Report Raises Concerns About the Safety of Hepatitis C Treatments

A look at reports of adverse reactions to the current crop of drugs suggests they may occasionally lead to severe liver disease.

January 25, 2017

A new report suggests that in a relatively small number of cases the direct-acting antivirals (DAAs) used to treat hepatitis C virus (HCV) may in fact contribute to the very sort of severe liver disease the treatment is meant to prevent, The New York Times reports.

This finding comes from a report from the Institute for Safe Medication Practices, a nonprofit in Horsham, Pennsylvania, that studies the safety of drugs. The group analyzed the U.S. Food and Drug Administration's (FDA) database on the reports doctors worldwide submit about adverse health events possibly associated with medications.

While the report could not make a conclusive statement about the possibility that hep C treatments may indeed raise the risk of severe liver injury, including liver failure, its authors stress that the possibility of such an association should be taken seriously.

The report looked at nine DAAs, including Gilead Sciences' blockbuster treatments Sovaldi (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir).

It is possible that adverse reactions to hep C treatments may occur if physicians incorrectly prescribe them to individuals whose liver function is too poor for them to tolerate the drugs or gain health benefits from curing the virus.

Looking at the 12-month period ending June 30, 2016, the investigators found 524 reports of people suffering liver failure following treatment with DAA;165 of them died. Additionally, there were reports of 1,058 people with severe liver injury.

Because doctors voluntarily report this data, it is likely that there are more people who fall into these categories but whose cases have not been reported to the FDA.

The liver health of people with hep C may be precarious, of course. The virus often goes undetected for decades, during which it may cause progressive scarring to the organ. Ideally, curing the virus reduces the risk of future progression of liver damage and may in fact dial back

such harm. Numerous studies have found manifold health benefits associated with successful DAA treatment. Nevertheless, there are those who will experience liver failure after being cured of HCV.

When it comes to the findings of this new report, it is not clear whether hep C drugs themselves contributed to such severe health outcomes. The picture is particularly cloudy because the report authors did not have access to the medical histories of the individuals reflected in the FDA data.

Robert S. Brown, MD, MPH, the director of the Center for Liver Disease and Transplantation at NewYork-Presbyterian/Columbia, who did not contribute to the report, told The New York Times that physicians treating patients with hep C should thoroughly assess their liver function in advance of treatment in case an individual's liver disease is severe enough to make giving them DAAs inadvisable.

To read the New York Times article, click here.
