

RELEVANCE BETWEEN FIBROSIS AND RESPONSE TO TREATMENT WITH PEGINTERFERON ALFA 2A VS ALFA 2B WITH RIBAVIRIN AMONG CHRONIC HEPATITIS C GENOTYPE 3 PATIENTS. RANDOMIZED OPEN LABEL STUDY.

Anna Kolakowska-Rzadzka¹, Hanna Berak¹, Marek Wasilewski¹, Janusz Stańczak¹, Krzysztof Bardadin², Bożena Walewska- Zielecka³, Andrzej Horban¹;

¹ Hospital for Infectious Diseases, Warsaw, Poland,

² Medical Centre for Postgraduate Education, Warsaw, Poland;

³National Institute of Hygiene, Warsaw, Poland

Background:

- Chronic infection with HCV genotype 3 is highly responsive to the combination therapy with peginterferon. According to guidelines for viral hepatitis the biopsy is not mandatory for HCV genotype 3, so it is not performed routinely.

Aim:

- To compare the efficacy of both alfa2a and alfa2b peginterferons and to determine the impact of stage of fibrosis, age, gender, weight and ALT level on sustained virological response (SVR) after standard 24 week treatment in patients infected with HCV genotype 3.

Methods:

- Sixty-seven naïve patients with HCV genotype 3 infection treated with pegylated interferons from 2004 to 2006 at our center were included to the study.

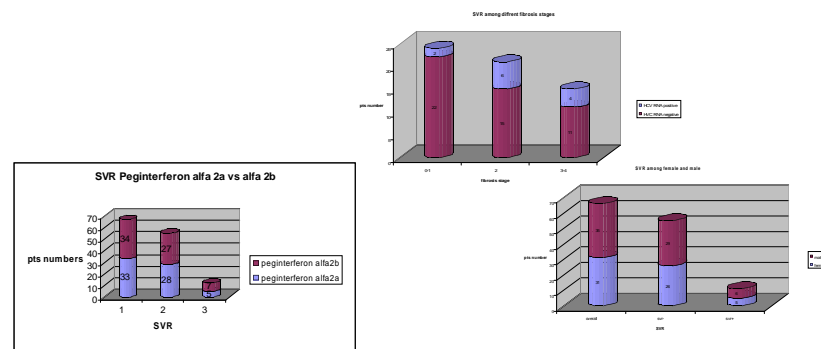
Thirty three patients received Peginterferon alfa2a (group A) and thirty four received Peginterferon alfa2b (group B) with weight based dose ribavirin for 24 weeks. HCV RNA was performed 24 weeks following therapy to determine SVR. Liver biopsies performed at sixty patients were analyzed according to Knodell's and Scheuer's scores and grouped depend of fibrosis stage. Seven biopsies were not performed because of contraindication (hemophilia).

- Comparison of baseline characteristics (table 1) and sustained virological response between the two groups was performed.

| | | OVERALL | GROUP A (pegIFN 2a) | GROUP B (pegIFN 2b) | p-value |
|------------------|--------|---------------|---------------------|---------------------|---------|
| Gender | Male | 26 | 15 | 21 | NS |
| | Female | 27 | 18 | 19 | NS |
| Staging | 0 | 8 | 2 | 6 | NS |
| | 1 | 16 | 8 | 8 | NS |
| | 2 | 23 | 12 | 11 | NS |
| | 3 | 10 | 6 | 4 | NS |
| | 4 | 2 | 1 | 1 | NS |
| Missing biopsies | | 7 | 4 | 3 | NS |
| age | | 39.0 (19.62) | 40 (19.62) | 39.8 (20.47) | NS |
| Weight kg | | 72.24 (10.02) | 70.3 (10.06) | 74.1 (10.20) | NS |
| ALT U/L | | 124 (19.60) | 143 (18.55) | 100 (10.00) | NS |

Results:

- Baseline characteristic of groups were comparable in terms of gender, fibrosis staging, age, weight and ALT baseline level and were not statistically significant.
- Overall SVR was 84% (28/33) in group A and 79% (27/34) in group B (p=NS).
- SVR among female was 83% (26/31) and 82% (29/35) among male patients (p=NS).
- SVR observed in pts with staging 3-4 fibrosis was 73% (11/15), in staging 2 fibrosis was 71% (15/21) and were lower than in staging 0-1 fibrosis 91% (22/24) (p=0.05)



Conclusions:

- In population with HCV genotype 3 we found no statistically significant differences in the sustained response rates between patients treated with peginterferon alfa 2a vs. alfa 2b. Better response in patients group with low fibrosis stage in both peginterferons was observed as single (alone) predictive factor for SVR in HCV genotype 3. However, patients with highly responsive genotype should be treated despite of the biopsy results.