







# DIRECT ACTING ANTIVIRALS (DAAs) FOR THE TREATMENT OF HCV INFECTION IN HIV/HCV COINFECTED PATIENTS: A CLINICAL EXPERIENCE

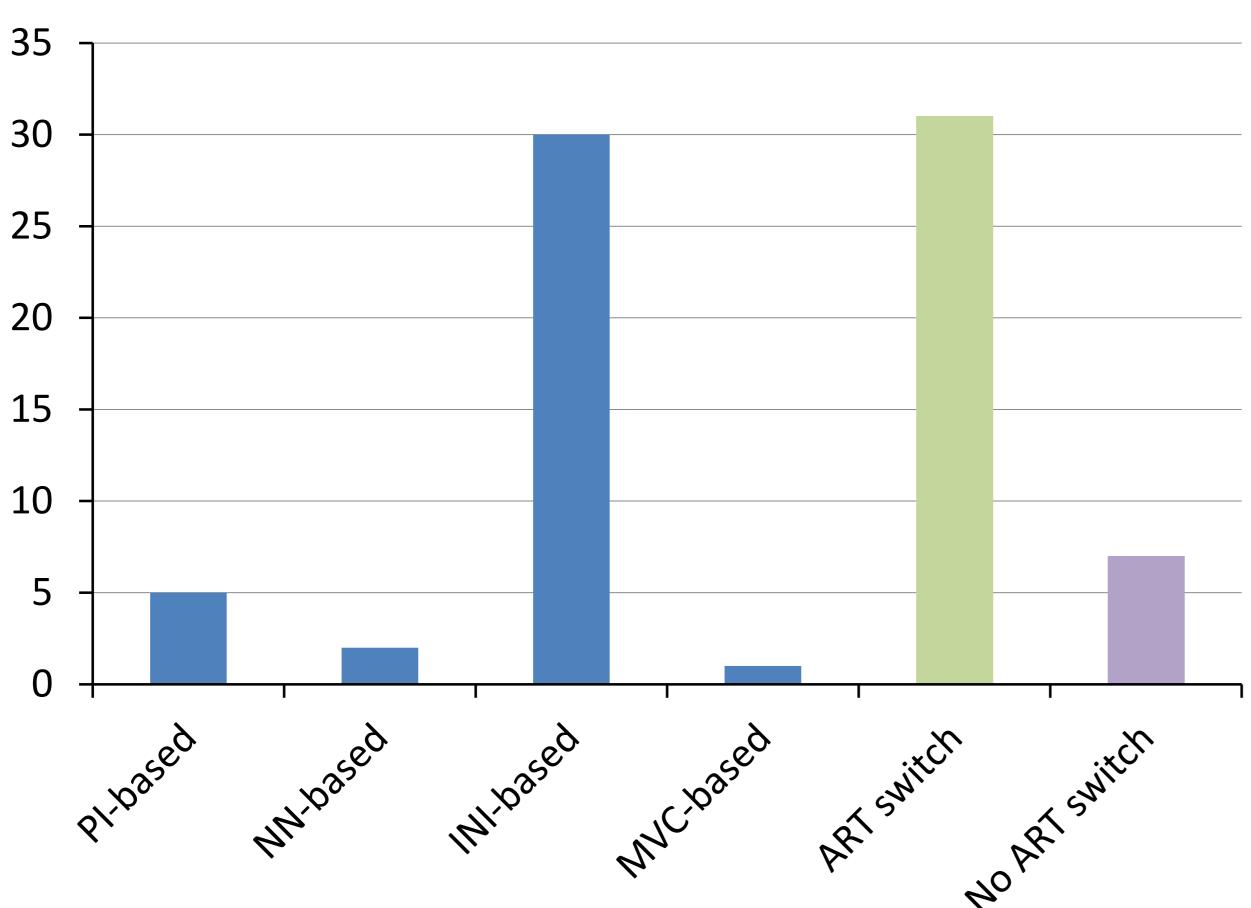
Giada Corinaldesi<sup>1</sup>, Renata Sentinelli<sup>1</sup>, Sabrina Guglielmi<sup>1</sup>, Elena Orsetti<sup>2</sup>, Sefora Castelletti<sup>2</sup>, Anna Marigliano<sup>3</sup>, Alessandra Riva<sup>3</sup>, Chiara Tontini<sup>4</sup>, Andrea Costantini<sup>4</sup>

<sup>1</sup>Pharmacy Unit, <sup>2</sup>Clinic of Infectious Diseases Unit, <sup>3</sup>Infectious Diseases Unit, <sup>4</sup>Clinical Immunology Unit, Ancona Hospital, Ancona, Italy

## Background:

HIV/HCV co-infection has an unfavorable influence on the natural history of HCV, resulting in an increased rate of progression to cirrhosis, HCC and end stage liver disease<sup>1</sup>. Although direct acting antivirals (DAAs) have proven effective in eradicating HCV infection in co-infected individuals<sup>2,3</sup>, few data on effectiveness and cost in clinical practice are available to date.

Figure 1: Distribution of ART regimens at the beginning of anti-HCV therapy and number of patients switched to other regimens before the initiation of DAAs treatment



Abbreviations:

PI: protease inhibitors; NN: non-nucleoside reverse transcriptase inhibitors; INI: integrase inhibitors; MVC: maraviroc; ART: antiretroviral therapy.

Figure 2: Distribution of DAAs regimens used in HIV-HCV coinfected patients

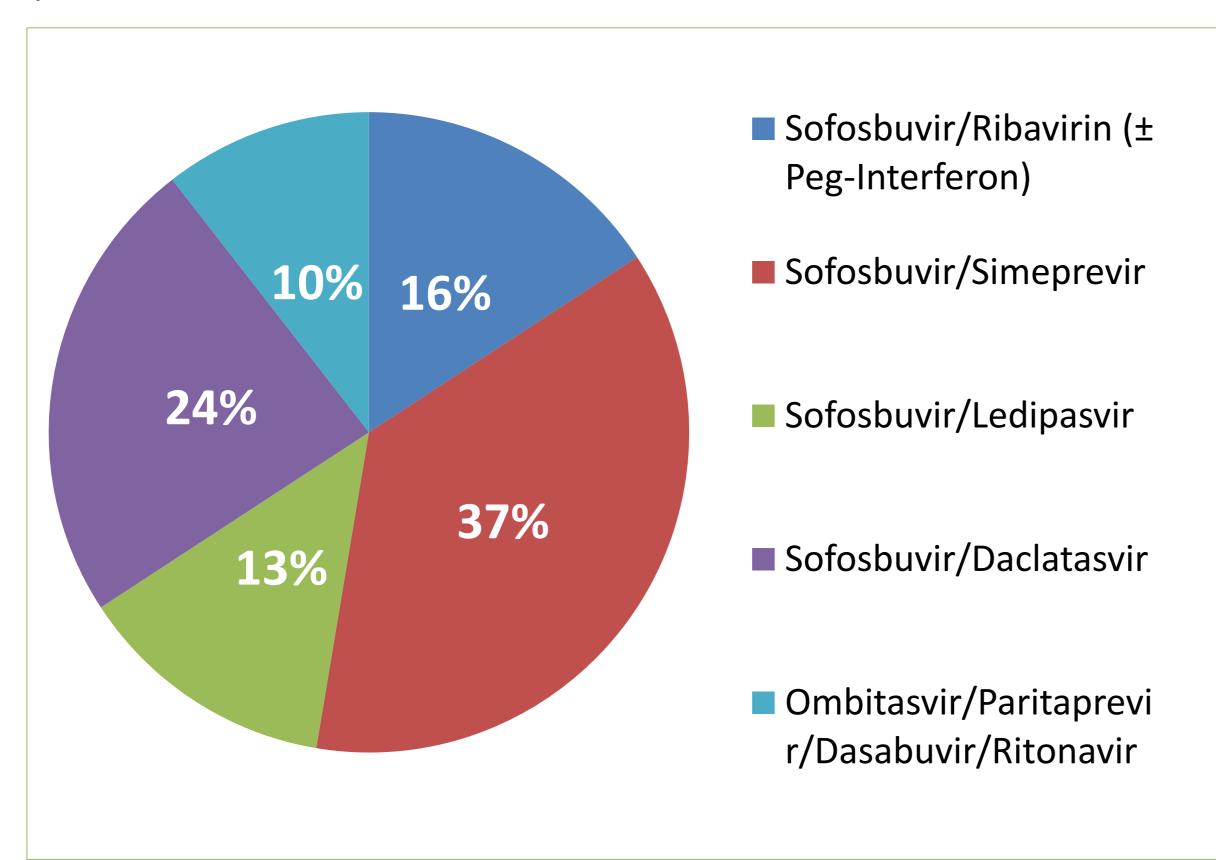


Table 1: Proportion of patients with undetectable HCV viral load (<12 UI/mL) assessed after the first month of treatment, at the end of treatment and 12 months after treatment discontinuation

	RVR	EOT	SVR12
n	27	30	20
%	71	100	91
Total	38	30	22

Abbreviations:

RVR: rapid virological response; EOT: end of treatment; SVR12: sustained virological response 12 weeks after treatment discontinuation.

## Objective:

This prospective study aims to assess efficacy and costs of DAAs in an outpatient population of HIV/HCV coinfected subjects.

#### Materials and Methods:

A database for DAAs prescription monitoring was created, including information on the overall cost of anti-HCV regimen for each patient. Patients were treated according to the local prescription regulations. Virologic response to DAAs was assessed at week 4 after treatment beginning (RVR), at the end of treatment (EOT) and 12 weeks after drugs discontinuation (SVR12). Additional clinical and laboratory data were obtained by medical records.

### Results:

Thirty-eight subjects were studied (males 79%, mean age 51 years), 24 undergoing a 12-week treatment course, 14 a 24-week course. Prior to initiation, 97% of patients had HIV plasma viral load below detection limit. Eighty-one percent changed at least one HIV medication to minimize the risk of drug-drug interaction; eventually 79% of patients were on a integrase inhibitor-based regimen at the beginning of anti-HCV therapy (Figure 1). Ninety-six percent of patients undergoing a 12-week DAA regimen had HCV genotype 1 infection, whereas 36% of patients on a 24-week regimen had genotype 3. An interferon-free regimen was chosen for 95% of patients. Preferred combinations are summarized in Figure 2.

Data on RVR, EOT and sustained virological response at 12 weeks are shown in Table 1. To date, 20 out of 22 patients (91%) have obtained SVR12. Eighteen percent of patients experienced mild side effects, mostly related to ribavirin co-administration (anemia, fatigue). Mean treatment cost was approximately euro 50.000 per patient.

#### Conclusions:

This prospective ongoing study shows the effectiveness and safety of DAA therapy in HIV/HCV coinfected individuals in the clinical setting, despite the high cost. Data collection on sustained virologic response after treatment discontinuation is still ongoing.

#### References:

- 1. Lo Re V, et al. Ann Intern Med 2014,160:369.
- 2. Sulkowski MS, et al. JAMA 2014,312:353.
- 3. Osinusi A, et al. J Hepatol 2014,60:S7.