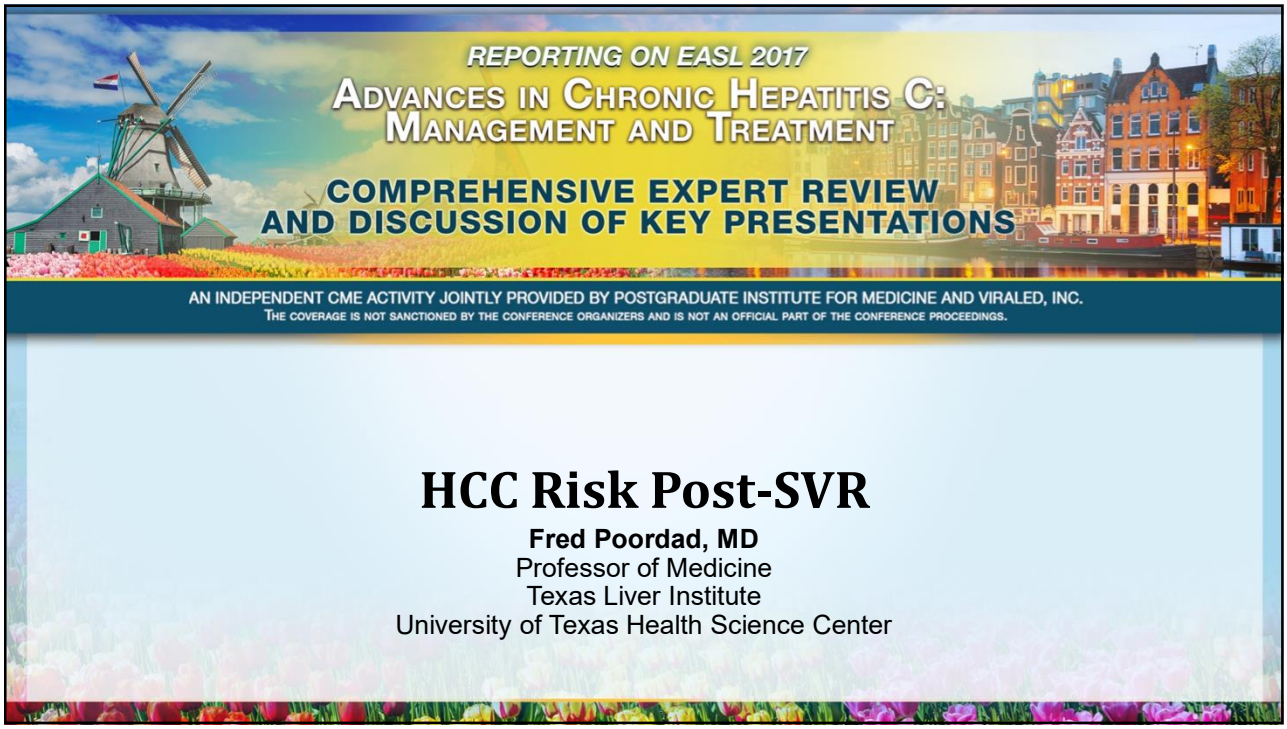

HCC Risk Post-SVR

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Among Cirrhotic Patients with a Hepatitis C Sustained Viral Response, the Risk of De-Novo Hepatocellular Carcinoma Relates to Baseline Factors and Not the Use of Direct Acting Antivirals: Results from a Nationwide Cohort

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Abstract PS-035

De-Novo HCC Risk Post-SVR Study: Background

Author	Journal	Recurrence or occurrence?	Country, setting	Sample	Frequency of HCC occurrence/ recurrence	Control group
Reig et al	J Hepatol, 2016	Recurrence	4 referral hospitals, Spain	Treated with IFN-free regimen after successfully treated HCC, N=59	28% after median follow-up of 5.7 months	None
Conti et al	J Hepatol, 2016	Recurrence	Liver clinics in Bologna, Italy	Treated with IFN-free regimen after successfully treated HCC, N=58	29% by 24 weeks post-treatment follow-up	None
Conti et al	J Hepatol, 2016	Occurrence	Liver clinics in Bologna, Italy	Cirrhotic patients treated with IFN-free therapy, N=285	3.2% HCC occurrence by 24 weeks post treatment follow-up	None
Cardos o et al	J Hepatol, 2016	Occurrence	One clinic in Portugal	Cirrhotic patients achieving SVR via IFN-free therapy, N=54	7.4% after median 12 months follow-up	None

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De-Novo HCC Risk Post-SVR Study: Methods

- Retrospective cohort study using
  - Scottish HCV clinical database (downloads @ April 2016)
  - Subsequent medical chart review (carried out February-March 2017)
- Definition of study cohort
  - Inclusion criteria
    - SVR attainment in 1997-2016
    - Liver cirrhosis at time of starting treatment
  - Exclusion criteria
    - Diagnosis of HCC prior to treatment
    - HBV/HIV co-infection
    - Attendance at a clinic with incomplete database or otherwise not able to participate in medical chart review
- Primary outcome event: first time diagnosis of HCC by cross-sectional imaging or biopsy
- Wide range of baseline patient characteristics extracted:
  - Age; gender ethnicity; postcode deprivation score; Child Pugh score; thrombocytopenia; alphafetoprotein; diabetes; alcohol history; smoking history; drug use history; prior genotype; clinic attended; number of prior treatment failures
- Survival analysis approach adopted
  - Start time = commencement of treatment
  - Stop time = earlier of: HCC occurrence; death; or reaching 31 Jan 2017
  - Used Cox regression to assess univariate and multivariate association between regimen (IFN-free vs. IFN-containing) and HCC

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De-Novo HCC Risk Post-SVR Study: Results - Baseline Description of the Cohort (N=857)

Characteristic		% of cohort (N=857)
Demographics	Average age	Mean: 49 years (sd:8)
	White ethnicity	92%
	Male gender	75%
Health Behaviours	History or heavy alcohol use	44%
	Current tobacco smoker	73%
	History of intravenous drug use	70%
Clinical	Thrombocytopenia (<100/10^9/L)	28%
	Child Pugh B/C	15%
	Diabetes	9%
Treatment	Treatment experienced	35%
	IFN-free regimen	32%

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De-Novo HCC Risk Post-SVR Study: IFN-Containing Patients vs. IFN-free Patients

Characteristic		REGIMEN		P-value
		IFN-containing (N=585)	IFN-free (N=272)	
Mean age		48.1 years	52.1 years	<0.001
Thrombocytopenic (<100 per 10^9/L)		22%	39%	<0.001
Child Pugh B or C		9%	30%	<0.001
Number of prior failed treatment episodes	0	73%	48%	<0.001
	1	21%	35%	
	≥2	7%	17%	

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De-Novo HCC Risk Post-SVR Study: Follow-up Time and Outcomes Events

		REGIMEN	
		IFN-containing (N=585)	IFN-free (N=272)
Follow-up, person years	Total Median per patient (IQR)	2697 3.5 (2.2-5.6)	475 1.7 (1.4-2.0)
Outcome events (i.e. HCC occurrence)	Total #	34	12
	# occurring <24 weeks post-treatment	6	5
	# occurring ≥24 weeks post-treatment	28	7
	Median time to even (min-max range)	2.5 yrs (0.3-8.5)	0.9 yrs (0.5-2.0)
	Crude rate, per 100 persons years	**1.26**	**2.52**

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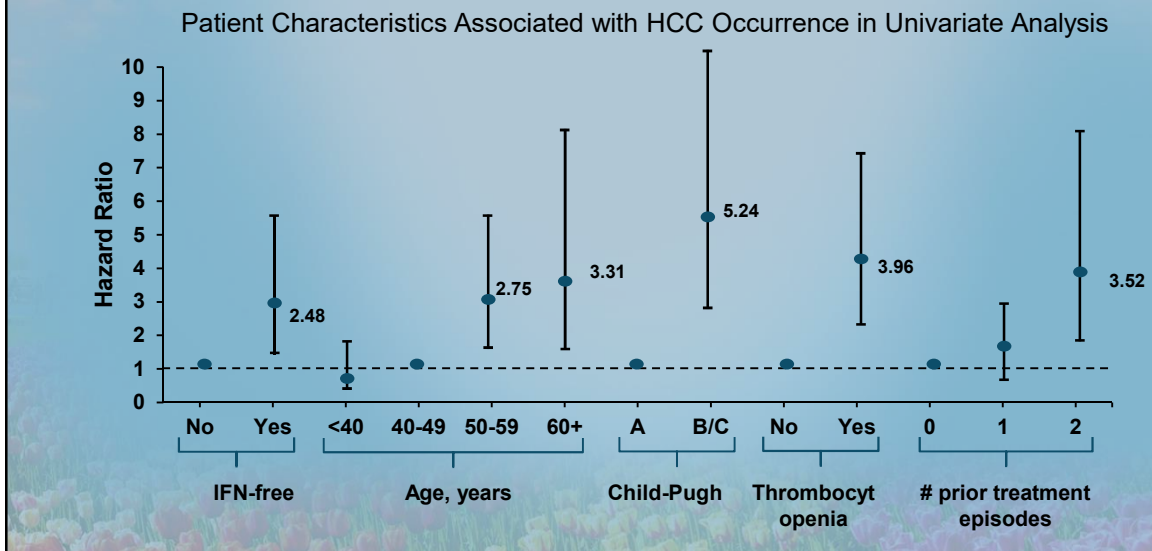
De-Novo HCC Risk Post-SVR Study: Patient Characteristics



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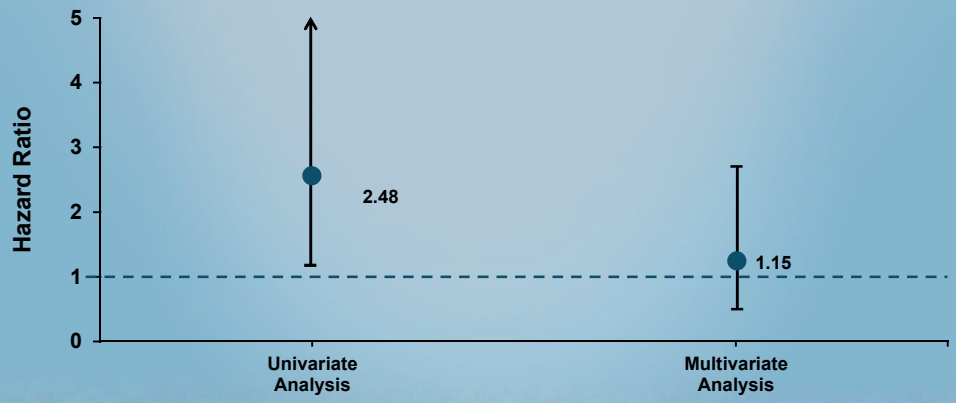
De-Novo HCC Risk Post-SVR Study: Results

Association Between IFN-Free versus IFN-containing Therapy and HCC Occurrence, in Univariate and Multivariate Analysis



*Multivariate analysis includes adjustment for: age, gender, ethnicity, Child Pugh score, thrombocytopenia, alpafetoprotein, genotype, treatment experience and clinic location

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De-Novo HCC Risk Post-SVR Study: Conclusions

- There is no evidence that IFN-free therapy increases the risk of HCC occurrence in patients achieving an SVR
- Baseline characteristics of patients treated with IFN-free regimens differ from those treated with IFN-containing regimens
- Multivariate analysis demonstrated that the risk of HCC occurrence was equivalent between these two groups of patients

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