Should primary care take over chronic HCV treatment?

BY BRUCE JANCIN
REPORTING FROM COLORADO IM

ESTES PARK, COLO. -- Direct-acting antiviral therapy for chronic hepatitis C virus infection has progressed to the point that it's time for primary care physicians to take on the treatment of all affected patients who don't have advanced fibrosis or other complex forms of the disease, Michael Kriss, MD, asserted at a conference on internal medicine sponsored by the University of Colorado.

"It's my strong opinion – and I think the opinion of hepatologists in general and, now, increasingly our professional societies – that any patient with chronic HCV with stage 2 fibrosis or less should be treated by their primary care provider," declared Dr. Kriss, a gastroenterologist at the university.

Referral to a specialist should be reserved for those more complex patients with stage 3 or 4 fibrosis, hepatocellular carcinoma, coinfection with HIV or hepatitis B virus, end-stage organ disease being considered for transplantation, prior exposure to an NS5A inhibitor, or concomitant secondary liver disease, such as nonalcoholic steatohepatitis, he continued.

Treatment of chronic HCV now entails just 8-12 weeks of DAA therapy, with a cure rate greater than 95% and almost no side effects. The costs have come down, too, because of increased competition.

The epidemiology of HCV infection is changing. The opioid epidemic is driving an increased incidence of acute infection, with nearly 34,000 new cases per year, most of which will go on to chronic infection. Moreover, 93% of acutely infected individuals and half of the estimated 3.5 million Americans with chronic HCV are unaware they are infected. The scope of the problem is too big for gastroenterologists and infectious disease specialists to handle alone, according to Dr. Kriss.

Contemporary treatment of HCV involves a six-step program that's simpler than that of many of the diseases primary care physicians currently manage.

1) Confirm chronicity by two measurements of HCV RNA obtained 6 months apart.
2) Stage the patient's fibrosis.
3) Order a baseline cross-sectional ultrasound to exclude cirrhosis or hepatocellular carcinoma, since the fibrosis staging methods aren't foolproof.
4) Make sure the patient is still positive for HCV RNA prior to therapy.
5) Commence DAA therapy. The simplest regimen is 8 weeks of glecaprevir/pibrentasvir (Mavyret), provided it's approved by the patient's insurance.
6) Get a repeat HCV RNA 12 weeks after conclusion of treatment to confirm there is a sustained virologic response.

The critical part is step 2, because that's how primary care physicians will decide which patients to treat in their office and which to refer to a specialist. Many biomarkers are available, some proprietary and others gratis.

Dr. Kriss is particularly partial to the free Fibrosis-4 (Fib-4) calculator, which provides an estimate of the amount of liver scarring based upon the patient's age, liver enzyme levels, and platelet count.

The American Association for the Study of Liver Disease/Infectious Diseases Society of America hepatitis C guidelines state that the nonproprietary biomarker assays are equivalent to transient elastography for staging fibrosis. Those guidelines are an "outstanding" and extremely user-friendly resource for primary care physicians interested in taking on the treatment of chronic HCV, Dr. Kriss added.

In selecting a DAA, another key resource is the HEP Drug Interactions website, which enables physicians to identify potentially problematic drug-drug interactions. The two most important interactions involve statins or proton pump inhibitors.

Recent studies have shown that the benefits of achieving a sustained virologic response include a clinically meaningful regression of advanced fibrosis at 1 year after treatment in roughly half of patients (Dig Dis Sci. 2018 Feb;63[2]:486-92) and a reduced risk of developing hepatocellular carcinoma (Hepatology. 2018 Jun;67[6]:2244-53).

Models of remote consultation pathways to link primary care providers with consultant HCV specialists are being developed. In a study of 600 patients at federally qualified community health centers in Washington, the risk-adjusted cure rate was 90.4% among patients assigned to a nurse practitioner, 87.6% if DAA therapy was prescribed by a primary care physician, and 84.8% if treated by a specialist. Treatment visit adherence followed the same pattern and correlated with cure rates (Ann Intern Med. 2017 Sep 5;167[5]:311-8).

Turning to a couple of controversial expansions of DAA into new populations, Dr. Kriss noted that the AASLD/IDSA guidelines state that active intravenous drug use should not be considered a contraindication to HCV therapy.

"Scaling up HCV treatment in persons who inject drugs is necessary to positively impact the HCV epidemic in the U.S. and globally," according to the guidelines.

This message was recently underscored by the positive results of the seven-country SIMPLIFY trial, in which 12 weeks of velpatasvir-sofosbuvir (Epclusa) in a population of recent IV drug users achieved a 97% cure rate, with only one reinfection in this high-risk population (Lancet Gastroenterol Hepatol. 2018 Mar;3[3]:153-61).

He reported having no financial conflicts regarding his presentation.

biancin@mdedge.com

Ref: Internal Medicine News Sep 15 2018, Vol 51 (14)
mdedge.com/internalmedicinenews