Randomized, open label trial comparing efficacy and safety of pegylated interferon alfa 2a vs alfa 2b treatment of patients with chronic hepatitis C infected with non 2/3 genotypes – Final analysis

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INTRODUCTION:

Therapeutical efficacy of interferon alfa 2a versus interferon alfa 2b both in combination with ribavirin was finaly analyzed at 24 week after end of treatment (SVR). 212 patients (pts) with chronic hepatitis C infected with non 2/3 genotypes were allocated to either group A (Pegasys, 40 KD) or group B (Pegintron, 12 KD).

PATIENTS AND METHODS:

Liver biopsies were analyzed according to the Knodell's and Scheuer's scores. The levels of ALT activity were determined with routine tests. On week 12, 48 and 72 HCV RNA was performed, determined with HCV RNA Assay and viral load (VL) with ca HCV Monitor test (both of Roche Diagn Sys.). The main study outcome was undetectable HCV RNA on 24 week after end of treatment.
Statistical analysis was performed with Chi-squared, Kruskal-Wallis and unpaired t-tests as appropriate. To compare the difference between the intervention groups an intention to treat missing equals failure analysis (ITT M=F) was performed. The 95% confidence interval (CI) was accepted. All analysis were performed using SAS 9.1.

RESULTS:

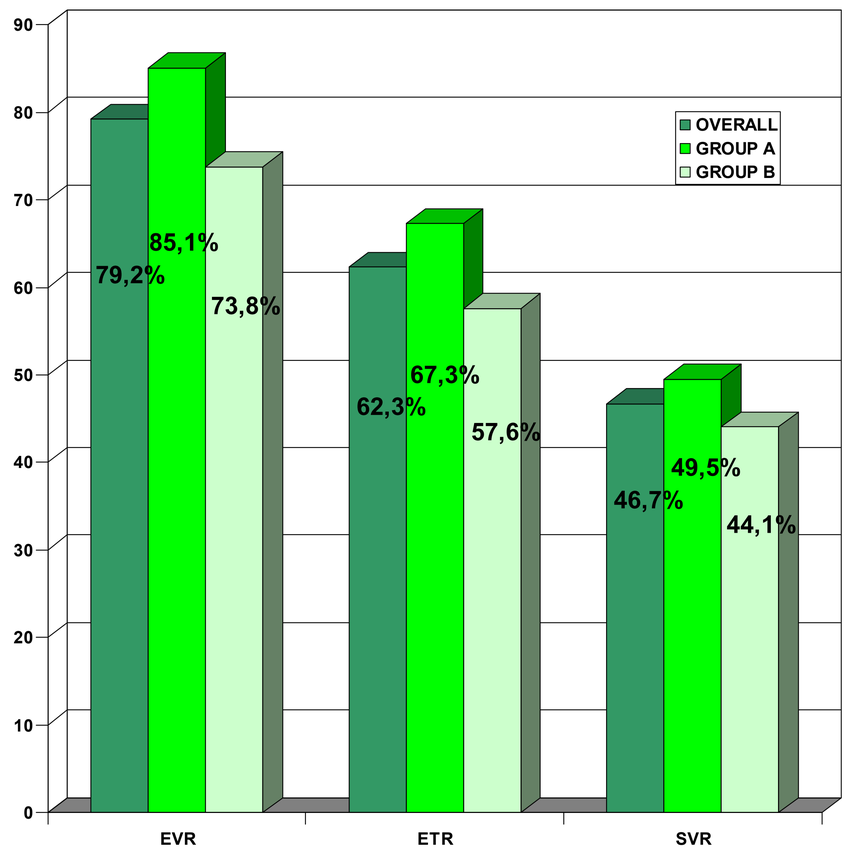
212 pts were randomized, 101 to group A and 111 to group B. The groups did not significantly differ in gender (p=0.12), staging (p=0.12), age (p=0.55) and baseline ALT (p=0.89). There was a significant difference in weight between the treated groups (p=0.037). 12 pts in A and 28 pts in B group have discontinuated the drug due to loss of EVR. 7 pts in A and 3 pts in B group were excluded due to toxicities and were further analyzed as treatment failure. 17 pts were lost to SVR observation.
The EVR rate for the A group was 85.1% (86/101) and 73.8% (82/111) in the B group. The difference was statistically significant.
The ETR for the A group was 67.33% (68/101) and 57.66% (64/111) in group B with no significant difference between the groups (ITT M=F: p=0.15).
The SVR for the A group was 49.5% (50/101) and 44.1% (49/111) in group B with no significant difference between the groups (ITT M=F: p=0.43).

Table I. Baseline characteristics

	Overall	GROUP A	GROUP B	p value
Gender: male female	**n (%)**			0.12*
	121 (57.08)	52 (51.49)	69 (62.16)	
	91 (42.92)	49 (48.51)	42 (37.84)	
Staging: 1 - 2 3 - 4 unknown	**n (%)**			0.12*
	166 (78.30)	85 (84.16)	81 (72.97)	
	37 (17.45)	12 (11.88)	25 (22.52)	
	9 (4.25)	4 (3.96)	5 (4.56)	
	median (IQR)			
Age (year)	44 (32 - 50)	44 (32 – 49)	44 (32 – 52)	0.55**
ALT (U/L)	96.5 (70 – 132)	102 (71 – 131)	95 (68 – 141)	0.89**
	mean (SD)			
Weight (kg)	75.36 (15.59)	73.03 (16.27)	77.49 (14.70)	0.037***

*Chi-squared test **Kruskal-Wallis test ***unpaired t-test SD-standard deviation
IQR – interquartile range

Table II. Results



CONCLUSION:

Differences in virologic response in both groups probably are caused by structure of the two types of interferon.