QR Code

Belgian Experience with Direct Acting Antivirals in People Who Inject Drugs.

Bielen R[1,2], Van Vlierberghe H[3], Bourgeois S[4], Moreno C[5], Vanwollegem T[6], Verlinden W[6], Mulkay JP[7], Decaestecker J[8,9], Cool M[9,10], de Galocsy C[11], Van Overbeke L[12], Janssens F[13,9], Van Steenkiste C[14,3], D'heygere F[15], Cools W[16], Nevens F[9], Robaeys G[1,2,9]

1. Faculty of Medicine and Life Sciences, Hasselt University, Hasselt; 2. Dept. of Gastro-Enterology, Ziekenhuis Oost-Limburg, Genk; 3. Dept. of Hepatology and Gastro-Enterology, University Hospitals Gent; 4. Dept. of Gastro-Enterology and Hepatology, ZNA Antwerpen; 5. Dept. of Gastro-Enterology and hepatopancreatology, Erasme Hospital, Brussels; 6. Dept. of Gastro-Enterology and Hepatology, University Hospitals UZA, Antwerpen; 7. Dept. of Gastro-Enterology and Hepatology, Hôpital Saint-Pierre, Brussels; 8. Dept. of Gastro-Enterology and Hepatology, AZ Delta, Roeselare; 9. Dept. of Gastro-Enterology and Hepatology, University Hospitals KULeuven; 10. Dept. of Gastro-Enterology, AZ Damiaan, Oostende; 11. Dept. of Gastro-Enterology and Hepatology, Hôpital HIS Bracops, Brussels; 12. Dept. of Gastro-Enterology and Hepatology, AZ Sint-Maarten, Mechelen-Duffel; 13. Dept. of Gastro-Enterology, Jessa Hospital, Hasselt; 14. Depat. Of Gastro-Enterology, AZ Maria-Middelares, Gent; 15, Dept. of Gastro-Enterology and Hepatology, AZ Groeninge, Kortrijk; 16, Faculty of Sciences, Centre for Statistics, Hasselt University.

THE AASLD LIVER MEETING® 2016 BOSTON • NOVEMBER 11-15

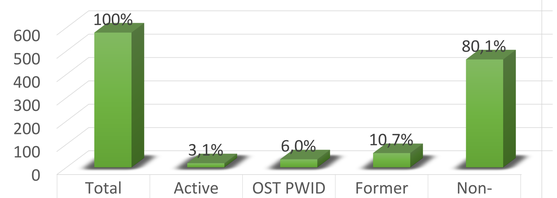
INTRODUCTION & AIM

Hepatitis C viral infection (HCV) remains one of the main causes of chronic liver disease worldwide. It has now become a curable disease due to the development of direct acting antivirals (DAA). Therefore, the WHO has set a target to eliminate HCV completely. To reach this target, people who inject drugs (PWID) need to be treated as they are the largest risk group for HCV in the Western world. Furthermore, treatment of HCV in PWID is recommended by the treatment guidelines. The aim was to study the uptake and outcome of treatment for HCV in PWID and the general population.

MATERIAL & METHODS

- Belgian, nationwide retrospective cohort study in 14 hospitals
- All patients treated between December 2013 and November 2015 with one of the following regimens were included:
  - simeprevir + sofosbuvir +- ribavirin
  - daclatasvir + sofosbuvir +- ribavirin
  - ombitasvir/paritaprevir/ritonavir +- dasabuvir +- ribavirin

Figure 1: Study population.



Active PWID: active drug use during HCV treatment, as described in patient files; OST PWID: patient receiving opiate substitution therapy during HCV treatment; Former PWID: patients who have used drugs intravenously at least once, but without any treatment concerning drug use; non-PWID: patients who never injected drugs.

RESULTS

Table 1: Differences in baseline characteristics between active PWID, OST PWID, former PWID and non-PWID.

	Active PWID (n = 18)	OST PWID (n=35)	Former PWID (n = 62)	Non-PWID (n = 464)	P-value
Age (y)	48 ± 8	49 ± 6	51 ± 8	61 ± 13	**0.001**
Male gender	17/18 (94.4%)	29/35 (82.8%)	52/62 (83.9%)	261/464 (56.3%)	**0.001**
BMI	22.72 ± 2.24	25.84 ± 6.75	25.74 ± 4.77	26.53 ± 4.61	**0.007**
Comorbidity					
- Diabetes	1/18 (5.6%)	2/35 (5.8%)	10/62 (16.1%)	103/464 (22.2%)	**0.026**
- Liver transplant	-	-	7/62 (11.2%)	38/464 (8.2%)	0.434
- HCC	-	-	6/62 (9.7%)	37/464 (8.0%)	0.394
- Ethyl	5/18 (27.8%)	13/35 (37.1%)	16/62 (25.8%)	37/464 (8.0%)	**0.001**
- Hemophilia	-	-	-	16/464 (3.4%)	0.130
- Renal insufficiency	-	-	5/62 (8.1%)	41/464 (8.9%)	0.213
HCV genotype					**0.001**
- 1a	7/18 (38.9%)	15/35 (42.9%)	29/62 (46.8%)	59/462 (12.8%)	
- 1b	2/18 (11.1%)	3/35 (8.6%)	8/62 (12.9%)	277/462 (60.0%)	
- 1 (other)	-	1/35 (2.9%)	2/62 (3.2%)	10/462 (2.2%)	
- 2	-	-	-	-	
- 3	5/18 (27.8%)	12/35 (34.3%)	17/62 (27.4%)	44/462 (9.5%)	
- 4	4/18 (22.2%)	3/35 (8.6%)	4/62 (6.5%)	69/462 (14.9%)	
- 5	-	-	-	2/462 (0.5%)	
- Mixed	-	1/35 (8.6%)	2/62 (3.2%)	1/462 (0.2%)	
Viral load (>800.000IU/ml)	13/17 (76.5%)	19/35 (54.3%)	29/55 (52.7%)	259/440 (58.9%)	0.194
F3 or F4 stadium (elastography)	16/16 (100%)	25/28 (89.3%)	46/55 (83.6%)	343/396 (86.7%)	0.177
HBsAg	2/17 (11.8%)	1/28 (3.6%)	1/49 (2.0%)	3/362 (0.8%)	**0.001**
HBsAb	5/15 (33.3%)	4/25 (16.0%)	9/14 (22.0%)	94/295 (31.9%)	0.125
HBV DNA	-	-	-	1/157 (0.6%)	0.841
HIV	1/18 (5.6%)	-	9/62 (14.5%)	32/464 (6.9%)	0.685
Treatment experienced	10/18 (55.6%)	18/35 (51.4%)	40/62 (64.5%)	256/461 (55.5%)	0.734
Reinfection	-	-	1/40 (2.5%)	-	0.218
Benzodiazepines	14/18 (77.8%)	15/34 (44.1%)	19/62 (30.6%)	96/459 (20.9%)	**0.001**
Other medication	2.61 ± 2.35	3.00 ± 2.45	3.50 ± 3.54	3.83 ± 3.48	0.354

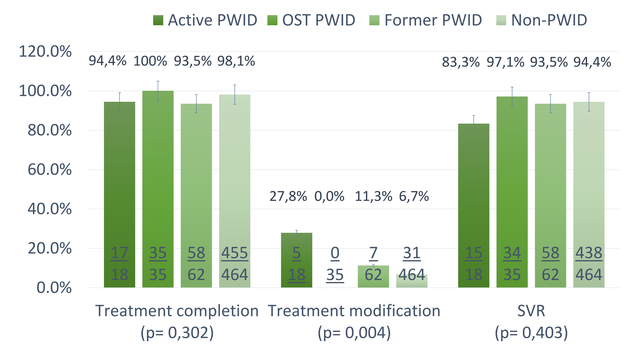
BMI = Body Mass Index (kg/m²), HCC = hepatocellular carcinoma present before treatment, ethyl = excessive use of alcohol before treatment, HBsAg = Hepatitis B surface antigen, HBsAb, Hepatitis B surface antibody, HBV DNA = Hepatitis B virus deoxyribonucleic acid, HIV= Human Immunodeficiency Virus, other medication = different co-medications during treatment.

Table 2: Antiviral treatment characteristics.

	Active PWID (n = 18)	OST PWID (n=35)	Former PWID (n = 62)	Non-PWID (n = 464)	P-value
Type of treatment:					
- simeprevir + sofosbuvir	9/18 (50.0%)	14/35 (40.0%)	22/62 (35.5%)	262/464 (56.5%)	-
- daclatasvir + sofosbuvir	8/18 (44.4%)	19/35 (54.3%)	38/62 (61.3%)	143/464 (30.8%)	-
- ombitasvir/paritaprevir ritonavir ± dasabuvir	1/18 (5.6%)	2/35 (5.7%)	2/62 (3.2%)	59/464 (12.7%)	-
Ribavirin	8/18 (44.4%)	20/35 (57.1%)	34/61 (55.7%)	186/450 (41.3%)	**0.028**
Side-effects:					
- fatigue	8/17 (47.0%)	10/35 (28.6%)	13/62 (21.0%)	112/455 (24.6%)	0.105
- anemia	3/17 (17.6%)	1/35 (2.9%)	5/62 (8.1%)	30/455 (6.6%)	0.200
- gastro-intestinal	1/17 (5.9%)	1/35 (2.9%)	5/62 (8.1%)	61/455 (13.4%)	0.102
- headache	2/17 (11.8%)	2/35 (5.7%)	3/62 (4.8%)	26/455 (5.7%)	0.552
- vertigo	-	1/35 (2.9%)	1/62 (1.6%)	15/455 (3.2%)	0.619
- rash	3/17 (17.6%)	3/35 (8.6%)	9/62 (14.5%)	75/455 (16.5%)	0.589
- arthralgia / myalgia	-	2/35 (5.7%)	1/62 (1.6%)	35/455 (7.7%)	0.138
- AoCLF	1/17 (5.9%)	-	2/62 (3.2%)	9/455 (2.0%)	0.546
- HCC < 1 year	-	-	2/62 (3.2%)	6/455 (1.3%)	0.735
- Psychological	4/17 (23.5%)	4/35 (11.4%)	4/61 (6.6%)	19/459 (4.1%)	**0.001**
Depression before treatment	12/18 (66.7%)	15/35 (42.9%)	21/59 (35.6%)	91/453 (20.1%)	**0.001**

Gastro-intestinal: constipation, diarrhea, nausea, anorexia; rash: rash and/or pruritus; AoCLF = acute-on-chronic liver failure. HCC< 1year: development of HCC within first year after treatment; psychological: depression, asthenia, nervositas.

Figure 2: Outcome of antiviral therapy.



SVR = sustained viral response 12 weeks after treatment completion.

Table 3: Extended model Tukey comparison.

	Estimate	Lower	Upper
Non-PWID vs active PWID	2.008	-1.096	5.112
Former PWID vs active PWID	1.635	--1.882	5.153

As one is part of the interval, there is no difference in SVR between the groups.

CONCLUSION

Although DAA are safe and effective also in (active) drug users, PWID are still highly underrepresented in a Belgian treatment cohort, even in the era of new DAA therapy. As this risk-group is at the heart of the HCV epidemic, more efforts are necessary to reach this group.

ACKNOWLEDGEMENTS & DISCLOSURES

This project is part of a PhD project within the Limburg Clinical Research Program of Hasselt University, Ziekenhuis Oost-Limburg Genk, and Jessa hospital Hasselt. The authors state that there are no conflicts of interest.

Contact information

Dr. Bielen Rob
Ziekenhuis Oost-Limburg
Schiepse Bos 6 3600 Genk
Tel: +3289/321560
Mail: rob.Bielen@uhasselt.be

AASLD AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

Ziekenhuis Oost-Limburg

universiteit hasselt KNOWLEDGE IN ACTION