

HEPATITIS C VIRUS (HCV) INFECTION EVALUATION OF PREVALENCE AND RELATED COSTS IN THE LOCAL HEALTH UNIT N.2, DISTRICT OF TREVISO

1)Bellin A.. 2)Giusti P.. 3)Schiavon A.. 4)Franchin G.. 5)Bettiol A.. 6)Bolcato J.. 7)Pirollo R.. 8)Chinellato A..

AULSS 2 MARCA TREVIGIANA

Background: Chronic HCV infection is a global health problem that affects more than 184 million people in the world. In Italy, it is estimated that more than one million people are affected by HCV, 330,000 of whom have cirrhosis . Furthermore, over 20,000 people die each year from chronic liver diseases, with 65% of them being HCV infected. In past decades, treatment of HCV infection was based on Peginterferon and Ribavirin. However, these therapies lead to a sustained virologic response (SVR), i.e. complete HCV healing, only in 50-60% of patients.

In 2011, Boceprevir and Telaprevir, two protease inhibitors, were approved by EMA for the treatment of HCV infection, although their effectiveness remains uncertain. From 2014, new drugs have entered the market, allowing SVR to be reached within 12 weeks from treatment beginning. These drugs, called Direct Acting Antivirals (DAA) target specific steps of the HCV life cycle.

Aim: This study investigated the management of hepatitis C in the LHU of Treviso, with the aim of providing real-world evidence on individual responsiveness to HCV treatments, updating health service planning, supporting clinicians in their daily practice, and providing information on direct costs for the national healthcare system. In addition, we aimed to overview the differences in clinical management and related costs of patients treated with old compared to new therapies.

Methods: This is a retrospective study on a population of LHU of Treviso. The population considered was treated with DAA between 2015-2016. For this analysis the Territorial Pharmaceutical Service databases of drug dispensing, hospital discharges, outpatient diagnostic tests and access to emergency services were used. Both old Interferon therapies and new therapies with Sofosbuvir, Daclatasvir, Simeprevir, Sofosbuvir/Ledipasvir, Paritaprevir/Ritonavir-Ombitasvir and Dasabuvir, were considered. All drugs were provided by hospital pharmacies at time of hospital discharge, except peginterferon that can be obtained also from community pharmacies.

Results: The study enrolled 2.957 people affected by HCV, corresponding to around 1% of all residents in the District of Treviso. In particular, 277 of them were treated with DAA between 2015 and 2016. The most frequent HCV genotype was the 1b (62.81%); considering costs, genotype 3 was associated with the highest expenditure. Only 2% of the treated population did not reach the SVR after DAA treatment.

In some patients complications either related to HCV virus or to HCV therapy were observed; the most common were thyroid disease or lymphoma, and hepatic complication.

Finally, costs related to new therapies resulted to be significantly higher compared to old therapies. The costs for a whole cycle of interferon therapy was 9,000€

Instead, the official costs for a cycle of DAA therapy can range between 27,000€ and 50,000€ (as published in the Italian “Gazzetta Ufficiale”). However, with the Managed Entry Agreements mechanisms, costs for the health care system could decrease, ranging from 29,000€ to a minimum of 17,000€, with mean cost are 26,500€.

Conclusion: In the population of the LHU of Treviso, a significant proportion of HCV-infected subjects was found. According to literature, genotype 1 was the most common, but genotype 3 was associated with the highest cost, since it has less therapeutic options compared to other genotypes. Similarly, the effectiveness found in this study resulted to be comparable or even higher compared to the efficacy reported in clinical trials. Compared to official prices, the real costs of DAA therapies for the National Healthcare System are significantly lower, therefore demonstrating a higher sustainability of these treatments. Despite costs and the debates in acceding to treatments, treating HCV-infected patients with new therapeutic options is crucial to avoid the disease progression.

Mohd Hanafiah, K., Groeger, J., Flaxman, A. D. & Wiersma, S. T. Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence. *Hepatology* 57, 1333–1342 (2013).