National Retrospective Hepatitis C Virus (HCV) Treatment-Associated Anemia Study: Key Findings

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Abstract

Nationally representative samples of 100 gastroenterologists (GEs) and 51 infectious disease specialists (IDs) extracted detailed medical history and treatment information from the records of 501 randomly selected patients with HCV-treatment associated anemia. Study data were transmitted to researchers by fax or mail. On average, 10.7 weeks elapsed between the initial HCV treatment and the diagnosis of anemia. It was not possible to determine from the patient records the length of time patients had anemia before being diagnosed. At initial HCV treatment, 98% of the patients had a hemoglobin level that was higher than 11.0 g/dL (mean =13.7 g/dL). By the time that 10.7 weeks to anemia diagnosis had elapsed, the hemoglobin level for 71% of the patients was below 11.0 g/dL (mean =10.3 g/dL). About 7% of the patients who were diagnosed with anemia received no treatment for their anemia. Key HCV treatment-related findings are presented below.

Background and Objectives of Study

Hepatitis C virus (HCV) infection is the most common chronic blood-borne infection in the United States, affecting 1.8% of Americans (CDC report, October 18, 1998, Vol. 47, No. RR-19). Monotherapy with alpha interferon and a combination therapy of alpha interferon and ribivirin are the two approved regimens for the treatment of HCV in the U.S. Either regimen may produce anemia as a side effect. According to a February 2002 NIH report, HCV treatment with ribivirin is associated with **hemolytic** anemia (*Chronic Hepatitis C: Current Disease Management*, February 2003). HCV treatment with interferon, particularly in high doses, may induce **pernicious** anemia because of the drug's immunomodulatory effects (Wilson RA, *J Clin Gastroenterol. 2001:33:426-427).*

The current study was conducted to foster a better understanding of the relationship between HCV treatment and anemia.
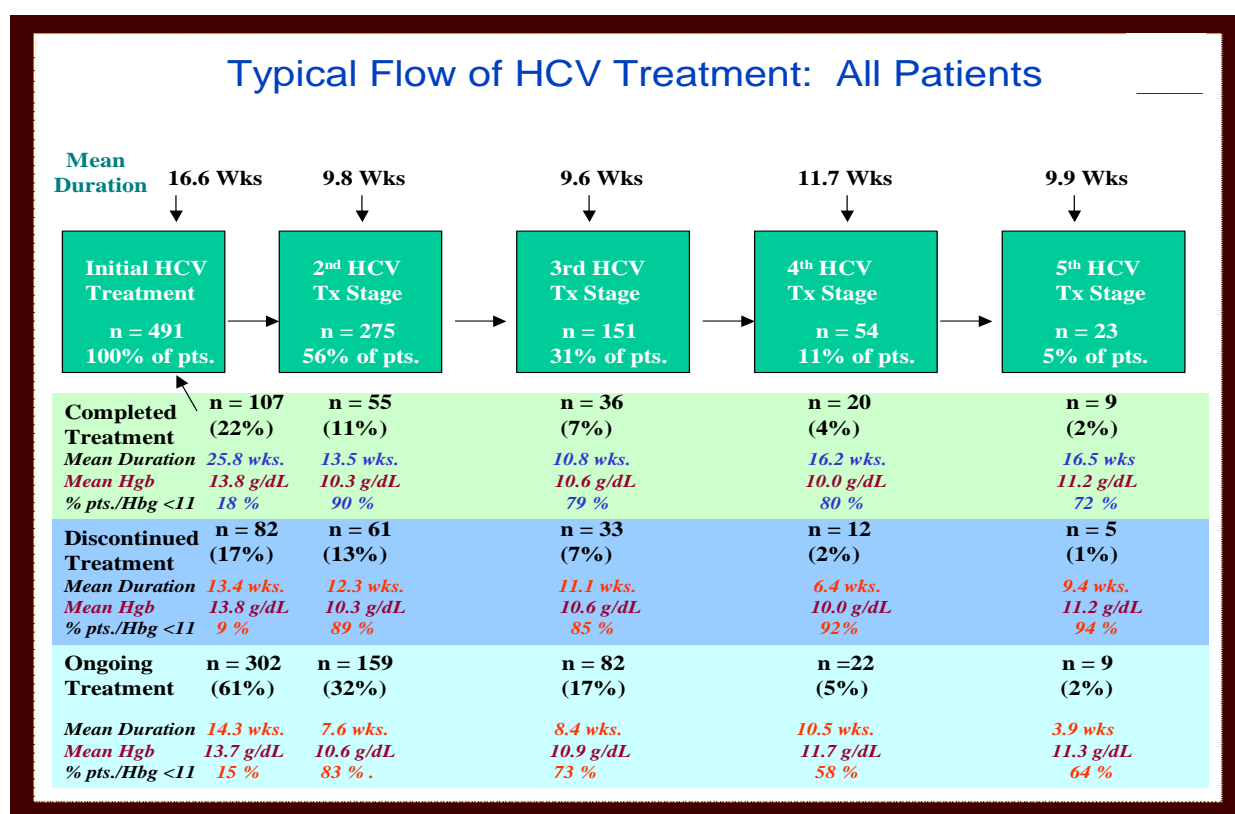
Methodology

Stratified nationally representative samples of 100 gastroenterologists (GEs) and 51 infectious disease specialists (IDs) extracted detailed medical history and treatment information from the records of 501 randomly selected patients with HCV-treatment associated anemia. The last four patients with HCV-treatment associated anemia who were treated by the physician study participant were selected for the study.

Study data were transmitted to researchers by fax or mail. Physician study participants had personally treated at least four patients with HCV treatment-associated anemia during the past six months. Statistical adjustments were made to ensure that each patient represented exactly the corresponding number of patients in the universe of total patients.

Key Findings of Study

- The mean interval between initiation of HCV treatment and the diagnosis of anemia was 10.7 weeks.

- The hemoglobin level for 98% of the patients was above 11.0 g/dL at the time HCV treatment was initiated.

- At initial anemia diagnosis, 84% of females had a hemoglobin level below 11.0 g/dL compared with 61% of males.

- The mean hemoglobin level at the time of anemia diagnosis was 10.3 g/L.

- The mean target hemoglobin level for all patients collectively was 12.5 g/dL.

- More than nine out of ten anemia patients (93%) were treated for anemia.

- Physicians had different standards for females than for males:

    - The mean hemoglobin level defining a person as anemic was:
        - 10.7 g/dL for females
        - 11.4 g/dL for males

    - The mean target hemoglobin level was:
        - 12.0 g/dL for females
        - 12.8 for males

- The mean difference between the hemoglobin level at initial HCV treatment and the target hemoglobin level was 2.5 g/dL.

- **Typical Flow of Hepatitis C Treatment:** Insight into the flow of patients through the HCV treatment process and the duration of treatment at each treatment stage can be gleaned from the figure below. Note that about three-fifths of the patients were still undergoing HCV treatment at the time of the study. HCV treatment was discontinued during the initial treatment phase for 17% of the patients. The most frequently cited reasons for discontinuation were related to "lack of therapeutic efficacy" (36% of reasons). One-third of the reasons were "side effect-related" ("non-anemia side effects" – 17%, "unspecified side effects" – 10%, and severe and persistent anemia – 7%).

Typical Flow of HCV Treatment: All Patients

Mean Duration	16.6 Wks	9.8 Wks	9.6 Wks	11.7 Wks	9.9 Wks
	Initial HCV Treatment n = 491 100% of pts.	2nd HCV Tx Stage n = 275 56% of pts.	3rd HCV Tx Stage n = 151 31% of pts.	4th HCV Tx Stage n = 54 11% of pts.	5th HCV Tx Stage n = 23 5% of pts.
Completed Treatment	n = 107 (22%)	n = 55 (11%)	n = 36 (7%)	n = 20 (4%)	n = 9 (2%)
Mean Duration	*25.8 wks.*	*13.5 wks.*	*10.8 wks.*	*16.2 wks.*	*16.5 wks*
Mean Hgb	*13.8 g/dL*	*10.3 g/dL*	*10.6 g/dL*	*10.0 g/dL*	*11.2 g/dL*
% pts./Hbg <11	*18 %*	*90 %*	*79 %*	*80 %*	*72 %*
Discontinued Treatment	n = 82 (17%)	n = 61 (13%)	n = 33 (7%)	n = 12 (2%)	n = 5 (1%)
Mean Duration	*13.4 wks.*	*12.3 wks.*	*11.1 wks.*	*6.4 wks.*	*9.4 wks.*
Mean Hgb	*13.8 g/dL*	*10.3 g/dL*	*10.6 g/dL*	*10.0 g/dL*	*11.2 g/dL*
% pts./Hbg <11	*9 %*	*89 %*	*85 %*	*92%*	*94 %*
Ongoing Treatment	n = 302 (61%)	n = 159 (32%)	n = 82 (17%)	n =22 (5%)	n = 9 (2%)
Mean Duration	*14.3 wks.*	*7.6 wks.*	*8.4 wks.*	*10.5 wks.*	*3.9 wks*
Mean Hgb	*13.7 g/dL*	*10.6 g/dL*	*10.9 g/dL*	*11.7 g/dL*	*11.3 g/dL*
% pts./Hbg <11	*15 %*	*83 % .*	*73 %*	*58 %*	*64 %*

About the Authors

Thomas Orsagh, Ph.D., is an internationally recognized economist who has made numerous scientific contributions during and after his distinguished academic career. Dr. Orsagh attended the Wharton School and obtained a Ph.D. from the University of Pennsylvania. Dr. Orsagh has served on the faculties of the University of Pennsylvania, Lehigh University, the University of Karlsruhe in Germany, and the University of North Carolina in Chapel Hill. He is a Fulbright Research Scholar, a former editor of the **Southern Economics Journal,** and was a member of a national Presidential Task Force.

Jack R. Gallagher, Ed.D., is a behavioral modeling scientist with more than 25 years of experience in medical and systems research. He is a former member of the University of Virginia School of Medicine faculty and was director of a five-university research consortium. Dr. Gallagher has published many scientific papers, presented at numerous national and international conferences, and has served on the editorial review boards of two national journals. Dr. Gallagher also is author of the book **Changing Behavior: How and Why.**

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