

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

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### 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

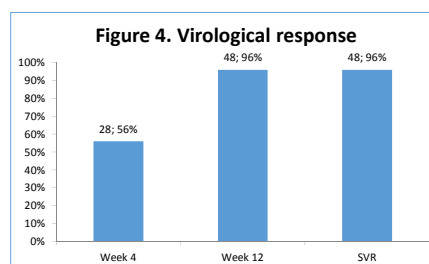
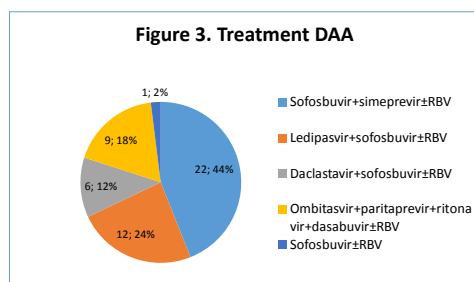
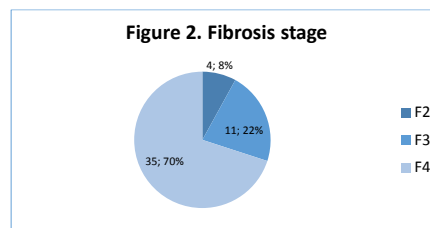
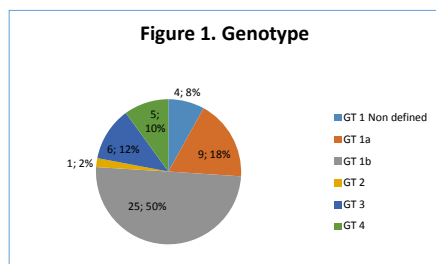
Prospective, descriptive and observational study carried out in a regional hospital from May 2015 to July 2016 with HCV patients. In this area, there are approximately 447 cases of positive HCV. Treatment with DAAs included sofosbuvir, simeprevir±ribavirina; ledipasvir+sofosbuvir±ribavirina; daclastavir+sofosbuvir±ribavirina; 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 (2 HIV co-infected); 12 (24%) with ledipasvir+sofosbuvir±ribavirina (1 HIV co-infected); 6 (12%) with daclastavir+sofosbuvir±ribavirina (1 HIV co-infected), 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. No patients had to stop the treatment because of adverse effects.



### 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.