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Bone mineral density improved in frail elderly women treated with zoledronic acid

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A single intravenous dose of the osteoporosis drug zoledronic acid improved bone mineral density in a group of frail elderly women living in nursing homes and long-term-care facilities, according to an article published online by *JAMA Internal Medicine*.

Nearly 2 million frail elderly Americans live in long-term care facilities and many of them have osteoporosis and bone fracture rates higher than less impaired elderly individuals. A hip fracture can be dire, decreasing mobility, independence and often leading to death, according to background in the study.

Susan L. Greenspan, M.D., of the University of Pittsburgh, and coauthors conducted a clinical trial to determine the efficacy and safety of zoledronic acid to treat osteoporosis in frail elderly women living in long-term care facilities. Zoledronic acid was chosen because it can be given in a single intravenous dose and the effect can last for two years.

The two-year study included 181 women 65 or older with osteoporosis, including women with cognitive impairment, immobility and multiple coexisting illnesses, who were living in nursing homes and assisted-living facilities. Of the women, 89 were assigned to receive a single 5-mg dose of zoledronic acid and 92 were assigned to receive placebo, while all participants received daily vitamin D and calcium supplementation.

The authors measured hip and spine bone mineral density (BMD) at 12 and 24 months, as well as adverse events, which included falls.

The average total hip BMD increased more in the treatment group than in the placebo group both at 12 months (2.8 percent vs. -0.5 percent) and at 24 months (2.6 percent vs. -1.5 percent), according to the results. The average spine BMD also increased more in the treatment group than placebo group at 12 months (3 percent vs. 1.1 percent) and at 24 months (4.5 percent vs. 0.7 percent).

Overall, in the measure of adverse events, there were no significant differences in the number of deaths, fractures or cardiac disorders. The treatment and placebo groups' fracture rates were 20 percent (18 women) and 16 percent (15 women), respectively, and mortality rates were 16 percent (14 women) and 13 percent (12 women), respectively. There were no significant differences between groups in the number of single fallers but more participants in the treatment group has multiple falls (49 percent vs. 35 percent), although this difference did not remain significant after adjusting for baseline frailty, the results indicate.

"In summary, we found that a single infusion of zoledronic acid in frail, cognitively challenged, less mobile elderly women improved bone density and reduced bone turnover for two years. This suggests that even a very frail cohort may benefit. However, prior to changing practice, larger trials are needed to determine whether improvement in these surrogate measures will translate into fracture reduction for vulnerable elderly persons," the study concludes.

In a related commentary, Robert Lindsay, M.B., Ch.B., Ph.D., of Helen Hayes Hospital, West Haverstraw, N.Y., writes: "In this issue of *JAMA Internal Medicine*, Greenspan and colleague present intriguing data on zoledronic acid, one of the most potent drugs in the bisphosphonate family - if not the most potent - approved for treatment of osteoporosis."

"First, this study includes 181 participants rather than the thousands usually involved in fracture studies. ... As the authors point out, the study

was not designed as a fracture study," the author continues.

"So what lessons can we derive from this study? ... It would be premature to use this study to immediately modify our clinical use of potent bone-active agents in the nursing home population with documented osteoporosis (i.e. those who have a low BMD as a major risk factor for fracture). ... Finally, this study draws attention to the need for large controlled clinical trials to determine if a combination of fall prevention strategies and treatment with bone-active drugs might produce additive benefits on fractures, especially in high-risk populations such as those living in nursing homes. These studies will be difficult, and Greenspan and her colleagues are to be congratulated on beginning to fill this void," the commentary concludes.

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