

CT Colonography Can Also Screen for Bone Loss

BY SUSAN BIRK
Contributing Writer

CHICAGO — CT colonography can screen as reliably for osteoporosis as dual-energy x-ray absorptiometry and can be used to screen simultaneously for bone loss and colorectal cancer, a study of 35 patients suggests.

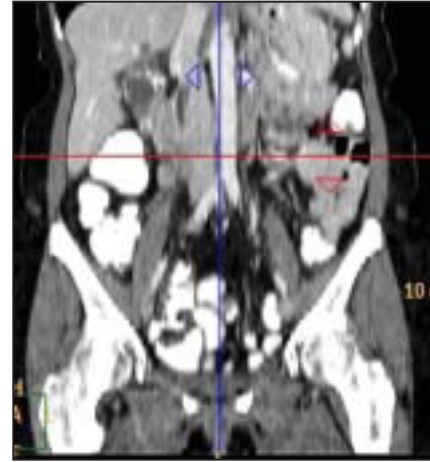
Of the currently accepted tests for colorectal cancer—CT colonography (CTC), flexible sigmoidoscopy or barium enema every 5 years, and colonoscopy every 10 years—“virtual colonoscopy stands out as the only one that can look outside the colon,” study investigator Dr. Aslam Rizwan said at the annual meeting of the Radiological Society of North America.

The study found excellent agreement between retrospectively derived bone mineral density (BMD) and T scores

from CTC data sets and BMD and T scores from dual-energy x-ray absorptiometry (DXA) in the same patients, reported Dr. Rizwan of the University of California, San Francisco.

The dual-purpose screening with CTC would provide information on osteoporosis risk with no additional radiation, Dr. Rizwan said. However, he emphasized that he is not suggesting that CTC replace DXA; rather, in patients who already are being screened for colorectal cancer, “the data [on BMD] is there; it’s available, and we should use it.” He added that “both techniques have been proven individually. We’re showing that it’s feasible to do both tests on the same patient at the same time. These patients are going to be screened for polyps, so for no extra cost we can also screen for [bone loss].”

Use of CTC to screen simultaneously for osteoporosis and colorectal cancer of-



CT colonography was as reliable as DXA at screening for osteoporosis.

fers “added value to a test you’re going to give anyway. The added value is that it can give you information on BMD,” said study coauthor Dr. Judy Yee, also of

the university. A total of 30 men and 5 women with a mean age of 66 years (age range 54-79) underwent both CTC and DXA. Two experienced readers independently calculated BMD and T scores from CTC data sets. CT bone density measurements were obtained with a bone mineral analysis software package at three vertebral bodies from T12 to L1. Density measurements also were obtained from fat and muscle to provide an internal reference for calculating BMD, T scores, and z scores.

The Centers for Medicare and Medicaid Services (CMS) do not now offer coverage for CTC, other than for diagnosis in symptomatic patients, said Dr. Yee, but “we hope there will be [screening] coverage in 2009.” Dr. Rizwan said that prospective studies are planned. He and Dr. Yee reported no financial conflicts of interest related to this study. ■

Low BMD Seen In Many Elderly Black Women

BY HEIDI SPLETE
Senior Writer

RIO GRANDE, P.R. — Approximately one in four elderly black women have osteoporosis, findings from a small study suggest.

Physicians should not ignore the possibility of osteoporosis in their older black female patients, although these women are not usually considered at high risk, compared with other demographic groups, said Dr. Sally P. Weaver, of the McLennan County Medical Education and Research Foundation, Waco, Tex.

Previous studies of osteoporosis in women have focused mainly on white women because of evidence of an elevated risk for osteoporosis in that population. Yet older women of any ethnicity are prone to age-related fractures if their bone mineral density (BMD) is low, she said in an interview.

Dr. Weaver and her colleagues measured BMD scans from the electronic health records of 44 black women aged 70 years and older. Patients with conditions that could affect bone turnover, vitamin D absorption, or calcium absorption were excluded from the study.

About 50% of the study participants met the criteria for osteopenia and 10% met the criteria for osteoporosis at the left femoral neck. Approximately 25% met criteria for osteopenia or osteoporosis at the lumbar spine. Overall, the left femoral neck had the lowest regional BMD. Dr. Weaver presented the results in a poster at the annual meeting of the North American Primary Care Research Group.

Dr. Weaver had no financial conflicts to disclose. ■

FDA Approves Yearly Zoledronic Acid for Men

BY JEFF EVANS
Senior Writer

The Food and Drug Administration’s recent approval of yearly zoledronic acid infusions for the treatment of low bone mass in men with osteoporosis will give clinicians a treatment option for men other than oral weekly therapy, according to Dr. Nelson Watts.

The agency’s decision brings the total number of indications for the intravenous formulation of zoledronic acid (Reclast) to three, including the treatment of postmenopausal osteoporosis (as well as the reduction of new clinical



IV dosing would be indicated for men with upper or lower GI problems and those who forget to take pills.

DR. WATTS

fractures in patients who have experienced a recent low-trauma hip fracture) and the treatment of Paget’s disease of bone. It is the only osteoporosis treatment that has been approved for the reduction of fractures of the hip, vertebrae, and other nonvertebral bones.

The other two drugs that are approved to increase bone mass in men with osteoporosis—alendronate (Fosamax) and risedronate (Actonel)—“certainly represent very good therapeutic choices with ...evidence in women for spine, hip, and nonvertebral fracture reduction,” said Dr. Watts, director of the University of Cincinnati Bone Health and Osteoporosis Center, which was one of the centers that participated in a randomized, double-blind trial that formed the basis for the FDA’s decision. Dr. Watts is a paid consultant to Novartis Pharmaceutical Corp., which manufactures Reclast, and

he is on the company’s speakers bureau.

Intravenous dosing would be medically indicated for men in three categories: those who can’t tolerate an oral agent because of upper GI problems, those with lower GI problems that interfere with drug absorption, and those who can’t remember to take an oral agent. “And certainly it can be considered a convenience option for someone who might be a candidate for oral therapy,” Dr. Watts said.

“We don’t have fracture reduction data in men, really, with any of these agents in terms of a preplanned primary end point [but] there’s no real reason to feel that bisphosphonates work any differently for osteoporosis in men than they do in women,” Dr. Watts said in an interview.

During the 2-year Novartis-sponsored trial that the FDA evaluated, 153 osteoporotic men received a 15-minute infusion of zoledronic acid once per year, and 148 other osteoporotic men received weekly oral alendronate. The men who were treated with zoledronic acid increased their lumbar spine bone mineral density by a mean of 6.1% over 2 years. This change in BMD was similar to the 6.2% increase in the alendronate group. Each patient in the study received 1,000 mg calcium and 800-1,000 IU of vitamin D each day. The men had a mean age of 64 years; some of them had significant osteoporosis secondary to hypogonadism.

In the trial, signs and symptoms of an acute phase reaction occurred in some patients in the first 3 days following the zoledronic acid infusion. Treatment with zoledronic acid was associated with myalgia (17.1%) fever (15.7%), fatigue (12.4%), arthralgia (11.1%), pain (10.5%), chills (9.8%), headache (9.8%), influenza-like illness (8.5%), malaise (5.2%), and back pain (3.3%). No patients developed osteonecrosis of the jaw. There was one death in each group; the two groups had similar rates of serious adverse events.

The FDA has “generally felt” that

drugs with proven antifracture efficacy in postmenopausal women can be approved, on the basis of noninferiority “bridging” studies without fracture data, for new dosing regimens or for new populations such as glucocorticoid users or men, Dr. Watts noted. That is why studies in those circumstances have been smaller and not powered to detect a reduction in fractures.”

Zoledronic acid, available as a 5-mg dose in a 100-mL ready-to-infuse solution, has been used by more than 164,000 patients in the United States since it was approved by the FDA in 2007, according to Novartis.

“Intravenous Reclast compares in price with the cost of a year’s therapy with a brand-name oral preparation. Medicare has generally covered this for postmenopausal women, and in some states it’s already covering it for men,” Dr. Watts said.

Zoledronic acid is covered under Medicare Part B, which applies to medical visits, tests, screenings, and intravenous medications. Part B covers 80% of Medicare-allowable charges, leaving 20% for secondary insurance or self-pay, he noted. ■

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