Determinants of Treatment Eligibility in Veterans With Hepatitis C Viral Infection

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ABSTRACT

Purposes: The objective of this study was to determine the percentage of veterans with active hepatitis C virus (HCV) infection who were deemed to be candidates for treatment and to identify factors associated with treatment ineligibility.

Methods: This was a multisite, retrospective cohort analysis of veterans with HCV infection within the Veteran Integrated Service Network 21. Patients evaluated between August and November 2015 who were viremic and not receiving HCV treatment were included in the analysis. Reasons for treatment exclusion were determined by an experienced clinician and recorded into a regional population management dashboard. Descriptive statistics were used to describe the population. The *t* test for normally distributed data, the Mann-Whitney rank sum test for data that failed normality testing, or the χ^2 test were used to examine differences between the treatment eligible and ineligible cohorts. Generalized linear mixed-effects models were conducted to estimate patient outcomes relevant to various disease states and characteristics while controlling for interfacility variability.

Findings: The cohort included 1,003 veterans within 5 medical centers; 988 (98.5%) were male, and 625 (62%) had a fibrosis 4 score >3.25, indicating the presence of ALD. According to clinician classification, 478 (48%) were considered HCV treatment candidates, whereas 525 (52%) were determined to be treatment ineligible. The most common reasons documented by clinicians for treatment ineligibility included unstable or uncontrolled comorbidities (n = 118 [22.4%]), excessive alcohol use (n = 116 [22.1%]), and treatment refusal by the patient (n = 69 [13%]). On the basis of statistical modeling and reporting odds ratios (ORs) and 95% CIs, diagnoses of active alcohol use disorder (OR = 0.68; 95% CI, 0.47–0.98; $P = 0.038$), hepatocellular carcinoma (OR = 0.24; 95% CI, 0.13–0.47; $P < 0.001$), and palliative care status (OR = 0.21; 95% CI, 0.05–0.99; $P = 0.049$) were statistically associated with treatment ineligibility, whereas posttraumatic stress disorder (OR = 1.48; 95% CI, 1.01–2.18; $P = 0.046$) was associated with treatment eligibility. There were no statistically significant differences found for other psychiatric diagnoses or an encounter for homelessness.

Implications: Results of this study indicate that a high percentage of patients may not be considered treatment eligible at initial clinical review. Within this veteran population, the presence of uncontrolled comorbidities and excessive alcohol use were the most commonly reported reasons for treatment ineligibility. On the basis of this analysis, processes could be established to address modifiable barriers to treatment, thus expanding the number of individuals receiving potentially curative therapy for HCV infection. (*Clin Ther.* 2017;39:130–137) Published by Elsevier HS Journals, Inc.

Key words: direct-acting antivirals, hepatitis C, population management, pretreatment assessment, treatment candidate.

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INTRODUCTION

Hepatitis C continues to be a major public health concern, with an estimated 2.7 million to 3.9 million chronic cases within the United States.[1] Within the Veterans Health Administration, hepatitis C virus (HCV) infection prevalence is noted to be 2 to 3 times that of the general US population.[2,3] In 2014, a total of 164,889 veterans had active HCV nationwide, and 10,056 were within the Veterans' Integrated Service Network (VISN) 21, which encompasses Veterans Affairs (VA) health care facilities within Northern and Central California, Nevada, and the Pacific Islands.[4]

National rates of HCV-related deaths continue to increase, and the comorbidities of HCV can be significant.[1] Untreated HCV infection is a leading cause of liver disease, and many cases progress to cirrhosis, hepatocellular carcinoma, or other end-stage liver complications.[5,6] These complications affect patients' quality of life and health care costs. Estimated annual health care costs per patient associated with HCV triple as the degree of liver fibrosis progresses from early ($810) to advanced ($2575) stages.[7] The direct health care costs in individuals with advanced liver disease (ALD) resulting in hepatocellular carcinoma are estimated at $176,455 per patient.[8] In 2014, 19% of veterans within VISN 21 with active HCV were estimated to have ALD.[9] The VA clinical guidelines published in 2015 emphasized treating special populations with HCV, including those with ALD or HIV coinfection, and suggested that the urgency of treatment be based on the risk of developing decompensated cirrhosis or dying from liver-related disease.[10–12] However, the current approach is to treat all patients with active HCV.[13]

Despite the VA's push for treatment, factors that may affect treatment rates include patient readiness and contraindications to treatment, along with finite resources, such as pharmaceutical budgets and clinic capacity. The estimated cost for a 12-week treatment with the most commonly prescribed medication is $94,500; however, the VA health system cost is based on a negotiated contract.[7] Health care systems must carefully allocate resources because of significant upfront pharmaceutical costs. In a study performed by Cachay et al[14] in a non-VA population of 562 patients coinfected with HIV and HCV, 303 were referred for treatment and 259 were not referred. The strongest predictor of not being referred for HCV treatment was the patient's lack of engagement in care as defined by missed clinic visits and follow-up.[14] Of the 303 referred for treatment, 88 (29%) started treatment. Primary reasons for not treating included ongoing drug or alcohol abuse, unwillingness to participate in the clinic protocol, uncontrolled neuropsychiatric disorders, or uncontrolled HIV disease in the context of ongoing drug or alcohol abuse. Within the VA, the high prevalence of these clinical issues suggests that not all veterans may be appropriate for treatment. This finding reinforces the need for clinical evaluation and assessment of barriers when determining treatment candidate status to ensure efficient use of resources.

PATIENTS AND METHODS

This was a retrospective analysis of data from 5 medical centers located within the states of California, Nevada, and Hawaii. This project did not meet the criteria for human research and did not require approval by the VISN 21 Institutional Review Board.

Data Source

The VISN 21 clinical HCV population management dashboard was developed in 2012 to identify HCV-positive patients and monitor them during and after treatment. In August 2015, a tracking tool was added to the dashboard in an effort to capture clinicians' decisions and data about patient eligibility for treatment. Pharmacists and physicians with experience in treating HCV used the dashboard to review patients at high risk of progression, primarily those with ALD, to determine HCV treatment eligibility. Eligibility criteria were based on VA guidelines derived from the Infectious Disease Society of America. A standardized dropdown menu was used to document possible reasons a veteran may have not been a treatment candidate. All HCV treatment providers were provided instructions to record the treatment candidate status and reasons for treatment ineligibility.

The VISN 21 DataMart and associated databases were used to obtain the pharmacy and demographic records used in this study. Automated data extraction routines capture pharmacy, diagnosis, laboratory, provider, and patient demographic data on a daily basis. Data were queried using Structured Query Language. Relevant disease states were identified