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Racial Disparities in Hepatitis C Treatment Eligibility

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ABSTRACT

Background. Hepatitis C (HCV) is more prevalent in African Americans than in any other racial group in the United States. However, African Americans are more likely to be deemed ineligible for HCV treatment than non-African Americans. There has been limited research into the origins of racial disparities in HCV treatment eligibility. Aim. The purpose of this study was to compare medical and non-medical characteristics commonly assessed in clinical practice that could potentially contribute to HCV treatment ineligibility disparities between African American and non-African American patients. Material and methods. Patients with confirmed HCV RNA considering treatment (n = 309) were recruited from university-affiliated and VA liver and infectious disease clinics. **Results.** African Americans and non-African Americans did not differ in prevalence of lifetime and current psychiatric disorders and risky behaviors, and HCV knowledge. HCV clinical characteristics were similar between both groups in terms of HCV exposure history, number of months aware of HCV diagnosis, stage of fibrosis, and HCV virologic levels. African Americans did have higher proportions of diabetes, renal disease, and bleeding ulcer. **Conclusions.** No clinical evidence was found to indicate that African Americans should be more often deemed ineligible for HCV treatment than other racial groups. Diabetes and renal disease do not fully explain the HCV treatment ineligibility racial disparity, because HCV patients with these conditions are priority patients for HCV treatment because of their greater risk for cirrhosis, steatosis, and hepatocellular carcinoma. The findings suggest that an underlying contributor to the HCV treatment eligibility disparity disfavoring African Americans could be racial discrimination.

Key words. Hepatitis C. African Americans. Treatment eligibility. Disparities.

INTRODUCTION

Hepatitis C virus (HCV) is more prevalent in African Americans than in any other racial group in the United States.[1] After initial exposure to HCV, African Americans are less likely to clear HCV infection naturally without pharmacologic intervention.[2,3] Compared to non-African Americans, African Americans are less likely to be tested for HCV, even when risk factors are determined to be present. African Americans are less likely to be referred and linked to HCV specialty care when they test positive for HCV in primary care settings.[4-6] African Americans who are referred for HCV specialty care are more likely to be deemed ineligible for HCV treatment than non-African Americans,[4] and African Americans are less than half as likely as non-African Americans to be offered or receive HCV treatment.[7-9] For all of the above reasons, the National Medical Association's HCV task force concluded that "Viral Hepatitis is not…an ethnic neutral infection" (p. 109).[4]

To date, the majority of HCV racial disparity research has been focused on disparities in HCV testing rates and HCV treatment outcomes,[10-13] specifically immunological and host genetic differences between African American and non-African American HCV patients.[8,14-16] There has been limited research into the origins of racial disparities in treatment eligibility.[17] Increased detection of HCV in African-American patients is of limited utility if it is not

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paired with increased service access and successful completion of treatment.

Recent implementation of mandatory birth cohort HCV testing[18] will likely eliminate racial disparities in HCV testing. The latest direct-acting agents (DAAs) have closed the racial disparity gap in treatment outcomes because more than 90% of patients who receive and complete treatment achieve SVR irrespective of race. However, African Americans will be less likely to receive the benefit of novel DAAs if racial disparities in treatment eligibility persist.

Historically, clinical trials and observational studies have had difficulties recruiting African American participants.[19-23] The low numbers of African American participants in research present a barrier to understanding why African Americans are more likely deemed ineligible for HCV treatment. Studies with adequate samples of African American participants might help fill this knowledge gap.

The purpose of this study was to assess and compare medical and non-medical characteristics commonly assessed in clinical practice that could potentially contribute to HCV treatment ineligibility disparities between African American and non-African American patients. Using a clinic sample of patients considering HCV treatment at university-affiliated and VA liver and infectious disease clinics, this study compared African American and non-African American HCV patients on demographics, lifetime and current medical and psychiatric comorbidity, HCV clinical characteristics, biological biomarkers, risky behaviors including substance use, and HCV knowledge.

MATERIAL AND METHODS

This study analyzed baseline data collected from a National Institute on Alcohol Abuse and Alcoholism (NIAAA)-funded randomized trial of multi-family psychoeducation for patients with HCV. The methods of the trial are described in greater detail elsewhere.[24] A sample of 309 patients with confirmed HCV RNA and considering HCV treatment were enrolled and completed baseline measures from three liver and infectious disease clinics at Washington University School of Medicine, the University of Texas Southwestern Medical Center, and the VA North Texas Health Care System. The study protocol was approved by Institutional Review Boards of each participating institution, and patients provided written informed consent prior to participation.

Demographic data including age, sex, race, marital status, education level, employment status, and religious preference was obtained through structured interviews. Data on lifetime and current medical conditions were obtained from a combination of patient medical records and self-report. The NIMH Diagnostic Interview Schedule for DSM-IV psychiatric disorders[25] provided diagnostic and recency data for lifetime and current psychiatric disorders. The World Health Organization Composite International Diagnostic Interview-Substance Abuse Module[26] assessed lifetime and current drug and alcohol use disorders and recency of substance use. Urine samples were tested for recent substance use using Roche OnTRAK test kits.[27]

Data on HCV exposure history, number of months aware of HCV diagnosis, HCV genotype, stage of liver disease, HCV RNA viral levels, and other biomarkers were extracted from patient medical records. The Special Projects of National Significance (SPNS) Module 20 for HIV (www.TheMeasurementGroup.com) was modified for use with HCV patients to assess HCV-associated risky behaviors. A 9-item true/false questionnaire tested participants' factual knowledge about HCV transmission, natural history, and treatment.

The primary focus of this analysis was to compare baseline medical and non-medical characteristics of the sample of treatment-contemplating African American and non-African American patients with HCV. Univariate findings are summarized using measures of central tendency and frequency distributions. Dichotomous variables were compared between the two groups using chi-squared analysis, substituting Fisher's exact tests when expected cell sizes were < 5. Numerical variables were compared between groups with *Student's t-tests*, using Satterthwaite comparisons in cases of unequal variances.

RESULTS

Demographics

Table 1 provides data separately for African Americans, others, and the total sample, noting significant subgroup comparisons. Compared to non-African Americans, African Americans were slightly older [t (-3.58) = 307, p = 0.0004] and less likely to be divorced (χ^2= 9.56, df = 1, p = 0.0020). African Americans were more likely to be Protestant (χ^2= 12.82, df = 1, p = 0.0003) and non-African Americans were more likely to be Catholic (χ^2= 7.99, df = 1, p = 0.0047). The two groups did not differ in proportions by sex, education, or employment status.

Medical comorbidity

African Americans were more likely to have lifetime and current diabetes mellitus (χ^2= 8.10, df = 1, p = 0.0043; χ^2 = 7.06, df = 1, p = 0.0079), renal disease (χ^2 = 5.67, df = 1, p = 0.0172; χ^2 = 6.59, df = 1, p = 0.0123), and bleeding ulcer (χ^2 = 8.94, df = 1, p = 0.0018; χ^2 = 7.20, df = 1, p = 0.0048), and lifetime tuberculosis

Table 1. Clinical Characteristics of Non-African American and African American Hepatitis C Virus (HCV) Patients.

	Entire sample	Non-African American Patients	African American Patients	Significance
N	309 (100%)	113 (37%)	196 (63%)	
Age	52.6 (7.5)	50.6 (8.4)	53.7 (6.8)	0.0004
Sex				ns
Female	120 (39%)	45 (40%)	75 (38%)	
Male	189 (62%)	68 (60%)	121 (62%)	
Marital Status (n=308)				
Married	68 (22%)	24 (21%)	44 (22%)	ns
Widowed	22 (7%)	5 (4%)	17 (9%)	ns
Separated	41 (13%)	10 (9%)	31 (16%)	ns
Divorced	91 (30%)	45 (40%)	46 (23%)	0.002
Never Married	86 (28%)	28 (25%)	58 (30%)	ns
≥ High school degree				ns
Yes	89 (29%)	33 (29%)	56 (29%)	
No	220 (71%)	80 (71%)	140 (71%)	
Employment Status (n = 268)				ns
Employed	51 (17%)	21 (22%)	30 (17%)	
Unemployed/disabled	217 (70%)	73 (78%)	144 (83%)	
Religious Preference (n = 220)				
Christian	190 (86%)	57 (81%)	133 (87%)	ns
Protestant	108 (49%)	22 (31%)	86 (57%)	0.0003
Baptist	90 (41%)	14 (20%)	76 (51%)	<.0001
Catholic	27 (12%)	15 (21%)	12 (8%)	0.0047
No religious preference	26 (12%)	13 (19%)	13 (9%)	0.034
Medical Comorbidity				
Any medical comorbidity				
Lifetime	285 (92%)	100 (89%)	185 (94%)	ns
Current	251 (81%)	82 (73%)	169 (86%)	0.0031
Heart disease				
Lifetime	52 (17%)	15 (13%)	37 (19%)	ns
Current	38 (12%)	9 (8%)	29 (15%)	ns
Stroke				
Lifetime	27 (9%)	5 (4%)	22 (11%)	0.0415
Current	17 (6%)	3 (3%)	14 (7%)	ns
Cancer				
Lifetime	32 (11%)	15 (13%)	17 (9%)	ns
Current	16 (5%)	7 (6%)	9 (5%)	ns
Asthma				
Lifetime	60 (19%)	22 (19%)	38 (19%)	ns
Current	46 (15%)	15 (13%)	31 (16%)	ns
Diabetes mellitus				
Lifetime	52 (17%)	10 (9%)	42 (21%)	0.0043
Current	50 (16%)	10 (9%)	40 (20%)	0.0079
Renal disease				
Lifetime	30 (10%)	5 (4%)	25 (13%)	0.0172
Current	28 (9%)	4 (4%)	24 (12%)	0.0123
Arthritis				
Lifetime	144 (47%)	47 (42%)	97 (50%)	ns
Current	136 (44%)	46 (41%)	90 (46%)	ns
Tuberculosis				
Lifetime	28 (9%)	4 (4%)	24 (12%)	0.0123
Current	1 (.32%)	0 (0%)	1 (.515)	ns

Epilepsy				
Lifetime	12 (4%)	2 (2%)	10 (5%)	ns
Current	7 (2%)	1 (1%)	6 (3%)	ns
Bleeding ulcer				
Lifetime	24 (8%)	2 (2%)	22 (11%)	0.0018
Current	12 (4%)	0 (0%)	12 (6%)	0.0048
Obesity				
Lifetime	19 (6%)	8 (7%)	11 (6%)	ns
Current	23 (7%)	10 (9%)	13 (7%)	ns
Psychiatric Disorders				
Any psychiatric disorder				
Lifetime	273 (88%)	100 (89%)	173 (88%)	ns
Current	166 (54%)	61 (54%)	105 (54%)	ns
Major depressive disorder				
Lifetime	177 (57%)	70 (65%)	107 (55%)	ns
Current	121 (39%)	40 (35%)	81 (41%)	ns
Posttraumatic stress disorder				
Lifetime	112 (36%)	41 (36%)	71 (37%)	ns
Current	69 (22%)	24 (21%)	45 (23%)	ns
Alcohol use disorder				
Lifetime	163 (53%)	63 (56%)	100 (51%)	ns
Current	31 (10%)	15 (13%)	16 (8%)	ns
Drug use disorder				
Lifetime	208 (67%)	75 (69%)	133 (70%)	ns
Current	33 (11%)	11 (10%)	22 (11%)	ns
HCV Clinical Characteristics				
Exposure History (n = 264)				
Don't know	128 (41%)	41 (16%)	87 (33%)	ns
Drug use paraphernalia	78 (25%)	32 (34%)	46 (27%)	ns
Blood transfusion	27 (9%)	9 (10%)	18 (11%)	ns
Tattoo or body piercing	16 (5%)	9 (10%)	7 (4%)	ns
Sex	6 (2%)	3 (3%)	3 (2%)	ns
Occupational	5 (2%)	3 (3%)	2 (1%)	ns
Medical procedure	3 (1%)	2 (2%)	1 (0.59%)	ns
Shot or stabbed	0 (0%)	0 (0%)	2 (1%)	ns
Other	15 (5%)	6 (6%)	9 (5%)	ns
Months aware of HCV Diagnosis	98.0 (95.6)	99.5 (96.3)	97.0 (95.5)	ns
Genotype				
1	196 (64%)	54 (48%)	142 (73%)	<.0001
2	18 (6%)	14 (13%)	4 (2%)	0.0005
3	6 (2%)	6 (5%)	0 (0%)	0.0021
4	1 (0.32%)	0 (0%)	1 (0.51%)	ns
Stage of fibrosis (n = 74)				
F0-F2	50 (68%)	20 (71%)	30 (65%)	ns
F3-F4	24 (32%)	8 (29%)	16 (35%)	ns
HCV RNA viral Level (n = 171)		2,604,854 (394,8389)	2,558,011 (3716030)	ns
Biological Markers				
ALT (n = 208)	72.6 (54.7)	80.3 (56.5)	68.1 (53.3)	ns
AST(n = 208)	63.4 (38.9)	67.8 (43.8)	60.89 (35.7)	ns
Bilirubin (n = 210)	0.7 (0.7)	0.7 (0.7)	0.7 (0.8)	ns
Alkaline phosphatase (n = 208)	92.0 (40.9)	94.8 (42.2)	90.4 (40.2)	ns
Albumin (n = 203)	4.3 (3.9)	4.8 (6.5)	4.0 (0.6)	ns
Creatinine (n = 208)	1.1 (1.4)	0.9 (0.2)	1.2 (1.8)	0.0272
Platelet count (n = 205)	212.2 (108.7)	192.5 (83.2)	222.8 (119.2)	ns

White blood count (n = 208)	6.5 (2.6)	6.2 (2.4)	6.7 (2.8)	ns
Absolute neutrophil count (n = 192)	139.9 (172.9)	73.1 (540.0)	174.2 (881.8)	ns
Hemoglobin (n = 208)	13.6 (2.0)	13.8 (1.9)	13.5 (2.1)	ns
Thyroid stimulating hormone (n = 82)	2.3 (2.6)	2.9 (3.5)	2.0 (1.9)	ns
Risky Behaviors				
Unprotected sex (n = 293)				
Lifetime	133 (45%)	52 (50%)	81 (43%)	ns
Last month	36 (12%)	16 (15%)	20 (11%)	ns
Sex with HIV+ person (n = 275)				
Lifetime	18 (7%)	10 (10%)	8 (4%)	ns
Last month	0 (0%)	0 (0%)	0 (0%)	ns
Had STD (not HIV) (n = 285)				
Lifetime	70 (25%)	24 (23%)	46 (25%)	ns
Last month	2 (0.70%)	0 (0%)	2 (1%)	ns
Smoked ≥ 1/2 pack per day (n = 298)				
Lifetime	223 (75%)	82 (76%)	141 (74%)	ns
Last month	128 (43%)	46 (43%)	82 (43%)	ns
Any risky behaviors (n = 303)				
Lifetime	187 (62%)	69 (62%)	118 (61%)	ns
In the last month	295 (97%)	107 (96%)	188 (98%)	ns
Smoked cigarettes in current month	132 (43%)	47 (42%)	85 (43%)	ns
Number of risky behaviors				
Lifetime mean (SD)	5.7 (2.8)	5.9 (2.8)	5.6 (2.8)	ns
Last month mean (SD)	1.1 (1.2)	1.0 (1.1)	1.1 (1.2)	ns
Sex with IDU (n = 278)				
Lifetime	144 (47%)	63 (64%)	81 (45%)	0.0021
In last month	12 (4%)	4 (4%)	8 (4%)	ns
Shared injection needles (n = 295)				
Lifetime	121 (39%)	39 (37%)	82 (43%)	ns
In last month	2 (0.6%)	1 (0.94%)	1 (0.53%)	ns
Injection drug use (n = 293)				
Lifetime	159 (51%)	59 (56%)	100 (53%)	ns
In last month	11 (4%)	5 (5%)	6 (3%)	ns
Used marijuana (n = 289)				
Lifetime	241 (83%)	87 (86%)	154 (82%)	ns
In last month	64 (22%)	23 (23%)	41 (22%)	ns
Used heroin (n = 299)				
Lifetime	155 (52%)	53 (49%)	102 (53%)	ns
In last month	16 (5%)	2 (2%)	14 (7%)	ns
Used cocaine (n = 298)				
Lifetime	219 (73%)	77 (71%)	142 (75%)	ns
In last month	23 (8%)	3 (3%)	21 (11%)	0.016
Drug use				
In last year	201 (65%)	73 (65%)	128 (65%)	ns
In last month	132 (43%)	45 (40%)	87 (44%)	ns
After HCV diagnosis	196 (63%)	74 (65%)	122 (62%)	ns
Alcohol use				
In last year	186 (60%)	63 (56%)	123 (63%)	ns
In last month	133 (43%)	44 (39%)	89 (46%)	ns
After HCV diagnosis	229 (74%)	84 (74%)	145 (74%)	ns
HCV Knowledge				
# correct of 9 true/false HCV knowledge items (n=107)	4.03 (1.38)	3.89 (1.35)	4.10 (1.41)	ns

ns: non-significant difference.

(χ^2 = 6.59, df = 1, p = 0.0123). There were no group differences in lifetime or current heart disease, stroke, cancer, asthma, arthritis, epilepsy, or obesity.

Psychiatric Disorders

African Americans and non-African Americans did not differ in any categories of lifetime and current psychiatric disorders.

HCV Clinical Characteristics and Biological Biomarkers

African Americans were more likely to be infected with genotype 1 (χ^2 = 18.09, df = 1, p < 0.0001), whereas non-African Americans were more likely to be infected with genotypes 2 (χ^2 = 14.17, p = 0.0005) and 3 (χ^2 = 10.71, df = 1, p = 0.0021). The groups did not differ in HCV exposure history, stage of liver disease, or HCV virologic levels. Creatinine levels were higher among African Americans compared to non-African Americans [*t* (-2.23) = 142.52, p = 0.0272), but the groups did not differ in any other assessments of other biological biomarkers, including hemoglobin levels.

Risky Behaviors

Non-African Americans were more likely than African Americans to have a lifetime history of sex with an injection drug user (χ^2 = 9.45, df = 1, p = 0.0021), and African Americans were more likely to have used cocaine in the last month (χ^2 = 5.80, df = 1, p = 0.0160). No significant differences between non-African Americans and African Americans were found in any of the other 13 assessments of lifetime and current risky behaviors.

HCV Knowledge

There were no differences between non-African Americans and African Americans in the number of correct true/false answers endorsed on the 9-item HCV knowledge questionnaire [*t* (-0.74) = 105, p = 0.4622].

DISCUSSION

Very few differences were found between African American and non-African American HCV patients that would contribute to HCV treatment ineligibility disparities. These two groups did not differ in education, employment status, prevalence of lifetime and current psychiatric disorders, and HCV knowledge. With the exception of lower prevalence of lifetime sex with an injection drug user and higher prevalence of cocaine use in the last month, African Americans and non-African Americans had similar profiles of lifetime and current risky behaviors. HCV clinical characteristics were also similar between both groups in terms of HCV exposure history, number of months aware of HCV diagnosis, stage of fibrosis, and HCV viremic levels.

African Americans did have higher proportions with diabetes, renal disease, and bleeding ulcer than non-African Americans, and higher creatinine levels reflecting renal disease comorbidity. This is consistent with a recent study conducted by Melia, et al. (2011).[28] The study found African Americans were more likely to be deemed HCV treatment ineligible, in part based on diabetes mellitus and renal insufficiency.

However, diabetes and renal disease do not fully explain the racial disparity in HCV treatment ineligibility, because HCV patients with diabetes or renal disease are in greater need of HCV treatment compared to patients without these conditions. HCV patients with diabetes or renal disease are priority patients for HCV treatment because of their greater risk for cirrhosis, steatosis, and hepatocellular carcinoma;[29,30] and the American Association for the Study of Liver Diseases' treatment recommendations provide detailed clinical guidance and safety and efficacy data on administration of DAAs for HCV patients with diabetes or renal impairment.[31] The lack of clinically meaningful differences in HCV characteristics between African American patients with HCV and those of other racial and ethnic groups in the current study suggests that the well-documented disparities in treatment eligibility may best be attributed to factors other than empirically-driven decision-making.

This study had some noteworthy strengths and limitations. The sample (n = 309) was larger than in most other HCV studies and, unlike prior studies, African American HCV patients constituted the majority (63%) rather than the minority of the sample. Composite variables representing lifetime and current medical and psychiatric comorbidity, use of alcohol and drugs, and risky behaviors were constructed by combining data from patient self-report and medical records; and urine samples were used to identify individuals with recent substance use who were not detected by self-report. Limitations of this study are its cross-sectional nature, absence of available data on amounts and frequencies of alcohol and drug use, and absence of available data on insulin resistance. Though clinicians may assess insulin resistance in determining treatment eligibility, attributable to poor treatment outcomes associated with interferon therapy,[32-34] insulin resistance as a predictor of suboptimal treatment outcomes with the latest interferon-free DAAs has not been established.[35,36]

This study found that African American and non-African American patients considering HCV treatment

appeared to be almost completely equivalent clinically. No clinical evidence was found to indicate that African Americans should more often than other racial groups be deemed ineligible for HCV treatment. The findings suggest that an underlying contributor to the HCV treatment eligibility disparity disfavoring African Americans could be racial discrimination. Future research should seek to determine if clinicians are inadvertently allowing their own subjective and socially-constructed biases about African Americans that are contrary to empirical data to influence their decision-making in HCV treatment eligibility determination. Identifying and correcting such assumptions among HCV clinicians may be needed to counter this discriminatory pattern. Racially discriminatory practice in the allocation of HCV treatment represents an important area of research, because barriers that inhibit equal opportunity for African American HCV patients to receive curable benefits of DAAs must be addressed and corrected. Otherwise, African Americans will continue to suffer from HCV-related liver complications and death at a greater rate than other racial groups in the US.

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