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Next Steps for HCV Patients Post-SVR: Best Practice Recommendations

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The advent of all-oral directly acting antiviral agents (DAAs) has led to high rates of sustained virologic response

The advent of all-oral directly acting antiviral agents (DAAs) has led to high rates of sustained virologic response (SVR), generally exceeding 90%, in patients with the hepatitis C virus (HCV).¹ Although SVR is associated with positive outcomes, including reduced risk of liver cirrhosis, hepatic decompensation, need for liver transplantation, and liver-related and all-cause mortality, a subset of patients who achieve SVR nevertheless continue to remain at long-term risk for progression to these conditions.

“With the increasingly frequent opportunity to celebrate virologic cure with patients comes the corresponding need to advise them about whether, when, and for how long ongoing care for liver disease is needed,” according to Jacobson et al, authors of a recent clinical practice update on caring for patients with chronic HCV who have achieved SVR.¹ “Thus, it is critical to identify the ongoing risks for the individual patient and the measures needed to mitigate those risks.”

The authors caution that “limited evidence is available to guide clinicians on which post-SVR patients should be monitored versus discharged, how to monitor and with which tests, how frequently should monitoring occur, and for how long.” The clinical practice update is intended to provide this guidance.

Achievement of SVR

Best Practice 1

SVR should be confirmed by undetectable HCV RNA at 12 weeks following completion of an all-oral DAA treatment regimen

Best Practice 2

Routine confirmation of SVR at 48 weeks post end of treatment is recommended. Testing for HCV RNA at 24 weeks post treatment should be considered on an individual patient basis.

Best Practice 3

Routine testing for HCV RNA beyond 48 weeks following end of treatment to evaluate for late virologic relapse is not supported by available evidence; periodic testing for HCV RNA is recommended for patients with ongoing risk factors.

The attainment of SVR 12 weeks after treatment completion has now replaced SVR 24 as the primary endpoint. According to the American Association for the Study of Liver Disease/Infectious Disease Society of America (AASLD/IDSA)'s 2016 Guidance document,² patients do not require another HCV RNA determination after SVR12 and can be dismissed from ongoing follow-up if they had Metavir F0-F2 fibrosis before treatment. However, recent data indicate that late relapse can occur, even in the absence of de novo infection. For this reason, many clinicians prefer to obtain another HCV RNA assay at follow-up week 24 and/or follow-up week 48. “There is no evidence at present that any particular viral genotype or patient type is more prone to this rare phenomenon,” the authors note.

Monitoring for Potential Hepatocellular Carcinoma (HCC)**Best Practice 4**

Surveillance for hepatocellular carcinoma with liver imaging +/- serum AFP should be pursued twice annually for an indefinite duration in all patients with stage 3 fibrosis or liver cirrhosis post-SVR.

Best Practice 5

Surveillance for HCC is not recommended for patients with stages 0–2 fibrosis post-SVR.

Best Practice 6

Intensification of HCC screening frequency in the immediate post-SVR context is not presently recommended.

In general, the risk of de novo HCC decreases after the attainment of SVR with interferon-based regimens. However, established cirrhosis is a risk factor for the development of HCC and there is no “finite point beyond which the risk of HCC in patients with a history of HCV-associated cirrhosis is reduced to the level of persons without a history of liver disease,” the authors point out. Available evidence as well as clinical experience suggest that surveillance is associated with decreased mortality from HCC and should be conducted at six-month intervals in all patients with cirrhosis, regardless of whether they have achieved SVR. Since HCC also occurs in patients with bridging fibrosis, the surveillance recommendations for patients with cirrhosis also apply to this population. Ultrasound is the recommended imaging modality for hepatoma surveillance.

Currently available evidence does not support routine screening after SVR for HCC in patients with F0–2 fibrosis, although clinicians may choose to obtain a final ultrasound during the year after SVR that follows DAA therapy.

Variceal Bleeding Prophylaxis

Best Practice 7

Initial endoscopic screening for esophagogastric varices is recommended for all patients with liver cirrhosis, independent of SVR.

Best Practice 8

Repeat endoscopic screening should be pursued for cirrhotic patients post-SVR at 2 to 3 years if no varices or small varices were identified on initial screening exam.

Best Practice 9

If no varices are identified on endoscopy 2 to 3 years post-SVR, cessation of further endoscopic screening may be considered on an individual patient basis, if there are no risk factors for progressive cirrhosis.

The authors write, “Increasing evidence points to the capacity for SVR to result in resolution or reduction of portal hypertension, especially in patients with Child-Pugh A cirrhosis, laying a foundation for a favorable change in the natural history of esophageal varices after SVR.” The risk of variceal bleeding is low after SVR is attained via interferon-based therapy.

The authors propose that if no varices are found on prior screening examination, a follow-up endoscopy after 2 to 3 years should be conducted and if no varices are found, and there is no evidence of another progressive liver disease, no further screening is necessary.

In the event of small varices on prior screening examination, no treatment is necessary; a follow-up endoscopy should be conducted after 2 to 3 years and if the varices are unchanged or smaller, no further screening is necessary. Otherwise, treatment and further follow-up are necessary.

If varices on prior screening have been treated with primary prophylaxis with beta-blockers and/or band ligation, endoscopy should be repeated after 6 to 12 months, treatment continued if varices are unchanged, and endoscopy should be repeated after 1 to 2 years. Treatment may be discontinued if varices are reproducibly considered sufficiently small to be low-risk.

Surveillance and/or treatment already instituted should be continued in decompensated patients or patients with a prior history of variceal bleeding.

Monitoring for regression of advanced fibrosis or cirrhosis**Best Practice 10**

Fibrosis assessment post-SVR with non-invasive tools such as liver elastography may be considered on an individual patient basis to assess for interval fibrosis progression or regression to guide clinical management, although improved fibrosis measurements should not alter the frequency of HCC surveillance at the present time.

Many patients who have achieved SVR are anxious to know if pre-treatment liver fibrosis can be reversed, independent of HCC risk. For this reason, non-invasive post-SVR assessment may be attractive to many patients. Nevertheless, available evidence does not support a broad recommendation for routine fibrosis testing, and the decision to conduct such testing should be “individualized, according to clinicians' judgment and/or patient preference.”

Counseling and Patient Education**Best Practice 11**

Patients who have achieved SVR should be counseled regarding sources of liver injury that may independently contribute to liver fibrosis, including alcohol, fatty liver, and other potential hepatotoxins, and should be evaluated for these and other sources of liver injury if serum levels of liver enzymes are elevated.

Although most patients who attain SVR have a “favorable clinical course,” some may experience the progression of liver fibrosis, hepatic decompensation and/or HCC, so all patients should undergo evaluation for modifiable risk factors for liver injury (eg, alcohol, drug use, fatty liver, and diabetes mellitus). Patients with fatty liver and/or diabetes should be counseled to avoid alcohol consumption and should be advised regarding liver-related complications of diabetes and the importance of continuing disease-specific management to optimize weight loss and glycemic control.

Conclusions

The authors state that they “expect and encourage long-term studies of outcomes after interferon-free DAA therapy, which will further refine our concepts of appropriate management and, like the guidelines governing antiviral treatment itself, should lead to dynamic reassessment of the best practices for management of patients post-SVR in the years ahead.”

References

1. Jacobson IM, Lim JK, Fried MW, AGA Institute Clinical Practice Update: care of patients who have achieved a sustained virologic response (SVR) following antiviral therapy for chronic hepatitis C infection. *Gastroenterology* (2017), doi: 10.1053/j.gastro.2017.03.018.
2. AASLD-IDS. HCV Guidance: Recommendations for testing, management, and treating hepatitis C. Available at: www.hcvguidelines.org. Accessed: April 9, 2017.

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