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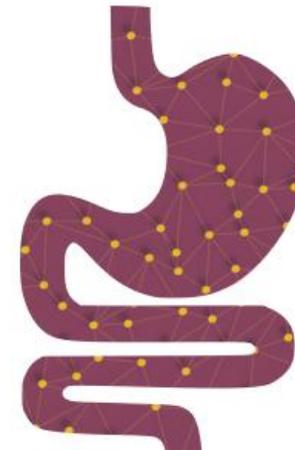


II JORNADA DE
FORMACIÓN CONTINUADA
EN GASTROENTEROLOGÍA
Y HEPATOLOGÍA
PARA RESIDENTES



24 y 25 de septiembre de 2021
Palacio de Congresos y Exposiciones de Ronda

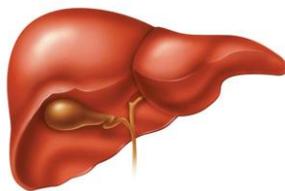
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Lectura crítica de artículo científico

Dra. Celia Pérez Estrada

Dr. Javier Ampuero



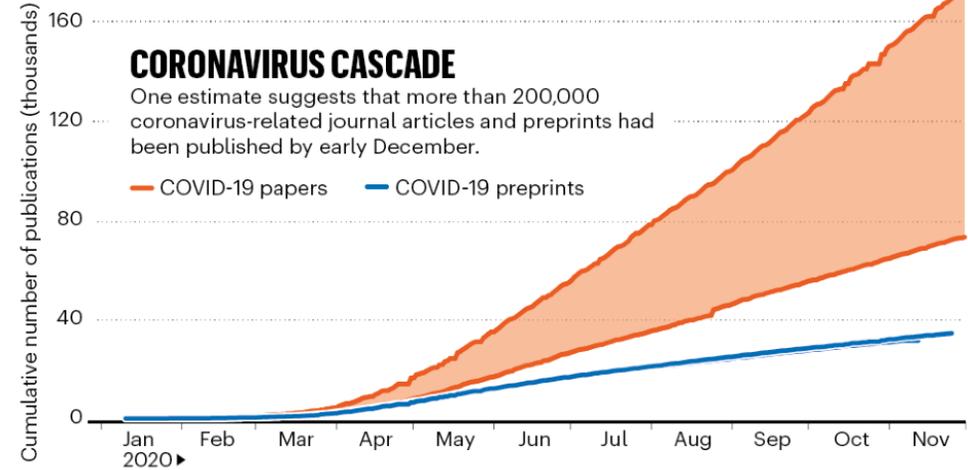
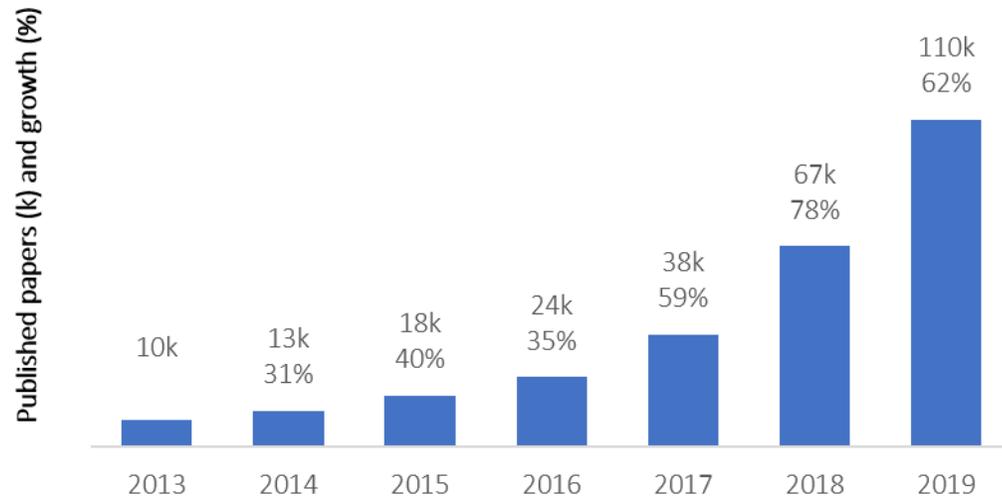
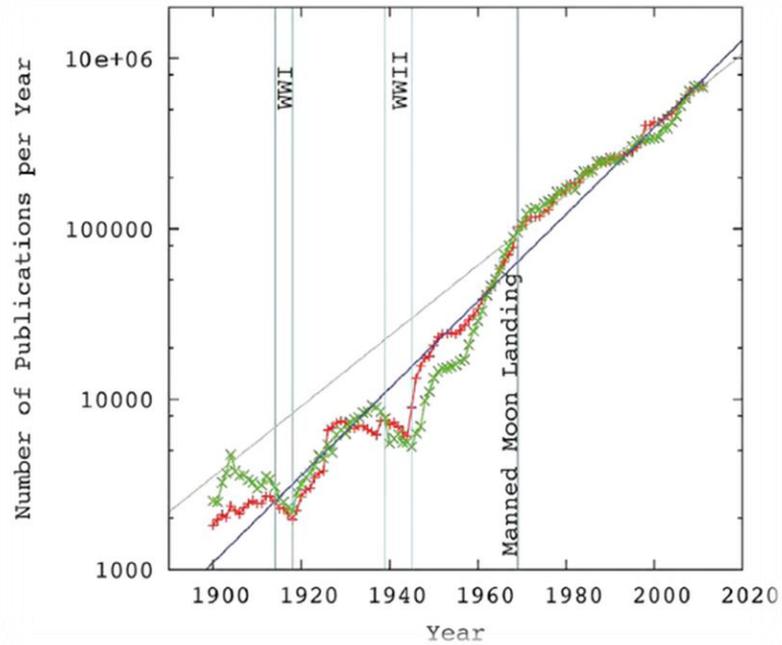
*UGC Enfermedades Digestivas
Hospital Universitario Virgen del Rocío
Sevilla, España*



¿Por qué es importante?

Lo esencial es invisible a los ojos

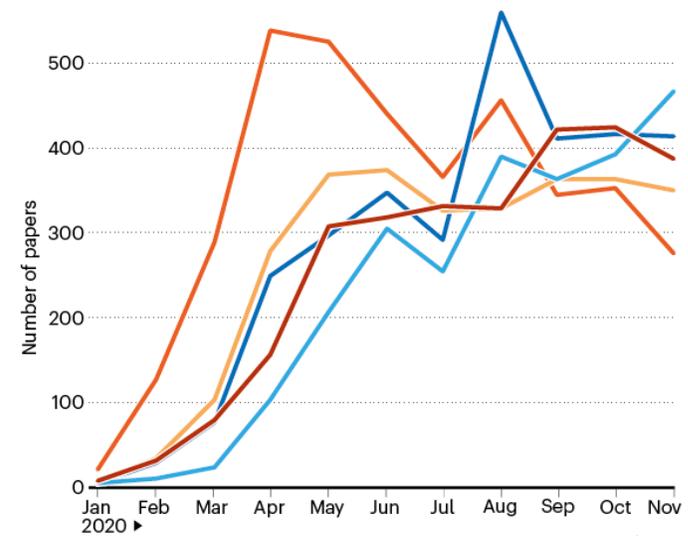


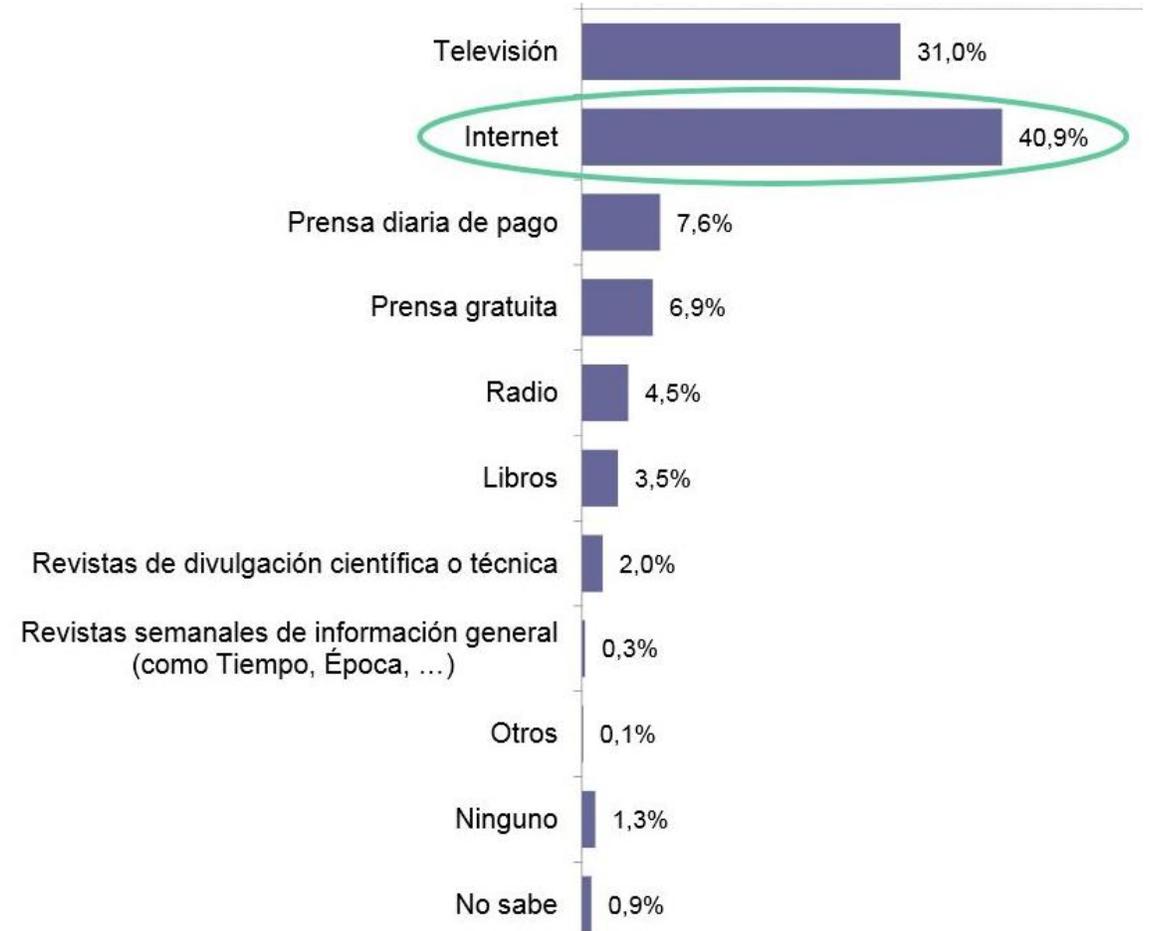
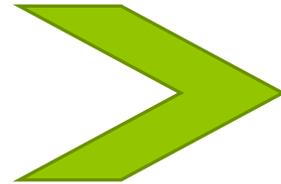
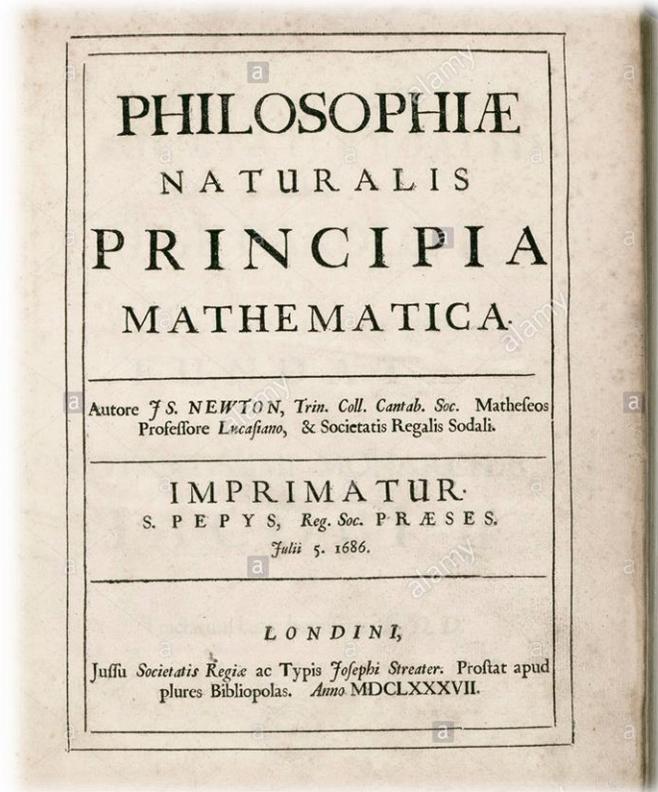


CORONAVIRUS PAPER TOPICS

After an early focus on modelling the spread of the pandemic, researchers are now turning to other topics, an analysis of PubMed papers and preprints suggests.

- Modelling epidemic, controlling spread
- Public health
- Diagnostics, testing
- Mental health
- Hospital mortality





¿Cómo y cuánto tiempo dedicar a un artículo?

Evitar quedar atrapado





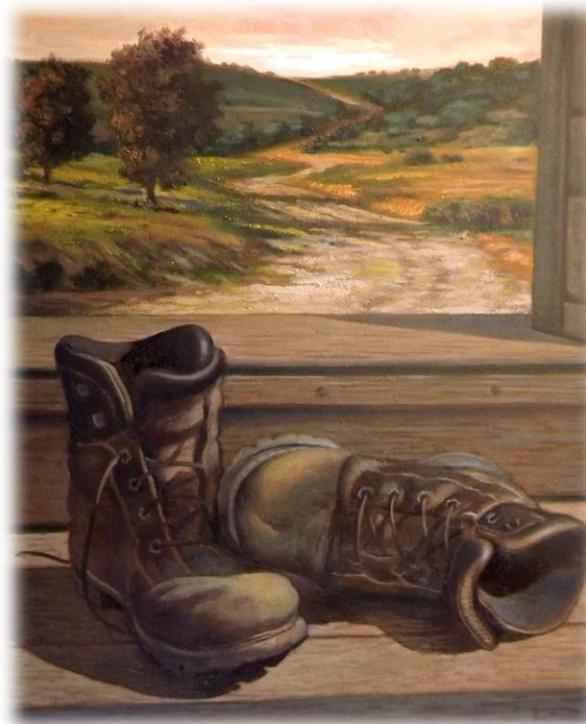
Programa de Habilidades en Lectura Crítica Español
Critical Appraisal Skills Programme Español

- 11 preguntas para dar sentido a un ensayo clínico
- 10 preguntas para ayudarte a entender una revisión
- 10 preguntas para entender un estudio sobre diagnóstico
- 11 preguntas para entender las Reglas de Predicción Clínica

- 10 preguntas para ayudarte a entender un estudio cualitativo
- 11 preguntas para ayudarte a entender un estudio de Casos y Controles
-  11 preguntas para ayudarte a entender un estudio de cohortes
- 11 preguntas para entender una evaluación económica

¿Cómo lo llevamos a la práctica?

Se hace camino al andar



1.- ¿El estudio se centra en un tema claramente definido?

- La población estudiada.
- Los factores de riesgo estudiados.
- Los resultados “outcomes” considerados.
- ¿El estudio intentó detectar un efecto beneficioso o perjudicial?



Research Article

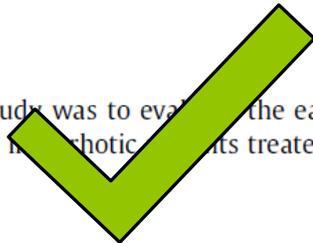


EASL | JOURNAL OF HEPATOLOGY

Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

The aim of this study was to evaluate the early occurrence and recurrence of HCC in cirrhotic patients treated with DAA.



Research Article

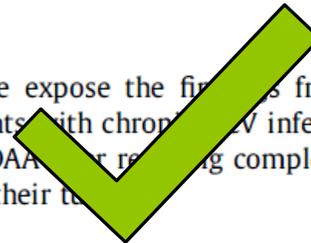


EASL | JOURNAL OF HEPATOLOGY

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy*

Reig et al. J Hepatol 2016

In this study we expose the findings from a well-defined population of patients with chronic HCV infection and HCC that were treated with DAA after reaching complete tumor response after treatment for their tumor.



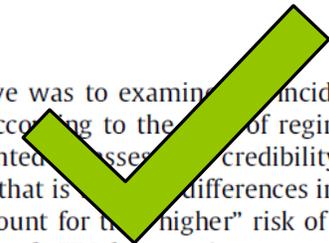
Research Article
Viral Hepatitis

JOURNAL OF HEPATOLOGY

The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

Our objective was to examine the incidence of *de novo* HCC occurrence according to the type of regimen received. In particular, we wanted to assess the credibility of the shifting case mix theory – that is, the differences in patient characteristics could account for the “higher” risk of HCC occurrence following receipt of IFN-free regimens vs. IFN-containing regimens.



2.- ¿La cohorte se reclutó de la manera más adecuada?

- ¿La cohorte es representativa de una población definida?
- ¿Hay algo "especial" en la cohorte?
- ¿Se incluyó a todos los que deberían haberse incluido en la cohorte?
- ¿La exposición se midió de forma precisa para minimizar sesgos?

Research Article



EASL JOURNAL OF HEPATOLOGY

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Conti et al. J Hepatol 2016

HBsAg positive, n. (%)	7 (2.0)
Child-Pugh A/B, n.	305/39

	Without HCC after DAAs (n = 318)	With HCC after DAAs (n = 26)
SVR12		
Yes	292	22
No		4
Previous HCC treatment		
Surgery (± RFA/TACE)	15	8
RFA (± TACE)	16	6
PEI	5	1
TACE	3	2

Research Article



EASL JOURNAL OF HEPATOLOGY

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy*

Reig et al. J Hepatol 2016

	Total cohort (n = 58)
Non-cirrhosis/cirrhosis, n (%)	3 (5.2)/55 (94.8)
Child-Pugh, A/B/C, n (%)	50 (91)/3 (5.4)/2 (3.6)
AFP, median [range] (ng/ml)*	11.45 [1-369]
HCC treatment before DAA	
Resection	20 (34.5)
Ablation	32 (55.2)
TACE	6 (10.3)



Research Article
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Innes et al. J Hepatol 2018

	IFN-free regimen	
	No (n = 585) Number (col%)	Yes (n = 272) Number (col%)
Alphafetoprotein category, ng/ml		
<10	277 (78.0)	125 (72.7)
≥10	78 (22.0)	47 (27.3)
Unknown	230 (-)	100 (-)
Alphafetoprotein, ng/ml, mean	9.6 (18.1)	10.9 (18.6)
Pre-treatment liver disease marker		
Child-Turcotte-Pugh score		
B/C	44 (9.5)	58 (30.4)
Unknown	121 (-)	81 (-)
History of heavy alcohol use		
No	288 (57.5)	121 (52.8)
Yes	213 (42.5)	108 (47.2)
Unknown	84 (-)	43 (-)

3.- ¿El resultado se midió de forma precisa con el fin de minimizar posibles sesgos?

- ¿Los autores utilizaron variables objetivas o subjetivas?
- ¿Las medidas reflejan de forma adecuada lo que se tiene que medir?
- ¿Se ha establecido un sistema fiable para detectar todos los casos?
- ¿Se clasificaron a todos los sujetos en el grupo exposición utilizando el mismo tratamiento?
- ¿Los métodos de medida fueron similares en los diferentes grupos?

Research Article



EASL JOURNAL OF HEPATOLOGY

Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

Before starting antiviral therapy, all patients without history of previous HCC underwent abdomen ultrasound. If a possible focal lesion was detected in the liver, the diagnostic work up was completed with contrast-enhanced ultrasonography (CEUS), and subsequent computerized tomography (CT) scan or magnetic resonance imaging (MRI) was performed to exclude the presence of HCC. On the other hand, all patients with a history of HCC underwent CT scan or MRI, besides ultrasound, to exclude HCC. At the end of antiviral therapy, 12 and 24 weeks thereafter, patients underwent repeated abdominal ultrasound evaluation. Again, any suspected focal lesion of the liver was re-evaluated with CEUS and CT scan or MRI to assess the occurrence or the recurrence of HCC.

Research Article



EASL JOURNAL OF HEPATOLOGY

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy²²

Reig et al. J Hepatol 2016

The follow-up policy for HCC patients who achieve complete radiologic response after TACE is to perform imaging with a magnetic resonance (MR) or computed tomography (CT) every 6 months. In patients treated by ablation a contrast-ultrasound is done at months 1 and 3; a MR or CT is performed every 6 months thereafter. Finally, dynamic CT or MR every 6 months is carried out in resected patients.

We registered 3 time periods for each patient in order to expose the time relationship between HCC treatment and achievement of complete response, the initiation of DAA, and the length of follow-up until HCC recurrence or last imaging follow-up without HCC recurrence. The first time period corresponds to 'time between HCC treatment and last achievement of complete response by imaging'. It reflects the interval between HCC treatment and the date of the last radiologic evaluation (which confirmed the complete response in each patient) prior to DAA therapy. The second time period - 'Time window between last complete response assessment and DAA initiation' - reflects the time between the date of the last radiologic confirmation of complete response, and the start date of DAA. The last time period - 'time for HCC evolution after starting DAA' - reflects the time between the date of the first dose of DAA and the date of radiologic tumor progression or the last radiologic evaluation during follow-up in those patients without radiologic HCC progression. Finally, we also registered the patients' status (alive/death) at the end of follow-up.

Research Article
Viral Hepatitis

JOURNAL OF HEPATOLOGY

The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

HCC diagnoses in this cohort will have been triggered either through (i) symptomatic onset of HCC, or (ii) six-monthly abdominal ultrasound screening (which, as per best practice guidelines, is offered to all patients diagnosed with cirrhosis in Scotland). We identified all new post-treatment diagnoses of HCC through the clinical database and medical records. All cases identified were cross-checked against insurance records for HCC registered in the Scottish Cancer database -which, at the time of analysis, provided complete individual-level data on cancer incidence up until 31 Dec 2014 - to ensure no HCC events were missed.

4.- ¿Han tenido en cuenta los autores el potencial efecto de los factores de confusión en el diseño y/o análisis del estudio?

- Restricciones en el diseño y en las técnicas utilizadas.
- Por ejemplo, análisis de modelización, estratificación, regresión o de sensibilidad para corregir, controlar o justificar los factores de confusión.



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EASL JOURNAL OF HEPATOLOGY

Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

Logistic regression was used to control for the confounding effects of multiple causal variables on developing HCC. At multivariate analysis, two variables resulted independently associated with HCC development: Child-Pugh class ($p = 0.03$, OR: 4.18, 95% CI: 1.17–14.8) and history of previous HCC ($p < 0.0001$, OR: 12.0, 95% CI: 4.02–35.74).

Subsequent analysis on the 59 patients with history of previous HCC, who had a high risk of recurrence, showed that baseline characteristics were relatively homogeneous (Table 3).

The 17 patients who experienced HCC recurrence after DAA treatment were individually characterized, in order to better evaluate the characteristics potentially associated with HCC recurrence (Table 4).

Research Article



EASL JOURNAL OF HEPATOLOGY

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy*

Reig et al. J Hepatol 2016

Subgroup analysis of patients with short time span between HCC treatment and DAA therapy

Seventeen (29.3%) patients started DAA treatment with a 'time between HCC treatment and last assessment of complete response by imaging' less than 4 months. Seven of these 17 patients (41.17%) developed tumor progression (2 BCLC stage 0 and 5 BCLC stage I at the time of HCC therapy). The pattern of recurrence in this subgroup of patients was: local recurrence in 2 patients, new intrahepatic lesions in 5 (one nodule in 4 patients and up to ≤ 3 nodules or equal 3 cm in 1 case).

Subgroup analysis of patients treated by surgical resection

Twenty patients of the cohort were resected patients who were free of recurrence at the time of DAA treatment evaluation. Only 4 of them presented high risk of recurrence according to the pathology of the resected tumor (2 patients with microvascular invasion and satellites, 1 patient with microvascular invasion and 1 with satellites). Two (50%) out of these high risk patients presented recurrence, while 5 (31%) out of the 16 in the low risk strata did so.

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Viral Hepatitis

JOURNAL OF HEPATOLOGY

The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

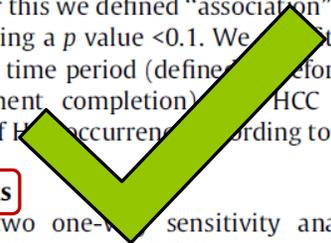
Innes et al. J Hepatol 2018

Statistical analysis

We calculated the unadjusted and adjusted association between treatment regimen and HCC occurrence using Cox regression. For the adjusted association between treatment regimen and HCC, we controlled for all co-factors associated either with the outcome (i.e. HCC occurrence) or with the primary exposure (i.e. treatment regimen). For this we defined "association" conservatively as that demonstrating a p value < 0.1 . We fitted an interaction term between time period (defined before and after 24 weeks post-treatment completion) and HCC occurrence to assess the timing of HCC occurrence according to treatment regimen.

Sensitivity analysis

We carried out two one-way sensitivity analyses (SA). In SA-1 we additionally censored follow-up time at the date of last HCC screening attrition (if at all). The HCC screening attrition date was defined as date of the last ultrasound screening test plus six months, with six months referring to the recommended regularity of HCC screening for patients with cirrhosis.¹⁷ In SA-2 we explored an alternative definition of treatment regimen; that being DAA-containing vs. DAA-free.



5.- ¿El seguimiento de los sujetos fue lo suficientemente largo y completo?

- Los efectos buenos o malos deberían aparecer por ellos mismos.
- Los sujetos perdidos durante el seguimiento pueden haber tenido resultados distintos a los disponibles para la evaluación.
- En una cohorte dinámica, ¿hubo algo que influyó en el resultado o en la exposición de los sujetos que entraron en la cohorte?

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EASL JOURNAL OF HEPATOLOGY

Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

Results: DAA therapy induced sustained virological response in 91% of patients. During 24-week follow-up, HCC was detected in 26 patients (7.6%, 95% CI: 4.99–10.84): 17 of 59 patients (28.81%, 95% CI: 17.76–42.07) with previous HCC and 9 of 285 patients (3.16%, 95% CI: 1.45–5.90) without previous HCC.

Patient	Days since HCC treatment
1	1301
2	73
3	
4	
5	
6	34
7	50
8	1016
9	99
10	237
11	95
12	482
13	970
14	700
15	483
16	778
17	406

Research Article



EASL JOURNAL OF HEPATOLOGY

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy[☆]

Reig et al. J Hepatol 2016

The overall median follow-up time after DAA was 5.7 months (0.4–14.6).

time from DAA start to recurrence was 3.5 months (1.1–8).



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The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

Total persons	857
Total person years follow-up	3,173
Average person years per patient	
Median	2.4
Mean	3.7
Number of outcome events (i.e. HCC occurrences)	
Total number of events	46
No occurrence <24 weeks post-treatment	11
No occurrence 24+ weeks post-treatment	35
Time to outcome event, person years	
Mean time to event	2.8
Median time to event	2.0
Minimum time to event	0.3
Maximum time to event	8.5
Crude outcome rate, per 100-person years (95% CI)	1.4 (1.1–1.9)

6.- ¿Cuáles son los resultados de este estudio?

- ¿Cuáles son los resultados netos?
- ¿Los autores han dado la tasa o la proporción entre los expuestos/no expuestos?
- ¿Cómo de fuerte es la relación de asociación entre la exposición y el resultado?

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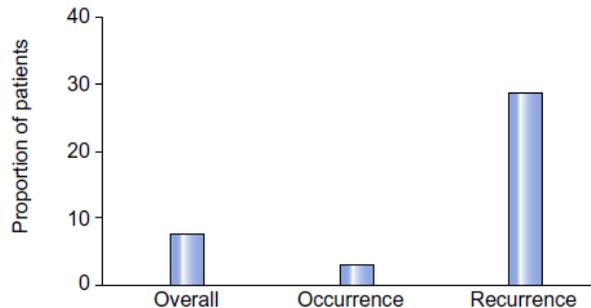


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Research Article



EASL JOURNAL OF HEPATOLOGY

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy

Reig et al. J Hepatol 2016

Results: Between 2014 and 2015, 103 patients with prior hepatocellular carcinoma received DAA, 58 of them met the inclusion criteria. After a median follow-up of 5.7 months, 3 patients died and 16 developed a subsequent HCC (27.6%). The pattern of recurrence was: intrahepatic growth (3 patients), new intrahepatic nodules (1 nodule in 5 patients, up to 3 nodules less or equal in 4 cases and multifocal in one patient) and infiltrative, ill-defined hepatocellular carcinoma and/or extra-hepatic lesions in 3 patients.

Conclusions: Our data show an unexpected high rate and pattern of tumor recurrence coinciding with HCV clearance and, although based in a very small cohort of patients, should be taken as a note of caution and prime a large scale assessment that exceeds the individual investigators capacity.

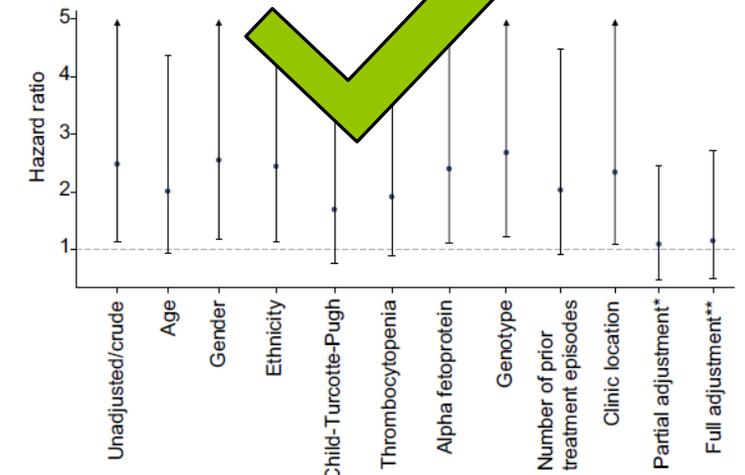
Research Article
Viral Hepatitis

JOURNAL OF HEPATOLOGY

The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

Results: A total of 857 patients met the study criteria, of whom 31.7% received an IFN-free regimen. Individuals receiving IFN-free therapy were more likely to be: older; of white ethnicity, Child-Turcotte-Pugh B/C vs. Child-Turcotte-Pugh A; thrombocytopenic; non-genotype 3; and treatment experienced. HCC occurrence was observed in 46 individuals during follow-up. In univariate analysis, IFN-free therapy was associated with a significantly increased risk of HCC (HR: 2.48; $p = 0.021$). However, after multivariate adjustment for baseline factors, no significant risk attributable to IFN-free therapy persisted (aHR: 1.15, $p = 0.744$).



7.- ¿Cuál es la precisión de los resultados?

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Research Article



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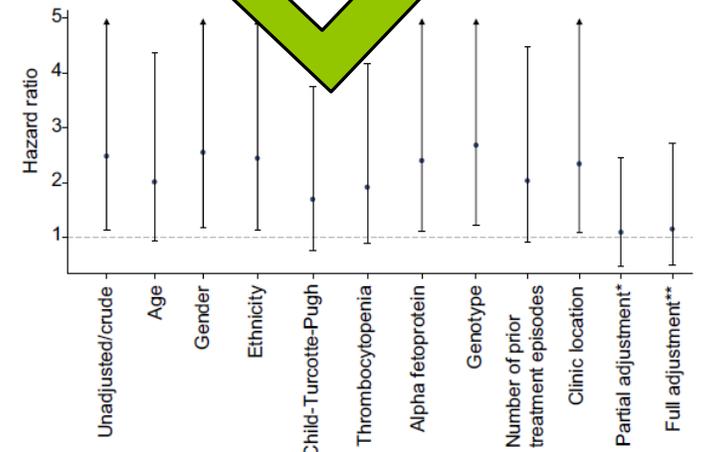
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8.- ¿Te parecen creíbles los resultados?

- ¿Puede deberse al azar, sesgo o confusión?

- ¿El diseño y los métodos son lo suficientemente defectuosos para hacer que los resultados sean poco creíbles?



Research Article

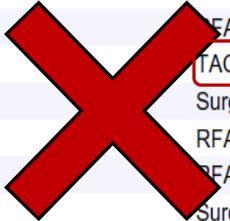


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Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

Patient	Days since HCC treatment	Previous HCC treatment
1	1301	Surgery
2	373	PEI
3	475	Surgery
4	202	RFA
5	260	RFA
6	664	TACE
7	50	Surgery
8	1016	RFA
9	99	RFA (+TACE)
10	237	Surgery
11	95	Surgery
12	482	RFA
13	970	Surgery
14	700	Surgery
15	483	RFA
16	778	TACE
17	406	Surgery



Research Article



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Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy

Reig et al. J Hepatol 2016

time from DAA start to recurrence was 3.5 months (1.1-8).

Patient	Treatment of HCC before DAA	Risk profile at pathology*	At time of starting DAA	
			BCLC	AFP (ng/dl)
1	Resection	Low risk	A	91
2	Resection	Low risk	A	18
3	Resection	Low risk	0	2.3
4	Resection	Low risk	A	12
5	Resection	Low risk	A	4.2
6	Resection	High risk	A	1
7	Resection	High risk	A	8
8	Ablation	n.a.	A	38
9	Ablation	n.a.	A	66.2
10	Ablation	n.a.	A	3
11	Ablation	n.a.	A	21.2
12	Ablation	n.a.	A	6.7
13	Ablation	n.a.	A	14
14	Ablation	n.a.	0	369
15	Ablation	n.a.	A	5
16	Ablation	n.a.	0	26



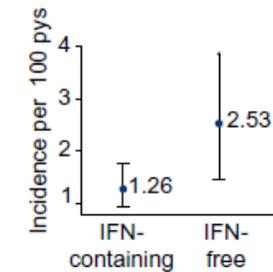
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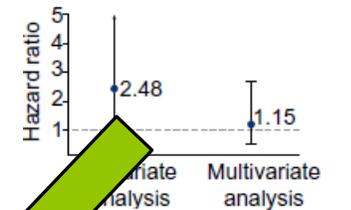
The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

Crude incidence of HCC occurrence by regimen



Association between IFN-free vs. IFN-containing therapy and HCC occurrence



Characteristics	IFN-containing patients	IFN-free patients
Mean age	51.1 yr	52.1 yr
% decompensated	9.5	30.4
% treatment experienced	27.6	52.2
% thrombocytopenic	22.1	39.3

1. The crude incidence of HCC occurrence for IFN-free patients is twice as high as for IFN-containing patients

2. But IFN-free patients are more likely to be thrombocytopenic, treatment experienced, decompensated, and older

3. Once these differences are accounted for, the association between IFN-free therapy and HCC occurrence disappears

9.- ¿Los resultados de este estudio coinciden con otra evidencia disponible?

Inicio del tratamiento con DAAs en 2015 en España

Research Article



Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016



No hay evidencia disponible



Research Article



Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy[☆]

Reig et al. J Hepatol 2016



A favor de evidencia disponible



Research Article
Viral Hepatitis



The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018



En contra de evidencia disponible



Nueva evidencia disponible

10.- ¿Se pueden aplicar los resultados en tu medio?

- Los pacientes cubiertos por el estudio pueden ser suficientemente diferentes de los de tu área.
- Tu medio parece ser muy diferente al del estudio.
- ¿Puedes estimar los beneficios y perjuicios en tu medio?

Research Article



EASL | JOURNAL OF
HEPATOLOGY

Research Article



EASL | JOURNAL OF
HEPATOLOGY

Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy^{††}

Reig et al. J Hepatol 2016

Sí

Research Article
Viral Hepatitis

JOURNAL
OF HEPATOLOGY

The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

Sí

11.- ¿Va a cambiar esto tu decisión clínica?

Research Article



EASL | JOURNAL OF
HEPATOLOGY

Research Article



EASL | JOURNAL OF
HEPATOLOGY

Early occurrence and recurrence of hepatocellular carcinoma in HCV-related cirrhosis treated with direct-acting antivirals

Conti et al. J Hepatol 2016

Unexpected high rate of early tumor recurrence in patients with HCV-related HCC undergoing interferon-free therapy^{*}

Reig et al. J Hepatol 2016

Sí

(todo lo que genera alarma se adopta rápidamente...)

Research Article
Viral Hepatitis

JOURNAL
OF HEPATOLOGY

The risk of hepatocellular carcinoma in cirrhotic patients with hepatitis C and sustained viral response: Role of the treatment regimen

Innes et al. J Hepatol 2018

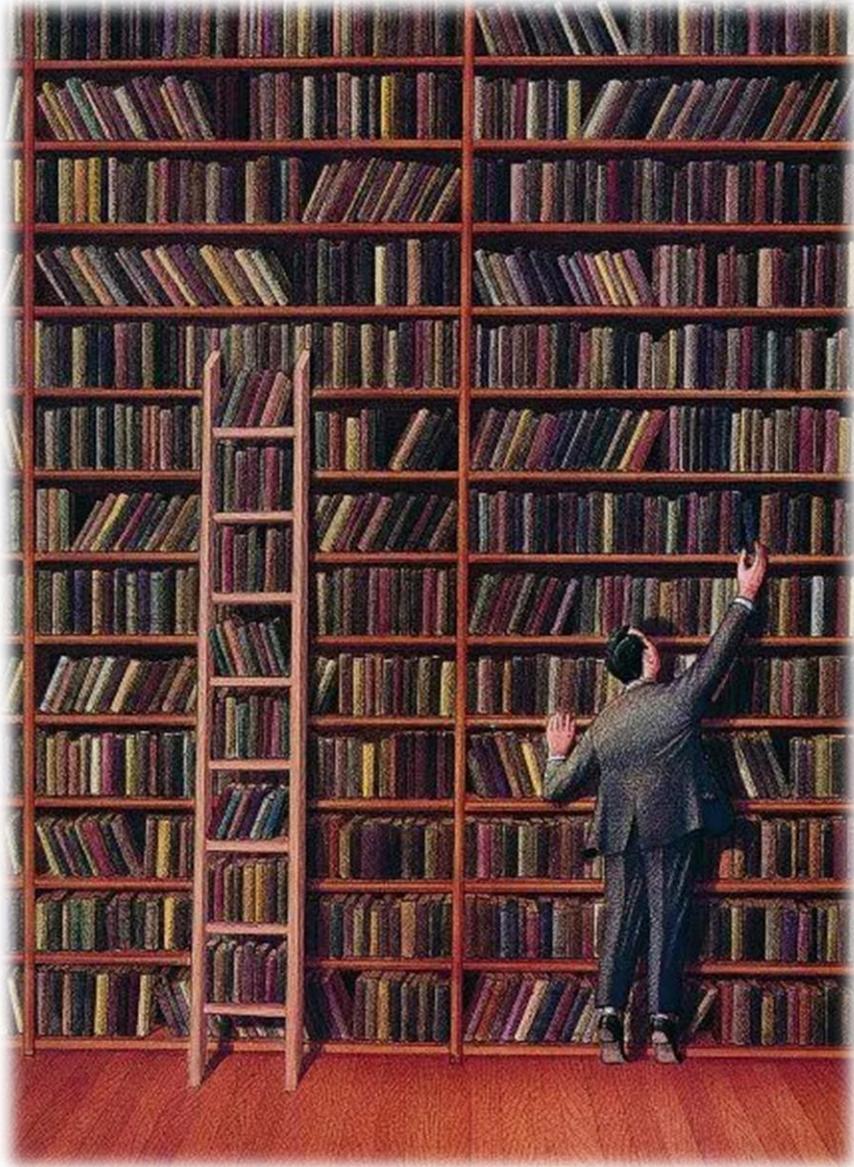
Sí

(aunque cuesta revertir...)

Conclusiones

¿Qué nos llevamos a casa?





- ❖ Las bases de datos y revistas electrónicas nos permiten acceder a la literatura científica rápidamente.
- ❖ Los procesos de publicación se han agilizado con el consecuente aumento exponencial de literatura científica.
- ❖ La calidad de los artículos científicos es muy variada.
- ❖ La lectura crítica es una técnica que:
 - ❖ Aumenta la efectividad de nuestras lecturas.
 - ❖ Garantiza que sólo las mejores evidencias científicas pasan a formar parte de nuestros protocolos y guías.

Quando leemos un artículo...

SIN LECTURA CRÍTICA



CON LECTURA CRÍTICA



We Can Do It!



jampuero-ibis@us.es



[@Dr_Ampuero](https://twitter.com/Dr_Ampuero)

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