

# An observational, prospective, multicenter study on the utilization and effectiveness of elbasvir/grazoprevir treatment association for chronic hepatitis C in France : No effect of alcohol consumption or dependence on treatment outcome

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## BACKGROUND

ZEPHYR is a French, multicenter, prospective, observational study on elbasvir / grazoprevir use in current practice. An hepatitis C direct acting antivirals combination therapy. Though efficacy and safety of direct acting antivirals have been evaluated in different real-world settings, patient reported outcomes (PROs) evaluating alcohol consumption in particular are scarce.

## AIMS

- This analysis aims to focus on specific secondary objectives of the Zephyr study:
  - To describe patient's addictive behaviours (alcohol consumption, tobacco use and drug abuse)
  - To describe SVR12 for patients according their declared alcohol consumption

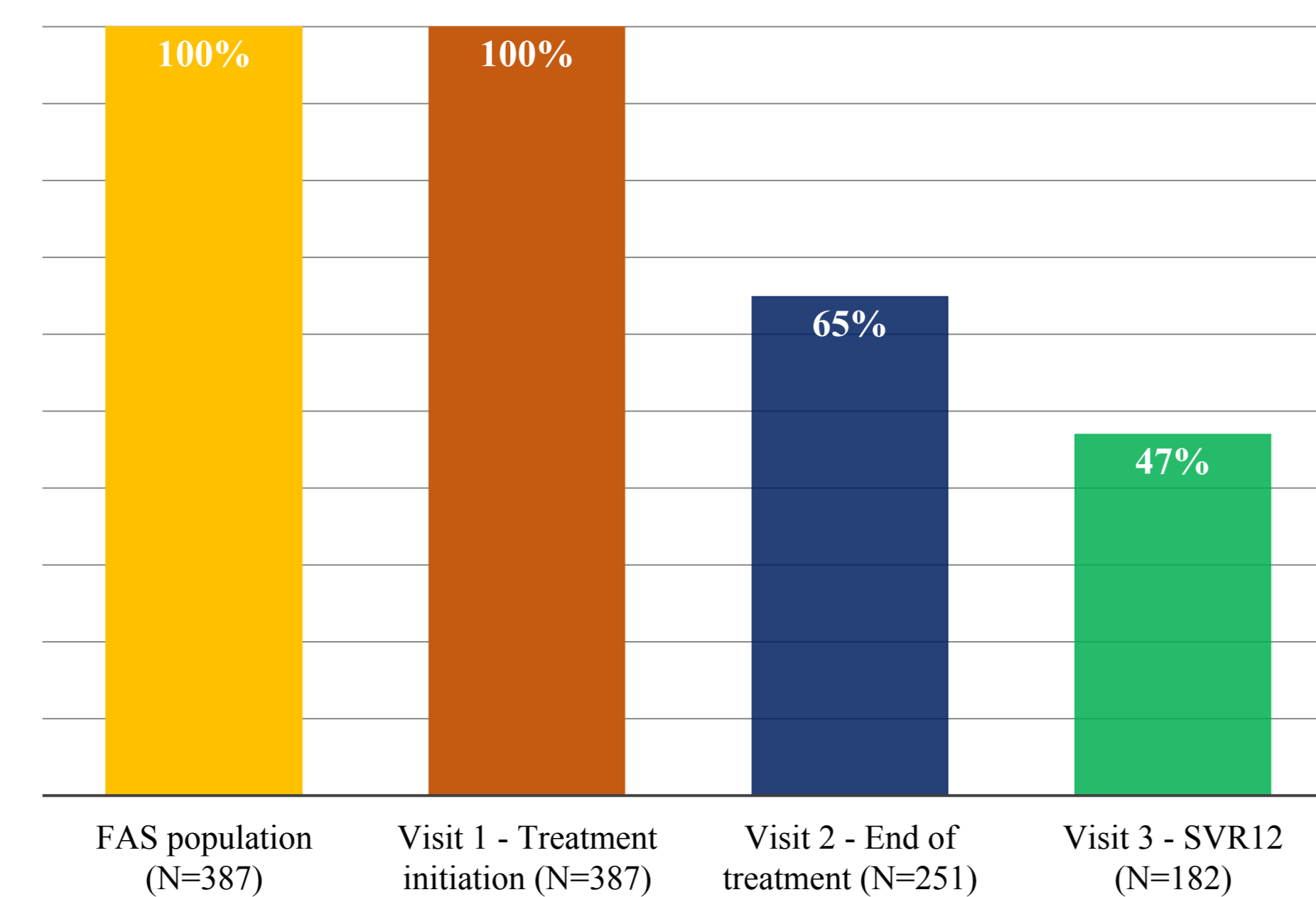
## METHODS

- This second Zephyr study planned interim analysis is based on available data in adult patients with confirmed chronic hepatitis C infection and who declared to have received at least one dose of elbasvir / grazoprevir (EBR/GZR) on the data cut-off: march 1<sup>st</sup>, 2019
- 117 physicians working in 67 hospitals and clinics are participating to Zephyr
- All the patients received the PROs and were free to fill them at the inclusion, end of therapy (EOT) and at follow-up week 12.

- AUDIT-C questionnaire: excessive alcohol consumption defined as  $\geq 3$  points;
- Life habits questionnaire (sociological data, tobacco use, drug abuse)

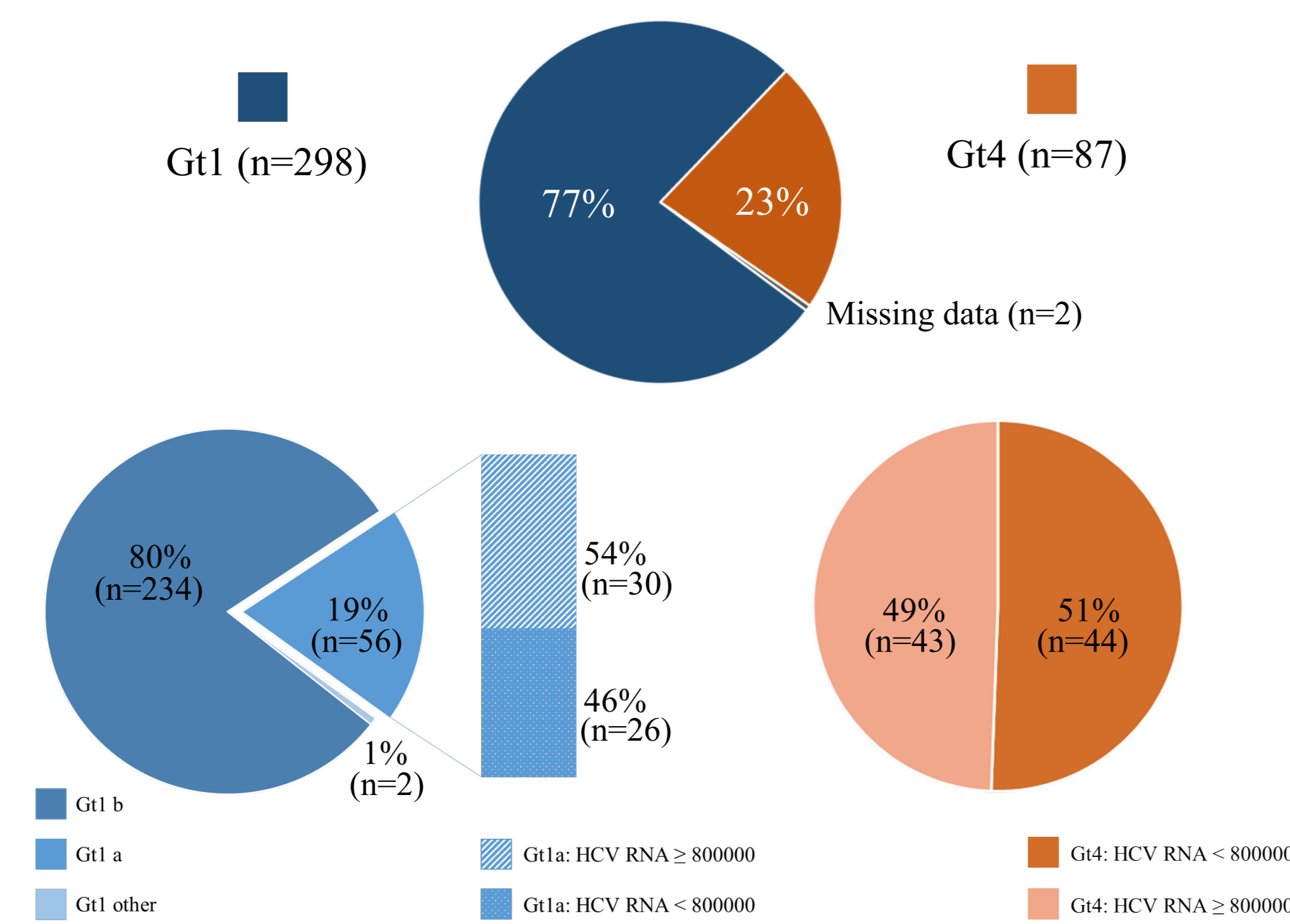


## Overall Population Analysis

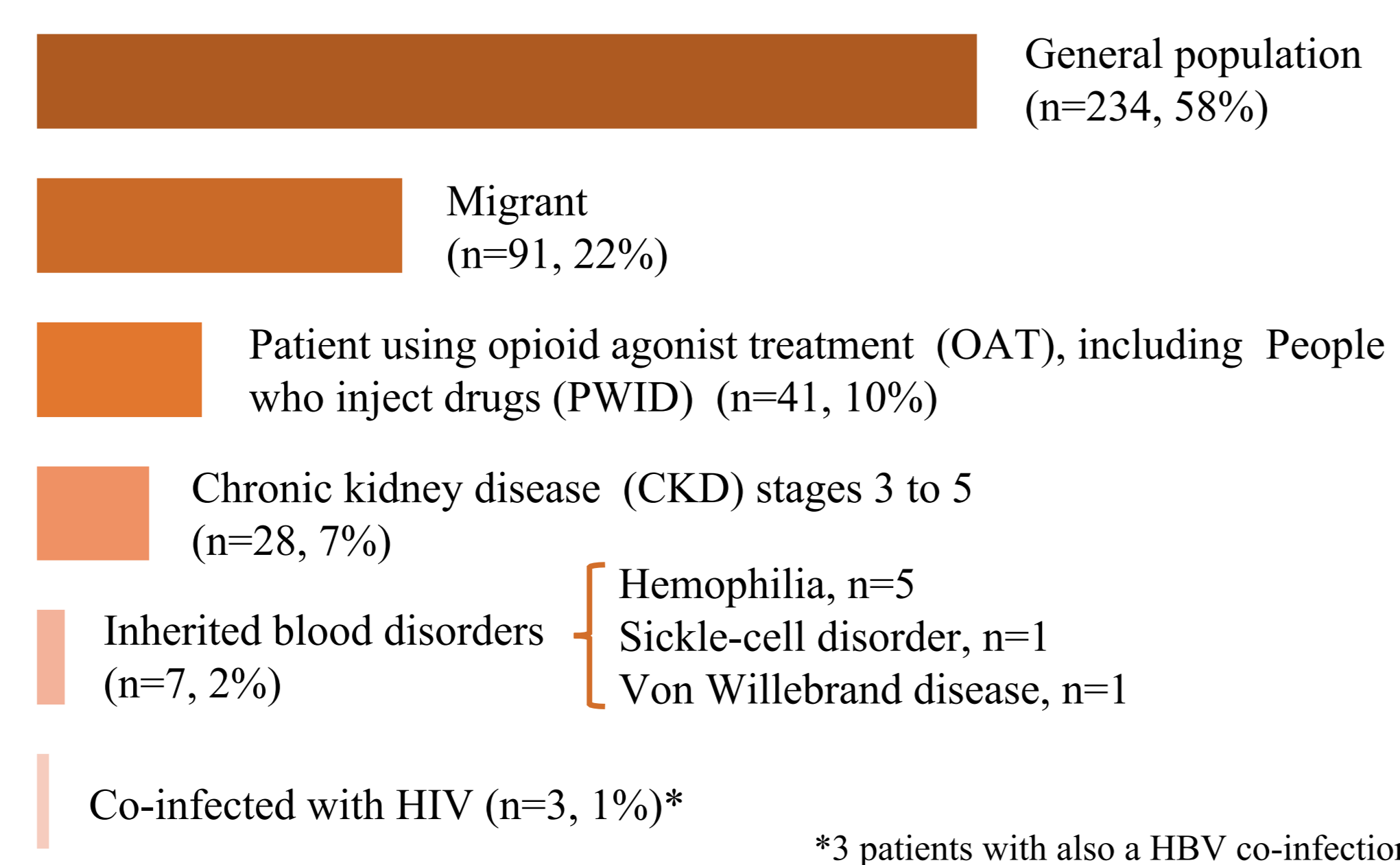


FAS: Full analysis set = all patients meeting all inclusion and exclusion criteria and receiving at least one dose of treatment. All subsequent analysis presented hereafter were based on the FAS population.

## Genotypes



## Subgroups of interest

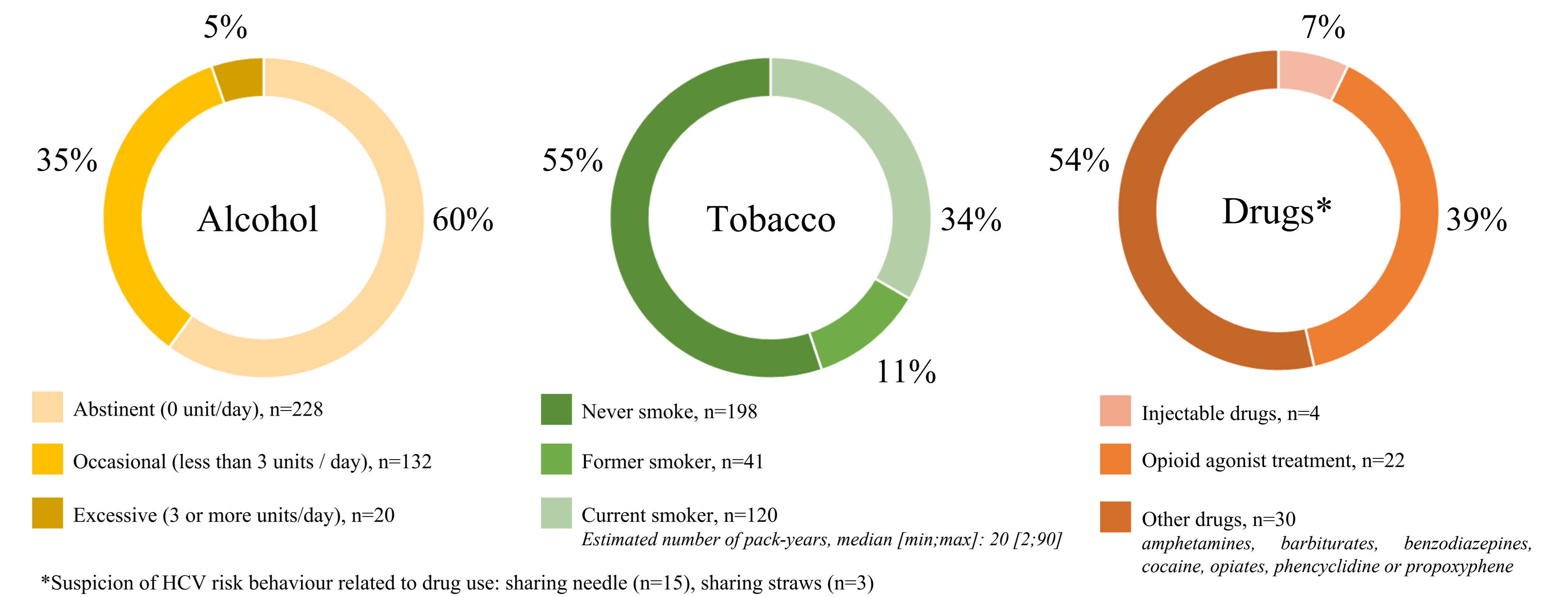


## Patients' characteristics

Socio-demographic data	n (%)
Male	199 (51)
Median age, yrs [min;max]	55.8 [20;90]
Median weight, kg [min;max]	70.0 [43;117]
Body mass index, kg/m <sup>2</sup> [min;max]	24.5 [17;48]
Patient who received an AME, n (%) (Government medical assistance)	33 (9)
Care support program, n (%)	112 (29)
Adherence to treatment / therapeutic education as main objective, n (%)	107 (96)
Involved nurse, n (%)	104 (93)
Disease history related data	n (%)
Mean time since infection, yrs $\pm$ SD	20.3 $\pm$ 14.7
HCV pre-treated, n (%)	38 (10)
Peg-interferon $\pm$ ribavirin, n (%)	23 (61)
Treatment failure, n (%)	34 (92)
Fibrosis METAVIR stage	
F0-F2, n (%)	279 (72)
F2-F3, n (%)	2 (0.5)
F3-F4, n (%)	93 (23.5)
Initial decision discussed in multidisciplinary meeting, n (%)	4 (1)
Treatment duration	
8 weeks, n (%)	25 (6)
12 weeks, n (%)	358 (93)
16 weeks, n (%)	2 (0.5)
Top 5 comorbidities	n (%)
Hypertension	99 (26)
Diabetes	35 (9)
Depressive syndrome	21 (5)
Cryoglobulinemia	21 (5)
Arthralgia	11 (3)
Concomitant treatments	n (%)
At least one concomitant treatment	185 (48)
At least one other concomitant anti-viral treatment	4 (1)
Top 10 other concomitant treatments	
Agents acting on renin-angiotensin system	63 (16)
Psycholeptics	47 (12)
Calcium channel blockers	39 (10)
Beta blocking agents	37 (10)
Drugs for acid related disorders	35 (9)
Drugs used in diabetes	34 (9)
Psychoanaleptics	30 (8)
Diuretics	27 (7)
Thyroid therapy	24 (6)
Analgésics	23 (6)

## RESULTS

## Addiction behaviour at treatment initiation



\*Suspicion of HCV risk behaviour related to drug use: sharing needle (n=15), sharing straws (n=3)

## PROs-FAS Analysis Population

	Treatment initiation Visit 1	End of Treatment Visit 2	SVR12 Visit 3
AUDIT-C questionnaire score-qualitative, n	248	150	162
Overall score < 3, n (%)	155 (63)	78 (66)	89 (68)
Overall score $\geq 3$ , n (%)	93 (37)	41 (34)	42 (32)
General population subgroup score < 3, n (%)*	95 (41)	45 (19)	59 (25)
General population subgroup score $\geq 3$ , n (%)	61 (26)	23 (15)	29 (12)
Migrant subgroup score < 3, n (%)	34 (37)	22 (24)	20 (22)
Migrant subgroup score $\geq 3$ , n (%)	13 (14)	10 (11)	8 (9)
Patient using OAT subgroup including PWID score < 3, n (%)	12 (29)	6 (14)	4 (10)
Patient using OAT subgroup including PWID score $\geq 3$ , n (%)	17 (41)	7 (17)	5 (12)
CKD stages 3 to 5 subgroup score < 3, n (%)	14 (50)	9 (32)	6 (21)
CKD stages 3 to 5 subgroup score $\geq 3$ , n (%)	1 (4)	1 (4)	1 (4)
Life habit questionnaire, n	300	153	159
Working currently, n (%)	102 (34)	61 (40)	65 (41)
Full time job, n (%)	79 (77)	44 (72)	49 (75)
Substance use for sexual intercourses, n (%)	2 (1)	2 (2)	1 (1)
Housing conditions, n	281	139	146
Permanent residency, alone or with family, n (%)	261 (93)	127 (91)	139 (95)
Permanent residency, with friends, n (%)	10 (4)	9 (6)	4 (3)
Homeless, n (%)	9 (3)	3 (2)	3 (2)
Permanent residency, alone, n (%)	1 (1)	0 (0)	0 (0)
Permanent residency, with family of with friends			

\*% were calculated using the numbers of patients in each subgroup of interest

## Efficacy-SVR

Sustained Virologic Response (SVR12)*	98.9% (168/170)
Patient with AUDIT-C score <3**	98.8% (84/85)
Patient with AUDIT-C score $\geq 3$ **	100.0% (38/38)

\* : Two patients failed to achieve SVR, one patient was Gt4b and one patient was Gt1b both born in sub-Saharan Africa and treated 12wks. Data was missing for 12 patients at the time of data cut off; data query is ongoing.  
\*\* : AUDIT-C score available at baseline/ patient achieving an SVR12

## CONCLUSION

For the first time, a real world evidence study with Elbasvir / Grazoprevir in France enables to describe patient's addictive behaviours and life habits at treatment initiation and during follow-up. According to this interim analysis, no effect of high levels of alcohol consumption on SVR12 was observed in HCV patients treated with EBR/GZR (SVR12=100%, N=38/38).