chronic hepatitis C (CH-C). Control of HCV infection is linked to strong immune responses. Little is known on the association between IL28B SNPs, innate and adaptive immune responses in relation to therapy outcome in CH-C.

**Aim** To evaluate the relationship between rs12979860 and rs8099917, pre-treatment frequency/phenotype of natural killer (NK) cells (innate immunity), HCV-specific immune responses (adaptive immunity), and Peg-IFN/ribavirin response.

**Method Patients:** 19 CH-C genotype 1 patients (15 males, median age 47 years) treated with Peg-IFN/ribavirin were divided in 3 groups: 10 responders (SVR), 5 non-responders (NR) and 4 relapsers (Rel).

**Results**

1. **Methods:** rs12979860 and rs8099917 were tested by direct sequencing. Baseline numbers of NK cells (CD3−/CD56+), their subsets CD56bright/CD56dim, CD3−CD56+/−CD16+/−, and expression of NK cell activation/inhibition (NK2G2D/NKG2A) markers were investigated by flowcytometry on peripheral blood mononuclear cells (PBMC). PBMC IFN-γ and IL-10 production after exposure to HCV-core, NS3, NS4, NS5 antigens was evaluated by intracellular cytokine staining. Results are presented as medians.

2. **Results**

   - 10 responders (SVR), 5 non-responders (NR) and 4 relapsers (Rel).
   - **Age:** 47 years) treated with Peg-IFN/ribavirin were divided in 3 groups: 10 responders (SVR), 5 non-responders (NR) and 4 relapsers (Rel).
   - Baseline numbers of NK cells (CD3−/CD56+), their subsets CD56dim/CD56bright, CD3−CD56+/−CD16+/−, and expression of NK cell activation/inhibition (NK2G2D/NKG2A) markers were investigated by flowcytometry on peripheral blood mononuclear cells (PBMC). PBMC IFN-γ and IL-10 production after exposure to HCV-core, NS3, NS4, NS5 antigens was evaluated by intracellular cytokine staining. Results are presented as medians.

3. **Results**

   - **Conclusion** High numbers of CD56bright NK cells, low numbers of unconventional CD3−CD56−CD16− NK cells, and low HCV-specific IL-10 production at baseline are associated with IL28B gene SNPs rs12979860 CC haplotype and successful antiviral treatment of CH-C genotype 1.

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**SUBANALYSES OF THE TELAPREIV ARM IN THE REALIZE STUDY: RESPONSE AT WEEK 4 IS NOT A SUBSTITUTE FOR PRIOR NULL RESPONSE CATEGORISATION**

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**Introduction** On treatment, a poor therapeutic response to peginterferon (P)/ribavirin (R) is defined as a <1 log10 decline in viral load at week 4. Null response (NR) to a current or prior course of PR is defined as a <2 log10 decline in HCV RNA at week 12. The FDA adopted the week 12 NR definition in its recent draft guidance. The REALIZE study uniquely enrolled classically defined prior NR, partial responders and relapers, and included an arm with a PR lead-in (L-I) phase. This design allows a comparison of on treatment response after 4 weeks of PR with prior response categories, including a comparison of ‘null response’, as well as the relationship between < or −1 log10 RNA decline and SVR in response to T/PR treatment.

**Method** Patients in the lead-in arm (N=240) received 4 weeks of PR followed by telaprevir (T) 750 mg 8 hourly for 12 weeks combined with PR followed by 32 weeks of PR alone. Control patients (N=121) received 48 weeks of PR. All patients received pegylated interferon alfa-2a.