

# REAL-WORD EFFECTIVENESS OF INTERFERON (IFN)-FREE SOFOSBUVIR (SOF) BASED REGIMENS IN PATIENTS WITH OPIOID SUBSTITUTION THERAPY (OST) – DATA FROM THE GERMAN HEPATITIS C REGISTRY (DHC-R)



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## Objectives

Opioid substitution therapy (OST) patients together with other risk groups, exhibit highest prevalence for chronic hepatitis C infection (HCV) in Germany. Treatment of chronic HCV was revolutionized by introduction of new direct acting antivirals (DAA), which have proven effectiveness in real-life setting. To overcome reluctance to initiate DAA therapy in OST it might be helpful to characterize this patient group in more detail. Aim of this analysis was to evaluate SVR12 rates for patients with and without OST (OST versus Non-OST) with regards to alcohol and cannabis consumption.

## Methods

The German Hepatitis C-Registry (DHC-R) is a national, multicenter real-world registry study, where patients are treated at the discretion of the physician. Data is collected using a web based system. This interim analysis includes data of 4,061 patients (Non-OST: 3.719 and OST: 342), who were treated with an IFN-free SOF-based regimen between February 1st, 2014 and June 30th, 2016.

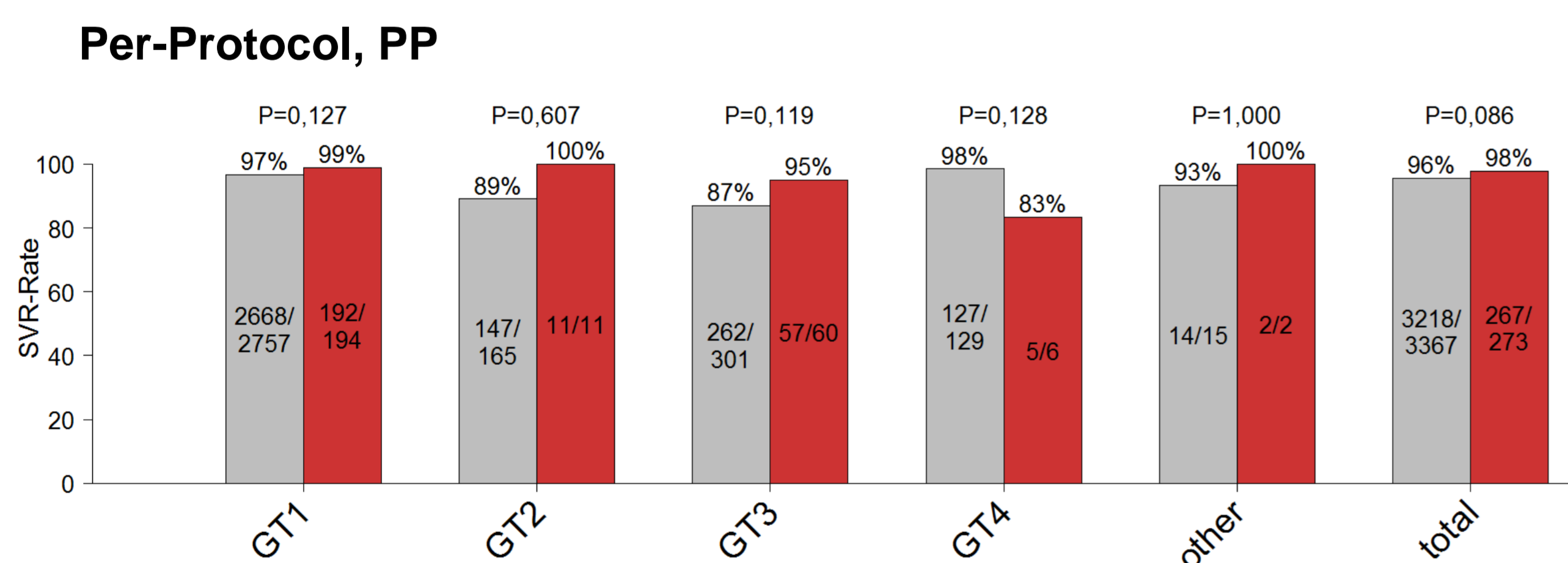
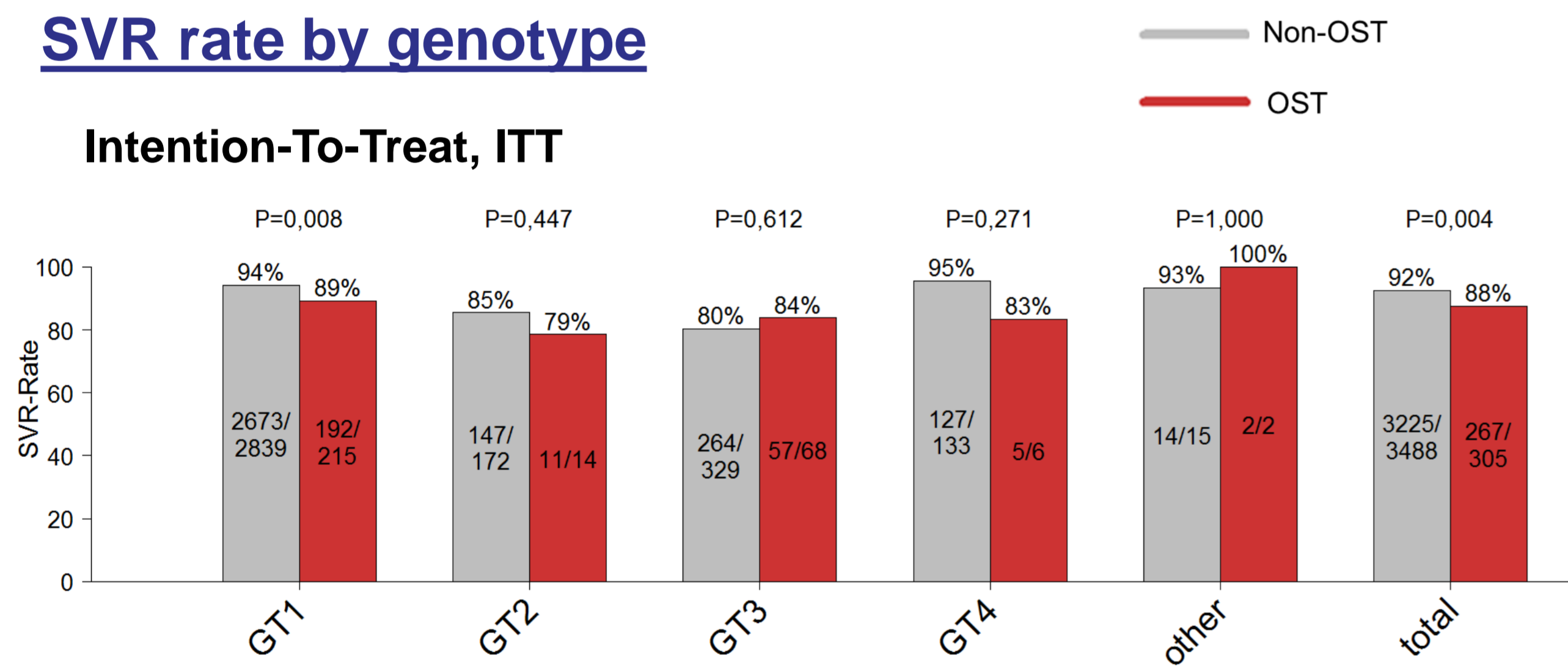
## Results

### Demographics:

		Non-OST (N=3719)	OST (N=342)	Total (N=4061)
Sex	N (%)			
	male	2044 (55,0)	265 (77,5)	2309 (56,9)
Age (years)	mean (sd)	54,5 (12,4)	46,6 (8,80)	53,8 (12,3)
	not available	45 (1,2)	5 (1,5)	50 (1,2)
Initial viral load	qual. positive nrb.	3 (<1,0)	0 (<1,0)	3 (<1,0)
N (%)	< 600000 IU/ml	3274 (88,0)	293 (85,7)	3567 (87,8)
	≥ 600000 IU/ml	397 (10,7)	44 (12,9)	441 (10,9)
Previous therapy	N (%)			
	yes	1899 (51,1)	113 (33,0)	2012 (49,5)
	no	1820 (48,9)	229 (67,0)	2049 (50,5)
HCV Genotype	N (%)			
	GT 1	3032 (81,5)	234 (68,4)	3266 (80,4)
	GT 1a	1246 (33,5)	182 (53,2)	1428 (35,2)
	GT 1b	1598 (43,0)	45 (13,2)	1643 (40,5)
	other GT 1 subtype	171 (4,6)	6 (1,8)	177 (4,4)
	GT 2	179 (4,8)	18 (5,3)	197 (4,9)
	GT 3	349 (9,4)	80 (23,4)	429 (10,6)
	GT 4	142 (3,8)	8 (2,3)	150 (3,7)
	other	17 (<1,0)	2 (<1,0)	19 (<1,0)
Cirrhosis	N (%)			
	yes	1111 (29,9)	111 (32,5)	1222 (30,1)
	no	2608 (70,1)	231 (67,5)	2839 (69,9)
Consumption of alcohol	N (%)			
	not available	12 (<1,0)	0 (<1,0)	12 (<1,0)
	no	3264 (87,8)	286 (83,6)	3550 (87,4)
	yes	443 (11,9)	56 (16,4)	499 (12,3)
	> 40 g/day men / > 30 g/day women	56 (1,5)	19 (5,6)	75 (1,8)
	≤ 40 g/day men / ≤ 30 g/day women	387 (10,4)	37 (10,8)	424 (10,4)
Consumption of cannabis	N (%)			
	not available	1 (<1,0)	0 (<1,0)	1 (<1,0)
	yes	100 (2,7)	52 (15,2)	152 (3,7)
	no	3618 (97,3)	290 (84,8)	3908 (96,2)

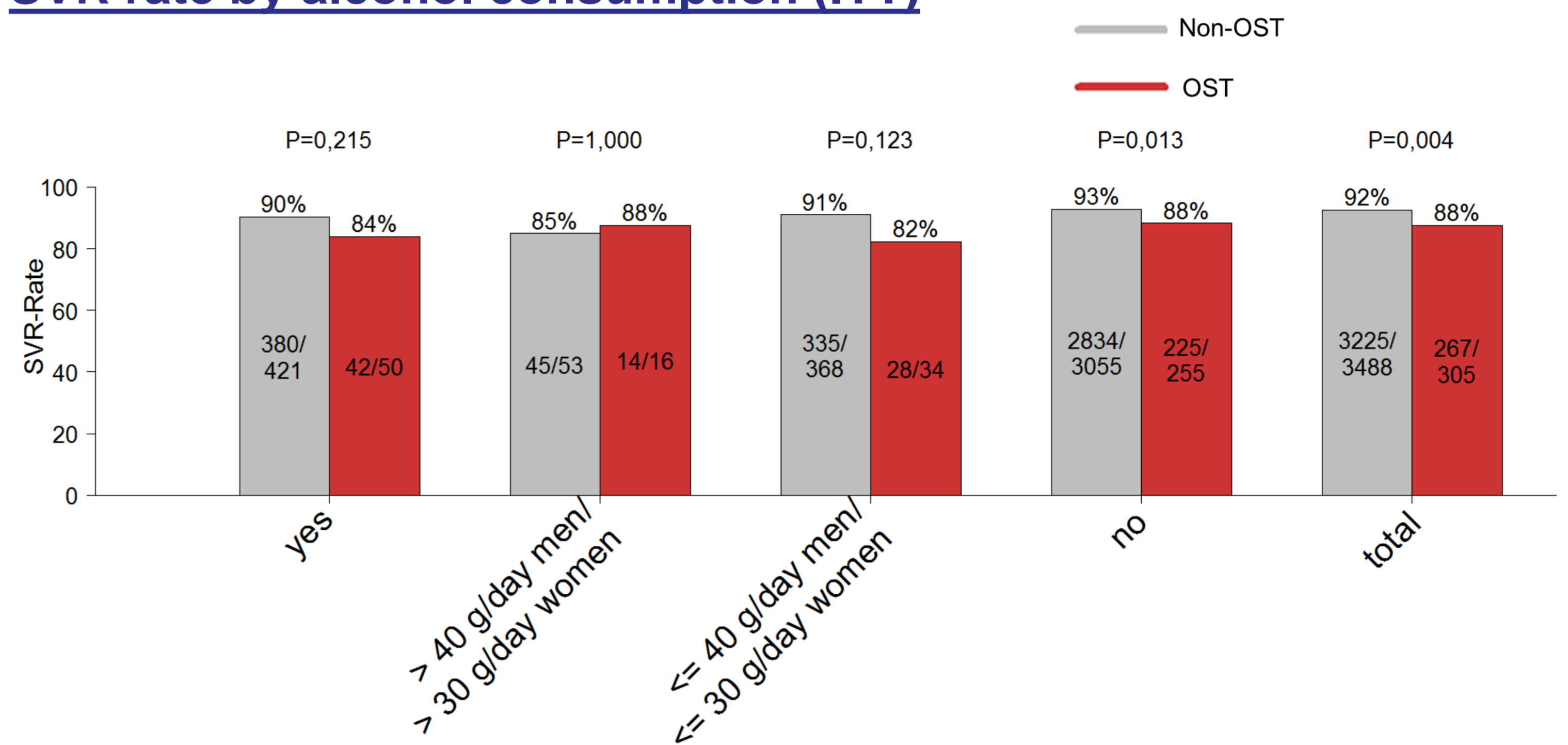
- HCV subtypes GT1a and GT1b are differently distributed among patients with or without substitution.

### SVR rate by genotype



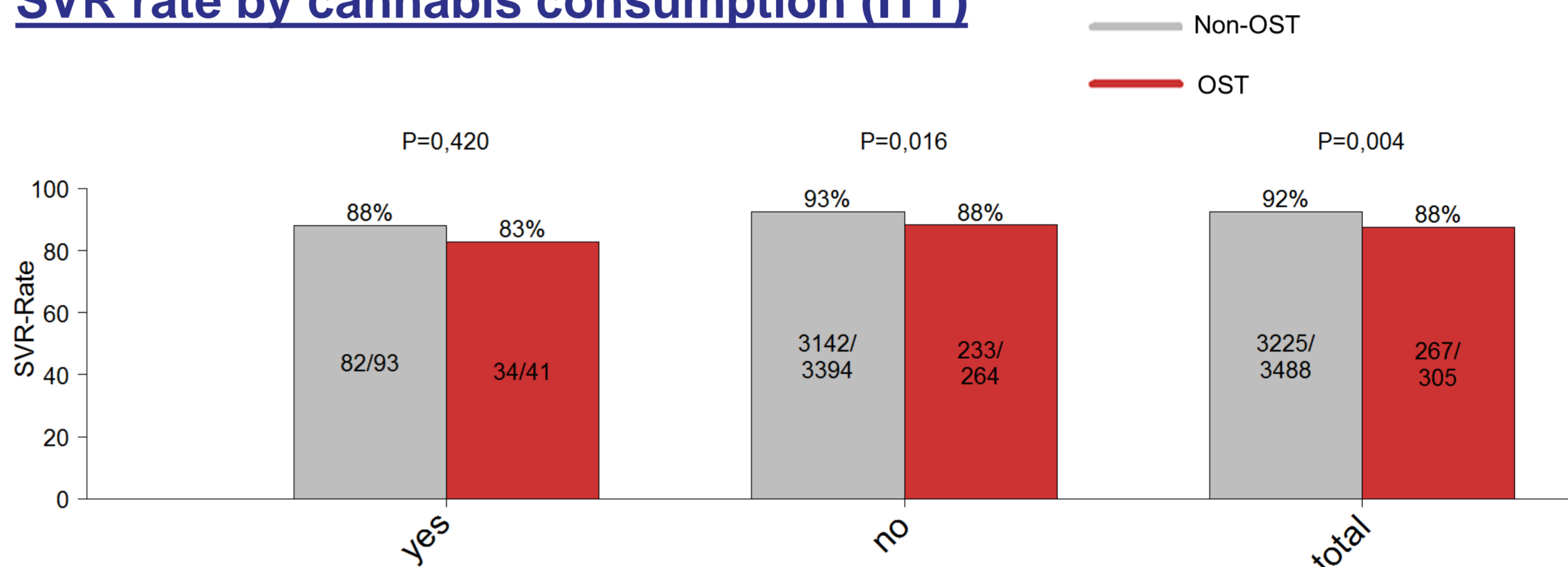
- OST patients had significant lower SVR12 in ITT but not in PP analysis in total and GT1 compared to Non-OST.
- Relapse rates did not differ between the groups, treatment compliance was estimated lower in OST.

### SVR rate by alcohol consumption (ITT)



- High SVR rates were achieved in OST and Non-OST patients. Alcohol consumption has no impact on SVR12 rates.

### SVR rate by cannabis consumption (ITT)



- SVR were comparable in patients with and without OST. Cannabis consumption has no impact on SVR12 rates.

### Relapse rates

	No substitution	Substitution
<b>Total</b>	3,4% (120/3488)	2,0% (6/305)
<b>HCV genotype</b>	GT1	2,5% (71/2839)
	GT2	7,0% (12/172)
	GT3	10,9% (36/329)
	GT4	0,8% (1/133)
	other	0,0% (0/15)
	0,0% (0/2)	0,0% (0/2)

### Treatment compliance (physician's estimation)

	No substitution	Substitution
During therapy / end of therapy	very good	91,3% (3026/3316)
	good	8,6% (285/3316)
	satisfying	0,1% (4/3316)
	bad	0,0% (1/3316)
	83,0% (225/271)	16,6% (45/271)
	0,4% (1/271)	0,0% (0/271)

- Treatment compliance was very good in most of the patients of both treatment groups based upon physician estimation.

## Conclusion

- IFN-free SOF-based therapies result in high SVR rates in OST and Non-OST patients.
- Differences of SVR rates in ITT and PP analysis of OST vs. Non-OST were not driven by a higher relapse rate but could be a result of less compliance estimated by the treating physician.
- Consumption of alcohol- and cannabis has no impact on SVR12.

**DHC-R** – Leberstiftungs-GmbH  
Deutsches Hepatitis C-Register

Die hier gezeigten Daten stammen aus dem **Deutschen Hepatitis C-Register (DHC-R)**, das die Deutsche Leberstiftung (über die Leberstiftungs-GmbH Deutschland) in Kooperation mit dem Berufsverband Niedergelassener Gastroenterologen Deutschlands (bng) führt.

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