The HEPAVIR-DAA and GEHEP-MONO cohorts for treatment against chronic hepatitis C virus infection including direct-acting antivirals: Real-life data from Spain

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DISCLOSURES

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HISTORY

- **Viral Hepatitis Study Group of the Andalusian Society of Infectious Diseases**

Grupo de Estudio de Hepatitis Virales (HEPAVIR) de la Sociedad Andaluza de Enfermedades Infecciosas (SAEI)

HEPAVIR-DAA Cohort
(NCT02057003)

- **Viral Hepatitis Study Group of the Spanish Society of Infectious Diseases and Clinical Microbiology**

Grupo de Estudio de las Hepatitis Vírica (GEHEP) de la Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica (SEIMC)

GEHEP-MONO Cohort
(NCT02333292)

saei
Sociedad Andaluza de Enfermedades Infecciosas

GEHEP

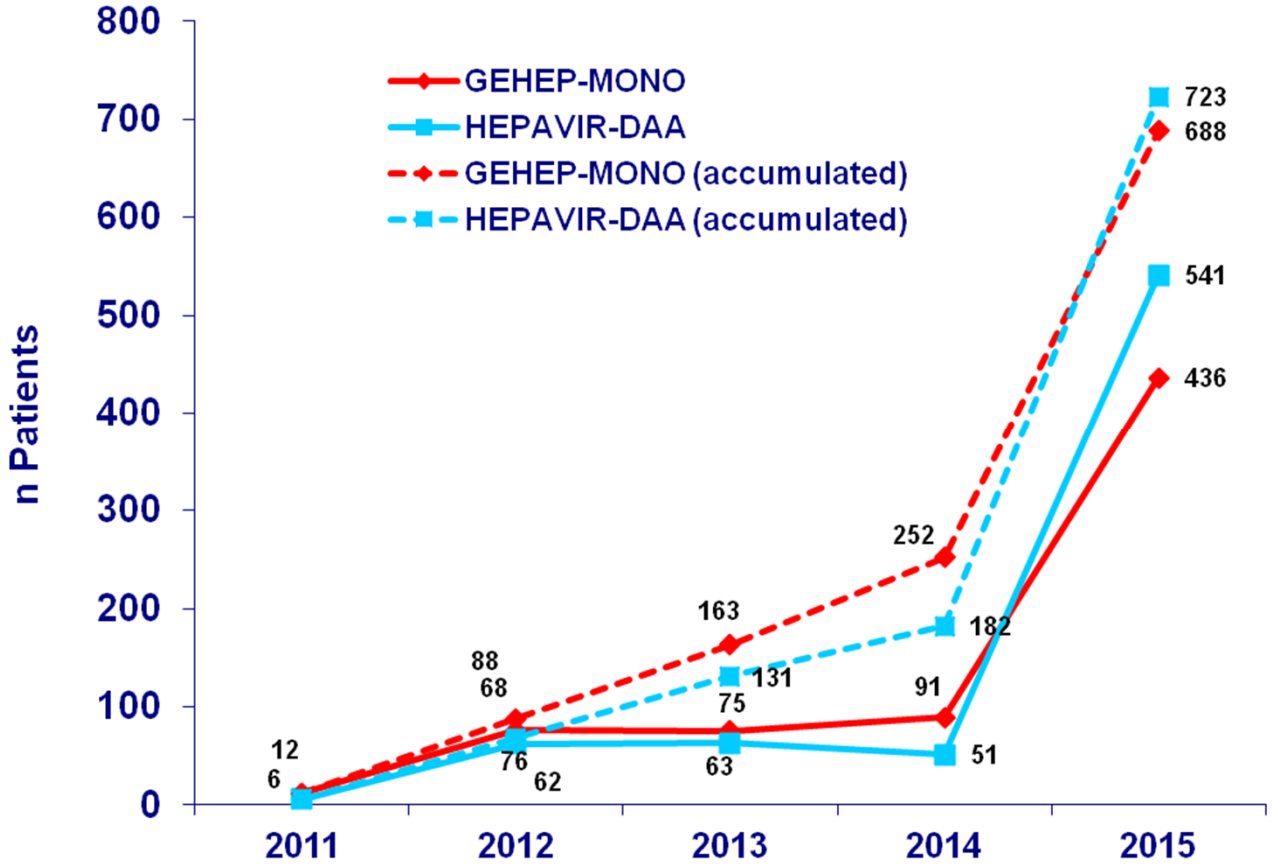
seimc

PARTICIPATING CENTRES

COHORT CHARACTERISTICS

- **Design:** Prospective, multicenter, open cohort
- **Area:** Infectious Diseases Units of 32 Spanish terciary care centers
- **Patients:** HCV-monoinfected (GEHEP-MONO Cohort) or HIV/HCV-coinfected patients (HEPAVIR-DAA Cohort) who initiate therapy against chronic HCV infection
- **Regimens:** All regimens that include any direct-acting antiviral (DAA) available in clinical practice

PATIENT RECRUITMENT BY YEAR



n=1411

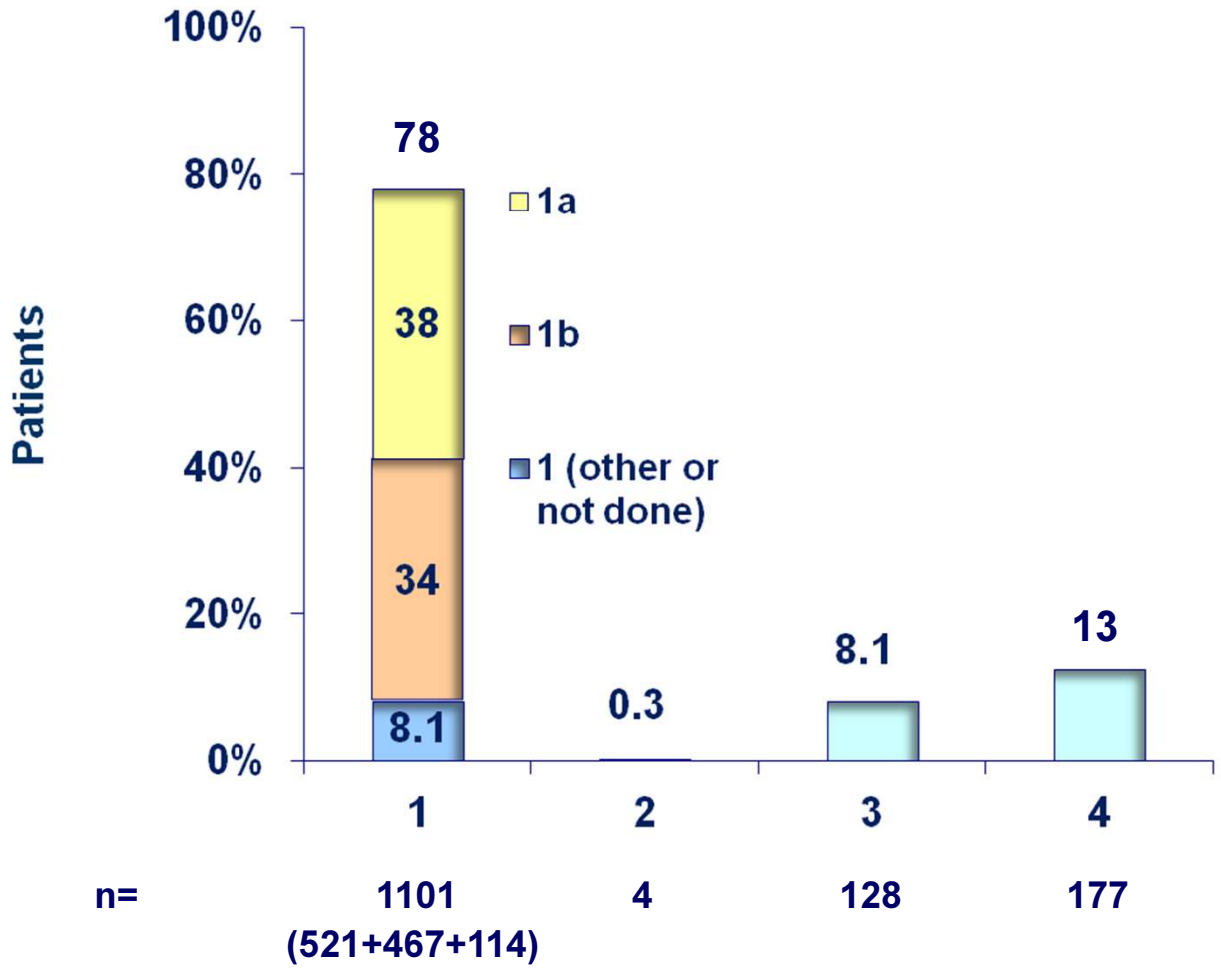
BASELINE CHARACTERISTICS (I)

Característic (n=1411)	
Median age (Q1-Q3), years	50.9 (46.5-54.9)
Male gender, n (%)	1057 (74.9)
HIV coinfected, n (%)	723 (51.2)
IL28B no-CC, n (%)*	726 (66.9)
Injecting drug users, n (%)	809 (57.3)
Previous response, n (%)	
Naïve	615 (43.6)
Relapse	200 (14.2)
Partial response	110 (7.8)
Null response	307 (21.8)
HCV RNA >$6*10^5$ IU/mL, n (%)	228 (16.3)

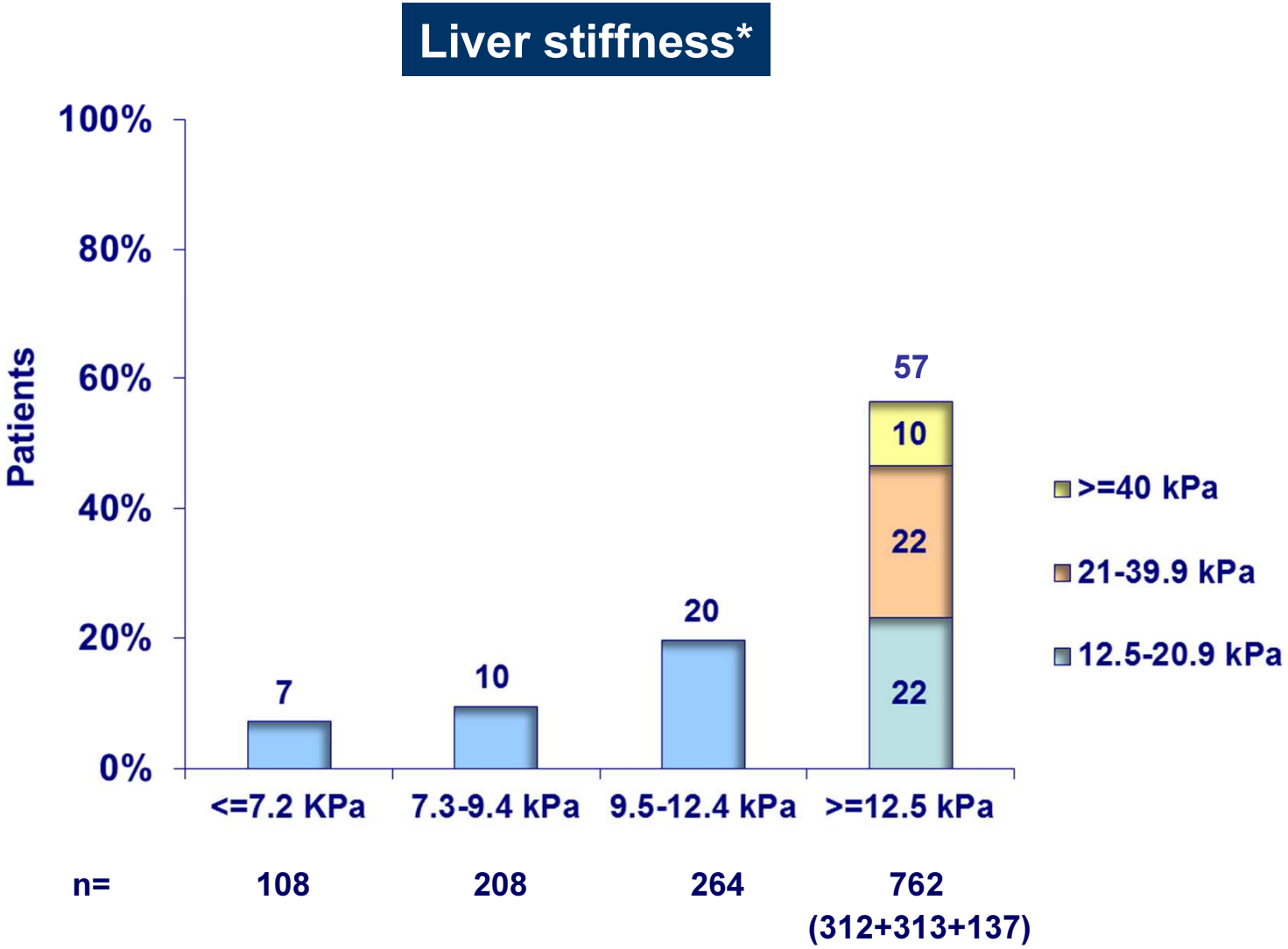
*available in 1085 patients

BASELINE CHARACTERISTICS (II)

HCV genotype distribution

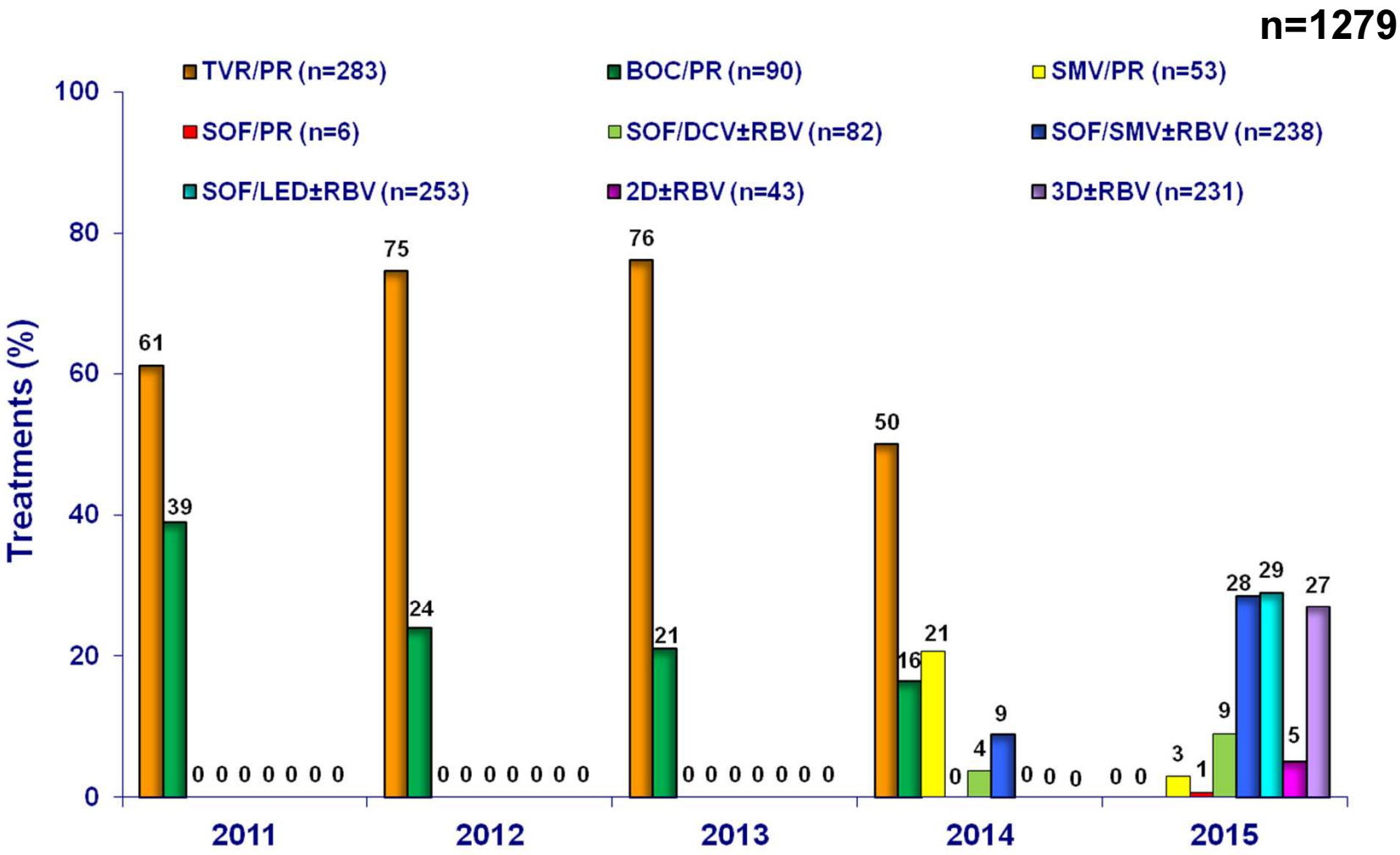


BASELINE CHARACTERISTICS (III)



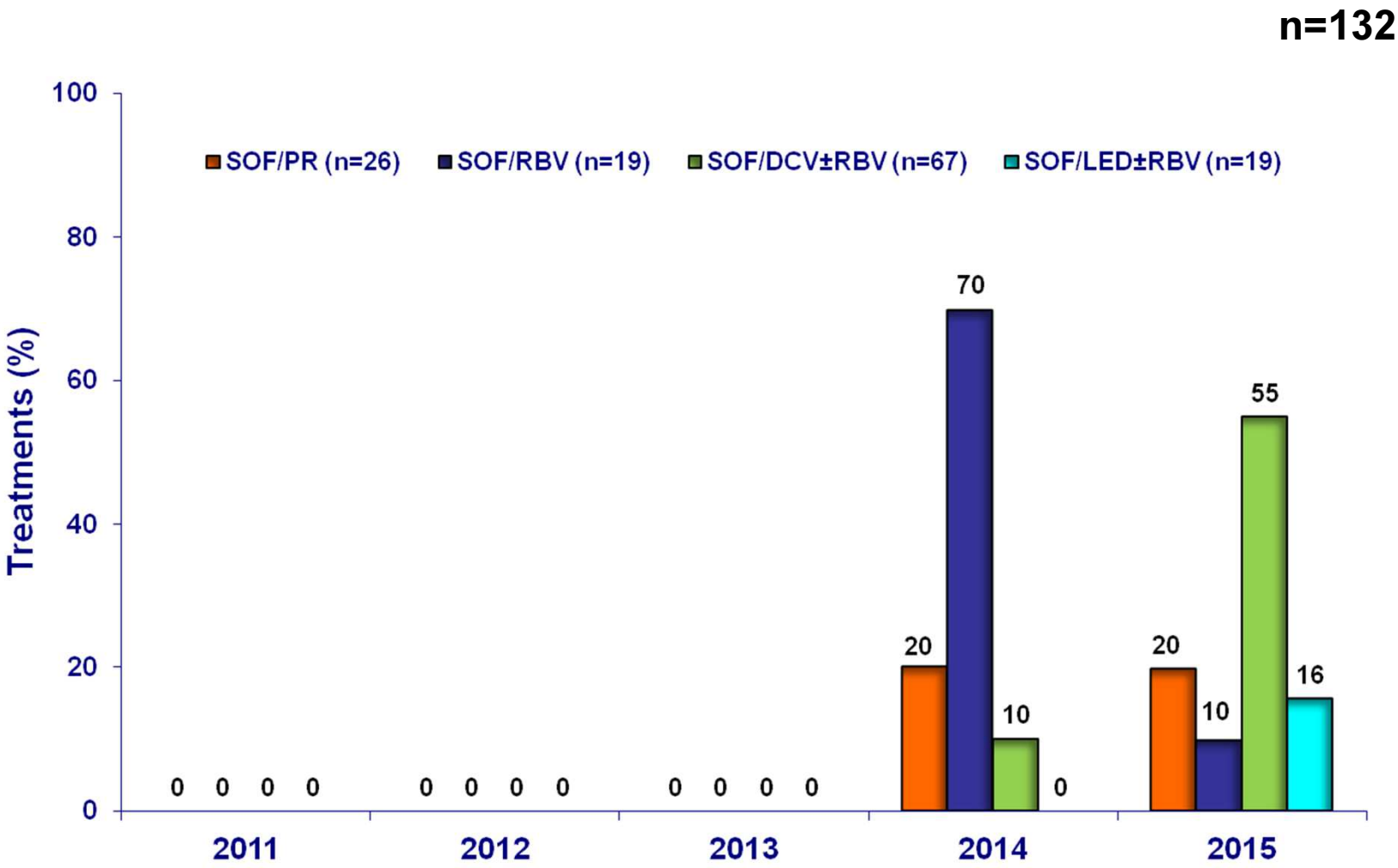
*determined by transient elastometry, available in 1373 patients

REGIMEN BY YEAR: HCV GENOTYPES 1 & 4



TVR: telaprevir; PR: pegylated interferon/ ribavirin; BOC: boceprevir; SMV: simeprevir; SOF: sofosbuvir; DCV: daclatasvir; RBV: ribavirin; LED: ledipasvir; 2D: paritaprevir/ritonavir + ombitasvir; 3D: paritaprevir/ritonavir + ombitasvir + dasabuvir.

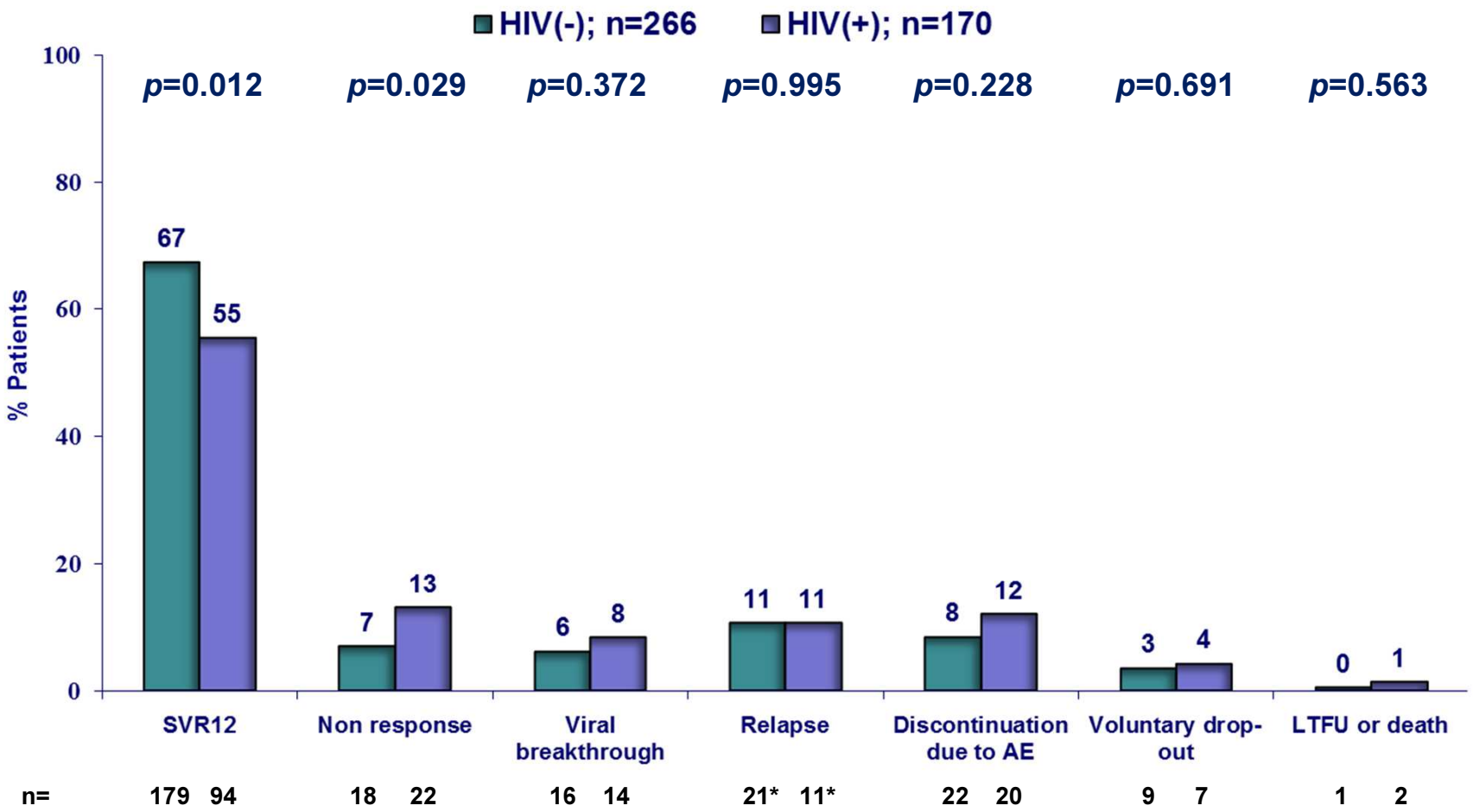
REGIMEN BY YEAR: HCV GENOTYPES 2 & 3



TVR: telaprevir; PR: pegylated interferon/ ribavirin; BOC: boceprevir; SMV: simeprevir; SOF: sofosbuvir; DCV: daclatasvir; RBV: ribavirin; LED: ledipasvir; 2D: paritaprevir/ritonavir + ombitasvir; 3D: paritaprevir/ritonavir + ombitasvir + dasabuvir.

RESPONSE TO THERAPY (I)

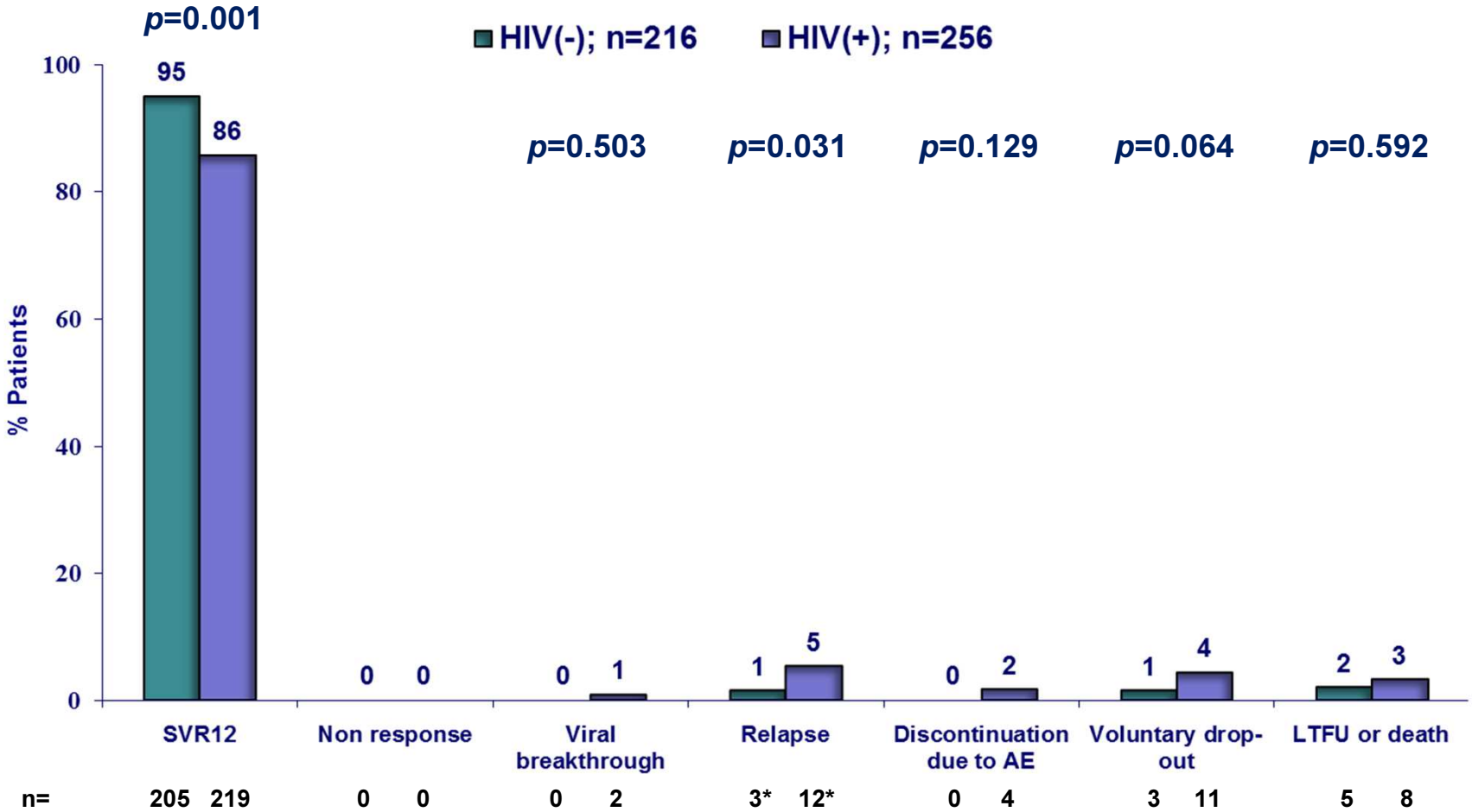
Interferon-based regimens



SVR12: sustained virologic response 12 weeks after scheduled end-of-therapy; AE: adverse events; LTFU: lost to follow-up;
*calculated for those who had reached end-of-treatment response [HIV (-): n=200; HIV (+): n=105]

RESPONSE TO THERAPY (II)

Interferon-free regimens



SVR12: sustained virologic response 12 weeks after scheduled end-of-therapy; AE: adverse events; LTFU: lost to follow-up;
*calculated for those who had reached end-of-treatment response [HIV (-): n=208; HIV (+): n=231]

CONCLUSIONS

- The number of both HCV-monoinfected, as well as HIV/HCV-coinfected patients treated with DAA in Spain has increased considerably in 2015, after implementing the National Plan on Hepatitis C.
- The vast majority of the patients treated with DAA so far showed advanced liver damage, as a consequence of the recommendations of the National Plan.
- Overall SVR12 rates improved considerably with all-oral regimens, reaching figures of ≥ 90%.
- HIV-coinfection still appears to have a negative impact on the response to DAA-based combinations, including all-oral regimens.

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COORDINATING CENTER:

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