Hep C Treatments Apparently Not Linked to Serious Adverse Health Events

Researchers reached this conclusion after reviewing data on more than 30,000 people.

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Direct-acting antivirals (DAAs) for hepatitis C virus (HCV) are not associated with an increased risk of serious adverse health events, according to a new analysis of more than 30,000 people with the virus. On the contrary, treating the virus is linked to a lower risk of a number of such outcomes, including the risk of death.

Previously, reports sent to the the Food and Drug Administration's voluntary Adverse Events Reporting System had raised safety concerns about DAAs.

Publishing their findings in JAMA Network Open, researchers led by Elizabeth A. McGlynn, PhD, at Kaiser Permanente in California, conducted a retrospective cohort study of 2012 to 2017 data from three health systems regarding 33,808 people with the virus.

A total of 62% of the cohort was male. The average age was 57 years old.

The investigators analyzed DAA treatment's association with a roster of serious adverse health events, including death, multiple organ failure, hepatocellular carcinoma (HCC, the most common form of liver cancer), decompensated cirrhosis, acute-on-chronic liver health event, acute myocardial infarction (heart attack), ischemic or hemorrhagic stroke, arrhythmia, acute kidney failure, non-liver cancer, hepatitis B virus (HBV) reactivation, hospitalizations and emergency department visits.

Looking at outcome rates per 1,000 cumulative years of follow-up, the study authors found that exposure to DAAs, compared with the lack of exposure, was associated with 10.7 versus 33.7 deaths, or a 68% reduced death rate.

DAA exposure was associated with at least a 30% reduction in the rate of seven other serious adverse health events, including multiple organ failure (44% reduction), decompensated cirrhosis

(38% reduction), heart attack (37%), and hemorrhagic stroke (53%).

None of the serious adverse events analyzed occurred at a higher rate among those who did not receive DAAs.

After adjusting the data to account for various differences between the cohort members, the investigators found that DAA exposure was associated with a 58% lower risk of death, a 39% lower risk of decompensated cirrhosis and a 53% lower risk of arrhythmia.

“Direct-acting antiviral exposure may not be associated with higher rates of any serious adverse events, including those related to liver, kidney and cardiovascular systems,” the study authors concluded. “Safety concerns based on previous reports did not appear to be supported in this study with more comprehensive data and rigorous statistical methods.”

To read the study abstract, click here.

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