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Economic Impact and Complications of Treated and Untreated Hepatitis C Virus Patients in Turkey

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ABSTRACT

Background: According to the Turkish Ministry of Health's guidelines, standard double therapy, a combination of pegylated interferon-alpha and ribavirin, was the only treatment option for patients with hepatitis C virus (HCV) infection until the end of 2011. **Objective:** The primary objective was to compare risk-adjusted clinical and economic outcomes between treated and untreated patients with HCV infection. **Methods:** Patients with HCV infection were identified from the Turkish National Health Insurance Database (2009–2011) using *International Classification of Diseases, 10th Revision, Clinical Modification* codes. The first prescription date was designated as the index date. Mortality and hepatocellular carcinoma (HCC) rates and health care costs of treated and untreated patients were compared using propensity score matching. Baseline demographic and clinical factors were controlled in the models. Subgroup analysis was conducted for patient groups with and without a cirrhosis diagnosis. **Results:** Out of 12,990 patients included in the study, 1,583 were treated for HCV infection. Out of 2,467 patients who had a cirrhosis diagnosis, 231 were treated,

whereas out of 10,523 patients without cirrhosis, 1,352 patients were treated. Treated patients were younger, less likely to be diagnosed with comorbid conditions, and less likely to reside in Central or Eastern Anatolia. After adjusting for baseline demographic and clinical factors, mortality (2.27% vs. 5.31%; $P < 0.001$) and HCC rates (0.69% vs. 1.96%; $P < 0.001$) were found to be lower for treated patients. Differences were more significant among patients diagnosed with cirrhosis. Treated patients incurred higher risk-adjusted annual costs (€6172 vs. €1680; $P < 0.001$), mainly because of pharmaceutical costs (€4918 vs. €583; $P < 0.001$). **Conclusions:** HCV infection treatment, although costly, significantly reduces mortality and HCC rates in Turkey.

Keywords: complications, health care costs, health care utilization, hepatitis C, treatment.

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Introduction

Hepatitis C virus (HCV) is a major global public health concern. It is estimated that 2% to 3% of the population in the world (130–170 million people) is infected with HCV infection [1]. With higher incidence in the southern and eastern regions, there are approximately 9 million patients with HCV infection in Europe [2–6].

Most acute HCV infections (60%–70%) are asymptomatic; therefore, many chronically infected patients do not know that they have been infected with HCV [7,8]. Individuals at an increased risk of HCV infection are injectable drug users, chronic hemodialysis patients, and recipients of blood or blood product transfusions before the 1990s (up to 70%, 15%, and 10%, respectively) [9–11]. Other risk factors for HCV transmission include unprotected sex, perinatal transmission, needle stick injury, and receipt of immunoglobulin [12].

In Turkey, HCV has a 2.2% seroprevalence [8] where almost 90% of the patients are infected with HCV genotype 1b, except in the city of Kayseri and its vicinity, where HCV genotype 4 accounts for 35% of the patients admitted to hospitals [13,14]. In 2005, Turkey had the lowest HCV infection treatment rates among European countries [15].

Treatment possibilities have improved dramatically over the past decade. As much as 51% of patients infected with HCV genotypes 1 or 4 and 90% of patients infected with HCV genotypes 2 or 3 can be cured after 24 to 48 weeks of antiviral treatment [16]. The main goal of treatment in chronic hepatitis C is the prevention of cirrhosis and hepatocellular carcinoma (HCC) by suppressing the virus to undetectable levels, and the efficacy of antiviral HCV treatment is measured through sustained virologic response (SVR).

The standard treatment for chronic HCV infection includes the double therapy combination of pegylated interferon-alpha

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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<http://dx.doi.org/10.1016/j.vhri.2015.08.004>

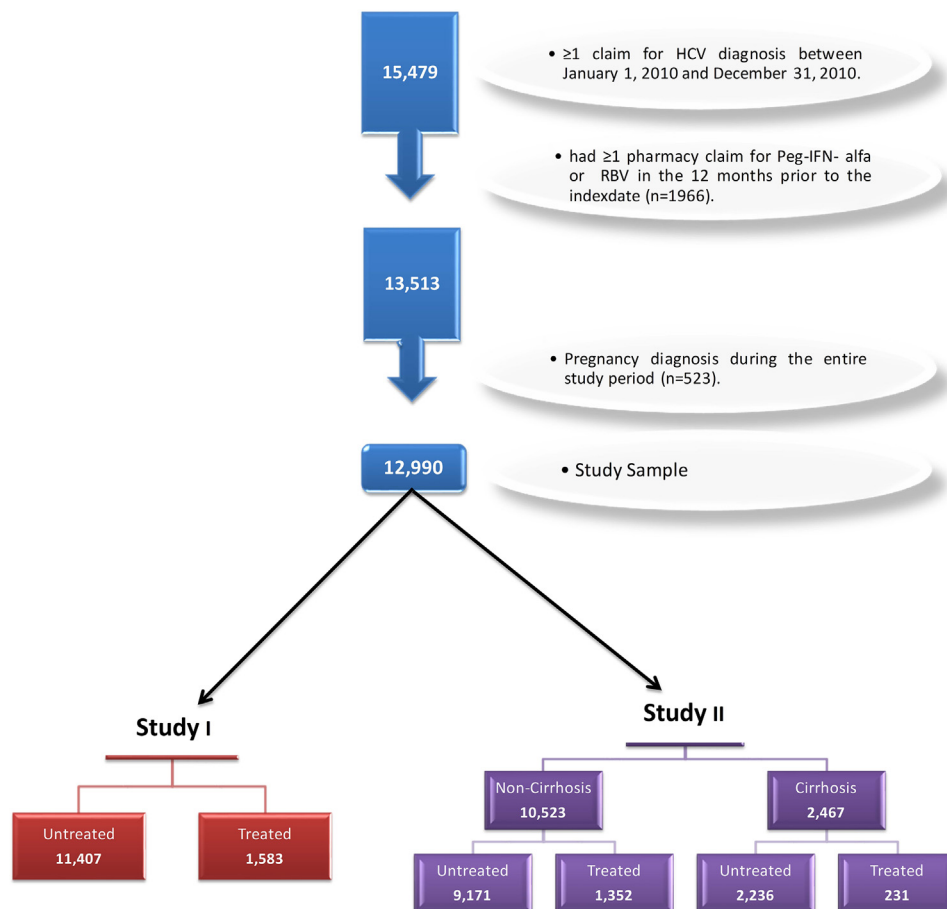


Fig. 1 – Patient selection criteria. HCV, hepatitis C virus; Peg-IFN- α , pegylated interferon-alpha.

(Peg-IFN- α) and ribavirin in patients infected with genotype 1 [17]. Two treatment strategies are being evaluated, which include adding one or two direct-acting antiviral agents to the standard double therapy and an oral direct-acting antiviral agent combination designed to inhibit different steps of the HCV life cycle [15,18,19]. According to the Turkish Ministry of Health's guidelines, standard double therapy is the only option to treat naive patients with HCV infection [20]. Although combination therapy of Peg-IFN- α and ribavirin significantly increases SVR and the probability of reaching SVR by 50%, the degree of response depends on various factors.

The clinical and economic burden of HCV is significant. Approximately 80% of the individuals exposed to HCV develop chronic infections, and 3% to 11% of those with chronic HCV infections will develop cirrhosis within 20 to 30 years [21,22] with the associated risk of liver failure and HCC [23,24]. HCV infection causes approximately 365,000 deaths annually as a result of complications [15]. In 2002, the number of estimated HCV-related deaths in Europe was 86,000 [3]. HCV doubles the risk of depression, increases the risk of HCC 25-fold, the risk of needing a liver transplant more than 60-fold, and the risk of cirrhosis 80-fold [25]. Existing literature indicates that chronic HCV infection lowers work productivity, increases health care utilization, and is associated with an elevated risk of liver-related morbidity and mortality [15].

There is limited research on the total economic burden of HCV on the Turkish health care system. To generate real-world evidence on the HCV-related economic burden and its resulting

complications in Turkey, this study aimed to compare health care outcomes between patients with HCV infection who were prescribed Peg-IFN- α with or without ribavirin and those who were not prescribed these medications.

Methods

Law 5502, by the Turkish Grand National Assembly, unified three existing social security and health insurance systems (e.g., Sosyal Sigortalar Kurumu (SSK), Bag-kur, and Emekli Sandigi) into a single system under the Social Security Institute (SSI) in 2006. Enrollment in the current existing Universal Health Insurance Fund within the SSI is mandatory, and contribution rates are determined by patients' ability to pay. All beneficiaries under the system are entitled to the same benefits package.

Payment by a health insurance fund is based on both a fee-for-service system and a bundled payment system, depending on disease category and services related to the particular disease. For example, laboratory services can be paid separately through the bundled payment system. Payment procedures are outlined by health budget law as access to HCV medications determined by the Ministry of Health protocol. Payment is determined by the health budget laws of the SSI.

Recognizing the importance of health information technology and health technology assessment, Turkey has invested in a nationwide integrated system to collect health care utilization outcomes electronically during the last few years. A claims and

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