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Antiviral Completion Rates and Sustained Viral Response in Hepatitis C Patients With and Without Preexisting Major Depressive Disorder

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Abstract

Background—Despite evidence suggesting that the majority of patients with hepatitis C virus (HCV) have psychiatric and substance use disorders, patients with these comorbidities have historically been excluded from antiviral therapy for HCV.

Objective—The authors compared antiviral completion and sustained virologic response (SVR) rates between hepatitis C (HCV) patients with versus those without preexisting major depressive disorder (MDD).

Method—The authors performed a chart review of HCV patients (30 with MDD and 25 control subjects) who attended an optional HCV education class and signed informed consent allowing collection of clinical data.

Results—The MDD group had completion and SVR rates similar to those of control subjects. Neuropsychiatric side effects and reasons for discontinuation of treatment were not different between groups.

Conclusion—Patients with MDD can be safely and effectively treated with antiviral therapy.

Antiviral treatment of patients with hepatitis C (HCV) and comorbid psychiatric illnesses has been the topic of much debate and controversy. Despite evidence suggesting that the majority of patients with HCV have psychiatric and substance use disorders (SUD), patients with these comorbidities have historically been excluded from antiviral therapy for HCV.^{1–6} In particular, healthcare providers have been reluctant to begin antiviral treatment in HCV patients with comorbid major depressive disorder (MDD), even if the MDD is in remission as a result of antidepressant treatment or the MDD episode was in the remote past.⁷

The reasons for excluding HCV patients with comorbid MDD are many and varied, but a primary justification has been the common occurrence of interferon-induced depression. Interferon (IFN)-alpha (including IFN-alpha, and pegylated IFN-alpha_{2a} and alpha_{2b}), in combination with ribavirin, is generally accepted as the treatment of choice for HCV.^{8–10}

However, IFN-based treatments are associated with various side effects; among the most common are neuropsychiatric side effects, in particular, depression, which can result in dose-reduction or antiviral treatment discontinuation.¹¹⁻¹³ Various studies have shown that approximately 20%–30% of patients will develop IFN-induced depression during the course of antiviral treatment.^{8,9,12-14} Because suicidal ideation, suicide attempts, and suicides are a consequence of MDD, particularly if untreated, providers may be reluctant to worsen depressive symptoms and thereby increase the risk of suicide.

The initial treatment guidelines for HCV cautioned against providing antiviral therapy for patients with comorbid psychiatric illnesses.¹⁵ However, there is little evidence to suggest that patients with psychiatric or SUD comorbidity are at higher risk for serious adverse events. Several studies have reported that patients with various psychiatric comorbidities, including schizophrenia, bipolar disorder, MDD, anxiety disorders, and active SUDs (including intravenous drug use) can undergo antiviral therapy and achieve sustained viral response (SVR).^{14,16,17} However, these studies were limited by the lack of a nonpsychiatrically-ill comparison group. Other studies that compared the course of antiviral treatment in patients with and those without psychiatric comorbidity have found no differences between groups in serious adverse psychiatric events; however, they did not specifically address completion rates or SVR.^{18,19} One study did compare treatment and response rates in patients without and those with various active psychiatric and/or substance use disorders and found completion of therapy and SVR did not differ significantly between groups.²⁰ Furthermore, patients who develop IFN-induced depression can be successfully treated with antidepressant medications and remain on antiviral therapy.^{12,21-23} Despite these studies, there have been no published reports of patients with preexisting and active MDD stabilized on antidepressants who have received antiviral therapy. Furthermore no studies have specifically compared completion and response rates of HCV patients with MDD to those who do not have MDD and were not on antidepressants before starting antiviral therapy.

The 2002 NIH Consensus Conference Statement on treatment of chronic hepatitis C revised the original 1998 treatment guidelines to be more inclusive and recommended that both clinical and research efforts be made to increase the availability of hepatitis C treatment to patients who were previously ineligible because of comorbid psychiatric illness and SUD.²⁴ The statement specifically recommended that there be research on patients with comorbid MDD in order to inform and guide antiviral therapy in these patients. The purpose of our study was to compare antiviral completion and sustained virologic response (SVR) rates between hepatitis C patients with versus those without preexisting major depressive disorder (MDD).

METHOD

Study participants were recruited from among all patients who attended an optional one-time Living with Hepatitis C education class conducted through the Northwest Hepatitis C Resource Center at the Portland VA Medical Center and signed informed consent (approved by the Portland VAMC Institutional Review Board) to allow data extraction from their electronic medical records. Patients who attended this class were screened for psychiatric and substance use disorders (SUDs). As part of our integrated-care model for treatment of patients with HCV, patients with comorbid psychiatric and SUDs were referred to mental health care providers who followed them through the course of antiviral therapy.²⁵ A total of 150 patients were treated with antiviral therapy for HCV between January 2002 and August 2005. Of these, 72 patients attended the education class and signed informed consent to allow collection of clinical data from the electronic medical record.

A patient was considered to have an MDD diagnosis if the patient's medical record included a DSM-IV-TR code for Major Depressive Disorder (Codes 296.2 or 296.3). Patients were

divided into two groups on the basis of the following criteria: 1) MDD group: a diagnosis of MDD within the 12-month period before starting antiviral therapy and antidepressant treatment within a 3-month period before starting antiviral therapy (N=38). Of the 38 patients in the MDD group, 21% (8/38) were excluded from further analysis for the following reasons: 1 patient was post-liver transplant; 1 patient was enrolled in a placebo-controlled prophylactic antidepressant study; 2 patients were taking only a low dose of trazodone for sedation and no other antidepressant; 1 patient met criteria for dysthymia but not MDD; and 3 patients met criteria for bipolar disorder but not MDD. The final sample size for the MDD group was 30. 2) Control group: no lifetime diagnosis of MDD before starting antiviral treatment and never treated with an antidepressant before starting antiviral treatment (N=34). Of the 34 patients in the control group, 26% (9/34) were excluded from further analysis for the following reasons: 2 patients were post-liver transplant; and 7 patients were enrolled in a placebo-controlled antidepressant prophylactic study. The final sample size for the control group was 25.

We collected data on demographic characteristics, psychiatric history, HCV laboratory results (including HCV genotype, early viral response [EVR], end-of-treatment response [ETR], and sustained viral response [SVR]), prescriptions (IFN, ribavirin, and psychotropic medications), emergency room visits and inpatient hospitalizations during IFN therapy, and clinic attendance. After an initial, computer-generated selection of patients for inclusion in the study, each patient's electronic medical record was reviewed manually to collect pertinent demographic, clinical, and laboratory data, as well as to confirm the psychiatric diagnoses.

All data were compiled into a local database, where they were organized and exported to SPSS 11.5 software for analysis. The categorical data for the two groups were compared by chi-square and Fisher's exact tests, and linear data were evaluated with between-groups analysis of variance, with p values less than 0.05 in two-tailed comparisons considered statistically significant. With a total sample size of 55, the power of this analysis for each dependent variable is 0.80 for effect sizes of approximately 0.40.²⁶ This effect size is comparable to a clinically significant effect.

RESULTS

Within the total sample (N=55), patients were predominately male, middle-aged, and Caucasian. There were no significant differences between groups in gender, age, or ethnicity. Significantly more patients in the MDD group than in the control group had comorbid posttraumatic stress disorder (MDD: 53% versus control subjects: 4%; $p < 0.001$), anxiety disorders (MDD: 30% versus controls: 8%; $p < 0.05$); alcohol use disorders (MDD: 43% versus controls: 8%; $p < 0.001$) or any SUDs (MDD: 37% versus controls: 8%; $p < 0.01$; Table 1). Also, the MDD group had significantly higher baseline scores on a self-report measure of depressive symptomatology than the control group (16.6 versus 7.5; $p < 0.001$). The antidepressants that MDD patients were prescribed before starting antiviral therapy are listed in Table 2; 60% of patients with MDD (18/30) were prescribed more than one antidepressant, and 40% were prescribed antidepressant mono-therapy.

The course of antiviral therapy is listed in Table 3. The two groups differed in type of antiviral therapy prescribed; 97% of the MDD group and 72% of the control group received pegylated IFN- α_{2b} and ribavirin (Table 3). There were no significant differences between groups in the percentage of patients with genotype 1 (MDD: 50% versus controls: 52%) and the mean length of treatment for patients with genotype 1 (MDD: 26.5 weeks versus controls: 28.9 weeks). However the mean length of treatment for the control group with genotype 2 was significantly longer than for the MDD group with genotype 2 (MDD: 21.5 weeks versus controls: 26.0 weeks; $p < 0.05$). There were no significant differences between the two groups in the number of patients with at least one emergency room visit during antiviral therapy (MDD:

30% versus controls: 16%). Only one MDD patient had an emergency room visit for psychiatric reasons. Inpatient hospitalizations were uncommon, and there were no inpatient hospitalizations related to psychiatric illness.

Treatment outcomes are listed in Table 4. There was no significant group difference in the percentage of patients who terminated antiviral therapy early for any reason (MDD: 40% versus controls: 32%). Thirteen percent of MDD patients were nonresponders, as compared with 8% of controls; 23% of MDD patients terminated antiviral therapy because of side effects, as compared with 12% of controls; and 3% of MDD patients had a serious adverse event, as compared with 12% of controls. There was no significant group difference in EVR after 12 weeks of antiviral therapy (MDD: 57% versus controls: 80%), in ETR (MDD: 60% versus controls: 60%) or in SVR (MDD: 50% versus controls: 52%). Among patients with genotype 1, 33% of the MDD group (5/15) versus 30% of the control group (4/13) achieved SVR. Among patients with genotype 2, 66% (10/15) of MDD patients versus 75% (9/12) of controls achieved SVR.

DISCUSSION

The results of our retrospective chart review suggest that patients with MDD diagnosed and treated with antidepressants before starting antiviral therapy were no more likely than patients without MDD to have side effects, adverse events, emergency room visits, or inpatient hospitalizations during the course of antiviral therapy. Furthermore, patients with MDD were no more likely than controls to have psychiatric complications, and no patients in this study attempted suicide during antiviral therapy. Although 40% of patients with MDD terminated treatment early, as compared with 32% of the controls, this was not a statistically significant difference. Overall SVR rates were 50% for the MDD group, which was virtually the same as the control group (52%). These results suggest that HCV patients with current MDD treated with antidepressants can safely and effectively receive antiviral therapy.

Depression is a common psychiatric comorbidity among patients with HCV. A retrospective study by el-Serag et al.⁴ showed that among veterans with HCV hospitalized in VA facilities between 1992 and 1999 who had a substance use disorder, 85% had been diagnosed with a depressive disorder. In a more recent prospective study, conducted by the Hepatitis C Resource Center (HCRC) at the Portland VA Medical Center (PVAMC), in which HCV patients were screened for psychiatric illness when they attended their initial hepatology appointment, 81% screened positive for depression, and between 35% and 40% had a Beck Depression Inventory score over 20, suggesting moderate-to-severe depression.⁵ Because of the high risk of IFN-induced depression, patients with HCV and comorbid depression have been excluded historically from antiviral therapy.

Limitations of our study include the almost all-male sample, their older age, being primarily Caucasian, and composed entirely of U.S. veterans. Thus, our findings may not be generalizable to other, nonveteran, HCV clinic populations. Also, we examined the medical records of 72 of the 150 HCV patients who were treated with antiviral therapy during this study time period; they may not be representative of all HCV patients who receive antiviral therapy. The sample size is relatively small, thereby limiting power to detect significant differences, and the design is a retrospective chart review. Patients in this study attended an optional, one-session HCV education class and signed informed consent; therefore, they may represent a particularly compliant group. Furthermore, MDD diagnoses were made on the basis of chart review, and patients were not assessed using structured psychiatric diagnostic interviews. Finally, the Portland VA Medical Center is the site of the Northwest Hepatitis C Resource Center, and it uses an integrated and multidisciplinary model of care that involves mental health care

providers in the management of antiviral therapy. Many clinics that treat patients with HCV may not have a similar model of care or may not have access to mental health care providers.

In summary, this study is, to our knowledge, the first to compare side effects, adverse events, completion, and SVR rates between patients with current MDD treated with an antidepressant and a nondepressed control group. The findings suggest that patients with MDD can undergo antiviral therapy and achieve SVR at rates similar to those of nondepressed patients, provided that an integrated care model with mental health care providers is utilized to manage patients during antiviral therapy. Studies such as this will ultimately increase the availability of antiviral therapy to a significant proportion of patients with HCV: those with comorbid depression and, more generally, those with comorbid psychiatric illness.

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TABLE 1

Demographic Characteristics and Psychiatric History

	MDD Group (N=30)	Control Subjects (N=25)	Statistic [df]	p
Age, years, mean (SD)	52.1 (5.2)	51.2 (7.1)	$F [1, 54]=0.27$	NS
Race/ethnicity			$\chi^2 [2] = 1.64$	NS
Not reported	3 (10.0%)	5 (20.0%)		
Caucasian	26 (86.7%)	19 (76.0%)		
Non-Caucasian	1 (3.3%)	1 (4.0%)		
Gender			$\chi^2 [1]=0.85$	NS
Male	29 (96.7%)	25 (100%)		
Female	1 (3.3%)	0		
Virus genotype			$\chi^2 [1]=0.02$	NS
1	15 (50.0%)	13 (52.0%)		
2/3	15 (50.0%)	12 (48.0%)		
Psychiatric history				
History of alcohol use disorder	13 (43.3%)	2 (8.0%)	$\chi^2 [1] = 8.58$	0.003
History of substance use disorder	11 (36.7%)	2 (8.0%)	$\chi^2 [1] = 6.21$	0.01
History of anxiety disorder	9 (30.0%)	2 (8.0%)	$\chi^2 [1]=4.13$	0.04
History of PTSD	16 (53.3%)	1 (4.0%)	$\chi^2 [1] = 15.54$	<0.001
History of dysthymic disorder	4 (13.3%)	1 (4.0%)	$\chi^2 [1] = 1.44$	NS
History of personality disorder	3 (10.0%)	1 (4.0%)	$\chi^2 [1]=0.73$	NS
Baseline BDI-II score	16.6 (9.0)	7.5 (7.5)	$F [1, 52] = 15.04$	<0.001

MDD: major depressive disorder; SD: standard deviation; PTSD: posttraumatic stress disorder; BDI-II: Beck Depression Inventory, 2nd Edition. (Baseline BDI-II inventories were completed by patients at the time of interferon treatment initiation.)

TABLE 2

Antidepressants Prescribed 3 Months Before Start of Antiviral Therapy

	MDD Group (N=30)		Control Group (N=25)	
	N	%	N	%
Antidepressant				
Amitriptyline	1	3%	None	
Bupropion	4	13%		
Citalopram	7	23%		
Doxepin	1	3%		
Fluoxetine	4	13%		
Imipramine	1	3%		
Mirtazapine	1	3%		
Nefazodone	1	3%		
Nortriptyline	2	7%		
Paroxetine	4	13%		
Sertraline	3	10%		
Trazodone	17	57%		
Venlafaxine	5	17%		

MDD: major depressive disorder; 60% of patients in the MDD group were prescribed more than one antidepressant medication.

TABLE 3

Course of Antiviral Therapy

	MDD Group (N=30)	Control Group (N=25)	Statistic [df]	p
Type of antiviral therapy				
Pegasys, Ribavirin	29 (96.7%)	18 (72.0%) ^a	$\chi^2 [1] = 6.68$	0.02
Peg-Intron, Ribavirin	1 (3.3%)	6 (24.0%)	$\chi^2 [1] = 5.24$	0.04
Interferon-alpha ₂ , Ribavirin	0	1 (4.0%)	$\chi^2 [1] = 1.22$	NS
Pegasys, no Ribavirin	0	1 (4.0%)	$\chi^2 [1] = 1.22$	NS
Viral genotype			$\chi^2 [1]=0.02$	NS
Type 1	15 (50.0%)	13 (52.0%)		
Type 2 or 3	15 (50.0%)	12 (48.0%)		
Length of treatment				
Genotype 1, mean (SD), range	26.5 (17.6), 2–48 weeks	28.9 (16.9), 5–48 weeks	$F [1, 27]=0.14$	NS
Median	24.1	27.4		
Genotype 2 or 3, mean (SD), range	21.5 (5.9), 4–25 weeks	26.0 (4.8), 21–37 weeks	$F [1, 26]=4.36$	0.05
Median	23.9	23.9		
Emergency Care Unit (ECU) visits				
Patients with ≥ 1 ECU visit during treatment	9 (30.0%)	4 (16.0%)	$\chi^2 [1] = 1.48$	NS
With mental health as primary diagnosis during ECU visit	1 (3.3%)	0	$\chi^2 [1]=0.85$	NS
With SUD as primary diagnosis during ECU visit	1 (3.3%)	0	$\chi^2 [1]=0.85$	NS
Inpatient (IP) stays				
Patients with at least 1 IP stay during treatment	1 (3.3%)	2 (8.0%)	$\chi^2 [1]=0.58$	NS
IP stays with mental health as primary diagnosis	0	0		
IP stays with SUD as primary diagnosis	0	0		
Patient non-compliance with treatment regimen	0	0		

MDD: major depressive disorder; SD: standard deviation; SUD: substance use disorder; NS: not significant.

^aOne patient was on Pegasys and then was switched to Peg-Intron.

TABLE 4

Treatment Outcomes

	MDD Group (N=30)	Control Group (N=25)	Statistic [df]
Terminated treatment early	12 (40.0%)	8 (32.0%)	$\chi^2 [1]=0.38$
Early non-responder	4 (13.3%)	2 (8.0%)	$\chi^2 [1]=0.40$
Unable to tolerate treatment side effects	7 (23.3%)	3 (12.0%)	$\chi^2 [1] = 1.18$
Serious adverse event	1 (3.3%)	3 (12.0%)	$\chi^2 [1] = 1.52$
Patients with early viral response (EVR) at 12 weeks after therapy initiation ^a	17 (56.7%)	20 (80.0%)	$\chi^2 [1] = 3.37$
Patients with end-of-treatment response (ETR) at completion of therapy	18 (60.0%)	15 (60.0%)	$\chi^2 [1]=0.00$
Patients with sustained viral response (SVR) 6 months after completion of therapy	15 (50.0%)	13 (52.0%)	$\chi^2 [1]=0.02$
Genotype 1	5 (33.3%)	4 (30.8%)	$\chi^2 [1]=0.02$
Genotype 2 or 3	10 (66.7%)	9 (75.0%)	$\chi^2 [1]=0.22$

MDD: major depressive disorder. All p values were nonsignificant.

^ap=0.07.