Sovaldi-Based Hep C Regimens Safe, Effective for Those With Chronic Kidney Disease

Those with stage 3 CKD saw their kidney function improve after treatment with various combo regimens, including Harvoni.

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People with chronic kidney disease (CKD) can safely take Sovaldi (sofosbuvir)-based hepatitis C virus (HCV) regimens and benefit from good cure rates of the virus. In addition, in a recent study, those with stage 3 CKD saw their kidney function improve after curing hep C.

Publishing their findings in the Clinical Journal of the American Society of Nephrology (CJASN), Harvard researchers conducted a retrospective observational cohort study of medical records of 404 people with stage 1 through 3 CKD and hep C who received medical care at Partners HealthCare in Boston.

This was the first study to specifically evaluate the effects of Sovaldi-based treatment in a population of people with CKD. The drug is excreted through the kidneys, which concerns researchers looking to develop safe and effective hep C treatments for those with CKD.

The regimens included Sovaldi and ribavirin, Sovaldi and Olysio (simeprevir) with or without ribavirin, and Harvoni (ledipasvir/sofosbuvir) with or without ribavirin.

The researchers defined CKD as an eGFR below 60, an albuminuria (abnormal albumin in the urine) of at least 30 or a proteinuria (abnormal protein in the urine) of at least 200. They determined kidney function by averaging all creatinine levels in patient records three months prior to their starting hep C treatment. For those individuals who did not have test results from this time period, the investigators expanded the period to 12 months prior to treatment.

The study authors identified 98 people who were prescribed a Sovaldi-based hep C regimen between November 2013 and December 2014 and included them in the main analysis. Compared with those who were treated for hep C, the 306 who were not treated were more likely to be women, nonwhite and have an eGFR below 60; they were less likely to have cirrhosis or have received an organ transplant.

The average age of the Sovaldi-treated cohort was 62. Seventy-eight percent were men, 65 percent were white and 19 percent were Black. The cohort commonly had other health conditions, including high blood pressure (88 percent), diabetes (49 percent), cirrhosis (38 percent) and HIV (9 percent). Thirty-two of them (33 percent) had received an organ transplant, including 20 who received a liver transplant, eight who received a kidney transplant and four who received transplants of both organs.

Fifty-four (55 percent) of the cohort members had genotype 1a of HCV, 18 (18 percent) had genotype 1b, 14 (14 percent) had genotype 2, seven (7 percent) had genotype 3 and five (5 percent) had genotype 4.

Before starting hep C treatment, the cohort members' average HCV viral load was 4.4 million. Their average eGFR was 60. Forty-one individuals (42 percent) had stage 1 or 2 CKD (defined by having proteinuria and an eGFR greater than 60) while 57 cohort members had stage 3 CKD (an eGFR below 60).

The average eGFR did not fluctuate significantly while the cohort members were on hep C treatment. Seventy-four percent of the individuals had stable kidney function tests, with no rise in creatinine of 0.3 or greater.

Overall, 81 percent achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Broken down by genotype the cure rates were: genotype 1a, 83 percent; genotype 1b, 89 percent; genotype 2, 86 percent; genotype 3, 43 percent; genotype 4, 60 percent.

Those with more advanced CKD were more likely to be cured, which researchers theorized was because those with poorer kidney function did not excrete the antiviral medications to the same degree, leading to higher drug concentrations in the body and ultimately more effective treatment. However, because this particular analysis was based on only a few people, it is not very statistically sound. Other studies have not shown such differences in cure rates based on CKD status.

After adjusting the data for various factors, the study authors found that among those with a baseline eGFR below 60 (stage 3 CKD), a hep C cure was associated with a 9.3 point improvement in eGFR during the post-treatment follow-up period. There was no such improvement among those with stage 1 or 2 CKD.

Breaking up the stage 3 CKD group by diabetes status, the researchers found that during the study's observation period, those with diabetes continued to see their eGFR decline despite hep C treatment while those without diabetes had a 4.5 point increase in eGFR.

Eighty-one percent of the cohort members reported at least one adverse health event, including 97 percent of those taking ribavirin and 28 percent of those who did not take that drug. Seventeen percent of the cohort experienced serious adverse health events. Eight percent discontinued treatment. Those taking ribavirin had a 2.9-fold increased likelihood of experiencing a serious

adverse health event.

There were two deaths among the cohort members, one due to acute atherosclerotic plaque rupture (a rupture in an artery) and another due to liver failure.

“Our study suggests the potential for kidney benefit in patients with CKD who undergo direct-acting antiviral treatment and achieve sustained virologic response,” the study authors concluded. “However, our conclusions are limited by the fact that there is no untreated control group.”

While the researchers noted that cure rates for those with genotypes 3 and 4 were suboptimal, they noted that in clinical trials, Gilead Sciences’ Epclusa (sofosbuvir/velpatasvir), which was approved in June 2016 and which contains Sovaldi, demonstrated cure rates between 95 and 99 percent among those with genotypes 1 through 6.

In an editorial published along with this paper, Richard Johnson, MD, of the University of Colorado, and Michiko Shimada, MD, PhD, of Hirosaki University Graduate School of Medicine in Japan, stressed that there are other hep C medications available that, unlike Sofosbuvir, are not excreted through the kidneys. They say that additional research on the effects of hep C drugs on those with compromised kidney function is needed.

Gilead’s Vosevi (sofosbuvir/velpatasvir/voxilaprevir), which was approved in July 2017 and which also contains Sovaldi, has boasted cure rates above 90 percent among those with genotypes 1 through 6 of hep C. AbbVie’s Mavyret (glecaprevir/pibrentasvir) was approved the following month and is specifically indicated for those with chronic kidney disease. One clinical trial of Mavyret including those with genotypes 1 through 6 of hep C and CKD saw a 98 percent cure rate.

To read a Hep feature article on treating hep C among those with CKD, click here. (The article does not reflect the findings of this new study.)

To read a press release about the study, click here.

To read the study abstract, click here.

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