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Impact of hepatitis C treatment on pain intensity, prescription opioid use and arthritis

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Abstract

Objective: To assess the impact of direct acting anti-viral (DAA) therapy for hepatitis C virus (HCV) infection on changes in pain intensity and prescription opioid use among Veterans.

Methods: We conducted a retrospective cohort study of Veterans with HCV who were seen in a rheumatology clinic at least once while receiving DAA therapy between January 1, 2010 and December 31st 2016. Demographic characteristics, HCV status, HCV treatment characteristics, numeric rating scale (NRS) pain scores and opioid prescription data were extracted from the electronic medical record. Pain scores were averaged over 6 months prior to HCV treatment and 6 months after completion of treatment. Prescription opioid dose was converted to a morphine equivalent daily dose (MEDD) and averaged across the two 6-month intervals. Generalized estimating equations were used to model the change in average pain and MEDD from pre- to post-HCV treatment. Effect size was assessed using Cohen's *d*.

Results: A total of 121 Veterans, 91% male with average age of 59 were included. Average pre-treatment pain was 4.4 (SD 2.4). The average reduction in pain scores was 0.6 points ($P = 0.02$, Cohen's $d = 0.22$) after treatment. Among 67 patients prescribed chronic opioid therapy at baseline, average pre-treatment MEDD was 52.4 mg (SD = 62.5 mg) and post-DAA treatment average MEDD was 49.5 mg (SD = 69.3 mg), representing a decrease by 2.9 mg ($P < 0.01$, Cohen's $d = 0.14$). Opioid dose reduction was seen in 43/67 patients and 12 patients discontinued opioids entirely.

Conclusion: Among US Veterans, subjective pain scores had modest improvement and opioid prescriptions were mildly reduced following treatment with DAA.

Keywords

arthritis; direct-acting anti-virals; hepatitis C; opioid; pain

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AUTHOR CONTRIBUTION

All authors participated equally in writing the manuscript.

CONFLICT OF INTEREST

The authors have no conflict of interest to report.

1 | INTRODUCTION

The hepatitis C virus (HCV) poses a major public health problem worldwide. The global prevalence of HCV infection is estimated to be 130–170 million.^{1–3} According to National Health and Nutrition Examination Survey (NHANES) data, the estimated prevalence of chronic HCV infection in the USA is 1%, which translates to roughly 2.7–3.2 million people.⁴ The prevalence rate among US Department of Veterans Affairs (VA) patients is considerably higher at 5.4%.⁵

Hepatitis C virus infection is a multifaceted systemic illness with hepatic and extra-hepatic manifestations. Patients with HCV infection are at increased risk of hepatic complications like cirrhosis, end stage liver disease, and hepatocellular carcinoma.^{6,7} Individuals infected with HCV are at 37% higher risk of early death.⁶ Extra-hepatic manifestations associated with HCV infection include mixed cryoglobulinemia, musculoskeletal pain, sicca symptoms, arthralgia/ arthritis, insulin resistance, renal disease, and non-Hodgkin's lymphoma.^{8,9} Although the exact mechanisms are unclear, extra-hepatic manifestations may be mediated by immune mechanisms rather than hepatic damage.¹⁰

Musculoskeletal pain impacts over 35% of adults in the USA and prevalence is higher among patients infected with HCV.¹¹ Arthralgia is reported in 23%–71% of patients with chronic HCV.^{8,10} Fibromyalgia is also more common among HCV-infected individuals, ranging 10%–20%, relative to 1.7%–5.4% in the general population.¹² HCV infection is also associated with chronic inflammatory arthritis and the incidence of HCV-related arthritis varies, between 2% and 20% and may be as high as 33% in US veteran patient populations.^{13–15} Prescription opioid medications have been frequently used to treat chronic pain among HCV-infected patients.¹⁵

Prior to the introduction of direct-acting antivirals (DAAs) for the treatment of HCV, interferon-based HCV treatment had poor adherence rates and was not well tolerated due to side effects such as fatigue, generalized aches and pains, and fever.^{16,17} Current HCV treatment with DAAs can achieve a sustained virologic response (SVR) in more than 90% of patients.^{18,19} However, there is limited data available regarding the change in pain severity, opioid use and hepatitis C-related arthritis after treatment with interferon-free HCV treatment.

The objective of this study was to explore the association of HCV DAA treatment with changes in pain intensity ratings, prescription opioid use among US VA patients seen at a single rheumatology clinic. Our study is the first to our knowledge to assess the changes in pain intensity scores and opioid prescribing after DAA therapy and achievement of SVR.

2 | METHODS

2.1 | Study design

We conducted a retrospective study to identify patients with HCV infection who were seen in a rheumatology clinic, were treated with DAA and achieved a SVR. A time frame between 1 January 2010 and 31 December 2016 was selected to capture those patients who

might have been seen in the rheumatology clinic 2–3 years before initiation of DAA treatment to assess tender (TJC) and swollen joint counts (SJC).

2.2 | Data source

Data were derived from the VA electronic medical record system and Corporate Data Warehouse (CDW), a collection of relational databases containing VA patient electronic medical record data. The local VA Institutional Review Board approved the study.

2.3 | Study population

Patients were included if they had a positive HCV test, received treatment with DAA and were seen in the rheumatology clinic between 1 January 2010 and 31 December 2016. Laboratory test codes identified patients with a positive HCV antibody or HCV RNA by polymerase chain reaction (PCR) or HCV genotype. International Classification of Diseases (ICD) 9/10 codes for HCV were also acceptable for identification. From this cohort, we identified patients during the study period who received care in the rheumatology clinic, were treated with DAA therapy and achieved a sustained viral response. Exclusion criteria included patients who failed to achieve a sustained virological response or who died during the study period.

2.4 | Data extraction

The following data were collected from the VA CDW: demographic characteristics of age, gender, race and ethnicity; mental health and substance use disorder diagnoses in the 6 months prior to and 6 months following DAA therapy; overall medical comorbidity as assessed by the Selim Comorbidity Index, a count of 30 medical and six mental health conditions,²⁰ in the 6 months prior to and following DAA therapy; achievement of sustained virological response defined as absence of detectable HCV RNA 3 months after completion of treatment, laboratory parameters of rheumatoid factor (RF), anti-cyclic citrullinated peptide antibody (anti-CCP), antinuclear antibody and cryoglobulin, average pain scores reported by Numeric Rating Scale (NRS) (where 0 = no pain and 10 = worst pain imaginable) 6 months before treatment initiation and 6 months after completion of DAA treatment. Inpatient pain scores were excluded from analysis because inpatient scores may be associated with acute pain conditions and not indicative of pain intensity associated with chronic pain. This methodology is consistent with prior research used to identify factors associated with improvement in pain intensity in a national cohort of VA patients with chronic pain.²¹

2.5 | Study procedures

Patients who received DAA therapy in the study period were identified through VA outpatient pharmacy prescriptions. The treatment initiation date was the day when the first prescription of DAA therapy was dispensed. The last day of treatment was calculated from the day of last prescription and the quantity of pills.

Prescription opioid status, duration, and current opioid dose were extracted from the pharmacy database for patients prescribed long-term opioid therapy (LTOT). LTOT was defined as receiving prescription opioids for 90+ consecutive days. We calculated a

morphine equivalent daily dose (MEDD) for those patients prescribed LTOT. We examined the proportion of patients prescribed LTOT leading up to initiation of DAA treatment and subsequent change in prescribed LTOT after achievement of SVR.

Manual chart review of rheumatology clinic notes was performed to determine if there was clinical evidence of hepatitis C-related arthralgia (defined as predominantly small joint pain but absence of inflammatory arthritis on exam in the setting of negative anti-CCP antibody) or hepatitis C-related arthritis (evidence of tender and swollen small joints in the setting of negative anti-CCP antibody with or without RF), tender joint count (TJC) or swollen joint count (SJC). These data were not extractable via CDW.

2.6 | Outcomes

The primary study outcome was change in the average 6-month pre- and post-DAA therapy NRS pain scores. Secondary outcomes assessed the change in average 6-month opioid prescription dose before and after DAA therapy expressed in MEDD for patients prescribed LTOT prior to initiating DAA therapy. We also evaluated the change in the TJC and SJC in a small subset of patients with hepatitis C-related arthritis who completed a rheumatology visit before and after DAA therapy.

2.7 | Statistical analysis

Descriptive statistics were used to describe patient characteristics of the cohort. Changes from pre- to post-DAA treatment in primary and secondary outcomes of pain intensity and opioid dose, respectively, were modeled using generalized estimating equations (GEE). We specified model-based variance estimation and unstructured correlations matrices for both models. We first modeled the bivariate association between time (ie, change from pre- to post-DAA treatment) and outcomes of interest. Subsequent multivariate models controlled for variables associated with pain and opioid treatment in prior studies using VA data.^{21,22} These included age, gender, race/ethnicity, mental health diagnoses, substance use disorder diagnoses, and medical comorbidities as assessed by the Selim Comorbidity Index. All inferential analyses utilized 2-tailed tests of significance and $\alpha = 0.05$. Analyses were conducted using SPSS version 22 (IBM, Armonk, NY, USA). The data regarding change in TJC and SJC following DAA therapy were limited to a small subset of patients and thus descriptive statistics only are presented.

3 | RESULTS

Between January 2010 and December 2016, 5373 patients were identified who had a positive lab test code for HCV or an ICD 9/10 code for HCV infection. Of these, 1360 received treatment with DAA and 159 were seen in the rheumatology clinic. Of the 159 patients, 21 deceased patients were excluded. Finally, of the 138 patients, 121 achieved a SVR (Figure 1). The majority of patients were male (91%) with a mean age of 59 years (± 5.8). Thirty-one per cent of participants identified as a racial or ethnic minority. Seventeen per cent had a mental health diagnosis in the 6 months prior to initiating DAA therapy, while 11% had a substance use disorder diagnosis during this period. Ledipasvir was the most common DAA therapy (58%). RF was positive in 57.5%, anti-CCP was positive in 17% and

cryoglobulins were positive in 35% of the patients tested (Table 1). Serologic testing for all patients was not available as the decision to test was based on the discretion of the treating provider.

3.1 | Primary outcome

The average pre-treatment pain intensity score in patients who achieved a SVR was 4.4 (SD = 2.4), and post-DAA treatment average pain intensity was 3.8 (SD = 2.4). The effect of time was associated with an average reduction in pain of 0.6 points ($P = 0.02$, Cohen's $d = 0.22$; Figure 2). After controlling for demographic and clinical characteristics, results were unchanged. Notably, 27 of 121 (22.3%) patients experienced a reduction in average pain NRS scores of 2 or more, which represents a clinically significant pain reduction.²³

3.2 | Secondary outcomes

Among the 67 patients prescribed LTOT at baseline, the average pretreatment MEDD was 52.4 mg (SD = 62.5 mg), and post-DAA treatment average MEDD was 49.5 mg (SD = 69.3 mg), representing a decrease by 2.9 mg from the pre- to post-treatment period ($P < 0.01$, Cohen's $d = 0.14$). Results were unchanged in multivariate analyses. Forty-three patients (64%) prescribed LTOT in the pre-DAA treatment period experienced an opioid dose reduction from pre- to post-DAA treatment, with 12 (18%) patients entirely discontinuing opioids.

After reviewing the rheumatology visits, we identified 24/121 (19.8%) with hepatitis C-related arthralgia. Hepatitis C-related arthritis was seen in 14/121 (11.5%) patients. Of the 14 patients, only 10 had a rheumatology clinic visit before and after DAA therapy. TJC and SJC in 8/10 individuals with hepatitis C-related arthritis demonstrated an overall trend toward improvement (Table 2).

4 | DISCUSSION

In this retrospective study of patients with HCV infection treated with DAA therapy who achieved a SVR, we identified a reduction in pain scores and opioid dose. In a previous study of 1600 patients, the most common extra-hepatic manifestations were arthralgia (23%) and myalgia (15%).⁹ Consistent with this and other studies,^{24,25} 19% of patients in the current study had arthralgia that could be attributed to HCV. These extra-hepatic manifestations are a significant source of pain and reduced quality of life among patients with HCV. DAA therapy might have an additional benefit in improving pain and inflammatory arthritis associated with hepatitis C.

In the current study, average pain scores decreased after DAA therapy, although the clinical significance of this change was modest. We also noticed that 22.3% of patients demonstrated a clinically significant improvement in pain intensity following DAA therapy. Previous studies have shown the impact of DAA therapy on patient-reported outcomes like physical fatigue, but did not report specifically on musculoskeletal manifestations or pain scores.²⁶ HCV-positive patients have reported higher pain scores and had higher tender joint counts in a prospective cohort of US veterans with rheumatoid arthritis.²⁵ DAA therapy has shown to have a modest impact on cryoglobulinemic vasculitis²⁷ but our study is the first to our

knowledge that evaluates the change in pain scores after DAA therapy for HCV infection. The average pain scores were also higher in our study group (4.4) compared to the VA Musculoskeletal Diagnosis Cohort (3.43).²⁸ The Musculoskeletal Diagnosis Cohort did not specifically address pain scores in hepatitis C-infected individuals or any change in pain scores after treatment as reflected in our study.

Our patient cohort had a higher MEDD of 52 mg before treatment compared to MEDD of 26-30 mg reported in previous VA studies not exclusive of HCV populations.^{29,30} In the current study, 64% of patients had a decrease in prescription opioid dose and nearly 18% of patients prescribed long-term opioid therapy were discontinued from opioids after achievement of SVR. High rates of opioid taper and discontinuation in this sample, coupled with small overall average reductions in pain, suggest that patients prescribed lower opioid doses were tapered or discontinued, while those on higher doses maintained pre-DAA therapy opioid dose. It is possible that the small reductions in pain experienced by patients' post-DAA therapy may be insufficient to facilitate opioid dose reduction in patients on high-dose opioid therapy. Although observed in a subset of patients, this reduction in daily opioid use might contribute to improved long-term mortality in the HCV infected population.

Hepatitis C virus-related arthritis is a non-erosive inflammatory arthritis associated with HCV infection with or without RF.³¹ In our cohort, 11% of patients had HCV-related arthritis, which is similar to the prevalence of HCV-associated arthritis described in previous studies, ranging from 2% to 20%.^{13,32,33} Although more than two-thirds of patients with HCV-related arthritis showed an improvement in TJC and SJC after DAA therapy, these data were limited to only to a small subset of patients whose joint counts were recorded post-DAA therapy. It is difficult to draw reliable conclusions given the small sample size.

This study has several limitations which include the retrospective study design and utilization of the outpatient pharmacy database to assess opioid prescription status, which is not a direct measure of use. As previously noted, the sample size for this study was small and precluded outcome analyses of TJC and SJC. Consistent with observational study designs, there may be factors other than DAA therapy that influence study outcomes of pain intensity and opioid use that were not measured and could account for study findings. The study primarily included men and the results may not be generalizable to a non-VA population. Over-the-counter pain medication or other non-opioid pain therapies were not captured in this study and may have played a role in pain scores and/or changes in opioid use. Due to the small sample size and retrospective nature of the study, we cannot draw strong conclusions about serologic status or improvement in inflammatory arthritis of patients seen in the rheumatology clinic. Future larger studies are needed to more fully explore the impact of a sustained viral response to pain scores in general and when prescribed, opioid use and dosage. Finally, we did not have a control group of HCV-infected patients who were not treated with DAA therapy to account for secular changes in opioid prescribing, or a control group of patients treated with DAA therapy who did not achieve SVR. This was primarily because most patients with HCV infection who receive care in the VA system were already treated for HCV, and if treated with DAA therapy, very few patients failed to achieve SVR.

Our study highlights several important implications. DAA therapy for HCV has the potential to decrease pain intensity, which in turn may lead to reductions in opioid use for chronic pain. DAA therapy may provide additional benefits to patients with an inflammatory hepatitis C-related arthritis. Our study suggests that achieving a sustained virological response with DAA therapy has the potential to provide measurable extra-hepatic benefits. Future larger studies are needed to more fully explore the impact of a sustained viral response to pain scores in general and when prescribed, opioid use and dosage.

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FIGURE 1.

Identification of veterans to be included in the study. DAA, direct-acting antivirals; ICD, International Classification of Diseases

FIGURE 2.

Average pain scores and opioid use before and after hepatitis C virus treatment with direct acting antivirals. Opioid use is graphed as morphine-equivalent daily dose

TABLE 1

Characteristics of veterans with HCV seen in a rheumatology clinic at a single center

Characteristic	N = 121 (%)
Mean age, y	59 ($\pm$ 5.8)
Males	110/121 (91.0)
Caucasian	78/121 (86.6)
Non-Hispanic	105/121 (86.6)
Ledipasvir as DAA therapy	70/121 (58.0)
Rheumatoid factor positive	42/73 (57.5)
CCP positive	8/47 (17.0)
Cryoglobulin positive	9/26 (34.6)
HCV-related arthralgia	24/121 (19.8)
HCV-related arthritis	14/121 (11.5)

CCP, cyclic citrullinated peptide; DAA, direct-acting antivirals; HCV, hepatitis C virus.

Characteristics of patients with HCV-related arthritis with a rheumatology clinic visit before and after direct-acting antiviral therapy

TABLE 2

Patient	RF	CCP	Cryoglobulin	ANA	TJC (pre)	SJC (pre)	TJC (post)	SJC (post)
1	Positive	NA	Negative	Negative	2	2	0	0
2	Negative	0	NA	NA	1	3	0	1
3	Positive	0	NA	Positive	4	4	2	1
4	Positive	Positive	NA	NA	0	1	0	0
5	Positive	0	Positive	Negative	6	6	3	1
6	Positive	0	Positive	Positive	3	3	0	0
7	0	Positive	NA	NA	3	5	1	1
8	Positive	NA	Negative	NA	1	5	0	8
9	Positive	0	NA	Negative	2	2	2	2
10	Positive	Positive	NA	Negative	0	2	0	0

ANA, antinuclear antibodies; CCP, cyclic citrullinated peptide; HCV, hepatitis C virus; RF, rheumatoid factor; SJC, swollen joint count; TJC, tender joint count.