Hospital Universitario
Puerta de Hierro Majadahonda

Comunidad de Madrid

Datos de practica clínica real

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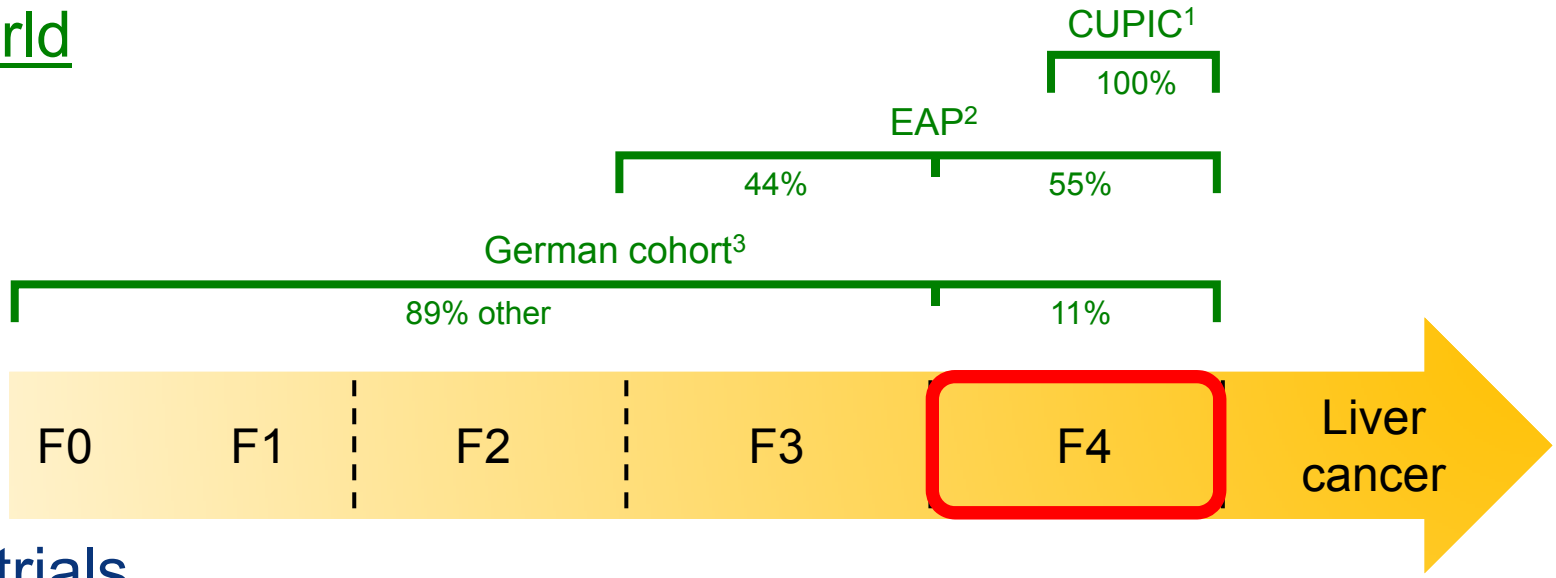
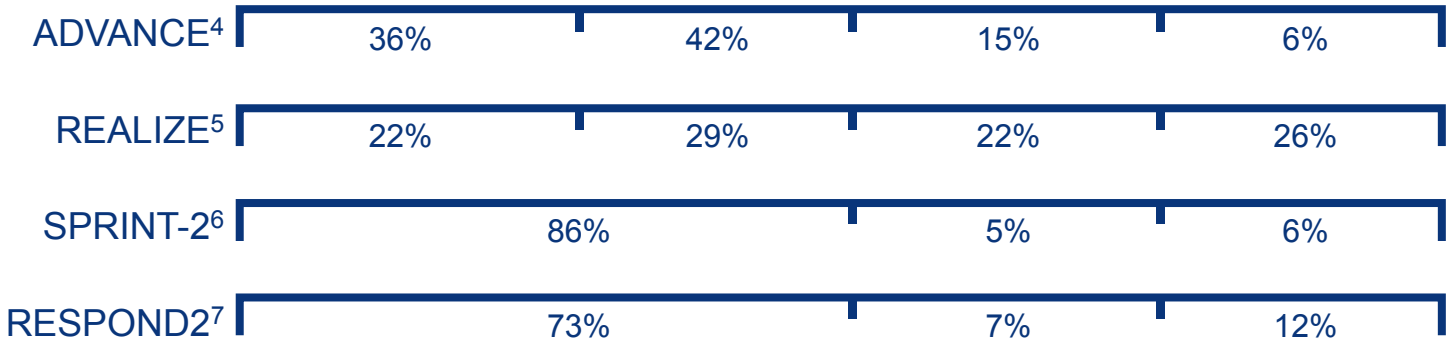
INVESTIGACIÓN PUERTA DE HIERRO

Treating Patients with DAAs in the Real World

Real world



Clinical trials



1. Hézode C, et al. Hepatology 2012;56(Suppl.):217A; 2. Colombo M, et al. Presented at AASLD 2012. LB15; 3. Berg T, et al. J Int AIDS Soc 2012;15 (Suppl. 4):18424; 4. Jacobson I, et al. New Eng J Med 2011;364:2405–16; 5. Zeuzem S, et al. New Eng J Med 2011;364:2417–28 6. Poordad F, et al. New Eng J Med 2011;364:1195–206; 7. Bacon BR, et al. New Eng J Med 2011;164:1207–17

COHORTES DE PRÁCTICA CLÍNICA

- Cohorte Acceso Precoz Francés – CUPIC
- Cohorte de Veteranos Americanos
- EAP Telaprevir
- Cohorte Uso Compasivo en España

Patient baseline demographics and disease characteristics

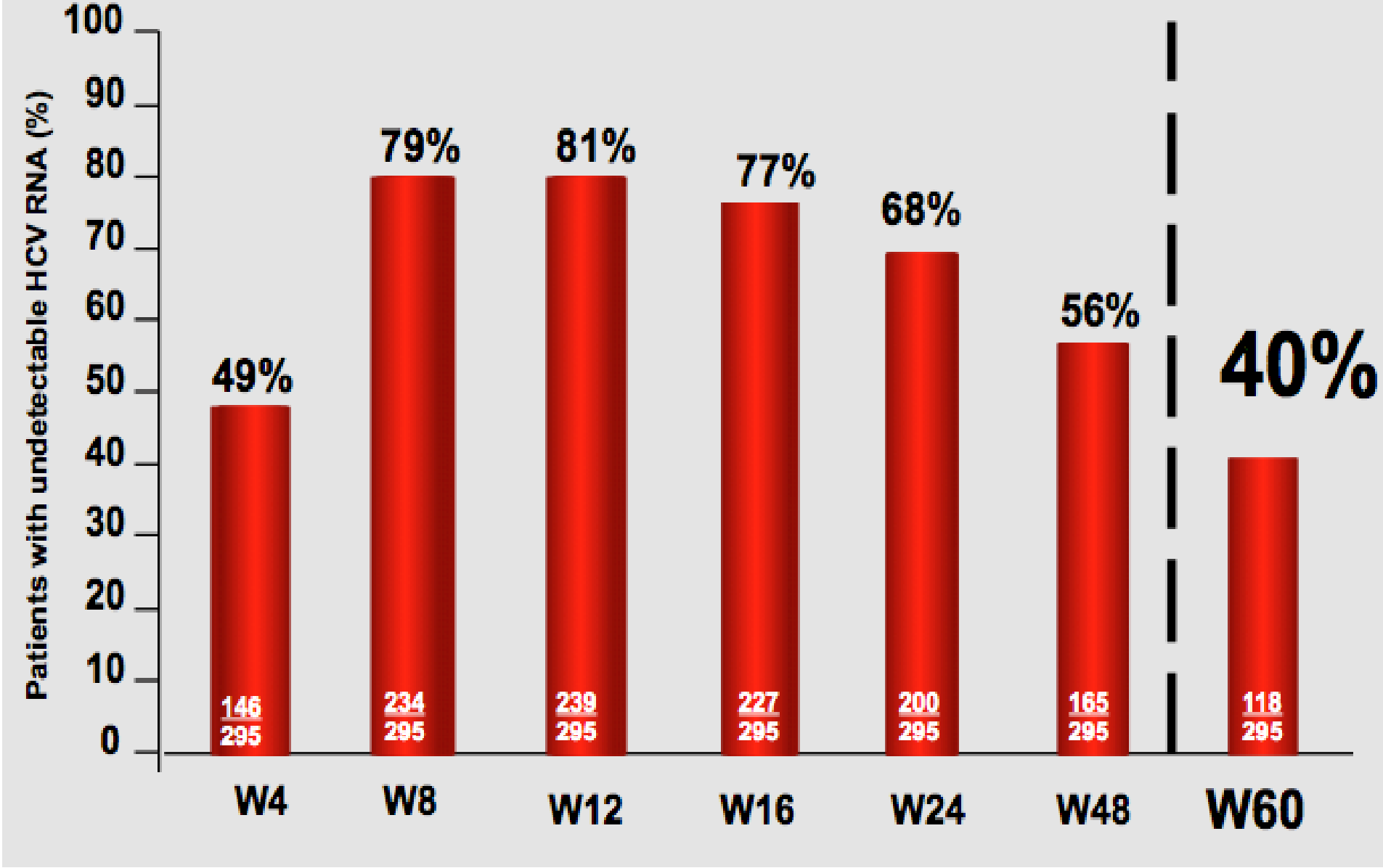
Characteristic	Telaprevir N=295	Boceprevir N=190
Male, %	201 (68)	133 (70)
Mean age, years (range) Mean BMI, SD (kg/m^2)	57 (27-83) 26.5 (18.2-40.4)	57 (34–79) 26.2 (18.1-39.4)
HCV genotype 1 subtype, n (%) 1a 1b Other	 98 (33) 162 (55) 33 (11)	 77 (41) 96 (51) 16 (8)
HCV RNA ≥800,000 IU/mL, n (%)	182 (62)	122 (64)
Treatment history, n (%) Prior relapse Prior partial response Prior null response Others	 116 (39) 135 (46) 28 (10) 15 (5)	 85 (45) 80 (42) 9 (5) 16 (8)
Exclusion criteria, n (%) REALIZE RESPOND-2	 99 (34) 137 (46)	 52 (27) 73 (38)

Patient baseline demographics and disease characteristics

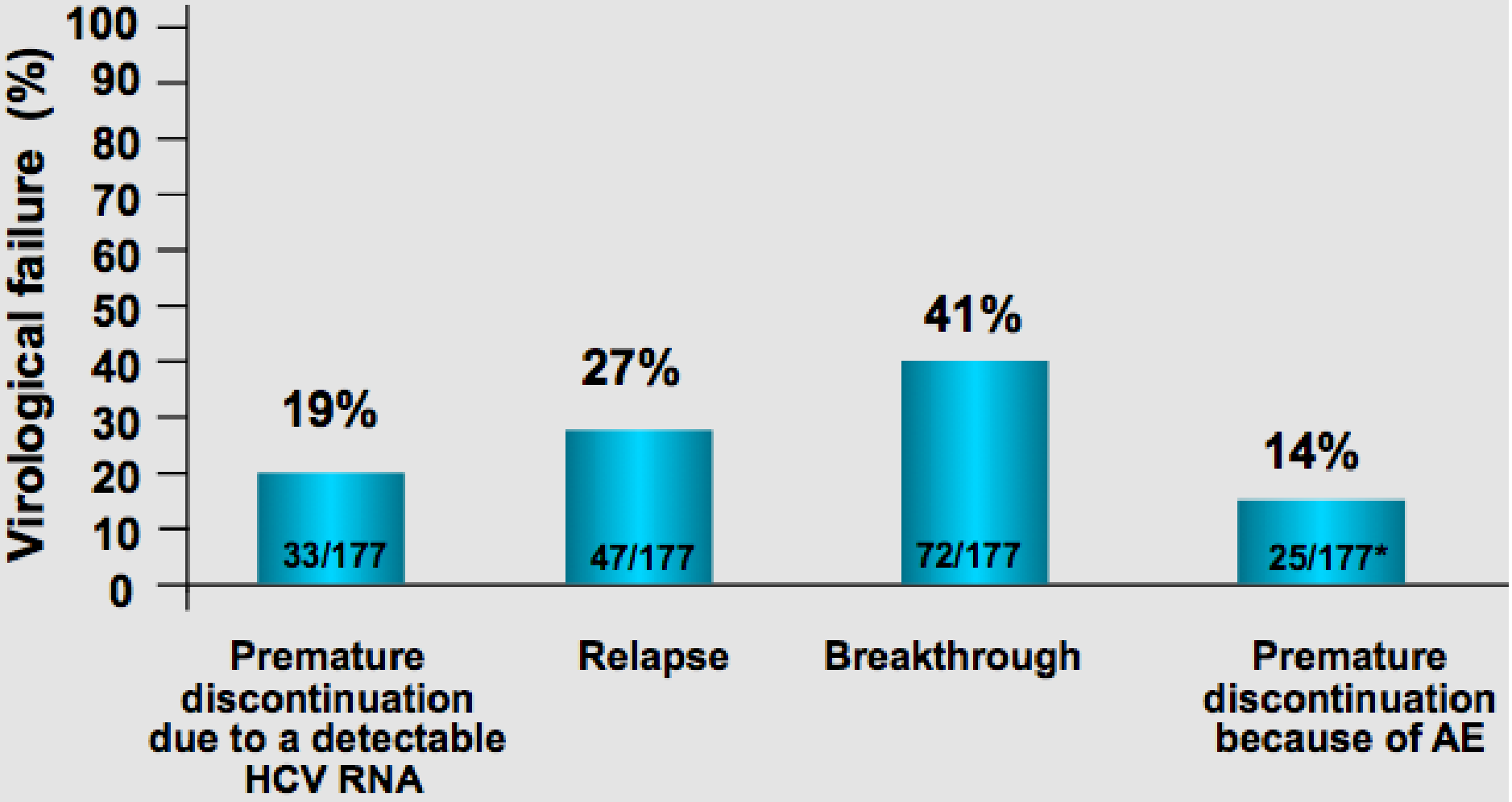
Characteristic	Telaprevir N=295	Boceprevir N=190
Child-Pugh score A/B, n (%)*	280 (95) / 6 (2)	177 (93) /1 (1)
MELD score, mean (range)	8.1 (6-22)	8.1 (6-28)
Prothrombin time ratio, mean % (range)	86 (27–100)	87 (23–100)
Serum albumin g/L, mean (range)	40.0 (20.7–53.2)	40.7 (27.0–50.3)
Total bilirubin µmol/L, mean (range)	15.5 (4.0–73.0)	15.2 (4.0–78.0)
Hb level g/dL, mean (range)	14.5 (9.0–19.7)	14.8 (10.8–18.4)
Neutrophils, mean (range) (10^9/mm^3)	3.3 (0.8-8.5)	3.2 (0.5-8.5)
Platelet count, mean (range) (10^3/mm^3)	151 (18–604)	144 (34–346)
Esophageal varices, n (%)	51/145 (35.2)	37/97 (38.1)

* Missing data : 21

Telaprevir: virological response (ITT)

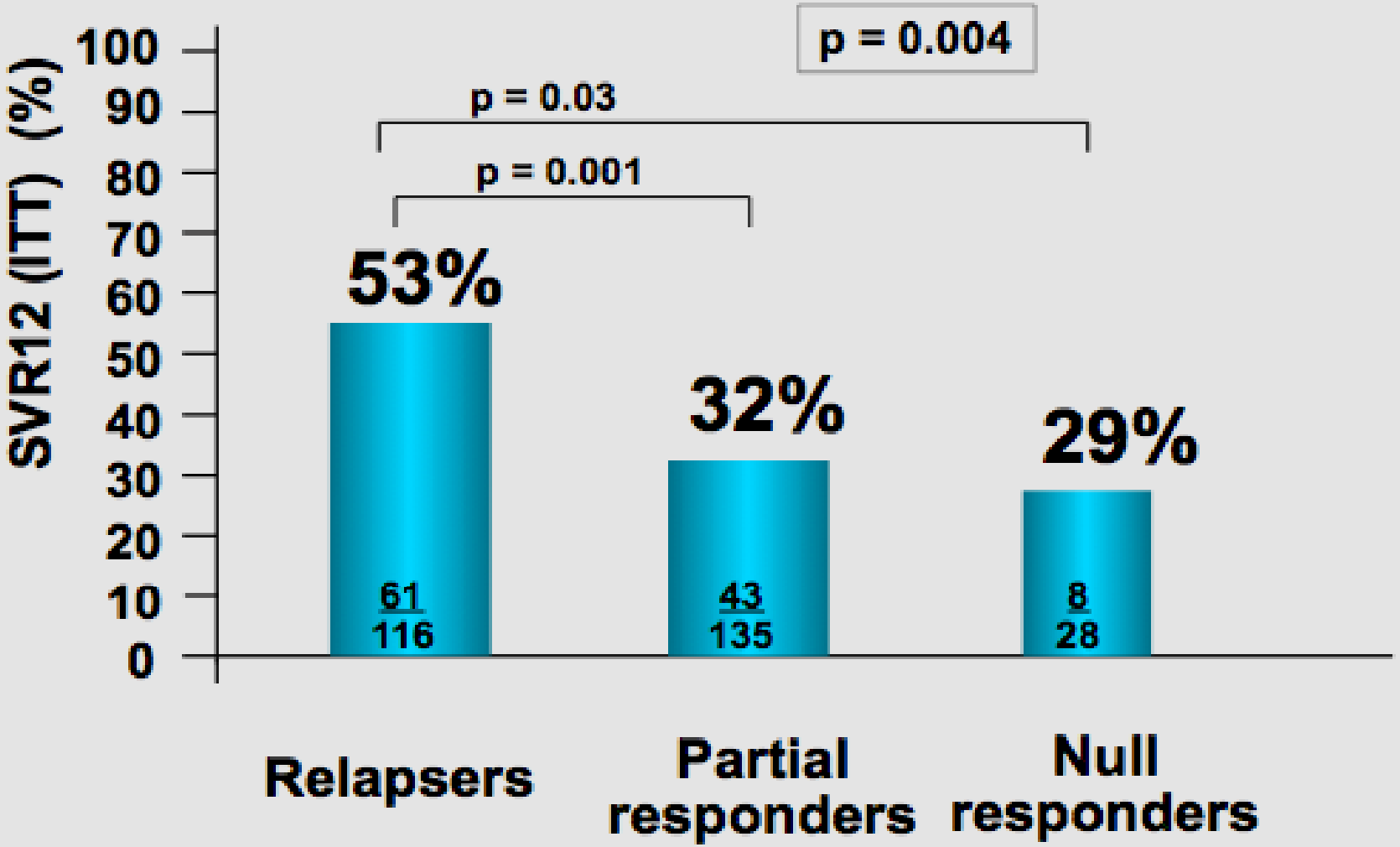


Telaprevir: treatment failure



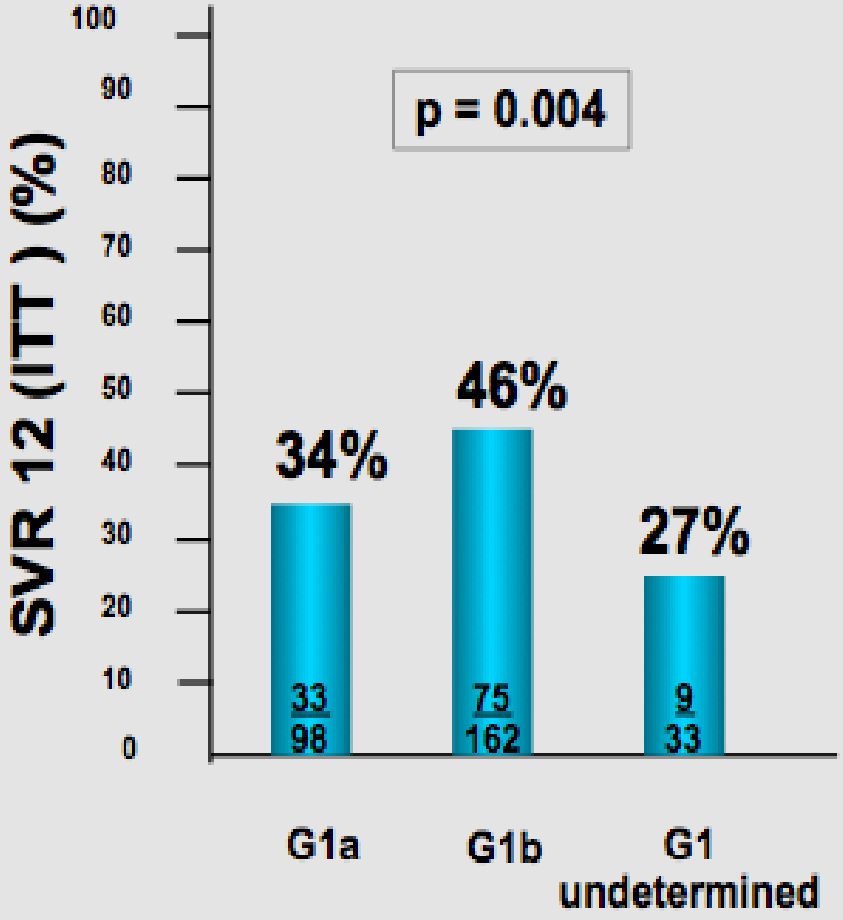
*22 without failure

Telaprevir: SVR12 according to response to prior treatment

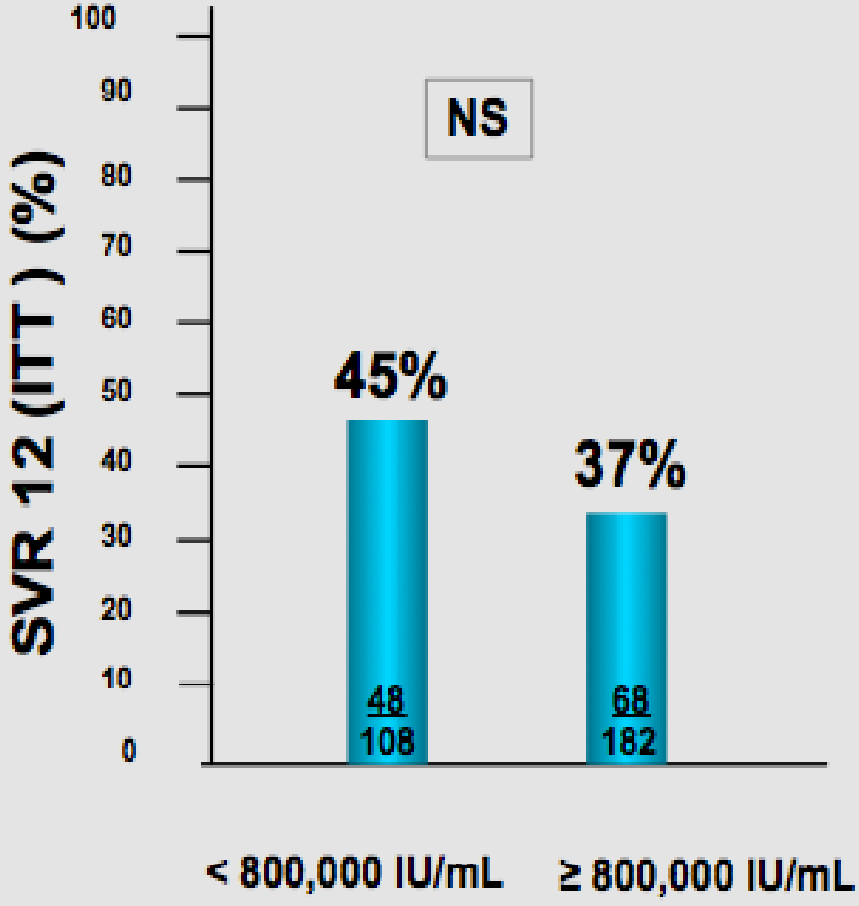


Telaprevir: SVR12 according to

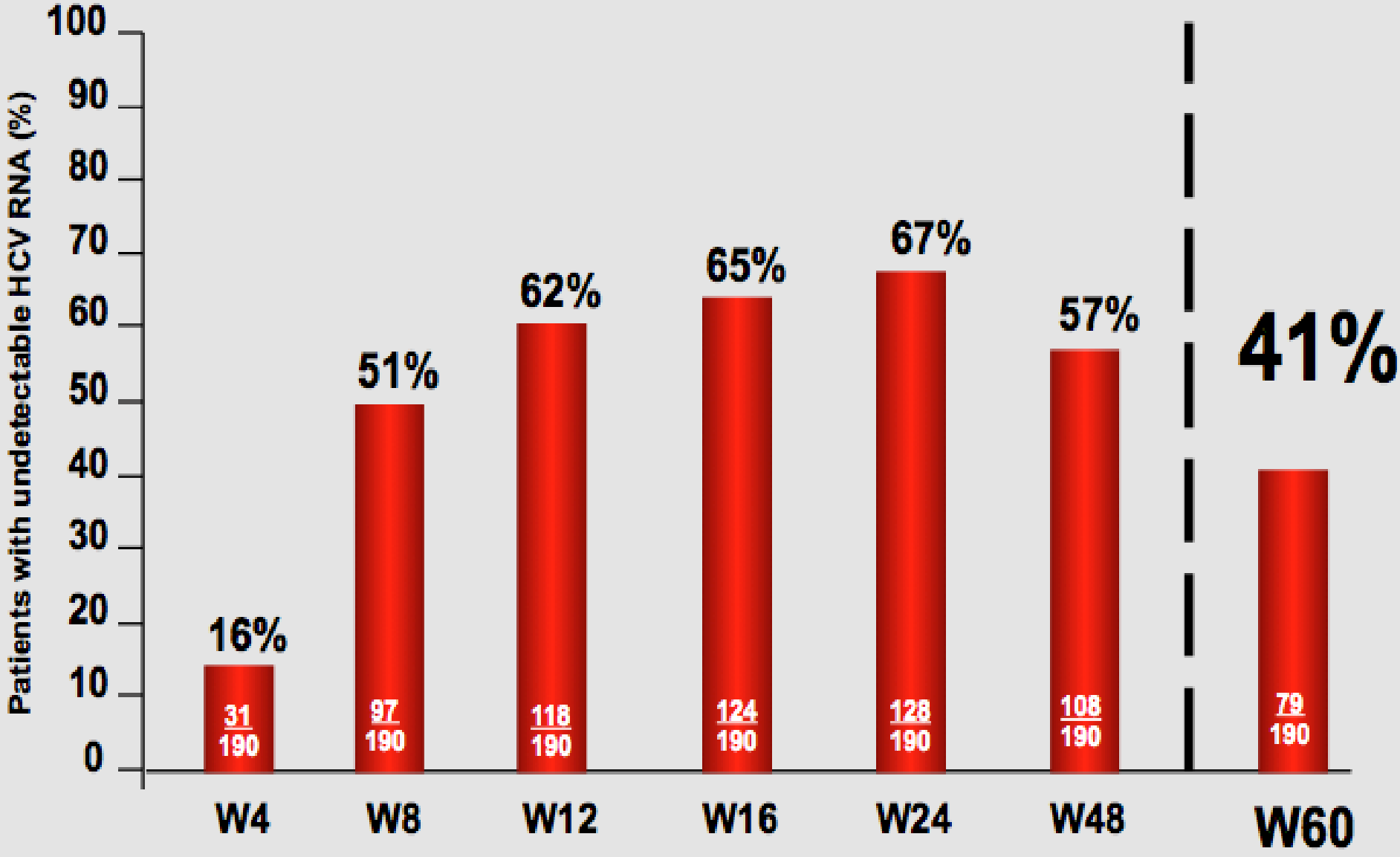
HCV subtype



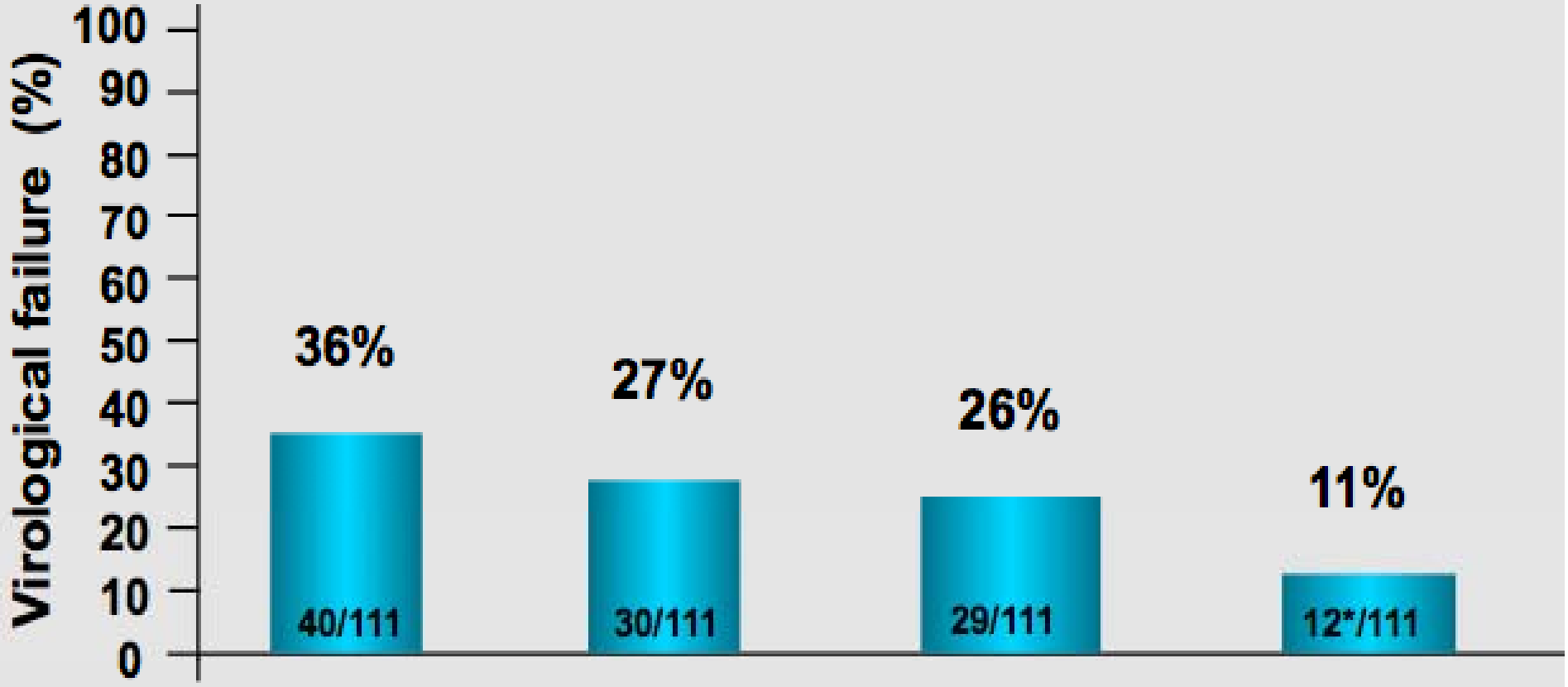
initial viremia



Boceprevir: virological response (ITT)

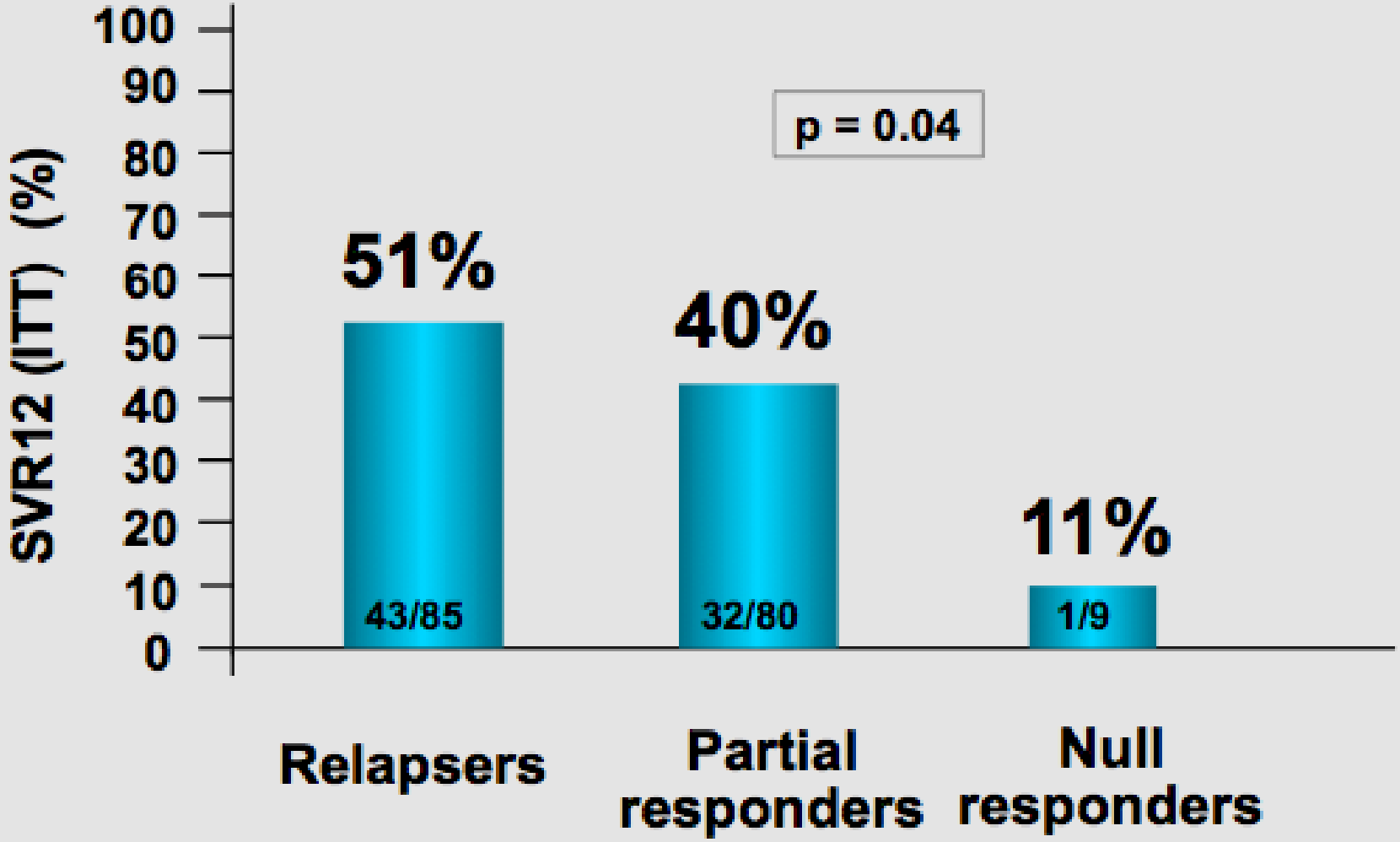


Boceprevir: treatment failure



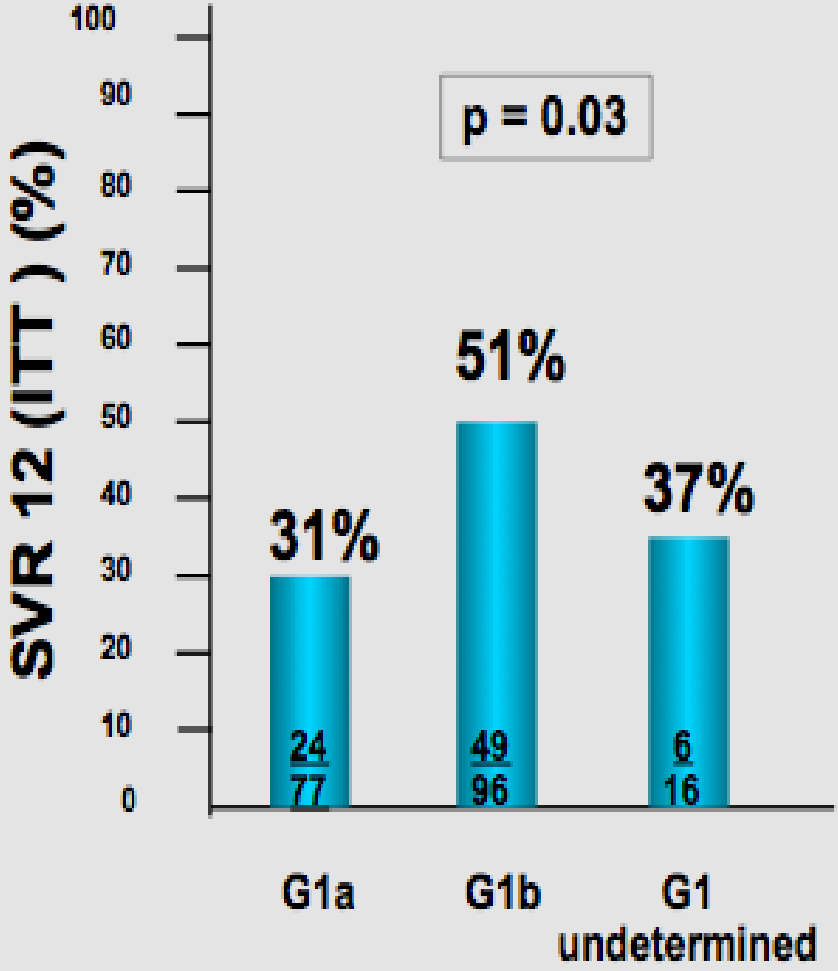
*10 without failure

Boceprevir: SVR12 according to response to prior treatment

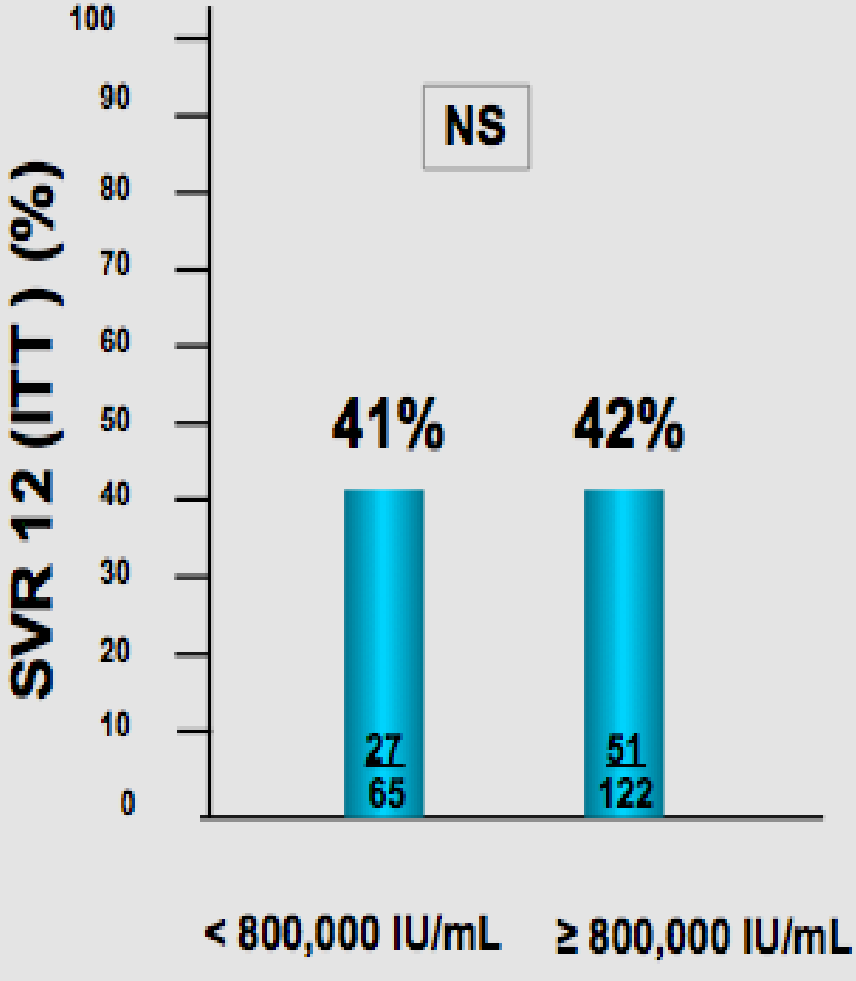


Boceprevir: SVR12 according to

HCV subtype



initial viremia



Multivariate analysis: baseline predictors of sustained virological response

Predictors	OR	95%CI	p-value
Relapser vs Partial or null responders	2.03	1.38-3.00	0.0003
Genotype 1b vs Genotype non 1b	1.92	1.3-2.84	0.0011

Telaprevir : SVR12 safety findings

Patients, n (% patients with at least one event)	Telaprevir n = 295
Serious adverse events (SAEs)	535 in 160 patients (54.2%)
Premature discontinuation / due to SAEs	139 (47.1%) / 63 (21.3%)
Death (3 septicemia, 1 variceal bleeding, 1 encephalopthy, 1 pulmonary neoplasia, 1 pneumonia)	7 (2.4 %)
Infection (Grade 3/4)	27 (9.1 %)
Hepatic decompensation (Grade 3/4)	15 (5.1 %)
Rash (grade 3/SCAR)	16 (5.4 %) / 2 (0.6 %)
Anemia (Grade 3/4 : Hb < 8 g/dL)	38 (12.9 %)
EPO use / blood transfusion	168 (57 %) / 53 (18 %)
GCSF use	8 (2.7 %)
TPO use	6 (2 %)

* SCAR: severe cutaneous adverse reaction

Boceprevir : SVR12 safety findings

Patients, n (% patients with at least one event)	Boceprevir n = 190
Serious adverse events (SAEs)*	321 in 97 patients (51.0%)
Premature discontinuation / due to SAEs	80 (42.1%) / 27 (14.2%)
Death (1 pulmonary infection, 1 anevrysmal beeding, 1 septicemia)	3 (1.6 %)
Infection (Grade 3/4)	8 (4.2 %)
Hepatic decompensation (Grade 3/4)	9 (4.7 %)
Rash (grade 3/SCAR)	2 (1.0 %)
Anemia (Grade 3/4: Hb < 8 g/dL)	19 (10.0 %)
EPO use / blood transfusion	119 (62.6 %) / 26 (13.7 %)
GCSF use	13 (6.8 %)
TPO use	3 (1.6 %)

* SAEs in patients; SCAR: severe cutaneous adverse reaction

COHORTE VETERANOS AMERICANOS

Cohorte de Veteranos Americanos: Características basales

Seguimiento prospectivo de pacientes genotipo 1 tratados con triple terapia (boceprevir o telaprevir) a partir del día 1 de enero de 2012.

Se tratan 661 pacientes con boceprevir y 198 con telaprevir. Se excluyeron pacientes coinfectados con VIH o VHB, trasplantados, con carcinoma hepatocelular y aquellos de los que no se disponía carga viral basal.

Características basales	BOC N=661	TLV N=198
Edad	57 + 6	58 +5
Hombres	95%	97%
Negros	25%	30%
Cirrosis	24%	41%
Diabetes	23%	29%
Naive	59%	49%
Respuesta nula	10%	19%
Respuesta parcial	11%	14%
Recidiva previa	18%	17%

Fortalezas: Observación robusta de tendencias de tratamiento en una amplia cohorte de práctica clínica.

Limitaciones: No se obtuvieron test ARN tan frecuentementecomo en los ensayos clínicos, no radonmizados, en espera de datos de RVS

C. Lisa Backus, et al. Week 24 and End of Treatment Response for Direct Acting Antiviral (DAA)-Based Therapy in Veterans With Chronic Hepatitis C. (Poster # LB-30). AASLD 2012 Boston

Cohorte veteranos americanos: resultados a final de tratamiento

ARN VHC indetectable a final de tratamiento N=692	BOC (n/N)	TLV (n/N)	Valor P
Global	**60% (320/532)**	**55% (88/160)**	**0.25**
Naïve no cirróticos	66% (179/270)	60% (31/52)	0.35
Todos los cirróticos	49% (55/112)	45% (26/58)	0.60
Respuesta previa nula	19% (9/48)	26% (8/31)	0.46
Respuesta previa parcial	59% (32/54)	62% (13/21)	0.83
Recidiva previa	67% (64/95)	85% (22/26)	0.08

C. Lisa Backus, et al. Week 24 and End of Treatment Response for Direct Acting Antiviral (DAA)-Based Therapy in Veterans With Chronic Hepatitis C. (Poster # LB-30). AASLD 2012 Boston

Cohorte veteranos americanos: conclusiones

- Las respuestas de esta cohorte de pacientes en práctica clínica habitual no presentaron diferencias en semana 24 o final de tratamiento entre BOC y TLV

- Los cirróticos tratados tanto con BOC como con TLV tendieron a presentar peores respuestas que los no cirróticos. En el análisis de sensibilidad, definiendo cirrosis como APRI>1.5 o FIB-4>3.25 no cambió el patrón de resultados.

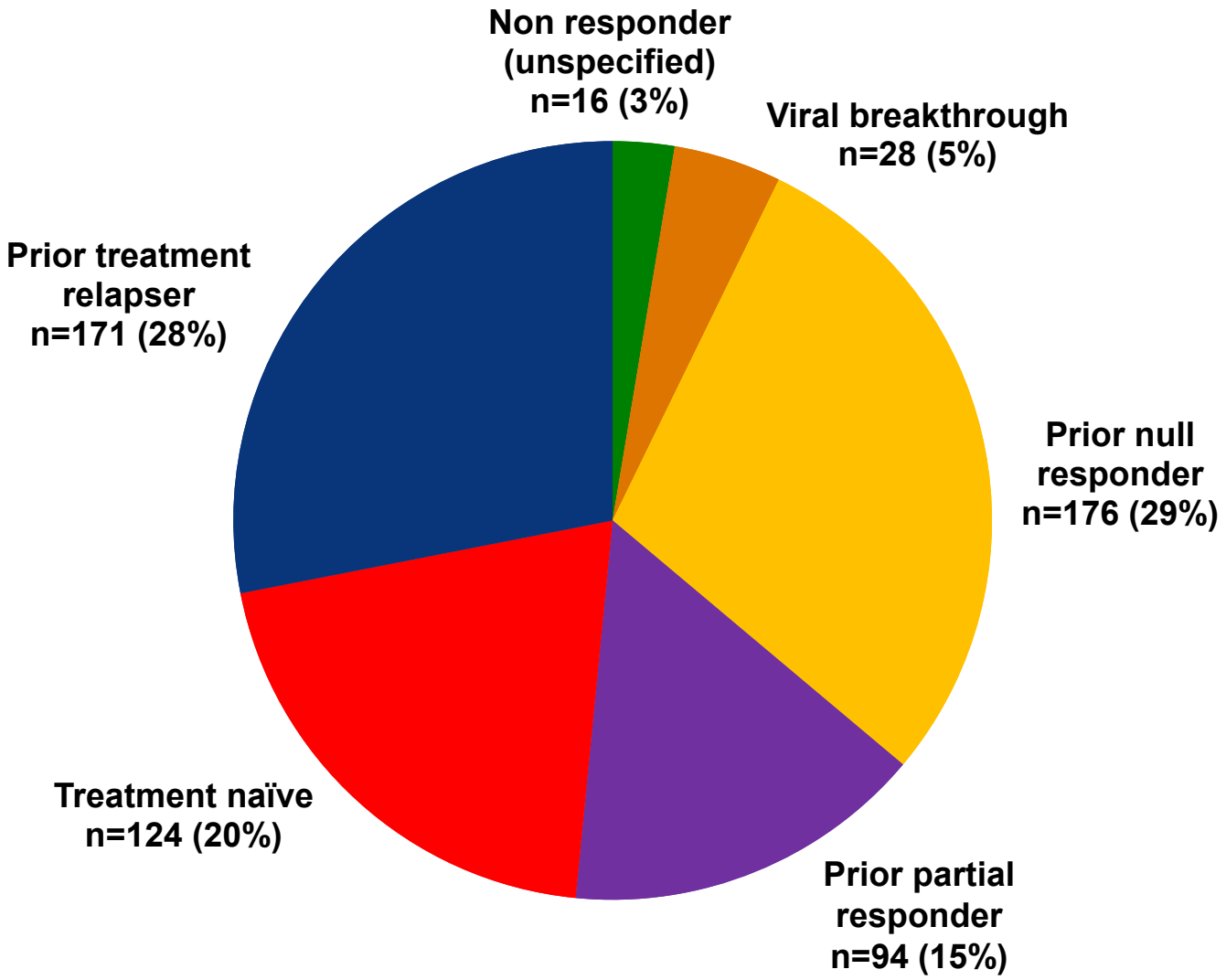
- Pacientes con respuesta previa nula tendieron a presentar peores respuestas que recidivantes y repsondedoresparciales tanto con BOC como con TLV.

- La alta tasa de respuesta a final de tratamiento es prometedora en comparación con los resultados de la doble terapia.

C. Lisa Backus, et al. Week 24 and End of Treatment Response for Direct Acting Antiviral (DAA)-Based Therapy in Veterans With Chronic Hepatitis C. (Poster # LB-30). AASLD 2012 Boston

Telaprevir EAP

Prior Response of Patients to HCV Therapy (Interim Analysis, N=609)



Colombo M, et al. AASLD 2012 Abstract LB–15

Indication for the initiation of telaprevir treatment

Telaprevir

INDICATION

- Telaprevir in combination with PR is indicated for the treatment of **genotype 1 chronic hepatitis C in patients with compensated liver disease**
- Patients with **Child-Pugh class A**
- Not recommended for patients with Child-Pugh B or C score ≥7 or decompensated liver disease

Recommended baseline laboratory values

- Baseline Hb levels:
  ≥12 g/dL (females)
  ≥13 g/dL (males)
- Baseline platelet count **≥90,000 /mm^3**
- Absolute neutrophil counts **≥1,500/mm^3**

- Patients who are not treated according to recommendations are at higher risk of developing severe complications

Telaprevir EU SmPC

Baseline Patient Demographics

	Bridging fibrosis (N=273)	Cirrhosis (N=335)	Overall (N=609)
Age years – mean (range)	52 (24–72)	55 (25–75)	54 (24–75)
Body mass index	26±3.6	27±4.4	27±4.1
Males sex – no. (%)	174 (64)	230 (69)	405 (67)
Race or ethnic group – no. (%)			
White	269 (99)	325 (97)	595 (98)
Black, Asian or other	4 (1)	10 (3)	14 (2)
HCV1 subtype – no. (%)			
1a	79 (29)	92 (28)	172 (28)
1b	185 (68)	226 (68)	411 (68)
Missing or unknown	9 (3)	17 (5)	26 (4)
HCV RNA $\log_{10}$ – IU/mL	6.2±0.05	6.1±0.05	6.1±0.03
HCV RNA ≥ 800,000 IU/mL – no. (%)	187 (68)	211 (63)	399 (66)

Data on file

Baseline Laboratory Parameters

	Bridging fibrosis (N=273)	Cirrhosis (N=335)	Overall (N=609)
MELD Score	7.1±1.1	7.6±1.6	7.3±1.5
Alpha fetoprotein - µg/L	10.0±13.6	19.1±31.8	15.0±25.7
Albumin – g/L	43.7±3.9	41.5±4.4	42.5±4.3
Bilirubin – µmol/L	11.8±6.3	13.8±6.9	12.9±6.7
Creatinine – µmol/L	71.8±15.2	69.9±15.2	70.7±15.2
Glucose – mmol/L	5.6±1.6	5.9±2.0	5.8±1.8
Hemoglobin – g/L	151.5±14.4	149.5±13.9	150.4±14.2
Neutrophils – x 10^9/L	3.4±1.4	3.1±1.1	3.2±1.3
Platelets – x 10^9/L	190.5±81.3	151.7±53.3	169.0±69.9
Prothrombin intl. normalised ratio	1.03±0.1	1.09±0.2	1.07±0.1

Data on file

Reason for Discontinuation

	Bridging fibrosis (F3) (N=273)	Cirrhosis (F4) (N=335)	Overall (N=609)
Any adverse event	32 (12)	53 (16)	85 (14)
Rash	15 (5)	15 (4)	30 (5)
Anemia	3 (1)	16 (5)	19 (3)
Asthenia	3 (1)	4 (1)	7 (1)
Abdominal pain	1 (0)	5 (1)	6 (1)
Nausea	3 (1)	3 (1)	6 (1)
Pruritus	1 (0)	5 (1)	6 (1)
Vomiting	4 (1)	2 (1)	6 (1)

Data on file

Grade 2–4 Drug-related Adverse Event

	Bridging fibrosis (F3) (N=273)	Cirrhosis (F4) (N=335)	Overall (N=609)
Subjects with one or more AE	171 (63)	247 (74)	418 (69)
Anemia	101 (37)	172 (51)	273 (45)
Rash	42 (15)	52 (16)	94 (15)
Thrombocytopenia	15 (5)	45 (13)	60 (10)
Pruritus	19 (7)	32 (10)	51 (8)
Asthenia	23 (8)	27 (8)	50 (8)
Nausea	12 (4)	24 (7)	36 (6)
Anorectal	14 (5)	21 (6)	35 (6)

Data on file

Serious Adverse Events

	Bridging fibrosis (F3) (N=273)	Cirrhosis (F4) (N=335)	Overall (N=609)
Subjects with one or more serious AE	31 (11)	54 (16)	85 (14)
Anemia	11 (4)	22 (7)	33 (5)
Rash	5 (2)	10 (3)	15 (2)
Pyrexia	2 (1)	3 (1)	5 (1)
Ascites	0	3 (1)	3 (0)
Cardiac failure	1 (0)	2 (1)	3 (0)
Thrombocytopenia	0	3 (1)	3 (0)

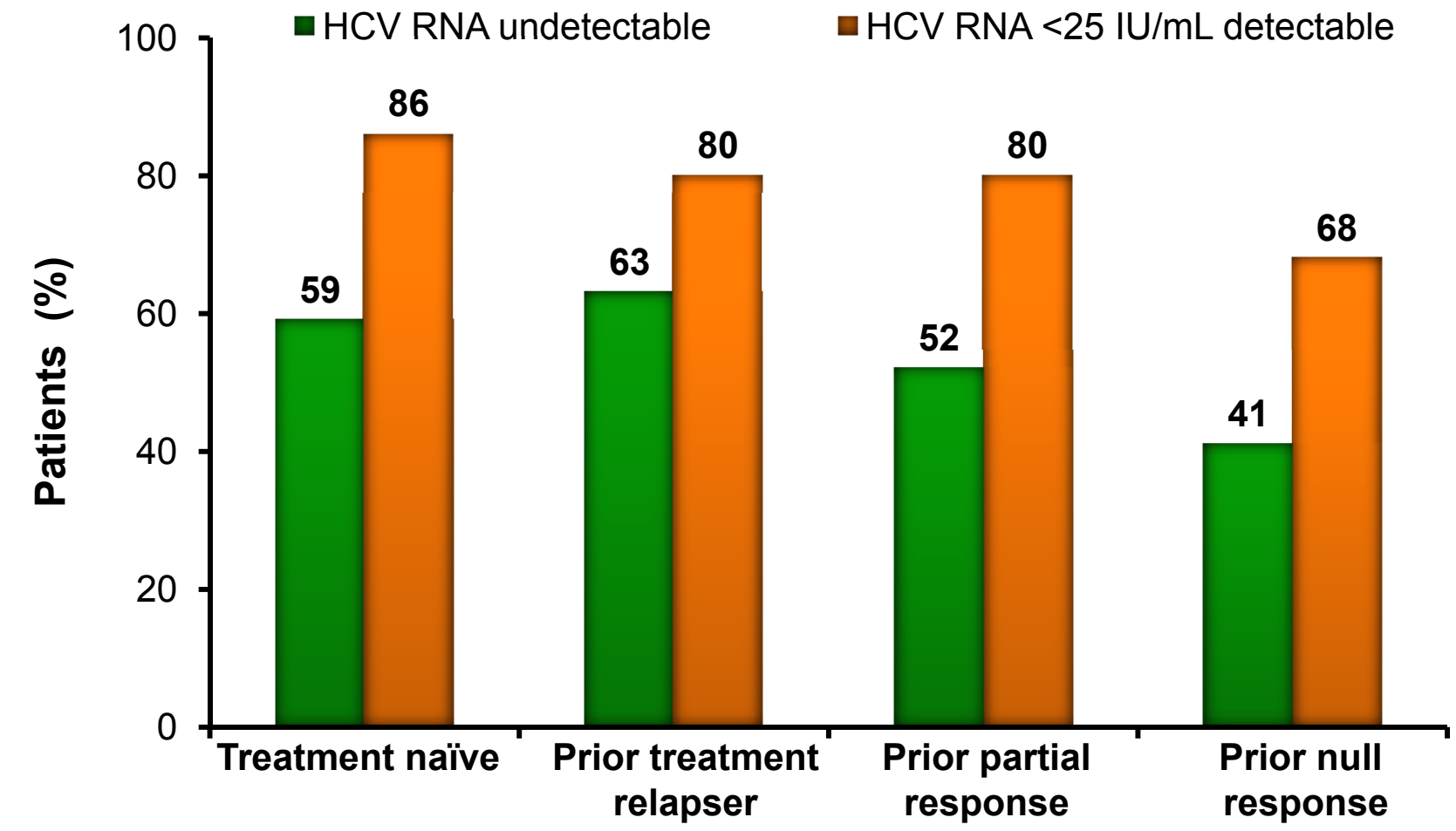
Data on file

Adverse Events with Fatal Outcome

	Patient 1	Patient 2	Patient 3
Age, years	52	51	65
Gender	Male	Female	Female
Fibrosis stage	F4	F4	F4
Baseline viral load, IU/mL	1,200,000	2,387,203	389,340
Last observed viral load, IU/mL	Undetectable	Undetectable	18,090
Date of death	4 weeks after telaprevir discontinuation	2 weeks after telaprevir discontinuation	4 weeks after telaprevir discontinuation
Adverse event	Anemia, dehydration, hepatic failure, hepatorenal syndrome, hypercatabolism, hyperglycemia, ketoacidosis, multi-organ failure	Ischaemic colitis, septic shock, multi-organ failure	Aplastic anemia, liver decompensation, multi-organ failure
Causality (determined by investigator)	Possibly related	Related	Unlikely related
Medical history	Diabetes		Low platelets (74,000/mm^3)

Colombo M, et al. AASLD 2012 Abstract LB–15

Patients with a Virological Response at Week 4



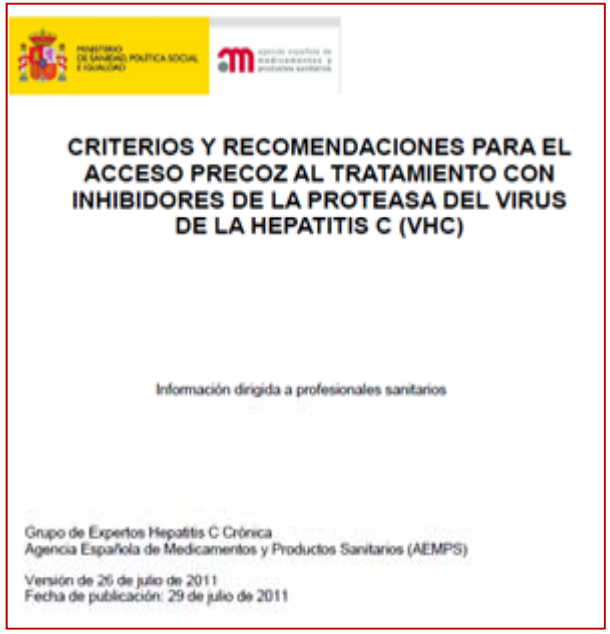
Colombo M, et al. AASLD 2012 Abstract LB–15

Uso Compasivo de Boceprevir en España

EFICACIA Y SEGURIDAD DE LA TRIPLE TERAPIA CON PEGINTERFERON, RIBAVIRINA Y BOCEPREVIR EN USO COMPASIVO EN PACIENTES CON HEPATITIS C GENOTIPO 1 CON FIBROSIS AVANZADA: ANALISIS INTERMEDIO A LAS 12 SEMANAS

AUTORIZACION POR PARTE DE LA EMEA

BOCEPREVIR 27/07/2011
TELAPREVIR 30/09/2011



CRITERIOS Y RECOMENDACIONES PARA EL ACCESO PRECOZ AL TRATAMIENTO CON INHIBIDORES DE LA PROTEASA DEL VIRUS DE LA HEPATITIS C (VHC)

Información dirigida a profesionales sanitarios

Grupo de Expertos Hepatitis C Crónica
Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Versión de 26 de julio de 2011
Fecha de publicación: 29 de julio de 2011

30/12/2011

COMERCIALIZACION

Calleja JL et al EASL 2013

EFICACIA Y SEGURIDAD DE LA TRIPLE TERAPIA CON PEGINTERFERON, RIBAVIRINA Y BOCEPREVIR EN USO COMPASIVO EN PACIENTES CON HEPATITIS C GENOTIPO 1 CON FIBROSIS AVANZADA: ANALISIS INTERMEDIO A LAS 12 SEMANAS

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO. Dr Pascasio, Dr Sousa, Dra Martinez Sierra, Dr Ferrer, Dña Maria Cuaresma

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AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS. Dra Cortizo, Dr López, Dra Sancho López

Calleja JL et al EASL 2013

objetivo general

Evaluar la seguridad y efectividad del tratamiento con boceprevir asociado a peginterferón alfa/ribavirina en pacientes genotipo 1 con fibrosis avanzada (F3(puentes de fibrosis)-F4 (cirrosis) en biopsia o fibroscan >9.5 Kpa).

objetivo específico

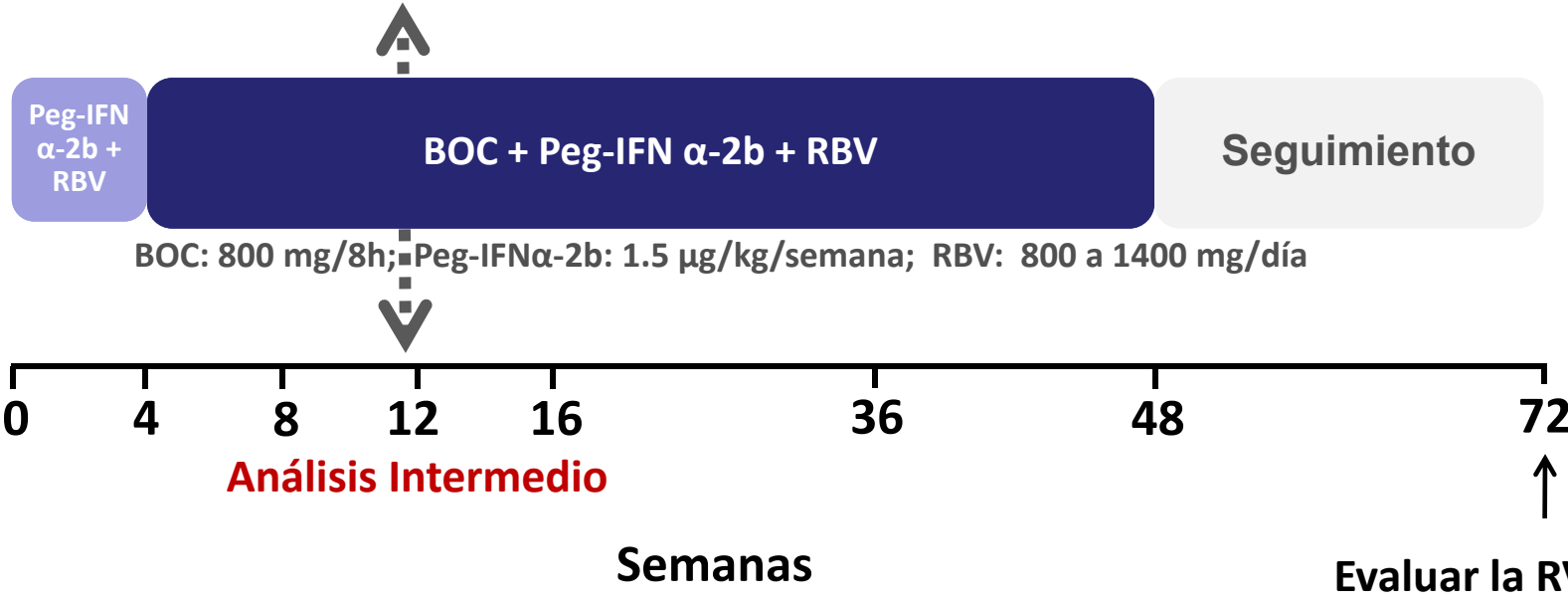
ANÁLISIS INTERMEDIO

Evaluar la seguridad y tolerabilidad en los pacientes incluidos en la cohorte que han recibido al menos 12 semanas de tratamiento antiviral.

Calleja JL et al EASL 2013

REGISTRO MULTICÉNTRICO PROSPECTIVO que ha incluido pacientes con hepatitis C genotipo 1 (naïves y fallo a un tratamiento previo) con fibrosis en puentes o cirrosis en tratamiento con triple terapia con boceprevir según ficha técnica.

1. Genotipo 1 del VHC, naïve o tratados previamente
2. F3/F4 en biopsia ó Fibroscan >9.5 Kilopascales
3. Concentración de hemoglobina >12 g/dl en mujeres y >13 g/dl en hombres
4. Hepatopatía compensada (Child-Pugh grado A).



Calleja JL et al EASL 2013

EFFICACY AND SAFETY OF TRIPLE THERAPY WITH PEGINTERFERON, RIBAVIRIN, AND BOCEPREVIR AS COMPASSIONATE USE IN SPANISH PATIENTS WITH HEPATITIS C GENOTYPE 1 WITH SEVERE FIBROSIS: INTERIM ANALYSIS AT 12 WEEKS.

PATIENTS CHARACTERISTICS	N=102
Male (%)	**64**
Mean age (years)	**54**
Genotype 1a/1b (%)	**18/82**
Mean baseline HCV RNA (log10 UI/Ml)	**6.2 log**
F4 (%)	**86**
Esophageal varices (%)	**22**
No responders(%) Relapsers Parcial responders Null responders	**81** 31 36 33

Calleja et al EASL 2013

EFFICACY AND SAFETY OF TRIPLE THERAPY WITH PEGINTERFERON, RIBAVIRIN, AND BOCEPREVIR AS COMPASSIONATE USE IN SPANISH PATIENTS WITH HEPATITIS C GENOTYPE 1 WITH SEVERE FIBROSIS: INTERIM ANALYSIS AT 12 WEEKS.

PATIENTS CHARACTERISTICS	N=102
Neutrophil (Mean, /mm^3)	**3.222**
Hemoglobin (Mean, g/dl)	**12.9**
Platelets (Mean, plaq/mm3)	**161,109**
< 90.000 Platelets (%)	19%
Total Bilirubin (Mean, mg/ml)	**0.91**
Albumin Mean, g/dL)	**4.2**
Prothrombin Time (Mean, ratio)	**84**

Calleja et al EASL 2013

EFFICACY AND SAFETY OF TRIPLE THERAPY WITH PEGINTERFERON, RIBAVIRIN, AND BOCEPREVIR AS COMPASSIONATE USE IN SPANISH PATIENTS WITH HEPATITIS C GENOTYPE 1 WITH SEVERE FIBROSIS: INTERIM ANALYSIS AT 12 WEEKS.

Patients, n (% patients with at least one event)	(n=102)
Serious adverse events (SAEs)	**33 (32.4%)**
Premature discontinuation	**33 (32.4%)**
Due to SAEs	10 (9.8%)
Discontinuing patient's decision	3 (2.9%)
Virological failure	20 (10.6%)
Death	
Septic shock, Multi-organ failure secondary to pneumonia	**2 (1.96%)**
Dose modification (Peg-IFN)	**8 (7.8%)**
Infection / Infection Grade 3-4	**19/ 5 (4.9%)**
Hepatic decompensation (Grade 3/4)	**4 (3.9%)**

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PREMATURE DISCONTINUATION

DUE TO SAEs	VIROLOGICAL FAILURE
10 (9,8%)	**20 (19,6%)**
Anemia (2)	No respond lead-in phase (13)
Neutropenia (1)	Virological failure at week 12 (7)
Septic shock of pulmonary origin (1)	
Hepatic decompensation (2)	
Metastatic disease (1)	
Hyponatremia (1)	
Gastrointestinal disorders (1)	
Cutaneous adverse reactions (1)	

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INFECTIONS

MILD INFECTION	INFECTION (Grade 3 / 4)
19 (18.6%)	**5 (4.9%)**
Upper respiratory tract infections (8)	Pneumonia (4)
Urinary tract infection (4)	Septic shock of pulmonary origin (1)
Acute Otitis (2)	
Recurrent gastroenteritis (2)	
Gingivitis (2)	
Glossitis (1)	

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EFFICACY AND SAFETY OF TRIPLE THERAPY WITH PEGINTERFERON, RIBAVIRIN, AND BOCEPREVIR AS COMPASSIONATE USE IN SPANISH PATIENTS WITH HEPATITIS C GENOTYPE 1 WITH SEVERE FIBROSIS: INTERIM ANALYSIS AT 12 WEEKS.

Patients, n (%)	(n=102)
Anemia	
Hg <10.0 g/dL	29 (28.4%)
Hb <8.0 g/dL	3 (2.9%)
EPO use	26 (25.5%)
Blood transfusion	9 (8.8%)
Ribavirin dose adjustment	27 (26.4%)
Neutropenia	
N < 1.000/mm3	44 (43.1%)
N < 500/mm3	5 (4.9%)
Use G-CSF	2 (2.0%)
Thrombopenia	
platelets <50.000	18 (17.6%)
platelets <25.000	1 (0.98%)

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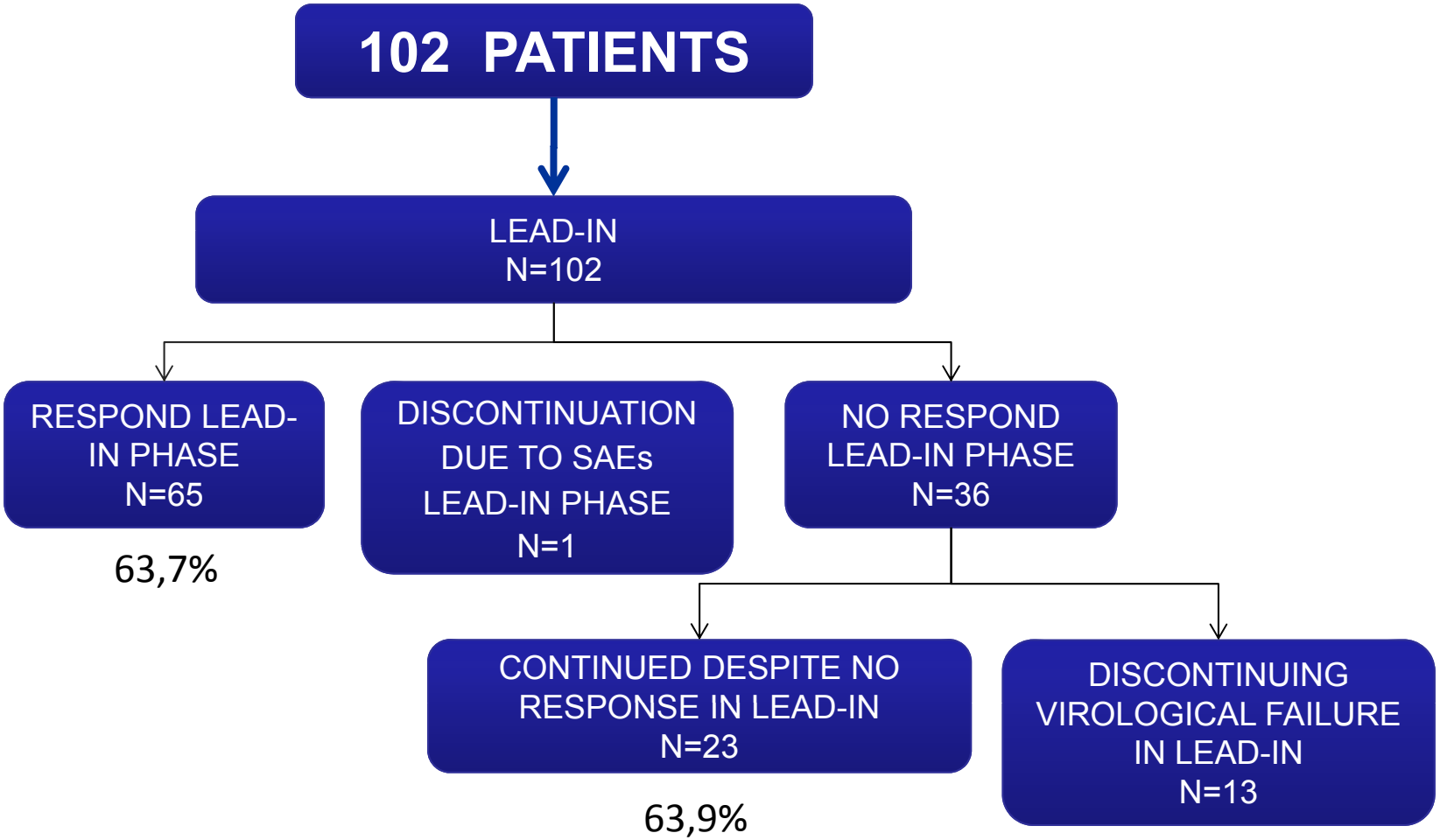

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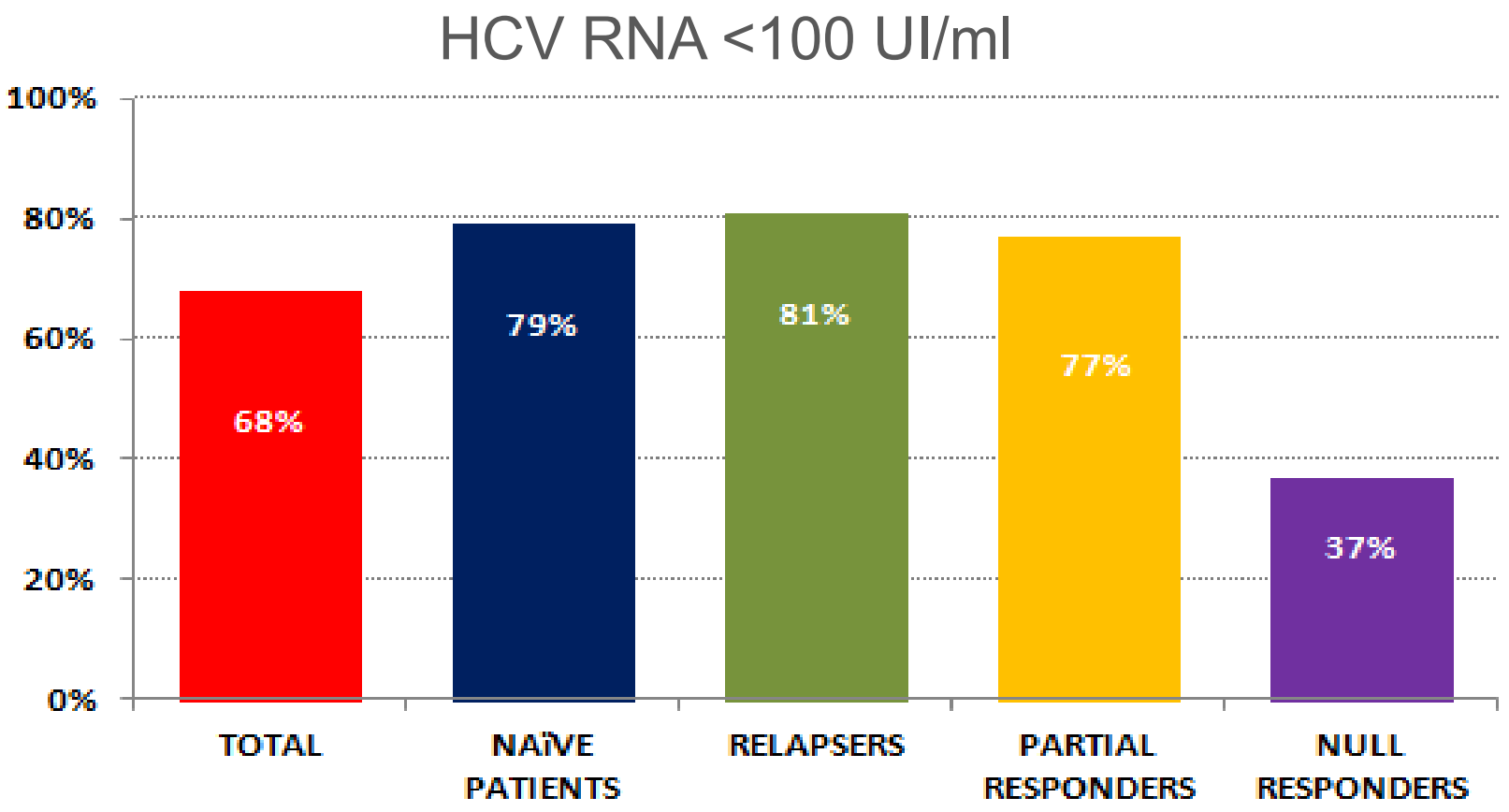
INTENT TO TREAT ANALYSIS



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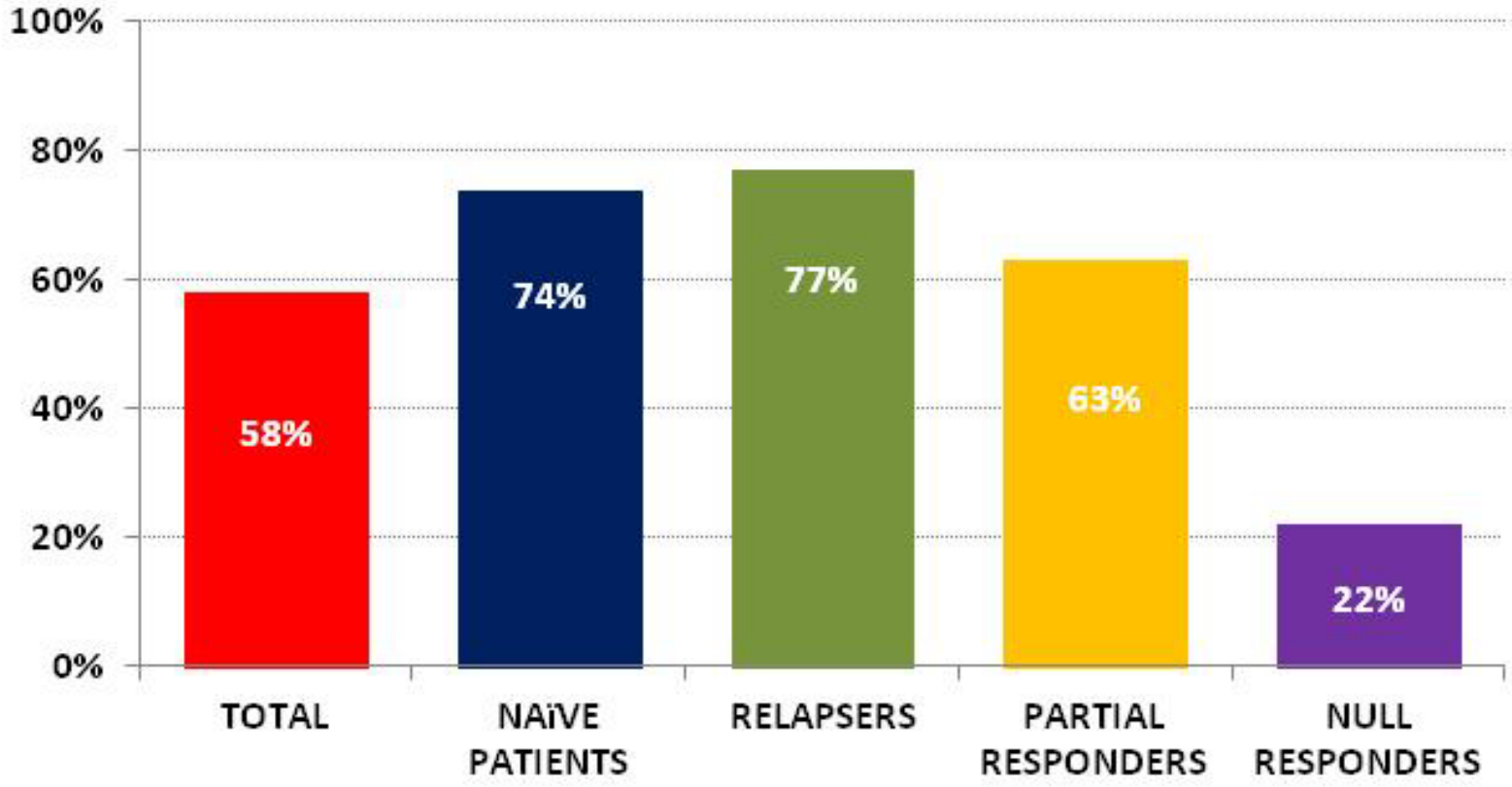
HCV RNA UNDETECTABLE



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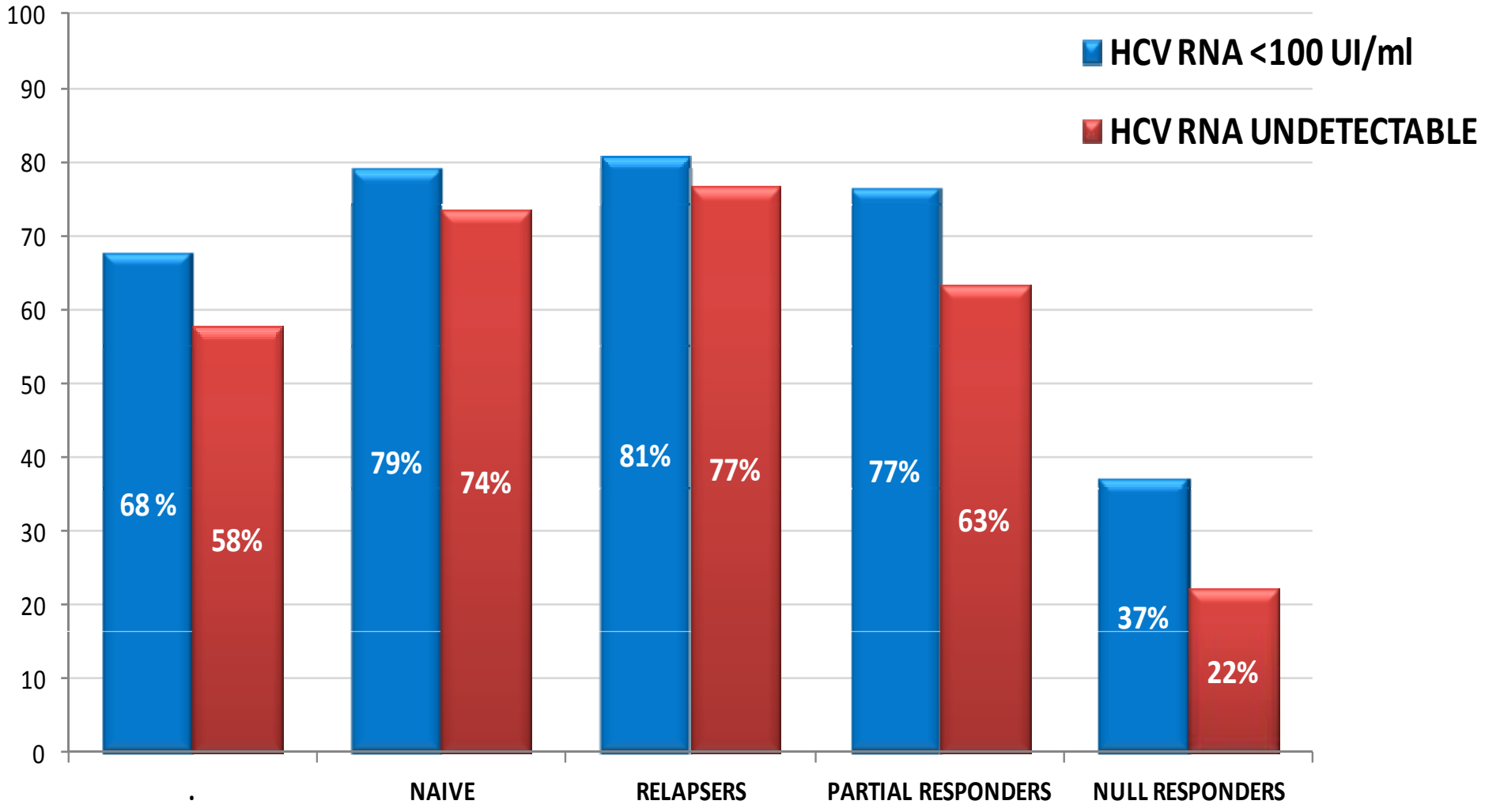

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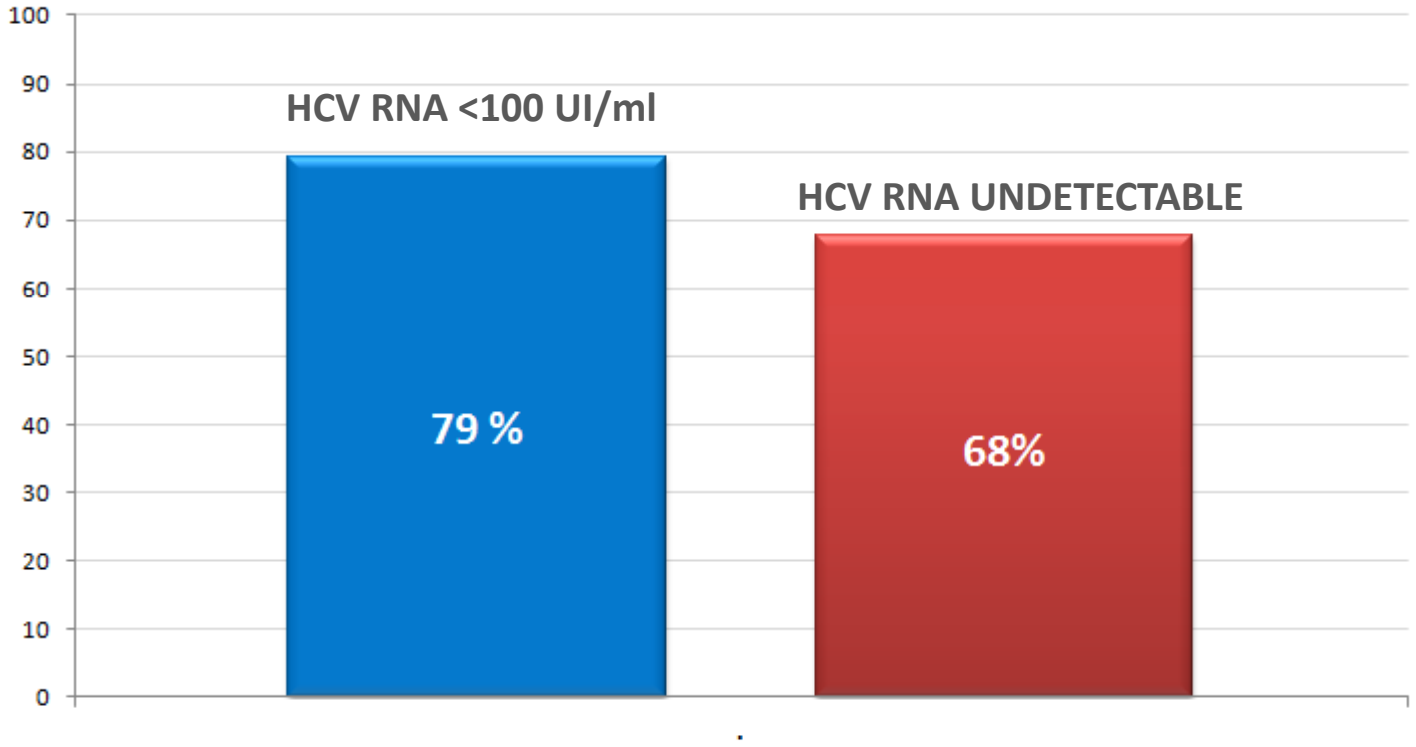
PER-PROTOCOL ANALYSIS



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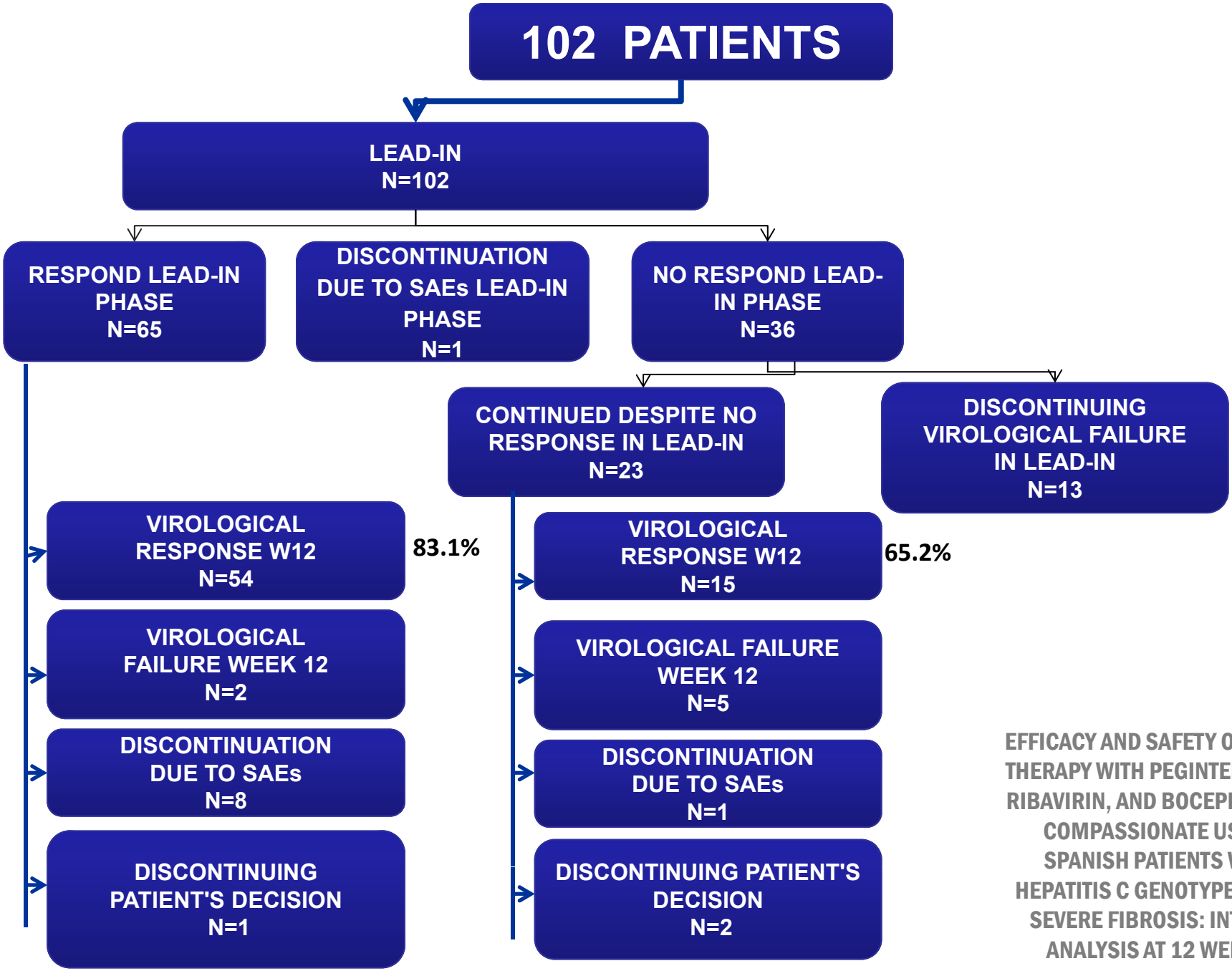

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FACTORS ASSOCIATED WITH

ANEMIA	PATIENTS Hb ≥10	PATIENTS Hb<10
Mean (DE) Baseline Hemoglobin	15.70 (3.91)	13.97 (1.54)*
Mean Age	53.2 (9.4)	56.7 (7.7)
FIBROSIS		
F3	92.9%	7.1%
F4	68.2%	31.8%
GENDER		
Male	84.6%	15.4%
Female**	48.6%	51.4%*

*p< 0.05.**Baseline Hb Female 13.7 vs 16.1 males (p<0.05)

INFECTIONS	PATIENTS WITHOUT INFECTION	PATIENTS WITH INFECTION
Mean Age	54.4 (9.3)	53.5 (8.2)
FIBROSIS		
F3	92.9%	7.1%
F4	79.5%	20.5%
GENDER		
Male	83.1%	16.9%
Female	78.4 %	21.6%

No significant differences of Hb, platelets and neutrophils basal were found.

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MARQUÉS DE VALDECILLA

ANEMIA IN A COHORT OF PATIENTS WITH CHRONIC HEPATITIS C ON TRIPLE THERAPY

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POSTER N 853

Baseline characteristics

n=140

Mean age	55 (SD9)
Male	54.3%
Median follow up	12 weeks (8-48)
Mean liver stiffness (LS)	16.7kPa (SD12.2)
Fibroscan grade (%)	< F2:19.3%; F3:25%; F4:55.7
BOC/TEL	60 (42.9%) / 80 (57.1%)
'Lead-in'	69 (49.3%)

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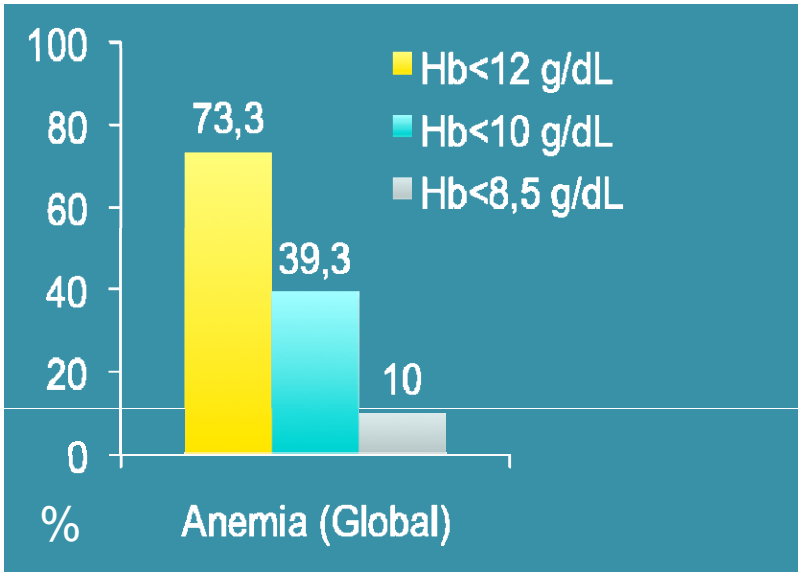
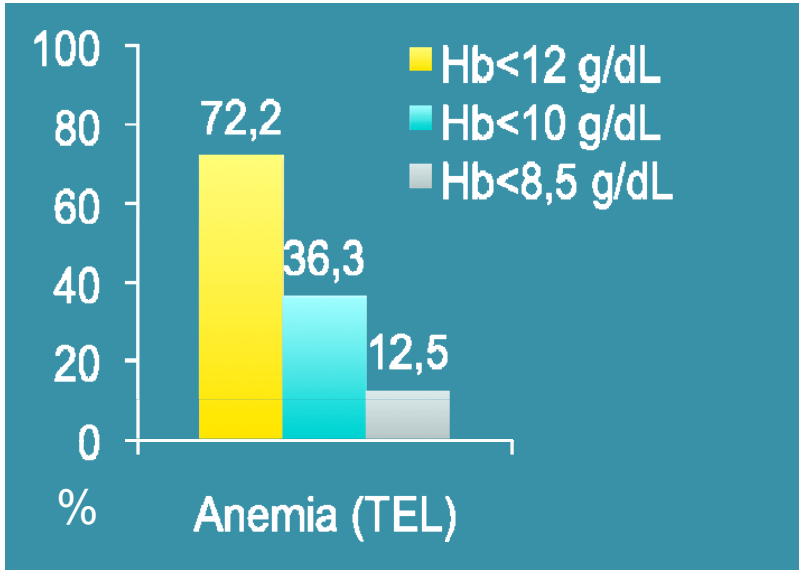
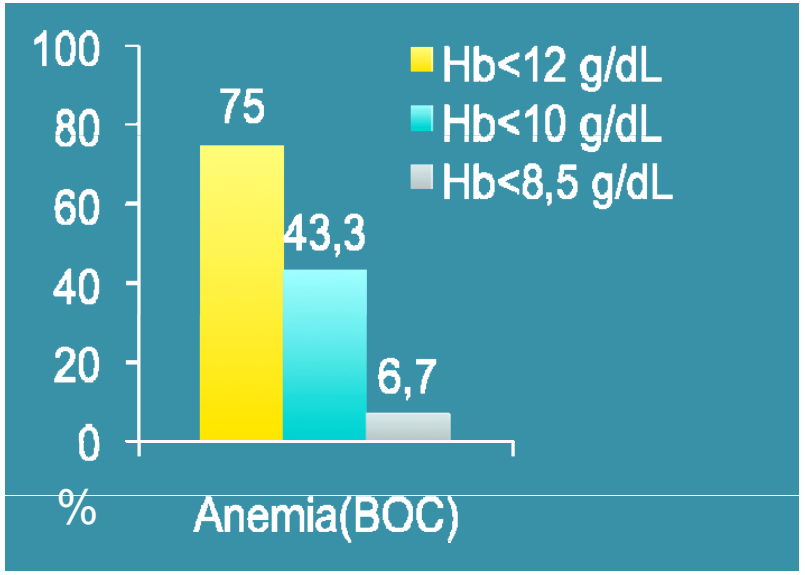
Incidence of anemia







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Conclusiones

- La eficacia en las cohortes de practica real será similar a los ensayos clínicos (en el mejor de los escenarios)
- La mayor parte de los efectos secundarios graves se concentran en pacientes avanzados
- La adecuada selección de pacientes mejora nuestra efectividad en la curación de pacientes