SOFOSBUVIR/LEDIPASVIR USE FOR HEPATITIS C VIRUS TREATMENT: OUR CLINICAL EXPERIENCE

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BACKGROUND

The development of direct-acting antivirals agents (DAAs) represents a significant improvement in hepatitis C virus (HCV) treatment, particularly to allow IFN-free therapy.

PURPOSE

To analyze the efficacy and safety of an interferon-free regimen—a fixed-dose combination of the nucleotide polymerase inhibitor sofosbuvir (400 mg) and the HCV NS5A inhibitor ledipasvir (90 mg).

METHODS

Observational study of patients who initiated therapy with sofosbuvir/ledipasvir between April and June 2015. Data was collected from electronic Clinical History and hospital's electronic prescribing software. Monitoring of treatment efficacy is based on repeated measurements of HCV RNA levels.

RESULTS

Patients: 33 (25 male, 7 female). 9 patients coinfented HIV

Duration treatment: 8 weeks for 2 patients, 12 weeks for 26 and 24 weeks for 5.

Type of patient 8 naive, 19 pretreated and 6 unknown

Genotypes 1a: 18 patients; 1b: 12 patients and genotypes 4: 3 patients

Hepatic fibrosis stage F4/F3/F2 corresponded to 14, 9 and 9 patients respectively.

Viral load after 4 weeks 54,5 % undetectable viral load,

Viral load after 12 weeks, 100 % undetectable viral load

Adverse events were recorded: asthenia (30,3%), headache (27,3%), pruritus (3%) and irritability (3%).

CONCLUSIONS

- ✓ More than 50% of patients treated with sofosbuvir/ledipasvir had an undetectable level of HCV RNA after 4 weeks and 100% after 12 weeks but these results are still preliminary; it is necessary to determine Sustained Virological Response to evaluate treatment efficacy.
- ✓ The main adverse effects were asthenia and headache and corresponded to the safety profile described in clinical trials.