Outcomes of Peginterferon alfa-2a and Ribavirin Combination Therapy in a Resident-Initiated, Multidisciplinary, Hepatitis C Clinic

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Introduction:

Clinical trials have shown that at least 40% of patients with chronic hepatitis C (HCV) are able to achieve sustained virologic response (SVR) with peginterferon-alfa/ribavirin (PegIFN/RBV) therapy along with adequate medical and psychiatric support. Those with a history of mental illness or multiple medical comorbidities are often excluded from clinical trials[1,2]. Hence, SVR is achieved less often in clinical practice. We proposed that an integrated, multidisciplinary approach to PegIFN/RBV therapy would result in SVR rates similar to those of clinical trials in a medically and psychiatrically complex cohort of patients.

Methods:

A pilot Hepatitis C Clinic was established in 2004, staffed by internal medicine residents, an attending gastroenterologist and psychiatrist, and a registered-nurse coordinator. All patients were underinsured/uninsured and underwent treatment for HCV with PegIFN/RBV combination therapy according to evidence-based protocols within the confines of managed-care formularies. Charts were retrospectively abstracted for demographics and baseline characteristics, virologic response, side effects, and reasons for discontinuation or non-initiation of therapy.

Results:

Forty-eight patients were evaluated. None were co-infected with human immunodeficiency virus (HIV). Twenty-two (46%) were not treated, and twenty-six (54%) were treated. Of the patients who were treated, twenty-two (84%) were genotype 1, three (12%) were genotype 2b, and one (3%) was genotype 4a.

Table 1: Demographic data for all patients

Gender	Male 15 (31%) Female 33 (69%)
Average Age	45.0 years
Average Weight of Treated Patients	191.3 lbs.
Baseline Viral Load	> 400,000 IU 29 (60%) < 400,000 IU 16 (33%) Not Available 3 (6%)
Pre-existing Psychiatric Diagnosis	38 (79%)

Table 2: Reasons not to treat with PegIFN/RBV

Personal Choice	6 (27%)
Unstable Psychiatric Illness	6 (27%)
Comorbidities	4 (18%)
Substance Abuse	2 (9%)
Viral Clearance	2 (9%)
Lack of follow up	1 (4%)
Minimal Fibrosis	1 (4%)

Table 3: Outcomes of PegIFN/RBV n=26

Nonresponders (NR)	5 (19%)
Early Viralogic Response (EVR)	13 (50%)
End of Treatment Response (ETR)	12 (46%)
Sustained Viralogic Response (SVR)	8/23 (34%)*
Relapse after ETR	2 (7%)
Dropouts	8 (30%)

* Three patients were omitted from the total number for evaluation of SVR. Two patients had not reached 24 weeks beyond the end of treatment. One patient was lost to follow up.

Table 4: Side Effects

Hyperuricemia	12 (46%)
Fatigue	10 (38%)
Myalgia	8 (31%)
Anemia	8 (31%)
Arthralgia	5 (19%)
Insomnia	5 (19%)
Neutropenia	5 (19%)

Table 5: Reasons for Discontinuation of PegIFN/RBV

Side Effects	6 (23%)
Viralogic Nonresponse	5 (19%)
Psychiatric Side Effects	1 (3%)
Poor Adherence	1 (3%)
Ongoing Substance Abuse	1 (3%)
Incarceration	1 (3%)

Conclusions:

Despite a patient population with mostly genotype 1 HCV and significant medical/psychiatric comorbidities, a similar number of patients achieved ETR/SVR as compared to those in clinical trials[1,2]. These data suggest that an integrative medicine practice can safely and effectively manage PegIFN/RBV therapy and serve as a model to expand access to antiviral therapy for many individuals with chronic HCV. Additionally, by incorporating a dedicated group of internal medicine residents, the pool of capable and willing providers of PegIFN/RBV therapy will be expanded.

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