Servicio de Farmacia
Hospital General Universitario Gregorio Marañón
Comunidad de Madrid

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GANADOR del VII Premio a la Excelencia y Calidad del Servicio Público en Comunidad de Madrid

EXCELENCIA

AENOR Empresa Registrada UNE-EN ISO 9001

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EXCELENCIA EUROPEA 400+ PUNTOS EFQM

Abstract Number: CP-096

FINAL RESULTS OF EFFECTIVENESS AND SAFETY OF DIRECT-ACTING ANTIVIRAL AGENTS IN THE TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION

Chamorro de Vega E, Gimenez Manzorro A,Gomez Marquez AM, Monje Garcia B, Escudero Vilaplana V, Lallana Sainz E, Lobato Matilla E, Revuelta Herrero JL,Herranz Alonso A, Sanjurjo Saez M.

Servicio de Farmacia. Hospital General Universitario Gregorio Marañón. Instituto de Investigación Sanitaria Gregorio Marañón (IiSGM). Madrid, España

OBJECTIVES

Direct-acting antivirals (DAAs) have become elective treatment for chronic hepatitis c virus (HCV) infection but final data regarding in routine medical practice are still limited.

OBJECTIVE: to assess treatment effectiveness and safety of DAAs in real practice.

METHODS

Design: descriptive, retrospective, non-interventional study.
Inclusion criteria: all HCV monoinfected patients who started treatment with DAAs from January 2014 to March 2015. Exclusion criteria: patients with liver transplant.
Variables: demographic, degree of fibrosis, clinical data (decompensated cirrhosis, hepatocellular carcinoma), response to previous HCV-treatment and viral genotype, viral load, analytical data and adverse events (AEs).
Primary effectiveness endpoint: sustained virologic response 12 weeks after the end of treatment (SVR12).
Secondary endpoint: end of treatment virologic response (EOTVR) and normalization of serum transaminases at the end of treatment.
Safety was evaluated by laboratory abnormalities and AEs.

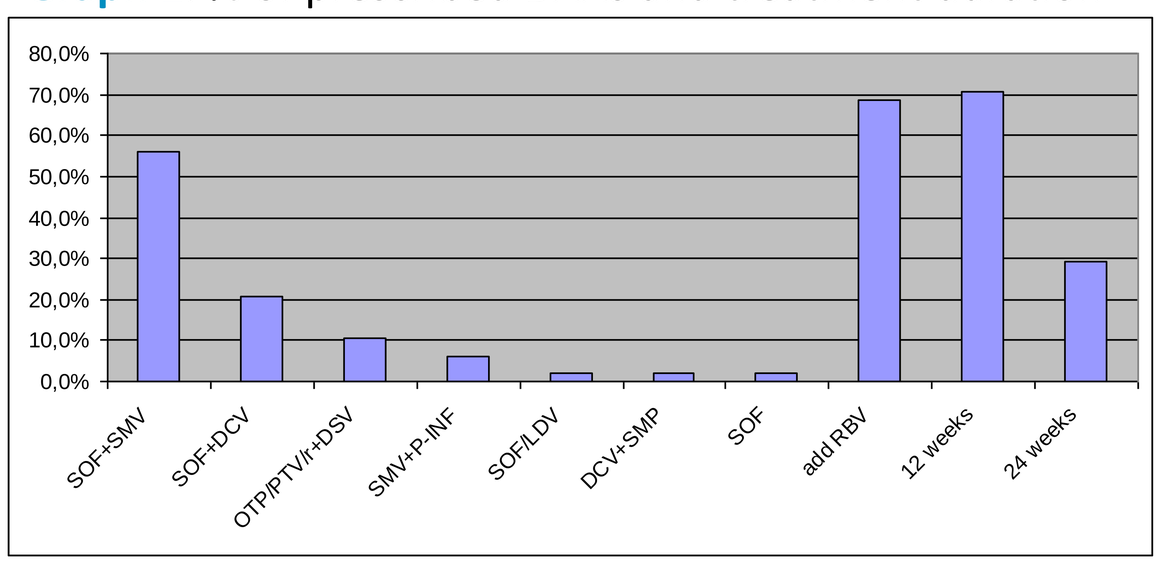
RESULTS

Forty-eight patients were included: 29 (60.4%) were male with an average age of 60 (SD=8.1). Fourty-two (87.5%) patients were cirrhotic, 17(40.5%) of these were decompensate, and 5(10.4%) had a hepatocellular carcinoma.

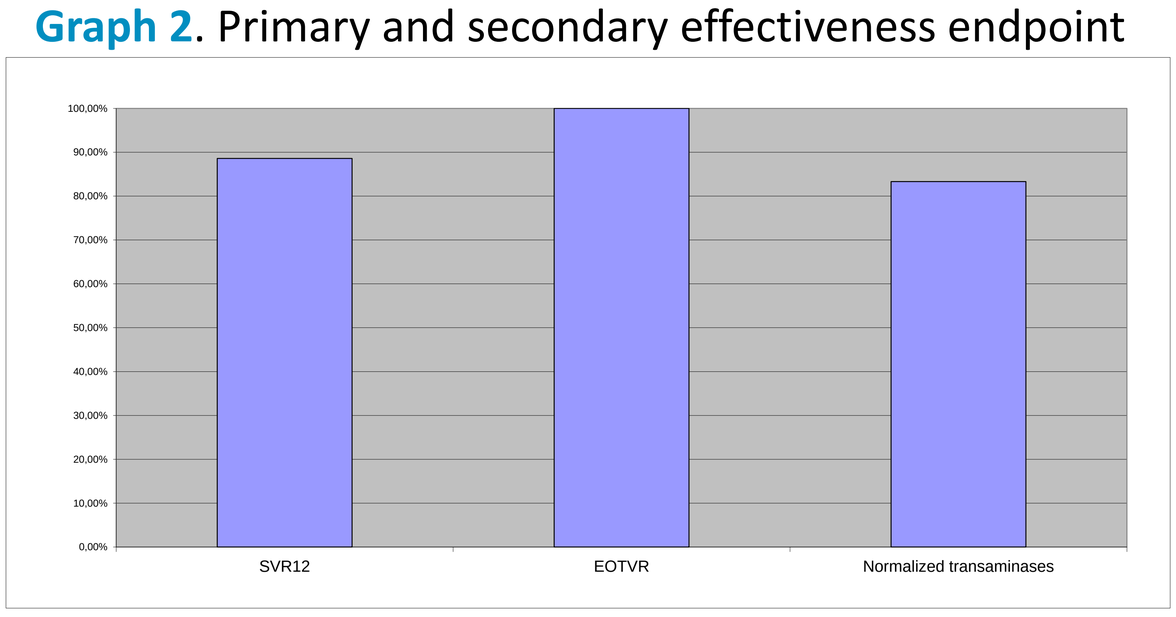
Table 1. Patient`s and viral`s characteristics.

Characteristics	N(%)
Prior treatment	
Naïve	24 (50.0)
Peginterferon-ribavirin	20 (41.7)
Protease inhibitor	4 (8.3)
Viral genotype	
1a	8 (16.7)
1b	33 (68.7)
2	1 (2.1)
3	4 (8.2)
4	2 (4.2)

Graph 1. % of prescribed DAAs and treatment duration



Graph 2. Primary and secondary effectiveness endpoint



Most frequent AEs were: asthenia 25(52%), ribavirin-associated anaemia 15(45.5%), pruritus 16(33.3%), dry skin 10(20.8%) and insomnia 10(20.8%).

CONCLUSIONS

Data show a high percentage of SVR12 and a totally virologic response at the end of treatment. Moreover, AEs did not differ from those described in clinical trials. DDAs seemed to be efficacious and well tolerated in real clinical practice.

esther.chamorro@iisgm.com

www.madrid.org/hospitalgregoriomaranon/farmacia

@farma_gregorio