Project ECHO™: Outcomes of Hepatitis C Treatment by Primary Care Providers

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Project ECHO Extension for Community Healthcare Outcomes

Background

An estimated 170 million patients worldwide are chronically infected with the hepatitis C virus (HCV), with 3.2 million in the United States. Fortunately, cure defined as sustained virologic response (SVR) permanently halts the progression of liver disease, reverses fibrosis in many patients and reduces the risk of hepatocellular carcinoma (HCC). However, treatment is complex.

Despite advances in therapy and remarkable improvements in cure rates, very few persons with chronic HCV are receiving treatment. Historically, few primary care clinicians have offered HCV treatment due to lack of training.

The Extension for Community Healthcare Outcomes (ECHO) model was developed at the University of New Mexico Health Sciences Center (UNMHSC) to improve access to care for complex health problems such as HCV infection for underserved populations. Using videoconferencing technology, ECHO trains primary care clinicians providers to treat complex diseases.

Objective

The objectives of this study were to:
1) Improve access to best practice care for HCV infection for minorities and underserved populations
2) Demonstrate the safety and efficacy of the ECHO model-based treatment for HCV in rural communities
3) Compare SVR rate achieved at an Academic Medical Center (AMC) based specialty clinic and ECHO partner sites.

Methods

ECHO Model

Using state-of-the-art telehealth technology, ECHO trains and supports primary care clinicians from underserved areas to develop knowledge and self-efficacy so they can deliver best practice care for complex health conditions like chronic HCV. Community clinicians take part in weekly HCV clinics, called "Knowledge Networks" by joining a videoconference or calling into a teleconference line. The clinicians present their cases to a multidisciplinary team of specialists from the fields of hepatology, infectious diseases, psychiatry, and pharmacy. These case-based discussions are supplemented with short didactic presentations.

Methods (cont.)

Study Population

Inclusion Criteria:
1) Treatment-naïve
2) Evidence of chronic HCV with detectable HCV RNA
3) 18 to 65 years of age
4) Initiation of treatment between September 7, 2004 and August 15, 2008

For exclusion criteria see figure.

Study Design

A prospective cohort study design was used. All patients received standard HCV treatment (per the ECHO clinical protocol) with pegylated interferon at standard doses and weight-based ribavirin. Growth factors were used as clinically indicated.

The study was approved by the UNMHSC Institutional Review Board. A waiver of informed consent was obtained as all patients received standard of care and data collected were considered part of routine care.

End Point

The primary end point was SVR, defined as an undetectable HCV RNA level 24 weeks after the end of treatment.

Assessment of Safety

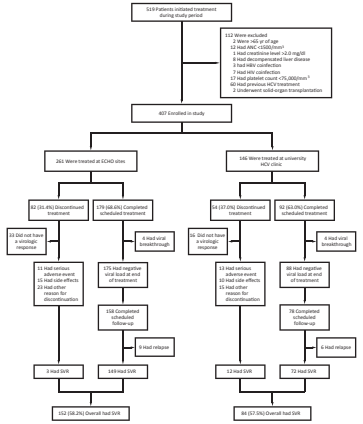
Safety was assessed by laboratory tests and visits on weeks 1,2,4, and monthly thereafter. Serious adverse events were reported and investigated.

Statistical Analysis

Continuous variables are expressed as mean ± SD. Group differences in continuous variables were analyzed by student's t-test and 95% Confidence Interval or the Mann Whitney U-test. P-values < 0.05 were considered statistically significant.

Results

FIGURE - Treatment and Follow-up of Patients



ANC denotes absolute neutrophil count, ECHO Extension for Community Healthcare Outcomes.

Baseline Characteristics of the Patients.*

Characteristic	ECHO Sites (N = 261)	UNM HCV Clinic (N = 146)	P Value
Age — yr	41.9±9.8	45.4±9.8	0.001
Male sex — no. (%)	190 (72.8)	66 (45.2)	<0.001
Race or ethnic group — no. (%)†			
White	244/256 (95.3)	134/146 (91.8)	0.15
American Indian	8/256 (3.1)	3/146 (2.1)	0.53
Black	4/256 (1.6)	3/146 (2.1)	0.72
Asian or Pacific Islander	0	6/146 (4.1)	0.001
Hispanic — no./total no. (%)†‡	156/242 (64.5)	60/145 (41.4)	<0.001
Weight — kg	85.3±15.9	80.3±17.7	0.007
Body-mass index§			
Mean	29.4±5.3	28.1±5.7	0.03
≤24.9 — no./total no. (%)	47/246 (19.1)	45/144 (31.2)	0.006
25.0–29.9 — no./total no. (%)	97/246 (39.4)	54/144 (37.5)	0.71
≥30.0 — no./total no. (%)	102/246 (41.5)	45/144 (31.2)	0.05
ALT — U/liter	103±78	97±73	0.44
APRI score¶	0.935±0.910	0.938±0.847	0.97
Log $_{10}$ viral load	5.92±0.94	5.84±1.01	0.43
HCV genotype 1 — no. (%)	147 (56.3)	83 (56.8)	0.50

* Plus–minus values are means ±SD. ALT denotes alanine aminotransferase.
† Race or ethnic group was determined by the provider.
‡ Data on Hispanic versus non-Hispanic ethnic group were missing for 20 patients.
§ The body-mass index is the weight in kilograms divided by the square of the height in meters.
¶ The aspartate aminotransferase (AST)–platelet ratio index (APRI), which was used to estimate the extent of fibrosis and cirrhosis, is calculated according to the following formula: [(AST level ÷ upper limit of the normal range) ÷ platelet count (10^9 per liter)] × 100. The higher the APRI score, the more likely a patient is to have extensive fibrosis.

Results (cont.)

Sustained Virologic Response According to Genotype and Site of Treatment.*

HCV Genotype	ECHO Sites	UNM HCV Clinic	Difference between ECHO Sites and UNM HCV Clinic	P Value
	no. of patients with response/total no. (%)		percentage points (95% CI)	
All genotypes	152/261 (58.2)	84/146 (57.5)	0.7 (−9.2 to 10.7)	0.89
Genotype 1	73/147 (49.7)	38/83 (45.8)	3.9 (−9.5 to 17.0)	0.57
Genotype 2 or 3	78/112 (69.6)	42/59 (71.2)	−1.5 (−15.2 to 13.3)	0.83

* The rates of sustained virologic response are not reported separately for six patients with genotype 4 or genotype 6.

Serious Adverse Events According to Site of Treatment.

Serious Adverse Event	ECHO Site (N = 261)	UNM HCV Clinic (N = 146)	P Value
	number (percent)		
Any	18 (6.9)	20 (13.7)	0.02
Hematologic disorders	0	2 (1.4)	
Cardiovascular disorders	0	3 (2.1)	
Gastrointestinal and hepatobiliary disorders	7 (2.7)	4 (2.7)	
Infections	3 (1.1)	5 (3.4)	
Psychiatric disorders	3 (1.1)	2 (1.4)	
Other disorders	5 (1.9)	4 (2.7)	
Treatment-related	13 (5.0)	15 (10.3)	
Leading to discontinuation of treatment	11 (4.2)	13 (8.9)	0.05

Conclusion

In this community-based study, we were able to demonstrate high rates of cure for HCV treatment delivered through the ECHO model. The SVR rates in our ECHO cohort were similar to those observed in our study's comparison group treated at the AMC and the rates reported in licensing trials for HCV treatment. Previous community-based treatment studies have failed to replicate the results of licensing trials. In addition, we met our goal of increasing treatment for underserved and minority patients. Our study cohort was predominately Hispanic.

The results of this study demonstrate that the ECHO model is an effective way to treat HCV in rural and underserved communities. ECHO represents a needed change in conventional paradigms of AMCs and specialist care being available only in urban areas. The project demonstrates that technology and inter-disciplinary collaboration can be used to leverage scarce specialty care resources.

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