Race and Hepatitis C Management within the Veterans Administration

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ABSTRACT

Objective: To examine black-white differences in hepatitis C treatment within the Veterans Administration (VA) and determine whether racial variation in specialty consultation explains differences in hepatitis C treatment between blacks and whites.

Methods: We performed a retrospective cohort study of 1040 veterans meeting VA eligibility criteria for hepatitis C treatment. We used multiple imputation to handle missing race data. Specialty consultation was determined from the VA outpatient medical dataset and hepatitis C treatment was determined from the VA decision support system. Conditional logistic regression was used to examine the association between race and hepatitis C treatment as well as race and specialty consultation.

Results: There was no statistical difference in specialty consultation between blacks and whites, OR= 1.23 (95% CI, 0.85-1.78). Among 505 patients who visited a specialist, there was no statistically significant difference in hepatitis C treatment between blacks and whites, OR= 0.55 (95% CI, 0.30-1.00).

Conclusions: Among veterans who met eligibility criteria for hepatitis C treatment there were no statistically significant differences in specialty consultation or hepatitis C treatment by race. There was a statistical trend towards less treatment for blacks.

Keywords: Hepatitis C, consultation, treatment, Veterans Health

INTRODUCTION

The prevalence of hepatitis C infection within the United States is 1.8%. Most people who become infected develop chronic infection, and chronic infection is the most common cause of liver failure and liver transplantation in the United States (Alter, 1999; Centers for Disease Control and Prevention,
Hepatitis C virus infection is particularly important within the Veterans Administration (VA), where the prevalence among veterans is more than twice that of the general population (Cheung, 2000; Dominitz, 2005). The VA uses nationally integrated computer information systems. These computerized systems, along with the high prevalence of Hepatitis C, makes the VA an important and excellent setting for studying hepatitis C management. Within VA medical centers, primary care physicians screen for infection among those at risk by testing patients’ serum for the hepatitis C antibody (CDC 1998; CDC, 2003; Strader, 2004), and then refer patients with positive screens to specialists trained to treat chronic hepatitis C infection, generally a gastroenterologist or infectious disease specialist. A quantitative hepatitis C RNA test is the gold-standard for confirming infection. Because most primary care physicians are not trained to treat chronic hepatitis C infection, patients typically will not receive treatment unless first evaluated by a specialist. If the specialist physician determines that a patient is eligible (Bini, 2005) for treatment and the patient agrees, then that patient is recommended for treatment. Treatment consists of weekly doses of interferon and daily doses of ribavirin (Strader, 2004).

While there are some studies to the contrary (Bini, 2005), many studies indicate blacks receive treatment for chronic hepatitis C infection less often than whites (Butt, 2007; Groom, 2008; Hall, 2004; Rousseau, 2008). This has substantial implications for health disparities for three reasons. First, among U.S. born persons six and older, hepatitis C infection is more prevalent among blacks than whites (3.2% vs. 1.5%) (Alter, 1999). Second, the incidence of hepatocellular carcinoma, a sequela of untreated chronic hepatitis C infection, is increasing faster among blacks than whites (El-Serag, 2003). Third, among patients with end stage liver disease, another sequela of untreated chronic hepatitis C infection, blacks are underrepresented on the wait-list for liver transplantation (Seaberg, 1998). If blacks receive treatment for chronic hepatitis C infection less often, then their burden of disease and disease sequelae may worsen relative to other groups. Unfortunately, there are no studies which examine the causal mechanisms of this treatment disparity despite the increased prevalence and increasing risk of hepatitis C sequelae among blacks.

HCV management involves multiple steps: access to a clinician, blood tests, specialty consultation, and treatment. Teasing out disparities in treatment therefore requires examining the steps leading to treatment. Racial differences in later steps may exist because of differences in the occurrence of previous requisite steps. If blacks receive treatment less often, it may be because blacks undergo specialty consultation less often. We therefore hypothesized that the clinical data in the VA information systems would reveal racial differences in the occurrence of specialty consultation as a cause of racial differences in hepatitis C treatment.

METHODS
This study was approved by the Philadelphia VA Institutional Review Board. The Philadelphia VA IRB was aware of the identification of HIV infected subjects in this study.

Data Source
The Veterans Health Administration is a nationally integrated healthcare system with nearly 8 million veterans enrolled. After each outpatient or inpatient encounter with the VA, the patient’s clinical record is coded, with standardized clinical information collected and stored in VA databases. Data for this study were obtained from three VA Medical SAS datasets: 1) The Inpatient Medical SAS Dataset (IMD), also known as the Patient Treatment File, which includes acute care, extended care, observation care and non-VA care records; 2) the visit and event files of the Outpatient Medical SAS Dataset (OMD) which includes all VA ambulatory care data; and 3) the Decision Support System (DSS), which includes pharmacy records. All datasets were extracted from the Austin Automation Center.
**Study Subjects**

Using the OMD and IMD, we identified all positive hepatitis C quantitative RNA laboratory tests generated between October 1, 1999 and March 31, 2006 from Clarksburg, WV and seven Pennsylvania sites: Altoona, Butler, Coatesville, Erie, Lebanon, Pittsburgh, and Wilkes Barre. For those with multiple tests, we consider only the first positive test, which we call the Initial Test. We only included patients who saw a primary care physician after the Initial Test. We only included patients who received at least minimal primary care. We defined minimal to be three or more visits during the study period from October 1, 1999 to September 31, 2006. Therefore, we included patients only if they had at least three primary care visits over the study period and had at least one primary care visit after the Initial Test. We call the first primary care visit following the Initial Test the Index Visit.

The VA uses standard inclusion/exclusion criteria when determining eligibility for Hepatitis C treatment (VA Centers of Excellence in Hepatitis C Research and Education, 1999), (see Inclusion/Exclusion criteria for treatment below). Using these criteria, we excluded any patient from our study who did not meet all of the laboratory eligibility criteria (except platelet count and thyroid indices as they were not available in our dataset). We also excluded any patient with evidence of previous hepatitis C treatment, patients younger than 18, and patients with HIV. The patients who met both inclusion and exclusion criteria formed the primary cohort. We examined the primary cohort for any association between race and specialty consultation as well as race and hepatitis C treatment. We also examined the association between race and hepatitis C treatment among the subset of patients in the primary cohort who received specialty consultation.

**Inclusion and Exclusion Criteria for Interferon and Ribavirin Therapy**

**Inclusion Criteria**
- Anti-HCV antibody positive
- Hemoglobin ≥ 13g/dL for males, Hemoglobin ≥ 12g/dL for females
- White Blood Cell Count ≥ 3000/mm$^3$
- Absolute Neutrophil Count ≥ 1500/mm$^3$
- Platelet Count ≥ 85,000/mm$^3$
- Total Bilirubin < 2.0mg/dL
- Albumin ≥ 3.2g/dL
- Serum Creatinine < 1.5mg/dL
- Thyroid Stimulating Hormone - within normal limits

**Exclusion Criteria**
- Hemoglobinopathy or hemolytic anemia
- Evidence of decompensated cirrhosis: Ascites, Varices, Encephalopathy
- Comorbid conditions that can interfere with treatment
  - CNS trauma or seizure disorder
  - Diabetes
  - COPD
  - Coronary Artery Disease
  - Congestive Heart Failure
  - Condition which require treatment with systemic steroids
- Substance Abuse
- Psychiatric Disorder
- Pregnancy
- Inability to comply with treatment
Primary exposure: Race
Patient race was obtained from the IMD and the OMD. Race coding within the VA is of two types, self-reported or recorded by clerical staff. Whenever possible we used self-reported race over that of clerical staff. Studies on the accuracy of clerical staff race coding in VA data (Kressin, 2003) indicate race is greater than 90% accurate when white or black race is coded. We included all patients identified as black or white.

Outcomes
We used clinic codes from the OMD to measure specialty consultation. We considered specialty consultation positive if it met three criteria: 1) A clinic code indicating gastroenterology or infectious disease consultation; 2) an ICD-9 code for hepatitis C (070.51, 070.54, 070.70, 070.90); and 3) date of service after the Index Visit. We used pharmacy records from the DSS to define hepatitis C treatment as follows: 1) prescription for interferon or pegylated interferon occurring after specialty consultation, or 2) interferon or pegylated interferon in combination with ribavirin occurring after specialty consultation.

Potential Confounders
We examined data generated during the year prior to the Index Visit to obtain information on baseline patient demographics, co-morbidities, and laboratory data. Age, gender, and VA service connectedness were obtained from the OMD and IMD. The VA standards for determining eligibility for hepatitis C treatment also include several exclusion criteria. VA Centers of Excellence in Hepatitis C Research and Education, 1999) Thus, we measured and controlled for these. Using ICD-9 codes from the OMD and IMD, we captured the following co-morbidities based on the presence of one inpatient or two outpatient primary or secondary diagnoses: Psychiatric Disorder including: Depression (296.20-296.39, 311), Other Affective Disorders (296.00-295.19, 296.40-296.99), Psychosis (295.00-295.90), or Neurotic Disorders (300); Comorbid illness including: CNS disease (330.00-349.00), COPD (491.00-492.99, 496.00-496.99), Diabetes (250.00-250.99), Ischemic heart disease (410.00-414.99), Congestive Heart Failure (428.00-428.99), and Hemoglobinopathy (282.00-283.99); Alcohol abuse (303.00-303.93, 291.00-291.99); Substance Abuse (292.00-292.99, 304.00-304.99); Cirrhosis (571.5); Decompensated Liver Disease (572.2-572.4, 572.8); Pregnancy (650.00); and CPT codes for Organ Transplant generated at any time between October 1, 1999 and September 30, 2006 (50380, 33945, 33935, 32851-32854, 47135-47136). HIV infection was considered positive if a patient had a positive HIV PCR test, or the pharmacy records from the DSS revealed prescriptions for HIV medication. From the OMD and IMD, we obtained serum ALT, total bilirubin, albumin, hememoglobin, serum creatinine, and white blood cell count. VA Medical Center site (VAMC) was extracted from all three datasets and defined as the site where the majority of care took place. Both internal VA sources and external studies have demonstrated the validity of VA databases for research (Kang, 1991; Kerr, 1999; Murphy, 2002).

Data Analysis
We used the t-test and chi-square test to compare demographic and clinical characteristics by race. We found no pregnant patients in the cohort. We calculated unadjusted odds ratios for the association between race and the outcomes of interest. 12.2% of the patients in our primary cohort had missing race data (127/1040, Figure 1). Using the primary cohort we performed multiple imputation with regression of all covariates onto ten imputed datasets to assign a racial classification to these subjects. We then performed conditional logistic regression to determine the association between race and specialty consultation, as well as the association between race and treatment. We also performed conditional logistic regression to determine the association between race and treatment among the subset that underwent specialty consultation. In each case, regression covariates included age, race, sex, serum ALT, alcohol disorder, substance abuse, psychiatric disorder,
and comorbid illness. We included ALT because of its importance as a marker for active hepatic inflammation and its common use in treatment decision making (Seef, 2002; Strader, 2004). We conditioned models on the VAMC site to control for any unmeasured factors that may differ by site or care. Finally, because of their potential use as exclusion criteria in the decision to treat, we also looked for modification of any associations between race and outcomes by the following terms: alcohol disorder, substance abuse, psychiatric disorder, and comorbid illness. All data were analyzed using the statistical package Stata 9.2.

RESULTS

Figure 1 illustrates creation of the study cohort. 2,118 persons had positive results for the quantitative hepatitis C test. Of these, 1,691 visited a primary care physician at least three times between October 1, 1999 and March 31, 2006, including at least one visit after the positive hepatitis C result. Of these patients, 1,058 met our inclusion and exclusion criteria. Finally, we identified 145 people whom had missing race data or could not be classified as black or white, 127 of whom had missing data. This yielded the primary cohort of 1040 subjects, 676 whites, 237 blacks, and 127 subjects whose race was subsequently imputed.

The demographic and clinical characteristics of the cohort are shown in Table 1. The average age was 52.4 years and 2.5% (26/1040) were female. Decompensated liver disease was more common among whites. Whites also had higher baseline serum Albumin, ALT, White Blood Cell counts, Hemoglobin, and Total Bilirubin levels compared to blacks. Blacks had higher serum creatinine levels, were more likely to have documented, psychiatric illness, and drug or alcohol related illnesses or comorbid illnesses.

<table>
<thead>
<tr>
<th>Table 1. Cohort Characteristics</th>
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<td>Demographic Variables</td>
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<td>VA related variables</td>
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<td>Service Connected &gt;=50%</td>
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<td>Comorbid conditions %</td>
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<td>Cirrhosis</td>
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<td>Total Bilirubin (IU/L)</td>
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<td>White blood cell count (x1000/μL)</td>
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Figure 1: Cohort Creation

2,118 with positive quantitative Hepatitis RNA-PCR result.

1,691 with three or more primary care visits.

1,479 without evidence of previous Hepatitis C treatment.

1,443 without evidence of HIV.

1,058 meeting laboratory inclusion criteria.

1040 with white or black race or missing race data: Primary Cohort.

505 underwent specialty consultation.

Examine for racial differences in specialty consultation and treatment.

Examine for racial differences in treatment.

145 patients identified as non-black, non-white or missing race. 127 of these had missing race data.
Among the 1040 patients with documented HCV infection, 505 (48.6%) subsequently underwent specialty consultation. The median time from primary care visit to specialty consultation was 16 days longer for blacks compared to whites (63 vs. 79). Overall, the frequency of specialty consultation was higher for blacks than whites, but not statistically significant (59.9% vs. 53.7%, p=0.10) (Table 2). To adjust for confounding we first imputed race for those with missing information on race. During the creation of the initial study cohort, 145 people were identified as neither black nor white, or had missing race data (Table 1). Of these, 127 had missing race data. After imputing the race for these 127 persons and performing conditional logistic regression to control for age, sex, service connection, serum ALT, psychiatric disease, alcohol disorder, substance abuse, comorbid conditions, and site of care, the adjusted difference between blacks and whites remained not significant (OR=1.22, 0.85 -1.77, p=0.27) (Table 2).

In the primary cohort of veterans with documented HCV infection 130/1040 (12.5%) subsequently received hepatitis C treatment. The median time from primary care visit to treatment was 87 days longer for blacks compared to whites (221 days vs. 308 days). Also, the overall percentage of veterans receiving treatment was greater for whites than blacks (26.2% vs. 13.4%, p=0.02). After full adjustment, however, the difference between blacks and whites was not statistically significant (OR=0.64, 0.36-1.15, p=0.14) (Table 2). Among the 505 veterans with HCV infection who subsequently underwent specialty consultation, the frequency of hepatitis C treatment also was higher for whites than for blacks (34.7% vs. 21.3%, p<0.01); however, after full adjustment, statistical significance was lost and only a trend towards statistically lower odds of treatment for blacks remained (OR=0.54, 0.30-1.00, p=0.05) (Table 2).

Results of conditional logistic regression are seen in table 3. Factors associated with specialty consultation included younger age and higher serum ALT. Substance abuse was a negative predictor of specialty consultation. Cirrhosis was the only predictor of treatment, while substance abuse, psychiatric disorder, and comorbid illness were either negative predictors or indicated a statistical trend towards being negative predictors.

The results of the interaction terms are listed in table 4. In two instances, being both black and having the disorder indicated lower odds of treatment than being black alone (alcohol disorder & psychiatric disorder). In the other two instances, being both black and having the disorder resulted in a higher odds of treatment than being black alone (substance abuse & comorbid illness). However, the column entitled “p-value for interaction” indicates that race did not significantly interact with any of the factors we studied. Thus odds of treatment for blacks with the disorders are not statistically significant than the odds of treatment for blacks without the disorder.
DISCUSSION

We assumed that we would find a racial difference in hepatitis C treatment between blacks and whites. Our hypothesis was that any racial difference in hepatitis C treatment would be accounted for by differences in specialties in specialty consultation. To the contrary, this cohort of veterans with evidence for hepatitis C infection revealed black and white veterans at most had differing rates of hepatitis C treatment which merely trended towards statistical significance after adjusting for confounders. Instead of explaining treatment differences, the opposite was true – there was no association between race and specialty consultation. If anything, blacks were more likely to undergo specialty consultation than whites. An analysis of the veterans who underwent specialty consultation further revealed only a statistical trend towards significance rather accounting for any treatment difference. These results agree with a prospective cohort study among veterans with Hepatitis C (Bini, 2005) which also showed that race was not an independent predictor of treatment. Our study stands in contrast to two previous retrospective cohort studies showing lower treatment among black veterans within the VA (Butt, 2007a; Rousseau, 2008). However, our results agree with Rousseau (2008) who found no association between race and specialty consultation. One of the strengths of our study is the use of standard VA criteria for hepatitis C treatment to define our cohort. Unlike some of the previous studies, each person in our cohort met inclusion laboratory criteria for treatment. Those with exclusion criteria were controlled for in our regression analyses. By using standard VA criteria to define our cohort we were able to ensure that only those patients who were eligible for treatment were included. A second strength is the use of multiple imputation to address the missing race data for a significant minority of the entire sample. Many retrospective studies which analyze existing data either fail to mention or fail to account for missing race data. This can result in biased results. Our use of multiple imputation, while imperfect, is considered the gold-standard for
dealing with missing data and its potential problems.

Our finding that 55.3% of veterans had undergone specialty consultation and 12.0% were given prescriptions for hepatitis C treatment is similar to results from other studies (Butt, 2007a; Fultz, 2003; Groom, 2008; Hall, 2004; Irving, 2006; Morril, 2005; Rousseau, 2008). The high prevalence of co-morbidities among HCV infected veterans, including psychiatric disease, alcohol and substance abuse, is also similar to other studies (Butt, 2007a; Fultz, 2003; Hall, 2004; Rousseau, 2008).

Both the strength of the effect size and the p-value for the association between race and treatment increased in statistical significance between the primary cohort and the subset of patients who underwent specialty consultation, reflecting the fact that only those were seen by specialists were treated in our cohort. A closer look at those most likely to be treated revealed a trend towards significantly lower odds for blacks. We do not want to simply dismiss this difference because it is not statistically significant. The difference may be important clinically. It may be due to clinical differences between blacks and whites we could not measure, such as the severity of disease. Our results indicated that blacks were seen by specialists on average 16 days later than whites. While this difference is not large, it does suggest that blacks are seeing specialists later than whites. Several studies have indicated that blacks present for medical care with more advanced disease than whites (Mandelblatt, 1991; Roach, 1995; Swindells, 2002; Yancy, 2003). On the other hand, our data also could not account for potential differences in the degree of liver fibrosis by race. Some evidence suggests black patients progress to cirrhosis more slowly than white patients (Bonacini, 2001; Wiley, 2002). If blacks in our cohort had less hepatic fibrosis, then treatment may be have been indicated less often than for whites. Our data suggest this is a possibility, as the frequency of cirrhosis among white patients was higher than among black patients in our cohort. Another possibility is the racial difference in genotype prevalence. Many studies have shown lower treatment responses among blacks than whites (Kinzie, 2001; McHutchison, 2000; Muir, 2004; Pyrsopoulos, 2001) with this difference partly due to racial differences in genotype 1 prevalence. Blacks are infected with this difficult to treat genotype more often than whites 88% vs. 67% (Alter, 1999). Additionally, blacks appear to respond to hepatitis C treatment less often than whites regardless of genotype (Kinzie, 2001; Pyrsopoulos, 2001). Specialists, therefore, may be deciding to withhold treatment if the risk of serious side-effects out-weighs the relatively low likelihood of treatment response. Alternatively, blacks patients may decide to forgo treatment more often than whites because of the relatively low chance of treatment success and known serious side-effects of therapy (CDC, 1998; Seef, 2002; Strader, 2004). Previous research on racial disparities in health suggests blacks have lower preferences for certain treatments compared to whites (Ayanian, 1999; Oddone, 2002; Smith, 2002; Whittle, 1997). In these cases, black patients prefer less invasive treatments and at times will forgo treatment entirely. It is possible that racial differences in treatment preferences, which were not measureable in our study, may have contributed to the trend towards statistical significance in our results.

Other potential explanations include discrimination within the healthcare setting and physician bias. Racial discrimination within medical care settings is well documented (Abreu, 2001; Schulman, 1999; van Ryn, 2000; Weisse, 2001). While we could not account for this in our study, the interaction terms enable us to comment on physician bias. Uncertainty of appropriate medical care can be a cause of racial disparities. Uncertainty can lead to racial disparities because without clear management guidelines, decision making is more susceptible to subjectivity, stereotyping, and biases which often operate to the detriment of minorities (Smedley, 2003). While the VA has clearly stated HCV treatment guidelines, there are no studies that indicate how well they are followed. The decision if and when to initiate hepatitis C treatment is sometimes unclear, as are the types of patients who will benefit most from treatment (Seef, 2002). Patients with psychiatric illnesses, HIV,
alcohol or substance abuse fall into a “grey” category for which the appropriateness of treatment is uncertain. The prevalence of these disorders among hepatitis C patients is high (Butt, 2007b; El-Serag, 2002; Goulet, 2005) and was high in our cohort. We detected no significant interactions between race and any of the factors: alcohol disorder, psychiatric disorder, substance abuse, or comorbid illness. Had we noted a clear drop in treatment rates among blacks with these disorders compared to blacks without these disorders, it might suggest that uncertainty was playing a stronger role. However, we did not find this. Instead, in two instances the odds of treatment actually increased among blacks with the disorder.

We note several limitations. Our study may not be representative of the entire VA nor other care settings. Our sample included few women and thus the results can not be generalized in this respect. Also, we could not capture patients who received hepatitis C consultation or treatment outside the VA. Veterans who have the financial means to do so may seek care both within and outside the VA. Finally, our sample size while not small is moderate in comparison to other studies.

In summary, black and white veterans in this cohort had similar odds of specialty consultation and statistically similar odds of hepatitis C treatment. A closer examination of those most likely to be treated revealed a trend towards significantly lower odds for blacks, suggesting specialty consultation is an important place to examine if treatment disparities exist. While access to specialists cannot explain any disparity, there is reason to expect that clinical differences and differences in clinical decision making by patient’s race may contribute to this disparity and require further study.

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