Hepatitis C Treatment and Risk of Death

October 30, 2014 By Lucinda K. Porter RN

Early this month, death entered the rooms of the Hep Forum. One of our members lost her mother. She believed this death was caused by the hepatitis C treatment, Sovaldi. Her elderly, but active mother had completed treatment a few months earlier, but never quite recovered. Her grief was deep, but her concern that others might be harmed was equally strong, and she sounded the alarm bells, warning people about Sovaldi.

I can't comment on the cause of her mother's death, as this is for doctors, and perhaps the courts to decide. I just don't know. However, I do take these warnings seriously, so I reviewed Sovaldi's safety data, and to my knowledge, there are no reports of death.

However, I had made a mistake--the member's mother hadn't only taken Sovaldi; she had also taken Olysio. I got sidetracked by the member's blaming Sovaldi, and it didn't occur to me to look up Olysio. What prompted me to further investigate this was news of three deaths in Japan associated with Janssen's Sovriad, known as Olysio in the US, and Galexos in Canada. These three brand names are generic simeprevir, aka simeprevir sodium in Japan. Each capsule contains 154.4 mg of simeprevir sodium salt, which is equivalent to 150 mg of simeprevir.

There were four deaths reported in simeprevir clinical trials conducted in the U.S. The causes of death were ruled as unrelated, and included the following: 1) bacterial meningitis and brain hemorrhage; 2) colon cancer; 3) presumed cardiopulmonary event; 4) bilateral pneumonia and septic shock.

The deaths in Japan had clearer associations to liver and kidney disease. The deceased were in their 40's to 60's. Bilirubin was elevated in all three deaths.

What You Can Do

If you haven't started hepatitis C treatment yet, consider your options. Fortunately, we have other hepatitis C treatment choices, now that Harvoni is FDA approved. Harvoni has clear benefits over Olysio, not just in safety, but in efficacy. In Harvoni studies, although there were elevations in bilirubin, the adverse events were mild and there were no deaths.

If you are already taking Olysio, keep in mind that this info is preliminary. We will see what the FDA warns in the U.S. On one hand, the risk of death from hepatitis C is real, and the death rate from Sovriad was low at one per 6300. This is still alarming, and it wouldn't hurt to be sure your medical provider has read the Blue Letter issued in Japan.

Your doctor should be watching your bilirubin levels, but it is a good idea that you watch them too. If your bilirubin rises, talk to your doctor immediately about these reports. Do not let your medical care fall through the cracks.

We want all of us to make it to the end, not just alive, but alive and hepatitis C-free.

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