

Interim results of an ongoing project to eradicate HCV in people who inject drugs at risk for non-adherence to direct-acting antivirals in Vienna

Raphael Schubert¹, Angelika Schütz¹, Cornelia Schwanke¹, Julian Luhn¹, Enisa Gutic², Tobias Lang², Hans Haltmayer¹, Michael Gschwantler²;

¹Suchthilfe Wien gGmbH, Ambulatorium Suchthilfe Wien, Vienna Austria, ²Wilhelminenspital, Department of Internal Medicine IV, Vienna, Austria.

BACKGROUND

Prevalence of chronic hepatitis C is high in people who inject drugs (PWID). An important subgroup of PWID – for whom we coined the term “**PWID with borderline compliance**” - is defined by the following characteristics:

- Because of their addiction and their poor compliance they are reluctant to go to specialized hepatitis centers and hence cannot be treated there. In addition they would not regularly ingest their medication when handed to them for self-administration at home.
- Most of them suffer from psychiatric comorbidities and have a very poor socio-economic status.
- In contrast, their compliance is excellent with respect to their daily visits at the low-threshold facility or pharmacy for ingestion of their opioid agonist therapy (OAT).

Our hypothesis was that chronic hepatitis C in these difficult-to-treat patients could be optimally managed if modern, interferon-free all-oral regimens were applied together with OAT under direct observation of a pharmacist, physician or nurse at a pharmacy or a low-threshold facility.

PATIENTS AND METHODS

Design:

The study was designed as an open-label, prospective cohort study and was approved by the local Ethics Committee.

Study population, antiviral therapy and primary endpoint:

249 PWID “with borderline-compliance” on stable OAT with chronic hepatitis C started interferon-free treatment of chronic hepatitis C. Seventy percent of the patients reported ongoing intravenous drug use and most of them had a very poor socioeconomic status. Baseline characteristics are summarized in the Table. The treatment-regimen was selected according to GT, fibrosis stage, pretreatment and current reimbursement policy of insurances.

The primary endpoint was virological cure.

Setting:

Patients received antiviral treatment together with OAT under direct observation of a pharmacist, physician or nurse at a pharmacy or at the “Ambulatorium Suchthilfe Wien” – a low-threshold drug treatment facility in Vienna, Austria. The “Ambulatorium Suchthilfe Wien” is part of the Suchthilfe Wien gGmbH, and also provides a syringe exchange program, a drop in center and a night shelter for PWID. Only in some cases the drugs were given to the patient for self-administration during the weekend. All examinations (including laboratory tests and assessment of liver stiffness before and during therapy were performed at the “Ambulatorium Suchthilfe Wien”.

Age ± SD (years)	38.8 ± 8.7
Male/female (n)	189/60
Genotype (n) 1/2/3/4	147/3/91/7 (not possible to assess in 1 patient)
Liver cirrhosis (n, %)	51 (20%)
HIV-coinfection	16 (6%)
Socio-economic characteristics	
Living in stable relationship yes no	33% 68%
Own housing yes no	48% 53%
Employment status employed unemployed	15% 85%
Criminal record imprisoned before not imprisoned before not known	68% 25% 8%

RESULTS

At present 179 patients have finished the treatment course and 12 weeks of follow-up.

Adherence to treatment:

Following the concept of directly observed therapy, adherence to antiviral therapy was excellent: Only 0.15% of scheduled dates for ingestion of the antiviral therapy in combination with OAT were missed by the patients.

Virological outcome:

Twelve weeks after end of therapy virological cure could be confirmed in 178/179 patients (**cure rate: 99.4%**). One patients died 3 weeks after end of treatment for reasons unknown.

Reinfections:

During follow-up reinfections occurred in 11/179 patients (6%).

CONCLUSION

Directly observed therapy of chronic HCV infection with modern DAA-regimens at a pharmacy or low-threshold drug treatment facility is highly effective in patients with borderline compliance receiving OAT. By this concept chronic hepatitis C can be cured in a group of difficult-to-treat patients, who are unable to be treated at hepatologic centers. It should be stressed that successful treatment of these patients is not only beneficial for themselves but also for the general population because further transmission of the virus may be prevented.

Contact: raphael.schubert@suchthilfe.at