

CS, female, 51 years

- anti-HCV was detected at a routine testing in a 51-year-old female patient no complaints, no history of drug abuse or blood transfusions
- June 2010 (6 months after diagnosis) she was referred for treatment
- ALT slightly increased
- Fibroscan: 5.8 0.5 kPa
- Genotype 1b.
- IL-28B rs12979860 T/C genotype.

- What would you do?

- Pat. was offered to participate in a triple therapy trial
- SILEN 1 trial\* (3 days lead in with PEGIFN/ribavirin followed by peginterferon/ribavirin/faldaprevir 120 mg daily for 12 weeks and PEGIFN/ribavirin for a total of 24 weeks).
- HCV-RNA became undetectable at week 4
- and remained undetectable throughout the whole therapy.
- She was HCV-RNA negative after 24 weeks of follow-up
- (SVR24) and had aminotransferases in normal range.



- What would you do?

- Two months later (32 weeks after and of treatment), she came to the out-patient unit because of abdominal pain\*.
- Laboratory test showed detectable HCV-RNA
- viral load: 1.33 E5 IU/mL.
- The positive HCH RNA was confirmed several times thereafter.
- Late relapse (> 24 weeks after EOT) was observed in 2/105 patients.\*

- What would you do?

- Cloning sequencing in this patient showed the same sequence in the sample taken after relapse as in the sample obtained at screening.
- Resistance analysis revealed no presence of viral resistance.

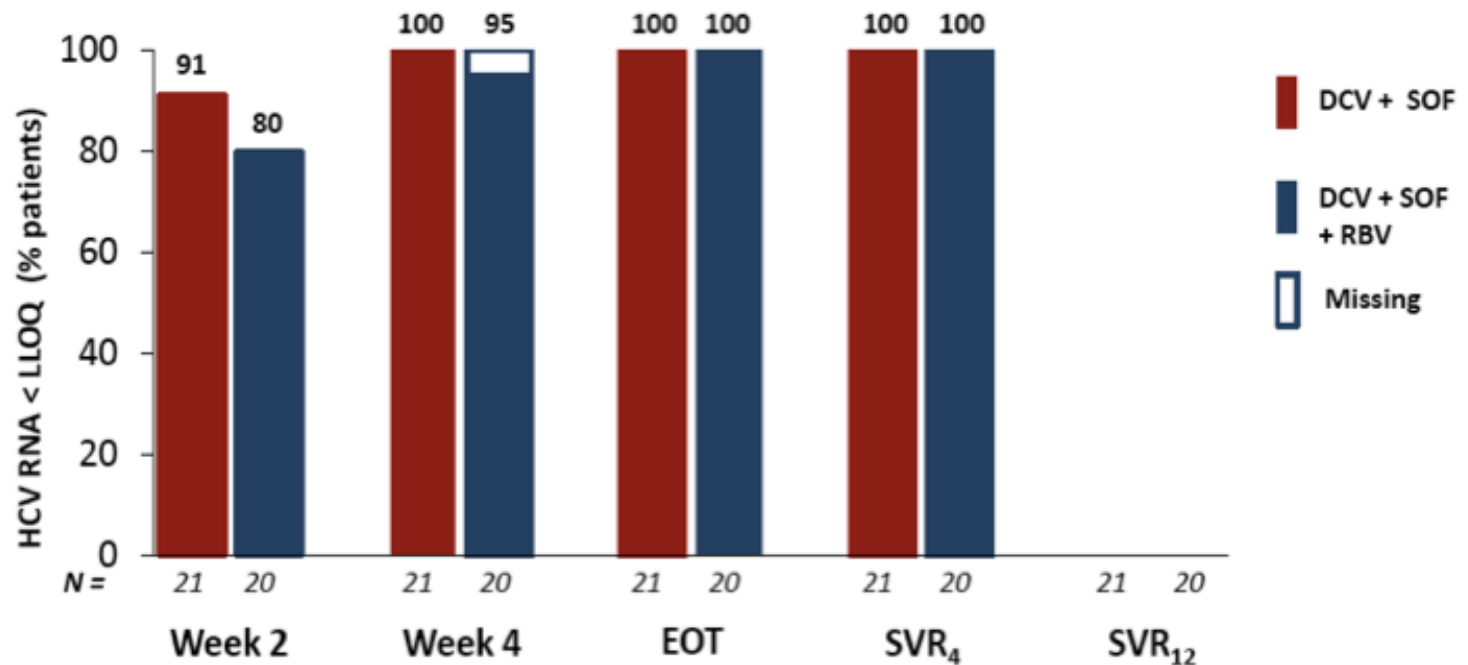


# RAV's in phase 3 studies

- Resistant variants were observed in 77% (299/388) of patients who did not achieve SVR.
- More commonly in subtype 1a (86%; 232/269) than in subtype 1b infections (56%; 67/119).
- Follow-up visit was available in 355 patients (median follow-up period: 9.6 months).
- Of patients with resistance at time of failure and at least 1 follow-up visit, 60% (153/254) lost resistance.
- The median time to wild type was 10.6 months (95% confidence interval [CI], 9.47-12.20) in subtype 1a and 0.9 months (95% CI, 0.00-2.07) in subtype 1b infections.

# SOFOBUVIR + DACLATASVIR IN TELAPREVIR/PEG RBV FAILURES

## Virologic Response During and After Treatment (mITT)



- She received a retreatment with pegIFN/RBV and telaprevir for a total of 24 weeks and was HCV-RNA undetectable at end of treatment.
- 72 weeks after end of treatment HCV-RNA is still undetectable.