



ARV Therapies and Therapeutic Strategies

INDEPENDENT REPORTING ON CROI 2017

Comprehensive Expert Review and Discussion of Key Presentations

An Independent CME Activity Jointly Provided by Postgraduate Institute for Medicine and ViralEd, Inc.
This coverage is not sanctioned by the conference organizers and is not an official part of the conference proceedings.

IS THE RATE OF HEPATOCELLULAR CA AFTER SVR INCREASING IN THE DAA ERA?

Renslow Sherer



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HEPATOCELLULAR CARCINOMA AFTER SVR WITH IFN-FREE REGIMENS IN HIV/HCV COINFECTION

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Abstract 139

GEHEP 002 Spanish HCV/HIV Cohort HCC After SVR w/ IFN-free Regimens

▲ 319 HCV/HIV patients with HCC in 32 Spanish centres, 1996-2016

▲ 45% pretreated

▲ 295 cases of HCC after median 16-24 months after SVR

Period 1 (≤2001): non-pegylated IFN

Period 2 (2002-2001): pegylated IFN plus ribavirin

Period 3 (2012-October 2014): DAA in combination with pegylated IFN

Period 4 (October 2014-2016): DAA IFN-free regimens

1. Median (Q1-Q3); 2. Available in 256 patients.
Merchante N et al CROI 2017 #139

Results (I): GEHEP-002 Cohort Characteristics of Patients (n=319)

Parameter	Value
Age (years) ¹	49 (46-52)
Male sex, no (%)	287 (90)
Previous daily alcohol consumption > 50 gr/day, no (%)	87 (27)
HBsAg, no (%)	41 (14)
HCV genotype, no (%) ²	
1	125 (49)
2	3 (1)
3	93 (36)
4	35 (14)
Previous therapy against HCV, no (%)	143 (45)
Previous SVR, no (%)	40 (12)

GEHEP 002 Spanish HCV/HIV Cohort HCC After SVR w/ IFN-free Regimens

Methods (II) Statistical Analyses

▲ In order to assess the possible associations between DAA use and the risk of HCC, three different analyses were performed:

▲ **The proportion of HCC cases after SVR** and the evolution of the proportion over time were analyzed

▲ **Frequency of HCC cases after SVR in HIV/HCV-cirrhotics** in each period was computed:

- Cases of HCC after SVR x 100 / patients with cirrhosis and SVR in each period

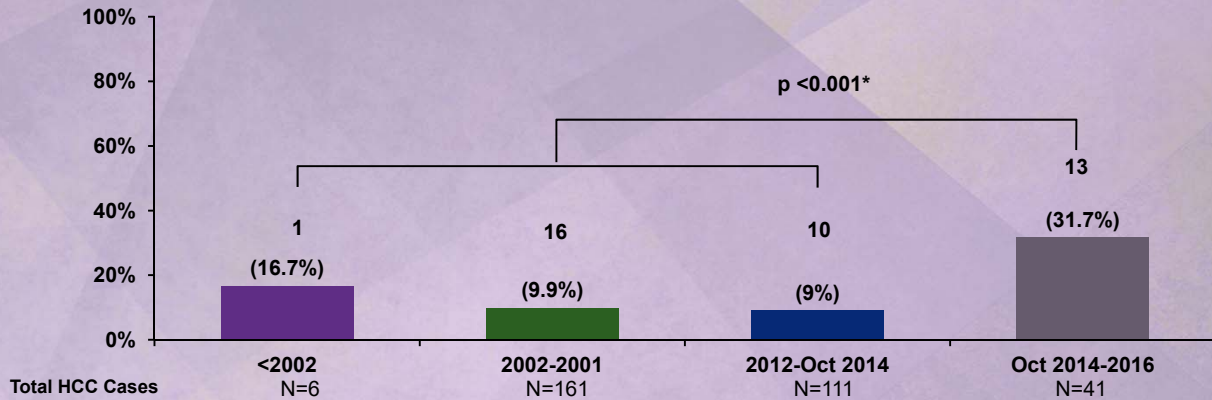
▲ **Incidence of HCC recurrence after SVR** in those patients with:

- Previous HCC treated with curative therapies (ablation, resection, LT)
- Undergoing therapy against hepatitis C
- No ultrasound evidence of HCC prior to hep C treatment

GEHEP 002 Spanish HCV/HIV Cohort HCC After DAA therapy

▲ Apparent increase in % of HCCs occurring after SVR in modern era, 31% vs 9-16%

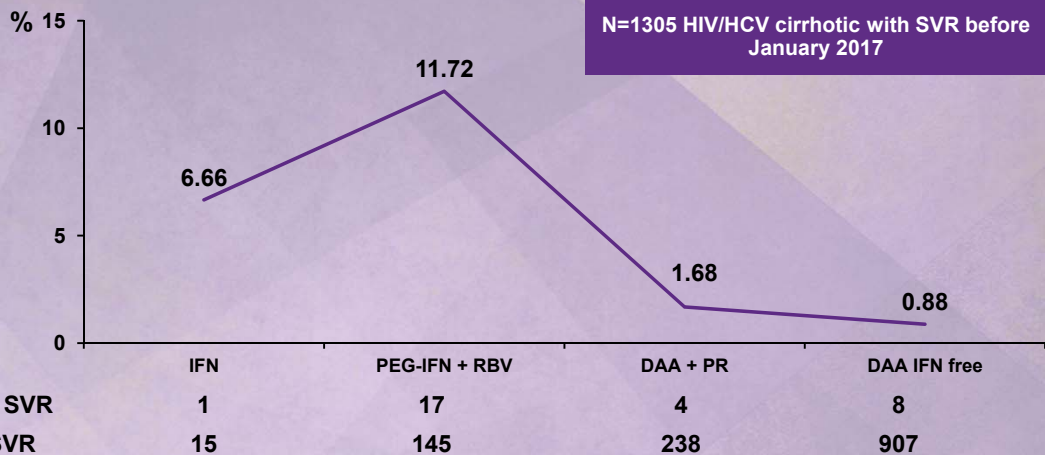
n HCC After SVR/Total n HCC



Merchante N, et al. 24th CROI; Seattle, WA; February 13-16, 2017. Abst. 139.

Frequency of HCC Diagnosis After SVR in HIV/HCV Coinfected Patients with Cirrhosis

19 centers from the GEHEP-002 cohort reported data of the number of HIV/HCV-coinfected patients with cirrhosis who achieved SVR in each period

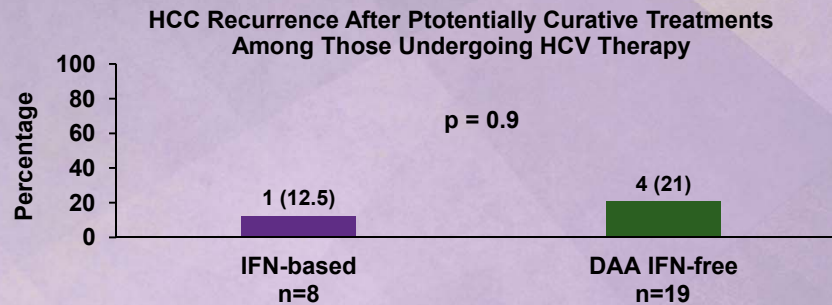


Merchante N, et al. 24th CROI; Seattle, WA; February 13-16, 2017. Abst. 139.

Results (V): Analysis 3 HCC Recurrence After Therapy Against HCV

39 patients with HCC received therapy against HCV after HCC diagnosis

- ▲ n=8 IFN-based. All of them after HCC curative therapies
- ▲ n=31 DAA IFN-free
 - n=19 with previous curative therapies against HCC and ultrasound evidence of lack of nodules prior to HCV therapy



Merchante N, et al. 24th CROI; Seattle, WA; February 13-16, 2017. Abst. 139.

Hepatocellular CA After SVR in HCV Pts on DAAs

- 1,154 Italian HCV Pts
 - 34% HIV/HCV
 - 16.7 mos F/U in DAA era
- 27 HCC cases: rate/100py
 - 21 1st event **1.44/100 pt-yrs**
 - 6 recurrent
- 10 during and 17 after DAA
- Compared to historical control rate of **1-3/100 pt-yrs**, no difference in incidence

Menzaghi B, et al. 24th CROI; Seattle, WA; February 13-16, 2017. Abst. 542LB.



Summary

- ◆ More HCC is being diagnosed among HIV/HCV and HCV mono infx pts following SVR in the DAA era
- ◆ No evidence of an increased RATE of HCC following SVR
- ◆ Limitations
 - Shorter period of follow up in DAA era....but larger numbers in cohorts make impact less likely
- ◆ Observation may be explained by:
 - greater inclusion of more HCV+ patients and more patients with advanced liver disease
 - improved adherence to recommended HCC screening w/ U/S within 6 mos of DAA Rx
 - Reduction in benefit of DAA to reduce HCC in more advanced patients