Hepatitis C Treatments Are Safe and Effective for Seniors

The first meta-analysis to examine hep C treatment outcomes in seniors versus non-seniors found that cure rates are comparable.

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As the U.S. population living with hepatitis C virus (HCV) ages, the safety and efficacy of direct-acting antiviral (DAA) treatment for the senior population is an important concern. The bulk of those living with HCV in the United States are baby boomers—those born between 1945 and 1965—about half of whom are over age 65 and the eldest of whom are just shy of 75 years old.

Research has indicated that hep C–related cirrhosis, which is severe scarring of the liver, will have a particular impact on those older than 60.

Now a group of German researchers has conducted the first systematic review and meta-analysis of available medical literature to assess the relative effects of interferon-free DAA regimens on seniors and their younger counterparts.

Their findings, published in Liver International, were highly encouraging. Hep C cure rates proved comparable between older and younger age groups, as did rates of serious adverse events. That said, compared with younger individuals, seniors had higher rates of milder adverse events while on HCV treatment, and, in particular, experienced a greater incidence of anemia when prescribed ribavirin. Fortunately, though, that particular drug is mostly no longer needed as an adjunct to DAA treatment.

Led by Johannes Vermehren, MD, of the University Hospital Frankfurt, the research team searched for Phase III clinical trials of interferon-free DAA regimens or studies conducted after a drug's approval. They sought papers that included data on age-based differences in hep C cure rates, divided by a cutoff age of either 65 or 75 years old. They required that all studies include a minimum follow-up period of 12 weeks after the end of treatment.

Sixty-three studies met the researchers' criteria and were included in their meta-analysis. These included 15 randomized controlled trials, 17 prospective studies and 28 retrospective cohort studies; three studies could not be assigned a study-type category. Five of the trials were conducted in China, Taiwan or Korea, nine were run in the United States, seven were European, 22 were done in Japan, one in India, one in Turkey and the remaining 18 in other nations.

Cumulatively, the studies included 34,082 participants, ranging from 10 to 11,464 participants.

The participants were treated with one or more of a collection of DAA regimens that included Sovaldi (sofosbuvir) with ribavirin; Harvoni (ledipasvir/sofosbuvir) with or without ribavirin; Sovaldi plus Olysio (simeprevir) with or without ribavirin; Daklinza (daclatasvir) plus asunaprevir; the Viekira regimen (ombitasvir/paritaprevir/ritonavir plus dasabuvir) with or without ribavirin; Technivie (ombitasvir/paritaprevir/ritonavir) with or without ribavirin; Epclusa (sofosbuvir/velpatasvir) with or without ribavirin; Zepatier (grazoprevir/elbasvir); Sovaldi plus Daklinza with or without ribavirin; Mavyret (glecaprevir/pibrentasvir); and Vosevi (sofosbuvir/velpatasvir/voxilaprevir).

The meta-analysis's authors deemed all the randomized controlled trials to be of good quality, while the other studies were of good or fair quality.

Overall, 93.7% of the participants younger than 65 years old and 92.8% of those 65 or older achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). These two rates were considered comparable, meaning that senior status has no bearing on the likelihood of being cured of HCV with an interferon-free DAA regimen. Cure rates were also comparable when the age of 75 divided the two cohorts.

Similarly, there was effectively no difference in the cure rate between seniors and non-seniors among those who had previously been treated but not cured by an HCV regimen. Interestingly, among those with cirrhosis, individuals 65 years old or older were 69.5% more likely to be cured of hep C compared with their younger counterparts.

Cure rates were also similar across the various genotypes of HCV as well as the different DAA regimens. The use of ribavirin did not have any apparent association with cure rates.

There was also a comparable risk of being diagnosed with cirrhosis across the age categories, whether divided by age 65 or 75.

Fourteen of the studies included safety data divided by age group, which collectively included 4,763 participants younger than 65 and 1,600 people 65 years old or older. There was no evidence of age-associated side effects resulting from the most recently approved DAA regimens, including Zepatier, Vosevi and Mavyret.

While on DAA treatment, those at least 65 years old had a 30% increased risk of adverse health effects compared with the younger cohort. That said, the rates of serious adverse health events were comparable between the two groups, as were rates of discontinuation of treatment.

Most of the studies that included people treated with ribavirin reported elevated rates of adverse health events. Seven such studies reported significant anemia among their participants, with a 2.8-fold higher rate among seniors compared with non-seniors.

There were eight deaths (0.5%) among the 1,600 participants included in the meta-analysis who

were at least 65 years old and 11 deaths (0.23%) among the 4,763 younger individuals. Each age group had two deaths (0.13% of the seniors and 0.04% of the non-seniors) that were possibly related to treatment, including worsening of liver function during therapy.

The study authors stressed that thanks to the recent addition of second-generation DAA regimens, including Mavyret, Epclusa and Vosevi, people receiving HCV treatment can now avoid ribavirin in most cases. In fact, clinical practice guidelines rarely recommend the drug.

Such guidelines currently recommend HCV treatment regardless of age, with the exception of individuals with a limited life expectancy—such as less than one year—that DAA therapy, liver transplantation or another type of treatment would not improve.

“Our data,” the study authors concluded, “indicated that DAA treatment for HCV is highly effective and safe in patients aged [at least] 65 years, thereby supporting current guidelines recommendations to treat all patients without age restrictions.”

“However,” they continued, “recent data suggest that treatment in elderly patients without significant fibrosis may only be cost-effective at lower prices. Moreover, there is still insufficient data to predict the long-term effects of HCV cure and its impact on overall survival in elderly patients, particularly in the absence of advanced fibrosis or cirrhosis, as the progression to cirrhosis may never occur.”

The researchers noted that there have been several studies of people, in particular women, who have had a long history of HCV infection and who nevertheless have experienced only mild progression of liver disease.

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