Heel Ultrasound Flags Low BMD in the Disabled

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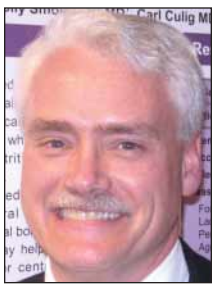
SAN DIEGO — Heel ultrasound is a promising way to initially identify low bone mass in developmentally disabled patients, Dr. Kelly D. Krohn said during a poster session at the annual meeting of the International Society for Clinical Densitometry.

The finding is important because low bone density "is a common, complicated problem in people who have physical disabilities," Dr. Krohn, director of clinical research, department of medicine, at Mercy Hospital in Pittsburgh, Pa., said in an interview. "A big part of it is that they're not able to bear weight. They're sitting in a wheelchair for 25-30 years and they have really fragile bones. But they're also challenging to bring to the office and do standard DXA [dual-energy x-ray absorptiometry] bone density testing on."

He and his associates used a portable heel ultrasound densitometer to screen 135 mentally and physically challenged men and women who were living in intermediate care facilities in Allegheny County, Pa. Screenings took place either in their residence or at the hospital's on-site medical clinic.



The researchers, who were led by Dr. Vinee Varma, also of Mercy Hospital, collected data on age, gender, race, and weight-bearing status.

They defined low bone mass as having a T score of –1.0 or lower.

If heel scans were positive, the researchers forwarded the results to the physician.

When indicated, patients were referred for a central DXA of the hip and spine.

The average age of the 135 patients was 50; about half (68) were men; and most (90%) were white.

Of the patients, 55% had full weight-bearing capabilities, 42% were unable to bear weight, and 3% were able to partially bear weight.

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DR. KROHN

Dr. Krohn and his associates found that 80% of the women and 72% of the men had evidence of low bone density on heel ultrasound. In addition, 91% of patients who were unable to bear weight had low bone mass, compared with 70% of patients who had full weight-bearing capabilities.

Subsequent central DXA scans performed in 91 patients confirmed the overall results of the positive heel ultrasounds. When the researchers used a heel ultrasound T score of –1.0 or lower, 70% had low bone mineral density (BMD) on central DXA. When they used a heel ultrasound score of –2.0 or lower, 81% had low BMD on central DXA.

In another component of the study, five patients with a normal heel ultrasound had central DXA performed. Low BMD was found in two of the five.

"Any screening test has failures," Dr. Krohn noted.

"You miss some and you overcall some. For us, heel ultrasound has been a nice way to get a good handle on [the BMD in] several hundred disabled residents. A large number of them have a real risk for fractures. This is an easy way to identify them," he said. ■

Estrogen Protective

Benefits for Bones *from page 1*

of Health. Results from both arms showed no benefit from hormone therapy in women aged 50-79 years for heart disease, the primary end point for both studies. Rates of strokes, venous clotting, and dementia in women aged 65 or older were higher on the women on hormones. A global index of risk and benefit showed a net increased risk among the 16,608 women who were randomized to active drug in the estrogen-plus-progestin study, and no net benefit compared with risk among the 10,739 women with a prior hysterectomy who received the hormone in the estrogen-only study, said Dr. Stefanick, who also chairs the WHI steering and executive committees.

A series of study collaborators took the podium to review the WHI results in the following areas:

► **Bones.** In what is deemed a clear-cut benefit, estrogen plus progestin led to significant drops in the rate of hip fractures, which fell by 33% compared with the placebo group, and clinical vertebral fractures, which dropped by 35%. Women taking estrogen only had almost identical declines.

► **Coronary diseases.** The incidence of coronary heart disease was the primary end point for both arms of the hormone study, and in both arms estrogen failed to show any benefit—a surprise given the expectation that estrogen would prevent heart disease, said Dr. Judith Hsia, professor of medicine at George Washington University, Washington. In the estrogen-plus-progestin arm, hormone therapy boosted the risk of myocardial infarction (MI) or coronary death by 24%. The increase in risk began to appear 1 year into the study, which was "not very reassuring" for estrogen-plus-progestin use, she said.

The picture was not as bad for estrogen alone, which overall led to a 5% decline in the incidence of MI and coronary deaths, compared with placebo, a difference that was not statistically significant.

Results from a recent analysis of the estrogen-only data that divided participants by their age at entry further showed that estrogen-only treatment produced a stronger trend toward fewer coronary events in the youngest women, who were aged 50-59 at entry. In this subgroup of 2,300, estrogen-only treatment cut the combined incidence of MI or coronary death by 37%, a result that came close to statistical significance. The combined incidence of MI, coronary death, or need for revascularization therapy was cut by 34% by estrogen only, a difference that was statistically significant. But among women aged 60-69, estrogen only had essentially no impact on coronary events, and in women aged 70-79, estrogen was linked with a nonsignificant 11% rise in the event rate. Dr. Hsia and other investigators stressed that this new finding in no way justifies routinely using estrogen only to treat women aged 50-59. Rather, the result was seen as "reassuring for women who need hormone therapy for menopausal symptoms," said Dr. JoAnn E. Manson, chief of the division of preventive medicine at Brigham and Women's Hospital, Boston.

► **Stroke.** Both forms of hormone therapy led to a significant rise in stroke risk. Estrogen plus progestin produced a 31% higher rate, compared with placebo, and estrogen alone led to a 39% higher rate.

► **Venous thrombosis.** The impact of hormone therapy on pulmonary embolism and deep vein thrombosis was even worse. Estrogen plus progestin more than doubled the risk for pulmonary embolism and nearly doubled the rate of deep vein thrombosis. Estrogen alone wasn't as dangerous, but it still produced a significant 47% rise in deep vein thrombosis. Estrogen alone raised the pulmonary embolism rate by 34%, a nonsignificant increase.

► **Urinary incontinence.** Hormone therapy's adverse effect on urinary incontinence is "one of the least-known results from WHI," said Susan L. Hendrix, D.O., a professor of ob.gyn. at Wayne State University, Detroit.

Women who had incontinence symptoms at baseline showed an increased severity after 1 year of treatment in both hormone-therapy arms of the study, and hormone therapy also boosted the incidence of new cases. In women getting estrogen plus progestin, stress incontinence was 87% more common than in the placebo group, a significant difference, and urge incontinence was 15% more common, a trend that just missed statistical significance. Women treated with estrogen only had more than twice the rate of new stress incontinence, compared with the placebo group, while urge incontinence again rose by 15%.

"This is a paradigm switch. For years we used estrogen to treat incontinence," Dr. Hendrix said. After the first report of this finding, in February 2005, the American College of Obstetricians and Gynecologists issued an updated practice bulletin in June that warned against using oral estrogen to treat or prevent urinary incontinence. But in March 2006, the American Urogynecologic Society still had a patient information page on its Web site that said hormone therapy could improve urine control, she said.

► **Cancer.** The biggest surprise for this end point was that estrogen alone had a neutral effect on the rate of invasive breast cancer. Estrogen plus progestin led to a significant 24% rise in the incidence of breast cancer, and it was this increased rate that crossed a prespecified risk threshold in late May of 2002 and led to the early halt of the estrogen-plus-progestin arm.

Results from more recent analyses also showed that estrogen-plus-progestin treatment was linked to significant increases in breast tumor size and number of positive lymph nodes, and in the percentage of patients with advanced-stage cancer at diagnosis, said Dr. Rowan T. Chlebowski, chief of the division of medical oncology and hematology at Harbor-UCLA Medical Center, Torrance, Calif.

Estrogen alone was linked with a 23% drop in the rate of invasive breast cancers, a difference that just missed statistical significance. This unexpected finding has since undergone additional analysis and the results will be reported soon, Dr. Chlebowski said.

Rates of invasive colorectal cancer fell by a statistically significant 44% in patients taking estrogen plus progestin, compared with placebo, making estrogen-plus-progestin the only intervention that has been proven to cut the rate of colorectal cancer. The incidence of colorectal cancer was essentially unchanged in women taking estrogen only.

► **Dementia and cognitive function.** Before WHI, "older women were being put on hormone therapy in the belief that it would slow the decline in women with existing dementia and prevent new cognitive impairment," said Sally Shumaker, Ph.D., professor of public health science at Wake Forest University, Winston-Salem, N.C. The WHI results showed how misguided that was. "Hormone therapy may accelerate dementia," Dr. Shumaker said.

The WHI Memory Study focused on 7,479 women aged 65 or older at baseline, with a primary outcome of probable dementia and a secondary outcome of probable dementia or mild cognitive impairment. During an average 4 years of follow-up, women treated with estrogen plus progestin more than doubled their incidence of probable dementia, compared with the placebo group, with a similarly increased rate of mild cognitive impairment. During 5 years of follow-up in the estrogen-only arm, the rate of dementia was 49% higher in the treatment group and the rate of cognitive impairment rose by a third.

Overall, when results for both treatment groups are combined, hormone therapy produced a statistically significant 76% rise in the incidence of probable dementia. Cerebral structure and volume studies are underway in an attempt to better understand these effects, Dr. Shumaker said.

► **Diabetes.** Hormone therapy improved serum levels of insulin and glucose in women who were undergoing treatment for diabetes at baseline.

► **Gallbladder disease.** In both treatment arms, women on hormone therapy had an increased rate of both gallbladder disease and gallbladder surgery. Both estrogen plus progestin and estrogen alone boosted the rates of disease and surgery by about 60%, statistically significant increases. ■