miller School of Medicine, Miami, FL, USA; [4] Liver Institute at Methodist Hospital, Dallas, TX, USA; [5] University of California San Diego, San Diego, CA, USA; [6] University of Florida, Gainesville, FL, USA; [7] Tulane University Hospital and Clinic, New Orleans, LA, USA; [8] Albert Einstein Center for Liver Disease, Philadelphia, PA, USA; [9] Indiana University School of Medicine, Indianapolis, IN, USA; [10] Emory Crawford Long Hospital, Atlanta, GA, USA

BACKGROUND

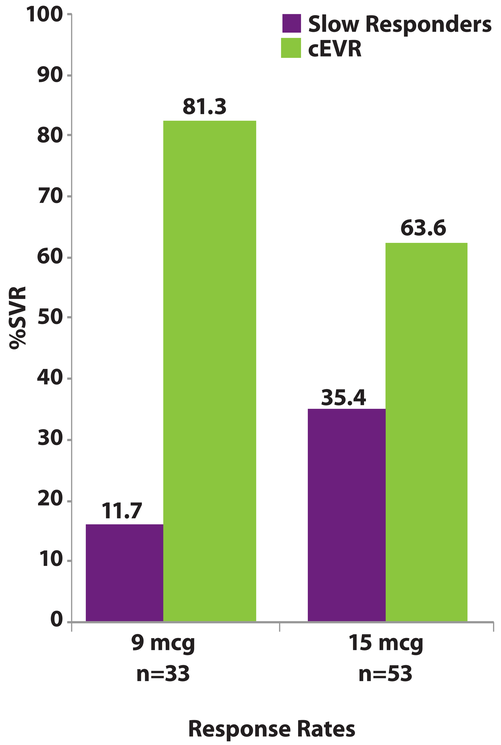
With time to viral negativity being an important factor in predicting response rates with Hepatitis C Therapy, a retrospective analysis was completed to determine the sustained virological response (SVR) rates in patients who were viral negative at Week 12 (cEVR) of Consensus Interferon/RBV therapy, or in patients deemed slow responders (pEVR at Week 12, viral negative at Week 24) in the DIRECT trial. The DIRECT trial was a US based, phase 3, randomized, multi-center trial determining the effectiveness of daily Consensus Interferon with weight-based ribavirin in documented prior non-responders to peg IFN/RBV therapy.



* Patients with < 2 $\log_{10}$ drop in HCV RNA between Week 12 and 24

RESULTS

Of these patients, 94 (38.3%) in the 9mcg arm achieved pEVR, with 17 patients achieving viral negativity at Week 24 on CIFN/RBV therapy. In this slow responder group, 2/17 (11.7%) went on to achieve SVR. In the same 9 mcg arm, 16 patients achieved cEVR at Week 12, with 13 (81.3%) maintaining SVR. In the 15mcg arm, 103 patients (42.6%) achieved pEVR, with 31 patients attaining viral negativity at Week 24. Patients who were slow responders in the 15 mcg treatment arm achieved 35.4% SVR (11/31). Twenty-two patients were viral negative at Week 12 of therapy, and of these, 63.6% went on to achieve SVR (14/22).



METHODS

487 patients administered at least one injection of either 9 or 15 mcg of Consensus Interferon in combination with ribavirin. Baseline demographics include:

- Genotype 1: 95-96%
- HVL (>400,000 IU/ml): 85-90%
- Average BMI: 29
- African-American: 17-21%
- F3-F4 fibrosis: 58-62%
- Documented response of < 2 $\log_{10}$ drop on prior peg-IFN/RBV therapy: 78-80%
- Average washout from previous peg-IFN/RBV Therapy: 453-594 days
- Presence of steatosis on biopsy: 51%

CONCLUSION

Defining viral response at Week 12 and 24 with Consensus Interferon and ribavirin in patients who were prior non-responders to peg-IFN/RBV therapy can help predict SVR rates in this difficult to treat group of patients. In the DIRECT trial, all patients attaining SVR demonstrated > 2 $\log_{10}$ drop at Week 12 of CIFN/RBV therapy. Regardless of treatment dose used, attaining cEVR or slow response while on therapy with Consensus Interferon and ribavirin leads to a high sustained virological response rate.