EVALUATION OF EFFICACY AND SAFETY OF HEPATITIS C VIRUS TREATMENT WITH THE NEW DIRECT ACTING ANTIVIRALS IN THE CLINICAL PRACTICE OF A REGIONAL HOSPITAL

Pharmacy Department. Hospital d’Igualada (Consortsi Sanitari de l’Anoia), Igualada, Spain

BACKGROUND
Hepatitis C virus (HCV) infection is one of the main causes of chronic liver disease worldwide. Clinical care for patients with HCV-related liver disease has progressed considerably during last years, thanks to improvements in the pharmacological treatment, specially with the new direct-acting antivirals (DAAs).

OBJECTIVE
To evaluate efficacy and safety of the treatment of HCV with the new DAAs in clinical practice.

MATERIAL AND METHODS
Prospective, descriptive and observational study carried out in a regional hospital from May 2015 to July 2016 with HCV patients. In this area, there are approximately 447 cases of positive HCV. Treatment with DAAs included sofosbuvir, simeprevir±ribavirina; ledipasvir+sofosbuvir±ribavirina; daclastavir+sofosbuvir±ribavirina; ombitasvir+paritaprevir+ritonavir+dasabuvir±ribavirina and sofosbuvir±ribavirina.

Variables studied were age, sex, hepatic fibrosis stage, HCV genotype, treatment duration, HCV-RNA level at weeks 4, 12, post-12 (sustained virological response, SVR) and adverse events.

RESULTS
The study included 50 patients with HCV treated with DAAs, 36 (72%) men and age 58.3 (43-78) years old. Only 4 (8%) were HIV co-infected. Thirty-five (70%) patients had grade 4 fibrosis (F4) with compensated cirrhosis and 11 (22%) with F3. Genotypes distribution was 1b (50%), 1a (18%), 3 (12%), 4 (10%), 1 (8%), 2 (2%). Twenty-two (44%) patients were treated with the combination sofosbuvir+simeprevir±ribavirina; 12 (24%) with ledipasvir+sofosbuvir±ribavirina; 6 (12%) with daclastavir+sofosbuvir±ribavirina; 9 (18%) with ombitasvir+paritaprevir+ritonavir+dasabuvir±ribavirina and 1 (2%) with sofosbuvir±ribavirina.

Twenty-eight (56%) patients achieved undetectable HVC-RNA level at week 4. At the end of the treatment, 96% of patients reached SVR. The only adverse event detected directly related to DAA was a case of photosensitivity skin reaction that was attributed to simeprevir.

CONCLUSIONS
- Treatment of patients with HCV with new DAAs is considered a highly effective and safe therapy, obtaining SVR of 96%.
- Only one adverse event directly related to DAA was observed.
- Although the endpoint of therapy is undetectable HCV RNA in 12 weeks post-treatment, in this study 28 (56%) patients reached SVR at week 4.