

# The New Era of DEXA

With two new treatments for osteoporosis available, more and more women are having their bone mass measured with densitometers.

Will this have a major impact on the practice of nuclear medicine?

**O**n August 12, 1996, outside the Geisinger Medical Group clinic in Wilkesbarre, PA, stands a 35-foot-long motor vehicle equipped with a dual-energy x-ray absorptiometry (DEXA) unit. An estimated 5000 women are expected to have their bones scanned in the mobile detection unit which will travel through 27 states across the country by the end of this year. On this day alone, 28 women over age 52 will have their bones scanned for free as part of the "BoneMatters Tour" sponsored by Sandoz Pharmaceutical Corporation and Lunar.

The reason for the tour? "To give women an opportunity to get and use information and not be victims of osteoporosis," according to actress Olympia Dukakis who has osteoporosis and is a spokeswoman for the tour. Educating women about their risk of osteoporosis is a noble deed. After all, osteoporosis is responsible for 1.5 million fractures every year costing the nation \$10 billion. The fact should not be lost, however, that Sandoz manufactures a calcitonin nasal spray (Miacalcin) approved by the Food and Drug Administration (FDA) early this year for the treatment of postmenopausal osteoporosis in women with low bone mass. Moreover, Lunar is the maker of a densitometer DEXA (called DPX-IQ) which is being used on the tour.

Interestingly, DEXA is only beginning to hit its stride. Barely a year ago, only about 1000 DEXA units were installed in hospitals and research centers throughout the U.S. Then, alendronate (Fosamax) was approved by the FDA in the fall of 1995 for the treatment of osteoporosis in women. The calcitonin nasal spray was approved soon after.

With the two new treatments, DEXA sales skyrocketed: A Lunar spokesman told *Newsline* that sales of its DEXA increased by 200% to 300% this year. "I would guess the number of DEXA machines in the U.S. more than doubled in the past year," said Robert Lindsay, MD, PhD, president of the National Osteoporosis Foundation and a professor of medicine at Columbia University in New York.

Reimbursement for DEXA has added to the increase in sales. The Health Care Financing Administration (HCFA) has had Medicare codes for DEXA reimbursement for about two years, but the codes



**This new peripheral DEXA unit is less expensive and takes less time to perform but is not as reliable as a tabletop DEXA unit.**

## A New, Less Expensive Type of DEXA

In February 1995, the Food and Drug Administration approved a new DEXA machine which measures bone mass in the forearm called peripheral DEXA (manufactured by Norland under the name pDEXA). It may become a widely popular technique—especially in private practices and small medical centers. The biggest advantage of pDEXA is cost savings: The price of the machine is about \$30,000 compared to \$100,000 or more for a standard DEXA. Adding to the cost savings, the forearm measurement is performed while a patient is sitting in a chair rather than lying on a table, so a smaller room can be used.

With the reduced costs of DEXA, one would think that Medicare would have a smaller reimbursement than for standard DEXA. Not

so. "There is only one code for DEXA even though peripheral DEXA takes less time and is cheaper to perform," said Robert Lindsay, MD, PhD, president of National Osteoporosis Foundation and a professor of medicine at Columbia University in New York. "pDEXA really should be reimbursed at a lower rate."

Peripheral DEXA may save money, but it is not without its problems. "It's still new, so there's not a lot of normal reference data," said Charles Chestnut, MD, a professor of medicine and radiology and director of the osteoporosis research group at the University of Washington in Seattle. Moreover, the reference data currently used to determine the healthy bone mass range and standard deviations are based on company research data, according to Chestnut. "Larger stud-

ies have not yet been done," he said. Another drawback: "pDEXA can't monitor the response to treatment because bone density changes are heterogeneous. The wrist may have lost bone, while the spine and hip have improved," Chestnut said.

The general consensus among the experts who spoke with *Newsline* is that pDEXA could be useful for first-time screening. It can rule out osteoporosis in those patients whose bone densities fall within one standard deviation of normal and can diagnose osteoporosis in those whose bone densities are 2.5 or more standard deviations beyond the healthy reference. For patients whose measurements lie somewhere between 1 and 2.5 standard deviations, a repeat DEXA on their hip or spine is recommended.

were not adopted by all 50 states until just a few months ago, according to Lindsay. Moreover, the Medicare reimbursement for DEXA was recently increased to an average of \$125 per scan.

“With the new treatments for osteoporosis, DEXA is more valuable overall,” said Charles Chestnut, MD, a professor of medicine and radiology and director of the osteoporosis research group at the University of Washington in Seattle. “More and more DEXA’s are springing up. Soon they will be everywhere.” *Newsline* decided to investigate the recent surge in bone density testing and to determine the potential effect on nuclear medicine practitioners.

#### How DEXA Became Part of Nuclear Medicine

Bone density measurements have been around for 25 years but have remained mainly in the research realm. In the early 1970s, researchers were able to measure bone mass in the wrist using single-photon absorptiometry with  $^{125}\text{I}$ .

By the mid-1980s, researchers could obtain hip and spine measurements using dual-photon absorptiometry which had a gadolinium source. Due to its radioactive source, the dual-photon densitometer was installed most often in the nuclear medicine department of hospitals. Since the \$5000 gadolinium source required replacement every year, said Chestnut, the dual-photon densitometer never came into widespread clinical use.

By 1989, DEXA became available and replaced the need for dual-photon absorptiometry. “Physicians began to use DEXA as a clinical tool, whereas dual photon was primarily a research tool,” Chestnut observed. DEXA was used to assess such medical conditions as estrogen deficiency and asymptomatic primary hyperparathyroidism.

Nuclear physicians, for the most part, were the

ones administering DEXA. Referring physicians, however, were not enthusiastic about sending patients to have their bones scanned for a disease that had no treatment beyond estrogen replacement therapy or calcitonin injections. This all changed with the approval of alendronate and the calcitonin nasal spray. Case in point: The University of Washington’s nuclear medicine department went from averaging 100 DEXA scans per month in 1995 to averaging 250 scans per month in 1996.

#### Will DEXA Remain Part of Nuclear Medicine?

Although the nuclear medicine department at Chestnut’s institution performs DEXA, he described the setup as “an anachronism.” He predicted that DEXA would not remain in the domain of nuclear

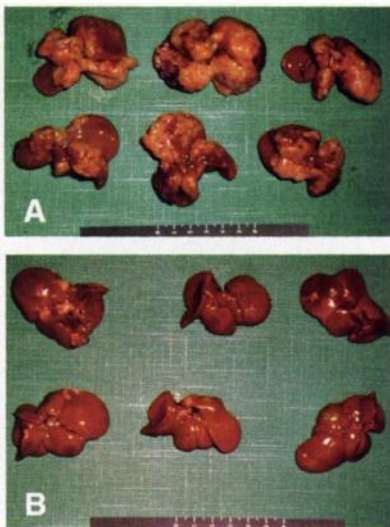
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### Osteoporosis: Not Just a Woman’s Disease

While some men gripe about reverse discrimination in the workplace, they may have a legitimate complaint when it comes to osteoporosis. After all, 1.5 million men suffer from osteoporosis and an additional 3 million are at risk for developing the disease. Yet, the two new treatments for preventing osteoporosis (alendronate and calcitonin) have been approved by the Food and Drug Administration only for postmenopausal women. Although doctors have been prescribing the medications to men, “the drugs’ efficacy has only been tested in women,” said endocrinologist John Stock, MD, professor of medicine at the University of Massachusetts Medical

School in Worcester.

Adding insult to injury, Stock said research studies on bone mass measurements in men lag two to three years behind those on women. Researchers still have not pinpointed a reliable reference range for healthy men to use as a gauge for unhealthy bone loss. Although men with certain conditions (such as prolonged use of steroid therapy) may have their bone mass measured with DEXA, the vast majority of those at risk for osteoporosis do not get screened. The good news is an ongoing epidemiological, slated to be published this fall, will provide a normal reference database for men.



### Erratum

In the August issue of *Newsline*, Figure 6A and B in a commentary written by Henry N. Wagner, Jr., MD titled, “1996 SNM Annual Meeting: Medical Problem Solving” was printed incorrectly. The correct images and accompanying explanation of the research follow:

The paradigm for radiotherapy with recognition-site ligands is: First, identify the recognition site on the tumor. Second, try treatment with the appropriate nonradioactive agonist or antagonist, depending on which has the desired effect for the specific recognition site. Third, treat the patient with a radiolabeled ligand in large doses.

Krenning and colleagues at the University Hospital Dijkzigt in Rotterdam, The Netherlands, described results in rats with neuroendocrine tumors expressing somatostatin receptors, who received large doses of  $^{111}\text{In}$ -somatostatin analog. The tumors were not present when the animals were killed, although the livers of animals treated with nonradioactive somatostatin analog were full of tumor (Fig. A and B).

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medicine but would be placed in radiology or other departments such as endocrinology or rheumatology where osteoporosis is treated. "DEXA is not as revenue producing [for nuclear medicine departments] as thallium heart imaging or bone scans," Chestnut said. Moreover, referring physicians such as endocrinologists may be inclined to purchase the relatively inexpensive DEXA machines and do the screenings themselves.

Osteoporosis researchers, however, are concerned that—at least early on—there will be little quality control over how DEXA is performed and interpreted. As with any new medical procedure, a learning curve of at least six months exists for both physicians and technicians.

Strangely enough, the unique problem with DEXA is the fact that it is user-friendly: the computer processes and prints out the result on a four-color graph comparing the bone mass measurement to the normal reference. (The bone mass measurements are compared to the average bone mass of a healthy young woman. Each standard deviation below the healthy reference means a two- to three-fold higher risk of osteoporotic fractures. A measurement greater than 2.5 standard deviations indicates osteoporosis.) Since physicians are not forced to interpret

the image itself, they may not necessarily refer patients to nuclear physicians or radiologists.

With DEXA's relative ease of use, endocrinologists, gynecologists and other specialists who treat osteoporosis have been purchasing machines of their own and having their lab technicians perform the scans along with other tasks. This is worrisome to those familiar with DEXA's complexities. "The only people who should be doing this are dedicated technicians," said endocrinologist John Stock, MD, professor of medicine at the University of Massachusetts Medical School in Worcester. "Nuclear medicine technicians are the best. Second best is a lab technician whose sole job is DEXA screening."

As with any imaging technique, DEXA is only as good as the person performing it. "It's easy to do DEXA badly," said Lindsay. "If you rotate the hip by 5 degrees too little or too much, you can change the results significantly."

Physicians, themselves, need to be aware of the intricacies of DEXA. For instance, the two manufacturers of a tabletop DEXA, Lunar and Hologic, have incompatible machines. If a patient has an initial screening on a Lunar machine and goes for a follow-up scan on a Hologic machine, a special software program needs to be utilized to compare results. Even different

machines made by the same manufacturer can yield different results. "These are technical glitches that need to be overcome," said Michael Kleerekopper, MD, a professor of medicine at Wayne State University in Detroit, MI.

Moreover, Lindsay pointed out that DEXA measurements sometimes can be falsely affected by arthritic changes in the bone. Osteofytes or calcifications can produce greater densities, which means a bone mass reading could be higher than the real bone density. "I personally look at every scan that is done," he said. "I can glean a lot from the picture." Thus, nuclear physicians could be in an optimal position to evaluate DEXA Scans.

Stock, Lindsay and the other osteoporosis researchers who spoke with *Newsline* did not have strong opinions on which, if any, specialty ought to "own" DEXA. Some felt that it would naturally be taken over by those who treat osteoporosis. Others seemed to think a partnership between nuclear physicians and referring endocrinologists would work well. A Lunar spokesman said his company has been "selling DEXA machines to a wide variety of physicians" and that "no one hospital department is predominantly buying the machines." For now, DEXA's role in nuclear medicine departments remains to be seen.

—Deborah Kotz

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on explicit clinical standards, not financial reviewers.

- Requires establishment of a toll-free hot line for enrollees to air their grievances, and MCOs would be obligated to respond within 48 hours in cases where a delay would significantly increase the risk to an enrollee's health.
- Patients with chronic illnesses, such as diabetes and AIDS, would have standing referrals enabling them to continue seeing a specialist on a regular basis without needing pre-authorization.
- Consumers would be guaranteed coverage for trips to the emergency room without needing pre-approval.
- MCOs spell out information on procedures for prior authorization and financial responsibility for care received both inside and outside the plan.

Upgrade quality of information available to consumers to compare health plans.

Although "there hasn't been an analysis of the bill by an actuarial firm, we've done an estimate on what the new standards would mean in terms of cost. They would add about 5% to health care premiums," said Leslie Moran, a participant at the drafting table representing the majority of state MCOs. On the other hand, "we recognize that there is a level of anxiousness among consumer and business populations and we felt that this agreement would help ease that," added Moran.

Regulating MCOs is "definitely an issue that states will grapple with given the rise in managed care coupled with plans to increase enrollment of Medicaid populations into managed care settings," says Randy Desonia, director of health policy studies at the National Governor's Association. Desonia predicts that New York's

effort is "the beginning of a big trend."

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Connecticut's insurance department has approved Aetna Inc.'s purchase of U.S. Healthcare Inc., but community activists say they are planning a law suit against the \$8.9 billion deal. This acquisition is Aetna's attempt to switch from an indemnity-based insurer to joining the ranks of managed health care organizations.