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ORIGINAL PAPER

The Role of Patient Religiosity in the Evaluation and Treatment Outcomes for Chronic HCV Infection

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Abstract To determine the influence of patient religiosity on the outcome of treatment of hepatitis C infection, a prospective, blinded, cohort study was performed on hepatitis C-infected patients categorized as 'higher religiosity' and 'lower religiosity' based on responses to a religiosity questionnaire. Comparisons were made between high and low religiosity patients on demographics, pre-treatment laboratory values, and response to treatment. Eighty-seven patients with complete questionnaires were placed in either higher (38) or lower (49) religiosity cohort. The patients (60% female) were ethnically diverse: African-American 39%; Hispanic 31%; white 29%. African-American race ($P = 0.001$) and female gender ($P = 0.026$) were associated with higher religiosity. The frequency of being offered treatment, accepting treatment, and completing treatment was similar in both religiosity cohorts ($P = 0.234$, 0.809, 0.367). Fifty-six patients completed the 24- or 48-week treatment with peginterferon and ribavirin. Depression was more frequent in the low religiosity group (38.2% vs. 4.6%, $P = 0.005$). Sustained viral response rate at 3–6-month post-therapy was similar in the higher (50%) and lower (57.6%) religiosity cohorts ($P = 0.580$; $n = 55$). Logistic regression modeling revealed that males having higher religiosity gave

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greater odds of SVR than those with lower religiosity (OR 21.3; 95% CI 1.1–403.9). The level of religiosity did not affect the decision to begin treatment for chronic HCV infection and was not associated with a better treatment outcome. A higher level of religiosity was associated with less depression among patients.

Keywords Religiosity · Religion · Hepatitis C virus · HCV · SF-36

Introduction

Medical treatment for chronic hepatitis C virus (HCV) infection is still unsatisfactory (Hoofnagle and Seeff 2006; Manns et al. 2006). The best current therapy, pegylated interferon in combination with ribavirin, achieves a sustained viral response (SVR) in only 54–63% of patients (Manns et al. 2001; Fried et al. 2002; Hadziyannis et al. 2004). Both viral and patient factors have been found to affect treatment outcomes (Hoofnagle and Seeff 2006; Manns et al. 2006). Viral factors, which have been associated with a poorer treatment response, include genotype 1 and viral load greater than 2 million copies/ml (Manns et al. 2001; Fried et al. 2002). The patient-related factors associated with a poorer response to therapy include failure of prior treatment, cirrhosis, African-American race, age over 40 years, male sex, and increased weight (Hoofnagle and Seeff 2006; Manns et al. 2001, 2006; Fried et al. 2002; Hadziyannis et al. 2004). In addition, psychiatric symptoms, personal problems, and a variety of social factors have been associated with reduced rates of viral clearance, possibly mediated through poor compliance (Hoofnagle and Seeff 2006; Kraus and Schafer 2001; McHutchinson et al. 2002).

Studies in other diseases have shown that patients' religious beliefs and practices may be associated with improved mental health (less depression, anxiety, substance abuse; greater well-being, hope, optimism, social support, and marital stability) (Koenig 2004) and mortality (Hummer et al. 2004; Powell et al. 2003). Some have identified improvements in physical health related to increased religiosity [less physical disability (Idler and Kasl 1997), improved blood pressure control (Koenig et al. 1998), and immune function (Koenig et al. 1997)], but these are more controversial (Powell et al. 2003). Religion may have an impact on quality of life in serious chronic illnesses, such as cancer and HIV infection (Weaver and Flannelly 2004; Pargament et al. 2004). The role of religiosity in the outcome of treatment for chronic hepatitis C infection has not been investigated. We hypothesized that increased religiosity may increase compliance, decrease emotional side effects, and increase rates of SVR in patients undergoing therapy for chronic HCV.

Methods

Patient Selection

This was a prospective, observational, blinded cohort study. Patients with HCV infection were identified in the outpatient gastroenterology clinic at the Ben Taub General Hospital, in Houston, Texas. Ben Taub General Hospital (BTGH), a 647 licensed-bed inpatient and outpatient care facility, is one of two tertiary care facilities in the Harris County Hospital District (HCHD). The Ben Taub Hospital had approximately 23,000 admissions and 143,000 specialty clinic visits yearly from 1992 through 2001. All patients in this study had been referred for assessment and treatment of known HCV infection (confirmed by PCR).

Exclusion criteria included the following factors: age under 18 years, human immunodeficiency virus infection, hepatitis B virus co-infection, and prior treatment for HCV. The study involved the following three assessments to which the patients gave informed consent: (1) A detailed multiple-choice questionnaire regarding personal religious views and practices was answered privately in the clinic. A research assistant checked the questionnaires for legibility and completeness. (2) Current and subsequent medical records were reviewed for baseline demographic, clinical, and laboratory data regarding HCV assessment and treatment. (3) The medical records were later reviewed for longitudinal data regarding the decisions about treatment. All aspects of care were routine without any special modifications for the study or for study patients. No aspect of the HCV evaluation or treatment was influenced by participation in the study or by the results of the questionnaires. Clinic physicians explained to each patient the risks and benefits of treatment for HCV. The final decision regarding treatment was made by patients and doctors without reference to the study. None of the clinic personnel had access to the information on the questionnaires or were directly informed about patients' participation in the study. The results of the questionnaires were not extracted or evaluated until after all patients had concluded treatment. After treatment was completed, the records were reviewed for data regarding compliance, toxicity, and efficacy of treatment. Clinic charts have free text areas for physicians to record history and physical findings. These were searched for any record of side effects, including fatigue, fever, arthralgias, myalgias, sleep disturbance, and depression. If these were noted in the record, then they were recorded as "present" in the research database. No attempt was made to quantify any side effect. The Baylor College of Medicine Institutional Review Board approved the study protocol.

Questionnaire

The questionnaire consisted of two parts. The first part assessed demographic factors, such as, age, gender, ethnicity, religious affiliation, marital status, educational level, socioeconomic status, primary language, and hepatitis C risk factors. The second part was a modification of the Multidimensional Religiosity/Spirituality Questionnaire first published by the Fetzer Institute in 1999 in response to a growing interest in research into the connections between religiosity/spirituality and health (Fetzer Institute, National Institute on Aging Working Group 2003). The 36 multiple-choice questions evaluate the self-reported importance of religion and spirituality in eight domains: Daily Spiritual Experiences; Values/Beliefs; Forgiveness; Private Religious Practices; Religious and Spiritual Coping; Religious Support; Religious/Spiritual Experience; Organizational Religiousness. The first question assessed the importance of religion: "How much strength and comfort do you get from your faith?" The second question assessed the frequency of religious attendance: "How often do you attend a religious service?" Prior experience with the questionnaire suggested that these two questions have the highest reliability (alpha r of .81 and .70, respectively) (Fetzer Institute, National Institute on Aging Working Group 2003) and may be just as effective as the full questionnaire to identify patients with a higher religiosity profile from those with a lower profile.

Statistical Analysis

Previous studies of the effect of religiosity on physical health have varied in methodology, hypotheses, and results (Hummer et al. 2004; Powell et al. 2003). Positive studies have demonstrated an effect of increased religiosity of varying magnitudes: 35% reduction in

functional impairment in the elderly; a 25% reduction in all-cause mortality; a 15% reduction in cardiovascular mortality; and a 10% reduction in mortality with stressful life events (summarized in reference Powell et al. 2003). Therefore, we hypothesized a 20% improvement in rate of SVR due to higher religiosity (for example, 50% SVR in lower religiosity and 60% SVR in higher religiosity). With an alpha of 0.05 and beta of 0.20, and an expected SVR rate of 50%, the sample size needed was estimated to be 22 in each group. All data analyses were done with Stata (StataCorp 2001) and PASS (Hintze 2004). Without reference to any demographic or clinical data, several strategies were hypothesized to be the best use of the questionnaire data to classify patients according to the intensity of religious importance and practice. These included using only the first two questions, one question from each of the eight domains, or more than one question from each domain. Strategies also included separation of the study patients into two cohorts or a larger number of cohorts. Venn diagrams were used to compare the strategies' effect on individual patient's classification. After a final decision was made regarding the definition of "higher religiosity" and "lower religiosity", patients in the higher religiosity cohort were compared to those in the lower religiosity cohort for both baseline demographics, clinical and laboratory assessment, and follow-up data. Analysis on comparisons consisted of Pearson's chi-squared (or Fisher's exact test) for ordinal outcomes and both the two-sample t test and the Mann–Whitney two-sample statistic for score outcomes (mean and rank, respectively). Independent association of religiosity with viral clearance rate adjusting for demographic factors was assessed by logistic regression modeling. The test statistic used for post-power analysis was a two-sided Z-test with pooled variance.

Results

Questionnaire Evaluation

The 36-question survey began with two questions: How much strength and comfort do you get from your faith? (1—A great deal, 4—None); How often do you attend a religious service? (1—More than once a week, 6—Never). Thirty-eight patients answered "1" to either of these questions, and "1" or "2" to the other question (43.6% of the study group). These were placed in the higher religiosity cohort. The remaining 49 patients (56.3%) were placed in the lower religiosity cohort. Further grouping was done using eight of the thirty-six questions, one from each domain. Ninety-three percent of patients remained in the same cohort as with only the first two questions. Additional subgroups were created and studied based on patients' responses to other questions in the questionnaire. No analysis yielded a different conclusion than when only the first two of the thirty-six questions were utilized; this was consistent with published analyses of the questionnaire (Fetzer Institute, National Institute on Aging Working Group 2003). Therefore, all comparisons are reported based on the assignment of patients using only the first two questions. Table 1 shows that the two religiosity groups were similar in baseline characteristics, with two exceptions: (1) women were more religious than men, and (2) African-Americans were more religious than whites and Hispanics. This is a consistent finding throughout the religiosity and health literature (Koenig 2004). Out of the 87 patients, 82 gave a religious affiliation. The religious affiliations were similar in the higher religiosity and lower religiosity cohorts (Fisher's exact $P = 0.209$): Protestant (79% vs. 65%), Catholic (8% vs. 12%), Orthodox (0% vs. 2%), Other (13% vs. 10%), None (0% vs. 10%), and No Response (0% vs. 1%).

Table 1 Demographics of the HCV-infected patients

	High religiosity	Low religiosity	Total
Patients	38	49	87
Mean age ± SD (range)	49.4 ± 9.1 (31–71)	47.6 ± 8.0 (28–67)	48.3 ± 8.5 (28–71)
Gender*			
Male	10 (26.3%)	24 (50.0%)	34 (39.5%)
Female	28 (73.7%)	24 (50.0%)	52 (60.5%)
Race*			
White	7 (18.9%)	17 (36.2%)	24 (28.6%)
African-American	22 (59.5%)	11 (23.4%)	33 (39.3%)
Hispanic	8 (21.6%)	18 (38.3%)	26 (31.0%)
Other	0 (0%)	1 (2.1%)	1 (1.2%)
Risk factors[a]			
Intravenous drugs	20 (31.8%)	28 (31.8%)	48 (31.8%)
Infected sexual partners	3 (4.8%)	5 (5.7%)	8 (5.3%)
Blood transfusion	14 (22.2%)	16 (18.2%)	30 (19.9%)
Tattoos	15 (23.8%)	24 (27.3%)	39 (25.8%)
Other risk factors	11 (17.5%)	15 (17.2%)	26 (17.2%)
Employment[b]			
Not working	21 (56.8%)	23 (49.0%)	44 (52.4%)
Part-time	5 (13.5%)	8 (17.0%)	13 (15.5%)
Full-time	11 (29.7%)	16 (34.0%)	27 (32.1%)
Language[b]			
English only	28 (77.8%)	32 (69.6%)	60 (73.2%)
Spanish only	2 (5.6%)	1 (2.2%)	3 (3.7%)
English/Spanish	6 (16.7%)	13 (28.3%)	19 (23.2%)
English only	28 (77.8%)	32 (69.6%)	60 (73.2%)
Education[b]			
Less than high school	10 (27.8%)	15 (32.6%)	25 (20.5%)
High school graduate	13 (36.1%)	16 (34.8%)	29 (35.4%)
Some college	11 (30.6%)	9 (19.6%)	20 (24.4%)
College graduate	2 (5.6%)	6 (13.0%)	8 (9.8%)

* Significant association with chi-square analysis (gender: $P = 0.026$; race [all categories]: $P = 0.005$; race [African-American versus non-African-American]: $P = 0.001$)

[a] Several patients had more than one risk factor (no applicable statistical test). Other risk factors include family history, nasal cocaine use

[b] One patient did not categorize gender; three patients did not answer race and employment status; and five reported no language preference or note their educational level

Patient Demographics

Subjects comprising a convenience sample of 89 patients were asked to participate and all agreed. These patients were all of the patients referred to the clinic for treatment of HCV infection during four continuous months. Eighty-seven of the 89 questionnaires were complete. Although no comparison groups were studied, the demographic makeup of this population resembles that of the BTGH gastroenterology clinic and HCHD in general

(Table 1). Fifty-two percent reported they were not working or unemployed. The average income of those employed was $15,500. Fifty percent of those working reported a yearly income below $12,000 (poverty level). Over 45.2% of patients identified more than one risk factor for hepatitis C acquisition; 31.8% had a history of injection drug use; and 19.9% received a blood transfusion prior to 1992.

Treatment

Chart review of the 87 patients with completed questionnaires was begun after all treatment had been completed, 19 months after the first questionnaire had been administered. Decisions for treatment were highly individualized based on severity of liver disease, co-morbidity, and psychosocial factors. Table 2 shows that 75% (65 out of 87) of patients were recommended for treatment with peginterferon and ribavirin. The decision against treatment was reached through close physician-patient interaction. Twenty-two patients were not offered treatment because of poor health (14) or inadequate pre-treatment follow-up visits (5) or normal ALT (3). The co-morbid conditions classified as 'poor health'

Table 2 Treatment of religiosity cohorts

	High religiosity	Low religiosity	Total
Patients	38	49	87
Offered treatment[a]	26 (68.4%)	39 (79.6%)	65 (74.7%)
Accepted treatment[b]	25 (65.8%)	37 (75.5%)	62 (71.3%)
Completed treatment	22 (57.9%)	34 (69.4%)	56 (64.4%)
Treatment	22	34	56
Pre-treatment laboratories (mean + SD)			
ALT (u/l)	66.3 ± 37.7	69.2 ± 50.4	68.1 ± 45.6
Albumin	3.7 ± 0.3	3.8 ± 0.4	3.8 ± 0.3
PT* (s)	12.3 ± 0.6	11.7 ± 0.6	12.0 ± 0.6
Bilirubin mg/dl)	0.67 ± 0.20	0.74 ± 0.38	0.71 ± 0.31
Creatinine (mg/dl)	0.80 ± 0.13	0.83 ± 0.15	0.82 ± 0.14
Depression[c]	1 (4.6%)	13 (38.2%)	14 (25.0%)
Genotypes	22	33	55
Sustained viral response[d,e]	11 (50.0%)	19 (57.6%)	30 (54.5%)
Genotype 1	18 (81.8%)	24 (72.7%)	42 (76.4%)
Sustained viral response	9/18 (50.0%)	10/24 (41.7%)	19/42 (45.2%)
Genotype 2 or 3	4 (18.2%)	9 (27.3%)	13(23.6%)
Sustained viral response	2/4 (50.0%)	9/9 (100%)	11/13 (84.6%)

* Significant mean difference with two-sample t test (PT: $P = 0.0037$, $n = 33$). Significant association with Fisher's exact test (depression: $P = 0.005$, $n = 56$)

[a] Twenty-two patients were not offered treatment because of poor health (14) or inadequate follow-up visits (5) or due to healthy/asymptomatic (3)

[b] Three patients did not accept treatment due to excellent health

[c] Depression reported as a side effect of treatment

[d] Hepatitis C genotype unknown in 1 patient

[e] Sustained viral response (viral clearance) was measured as the absence of HCV viral RNA at 3–6-month post-treatment

included decompensated cirrhosis, anemia, leukopenia, thrombocytopenia, unstable cardiac disease, and neuropsychiatric disease. Patient religiosity was not associated with the decision to recommend treatment (Table 2).

Ninety-five percent (62 out of 65) of patients offered treatment agreed to begin treatment (Table 2). The frequency of initiating treatment did not vary according to religiosity (Table 2). Pre-treatment liver chemistries were similar between both religiosity cohorts. Liver biopsies were performed prior to treatment on only 28 patients. Twenty-one percent (18 out of 87) of all patients were diagnosed with cirrhosis at the time of this study; histological confirmation was available for 50% of these patients. Ten cirrhotic patients were offered treatment. The frequency of cirrhosis (suspected or confirmed) was similar in both religiosity cohorts (data not shown). Table 2 shows that 76% (42 out of 55) of the patients who were treated were infected with HCV genotype 1; the remainder of patients were genotype 2 or 3 (13 out of 55, 24%). The genotype was unknown for one patient in the lower religiosity cohort. The distribution of genotypes in the higher religiosity cohort was skewed in favor of genotype 1 (18 out of 22, 81.8%) compared to the lower religiosity cohort (24 out of 33, 72.7%) ($P > 0.10$).

All treatment was with peginterferon alpha 2b (180 micrograms subcutaneously every week) and ribavirin (1,200 mg daily in two doses if over 175 lbs; 1,000 mg daily in two doses if less than 175 lbs). Treatment duration was 12 months for genotype 1, and 6 months for genotypes 2 and 3. Ninety percent of patients (56 out of 62) who initiated therapy completed the full course. Religiosity did not affect the ability or willingness to complete therapy. Reasons for terminating treatment included poor attendance at clinic and medication side effects. Adverse events were equal in both religiosity cohorts. Among 56 treated patients, the higher religiosity cohort reported a significantly decreased incidence of depression as a side effect of therapy (4.6% vs. 38.2%, $P = 0.005$).

Of those who completed therapy, 55.4% (30 out of 55) had negative HCV PCR 3–6 months (sustained viral response, SVR) after the completion of therapy. The frequency of SVR was similar in the higher religiosity group (11 out of 22; 50.0%) and the lower religiosity group (19 out of 33; 57.6%) (Table 2). As expected, there was a positive relationship between HCV genotypes and viral clearance. The SVR in treated patients with genotype 1 was 45.2% (19 out of 42), but 84.6% (11 out of 13) in patients with genotypes 2 and 3. Since there was an unequal distribution of genotypes between the higher and lower religiosity cohorts, results of treatment were analyzed according to genotype in the two groups. The viral clearance rate for genotype 1 was 50% in the higher religiosity group (9 out of 18) and 41.7% in the lower religiosity group (10 out of 24) ($P > .10$). Specific to genotype 1, with sample sizes 18 and 24, the post-power analysis revealed only an 11% chance to detect a difference between the proportions of 0.10. The viral clearance for genotype 2 and 3 was 50% for the higher religiosity group (2 out of 4) and 100% for the lower religiosity group (9 out of 9) ($P > .10$).

Response to treatment did not vary by ethnicity. Of the 56 treated patients, 12 were white (8 with SVR; 67%), 21 were Hispanic (11 with SVR; 52%), and 20 were African-American (10 with SVR; 50%).

As was noted above, there was a disproportion of gender and race between the two religiosity cohorts. A significantly larger percentage of females (74%) and African-Americans (59%) occurred in the higher religiosity cohort when compared to females (50%) and African-Americans (24%) in the lower religiosity cohort (gender $P = 0.019$, race $P = 0.015$). Sixty percentage of the males in the higher religiosity group were African-American while 28% of the males in the lower religiosity group were African-American ($P = 0.181$). Fifty-six percentage of the females in the higher religiosity group

were African-American while 21% in lower religiosity group were African-American ($P = 0.052$).

Logistic regression modeling was used to determine the effect of religiosity on SVR by taking into account the disproportion of gender and race between the cohorts. Genotype was also considered in the model due to the obvious effect of genotype on frequency of SVR. Each of the possible two-way interactions was evaluated for the model. Only one of the interactions, religiosity grouping with gender, added considerable importance to the model (Likelihood Ratio Test $P = 0.0276$). The results of fitting the final model indicated that patients with genotype 2 or 3 have an almost eightfold chance of eradication compared with patients whose genotype was 1 (OR 7.9; 95% CI 1.4–46.2). Gender and race were not strong confounders ($P = 0.439$, 0.772, respectively) but contributed to evidence of the interaction (religiosity grouping with gender) as an effect modifier ($P = 0.041$). Further inspection of the interaction revealed that for males, not females, having higher religiosity gave greater odds of eradication compared with having lower religiosity (OR 21.3; 95% CI 1.1–403.9).

Discussion

Outcomes related to treatment of chronic HCV infection are influenced by many clinical variables including patient age, severity of liver disease, co-morbid conditions, ethnicity, and HCV genotype (Hoofnagle and Seeff 2006; Manns et al. 2006; Fried et al. 2002). Our study tried to determine how patient-reported religiosity affected treatment and outcomes of chronic HCV infection. The three questions we aimed to answer were the following: Is self-reported religiosity associated with the desire for treatment? Is self-reported religiosity associated with completion or discontinuation of therapy? Is self-reported religiosity associated with frequency of SVR?

Prior studies have shown that religious beliefs influence decisions patients make about complex or difficult therapies (Silvestri et al. 2003). Treatment for HCV is lengthy, complicated, and for some, unpleasant. In addition, SVR occurs in only about half of the patients. Curlin and Roach found that patients most often refuse medical recommendations for religious reasons when the medical situation is unclear or the treatment offers only moderate possibilities of benefit (Curlin and Roach 2005). In our study, we could not demonstrate a statistically significant association between religiosity and the decisions to accept or complete therapy. One positive finding of our study was that the proportion of patients reporting depression at least once during treatment was much less in the higher religiosity group (4.6%) than the lower (38.2%). Some prior studies have found a positive association between religiosity and mental health: less depression, anxiety, substance abuse; greater well-being, hope, optimism, social support, and marital stability (Koenig 2004; Wink et al. 2005). Religion has been shown to have an important role in patients' coping with numerous chronic and severe diseases (Koenig 2002), including cancer (Canada et al. 2006; Tarakeshwar et al. 2006) and HIV infection (Cotton et al. 2006; Szaflarski et al. 2006). In a meta-analysis of 49 empirical studies (including stress due to cancer, aging, hospitalization, and waiting to see a doctor), spiritual and religious coping resources were associated with important psychological benefits (Ano and Vasconcelles 2005). We did not design the study so that depression severity could be compared between the two groups. We could not demonstrate that the lower frequency of depression in the higher religiosity group definitely affected other health outcomes in our study patients. Specifically, compliance with therapy and continuation with therapy until completion were the same in both religiosity groups.

As expected, our study demonstrated that patients with HCV genotype 1 infection have a much lower rate of SVR (45%) than those with genotype 2 and 3 (85%). The fact that HCV genotypes were unequally distributed between the religiosity groups complicates interpretation of the data. Since the numbers of genotype 2 and 3 infections were small, the influence of religiosity on SVR rate can be assessed by looking at genotype 1 infections alone. SVR occurred in 50% (9/18) of patients in the higher religiosity group and 42% (10/24) of the lower religiosity group. This difference approximates the 20% increase in SVR among those of higher religiosity, which we hypothesized before the study. This difference was not found to be statistically significant. The subgroup analysis of only genotype 1 patients limited the power to detect a 10% difference to 11%.

Our study demonstrated some well-known associations between ethnicity, gender, and religiosity (Koenig 2004). The higher religiosity group had proportionately more females (74%) and African-Americans (59%) than the lower religiosity group (50 and 23%, respectively). Since we were interested in the association between religiosity and SVR, logistic regression modeling was used to isolate the influence of ethnicity and gender and genotype from the influence of religiosity. Genotype was the most important influence on frequency of SVR. The model suggested that gender made some contribution to the difference in SVR between the religiosity groups. Higher religiosity was associated with higher frequency of SVR for males only, with an odds ratio of 21.3 [CI 1.1, 403.9]; however, the very wide confidence interval implies caution with this result.

Neither patient acceptance of the recommendation for treatment, nor patient compliance with treatment varied with religiosity. Only three patients failed to take a physician's strong recommendation for treatment because of perceived low benefit when compared to current good health. These patients were split between the higher religiosity (1) and lower religiosity (2) groups. Only six patients who began treatment failed to complete the full course. These were equally split between the religiosity groups. The excellent compliance we observed may be due to the process of referral. There are delays and many hurdles that must be overcome to get into this specific gastroenterology clinic. Patients who finally see a physician and undergo evaluation usually are highly motivated. This alone may account for the lack of influence of other factors, such as religiosity.

The response to treatment in our group of patients (45% SVR with genotype 1; 85% SVR with genotypes 2 and 3) was comparable to that reported in three large randomized clinical trials (42–53% SVR with genotype 1; 75–80% with genotype 2 and 3) (Manns et al. 2001; Fried et al. 2002; Hadziyannis et al. 2004). These multicenter trials were composed of predominantly white patients (only 3–6% African-Americans). Our patients were ethnically diverse (39% African-American) and from low socioeconomic backgrounds (Table 2). In other studies, African-Americans have shown a poorer response to combination therapy with peginterferon and ribavirin (Jeffers et al. 2004; Muir et al. 2004; Pyrsopoulos and Jeffers 2007). In three trials with 78 (Jeffers et al. 2004), 100 (Muir et al. 2004), and 200 (Pyrsopoulos and Jeffers 2007) African-Americans with genotype 1, SVR of 26, 23, and 28%, respectively, was achieved. This compared to SVR in Non-Hispanic whites of 39, 66, and 52%, respectively. In our study, 47% of African-Americans with genotype 1 obtained an SVR. We do not know why our study showed such a high SVR rate for African-Americans. African-Americans are reported to have a higher level of religious commitment and participation than other races (Koenig 2004). Our study supported the association between African-American race with increased religiosity (Table 2). Even though there was a suggestion that males of high religiosity had higher SVR than males of lower religiosity, we could not conclusively demonstrate that religiosity was associated with SVR for the entire group.

As in most other studies exploring the role of religiosity and spirituality in health, we assigned patients to a higher religiosity and lower religiosity group according to the results of a self-administered questionnaire (Fetzer Institute, National Institute on Aging Working Group 2003). The identifying terminology ("higher religiosity" versus "lower religiosity") is imprecise and may be misleading. Many published surveys indicate that 90% of American patients are religious to some extent (Koenig et al. 2004). Ninety percent of patients use religion to cope with illness, and 40% say that it is the most important method of coping (Koenig 2004). According to our questionnaires, religion played a role in most of our patients' lives. Only 10% of the patients in our study indicated absolutely no regard for spirituality or religiosity. Comparing the outcomes of these 10% with the most religious showed no difference in treatment outcomes (data not shown).

Studies on the relationship between religion and health can have several methodological problems (Flannelly et al. 2004). Our study was a prospective cohort study specifically designed to show the effect of religiosity on HCV evaluation and treatment. This is a strong study design for the assessment of the association of religion and health (Flannelly et al. 2004). Cohorts were determined through a self-reported questionnaire, "an essential element of research on religion and health" (Flannelly et al. 2004). The questionnaire used has been shown to be reliable and valid in prior studies (Fetzer Institute, National Institute on Aging Working Group 2003). Self-reported attendance at religious services is the question that has demonstrated the most robust association between religion and health (Powell et al. 2003). We may have missed an effect of religiosity for several reasons. First, we did not achieve a sample size of genotype 1 patients large enough to rule out a type 2 error. However, the sample size was large enough to demonstrate the well-known associations between religion, gender, and race. Second, almost the entire group was religious to some degree. Therefore, the effect of differences in religiosity within the group may not be able to be discerned. Studies that have demonstrated a 25% reduction in mortality with attendance at religious services have shown this effect with attendance of as little as once per month (Hummer et al. 2004; Powell et al. 2003). Sixty-six percent of our patients who completed the study had attendance at least that frequently. Third, the study sample was not randomly selected. The need for random sampling, however, is not great when studying individuals with specific health conditions (Flannelly et al. 2004).

The literature of religiosity/spirituality and health has been the subject of several reviews (Koenig et al. 2004; Modjarrad 2004) and critiques (Sloan and Bagiella 2002; Yeager et al. 2006). The results of this study should not be viewed as belittling the effect of patient religiosity on important outcomes of disease. Although most patients showed deep appreciation for being asked about their religious beliefs and practices, the assessment of religiosity was not integrated into patient care. In our study, no attempt was made to incorporate patients' religious views into the doctor-patient relationship. Apart from administering the questionnaire, no systematic attempt was made to validate or encourage patients' religious beliefs. No attempt was made to assess unmet spiritual needs or use the patients' spirituality as an avenue of connection, comfort, or healing. The study did not attempt to mimic or document the optimum doctor-patient interaction regarding spirituality or religiosity. That being said, our study is compatible with the notion that higher levels of patient-reported religiosity may influence the frequency of depression and SVR in some patients undergoing treatment of hepatitis C infection. Further studies would have to be performed to substantiate this conclusion.

Conclusions

The level of religiosity did not independently affect a patients' decision for treatment of HCV, nor frequency of sustained viral response post-treatment. Higher level of religiosity was more frequent in African-Americans and females and associated with a decreased incidence of depression.

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