

## More Bone Density Testing Is Needed, Not Less

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**Editor's Note:** In this issue of the *JBMR*, we introduce a new feature called *Viewpoints*. The intent of *Viewpoint* articles is to provide rapid, critical commentaries, generally reflecting differing perspectives, on pressing topics arising in the bone field that the editors believe deserve immediate discussion and dissemination. *Viewpoints* will be concise, focused opinions of new original studies or other issues that are deemed to have immediate impact on understanding bone and mineral biology or clinical practice. The inaugural *Viewpoint* articles, which appear in this issue, address the recent controversy surrounding the proposed frequency for performing bone mineral density in older postmenopausal women.

**B**one mineral density (BMD) testing by dual-energy X-ray absorptiometry (DXA) is the international standard for the clinical assessment of skeletal health. DXA is used to diagnose osteoporosis, to assess fracture risk, and to monitor changes in BMD over time. These clinical applications are supported by the following:

1. A strong correlation between skeletal mechanical strength and BMD measured by DXA<sup>(1)</sup>;
2. A robust relationship between fracture risk and BMD measured by DXA in clinical trials and epidemiological studies<sup>(2)</sup>;
3. The primacy of DXA in the 1994 World Health Organization (WHO) classification of skeletal health into normal, osteopenic, or osteoporotic categories<sup>(3)</sup>;
4. DXA's pivotal role in identifying eligible subjects in all registration trials for medications now approved to treat osteoporosis<sup>(4)</sup>;
5. Excellent accuracy and precision of DXA<sup>(5)</sup>; and
6. Low patient exposure to ionizing irradiation with DXA.<sup>(6)</sup>

The WHO's Fracture Risk Assessment Tool (FRAX) algorithm employs femoral neck BMD by DXA as the only validated bone density measurement.<sup>(7)</sup> Serial BMD performed by DXA is used to monitor the course of patients who are treated with U.S. Food and Drug Administration (FDA)-approved drugs for osteoporosis.<sup>(8)</sup> In fact, DXA is the only measurement technology recognized by the Center for Medicare and Medicaid Services

(CMS) in the United States for monitoring therapy with serial BMD measurements.<sup>(9)</sup> DXA is also the technology recommended by the U.S. Surgeon General<sup>(10)</sup> and the U.S. Preventive Services Task Force (USPSTF)<sup>(11)</sup> for population screening. Osteoporosis screening strategies with BMD testing are cost-effective.<sup>(12)</sup> Increases in BMD testing rates in appropriately selected patients have been proven to reduce the incidence of fractures and reduce healthcare costs, including the expenses associated with BMD testing and treatment.<sup>(13,14)</sup>

More sophisticated technologies may come along, in time, that can be used in clinical practice to measure skeletal features not currently identified by DXA, such as bone strength, true volumetric density (mg/cm<sup>3</sup>), dynamic features of bone remodeling, and skeletal microarchitecture. Currently, however, there is no other skeletal health assessment technology that provides as much clinical information as DXA for screening, identification of patients at high risk for fracture, and monitoring patients, whether or not they are on drug therapy.

The recent study by Gourlay and colleagues<sup>(15)</sup> from the Study of Osteoporotic Fractures (SOF) has raised questions about intervals between BMD measurements in older postmenopausal women. The study cohort of 4957 women was a subset of 8514 women in SOF who had BMD testing by DXA. Women in SOF were excluded from this analysis if there was a diagnosis of osteoporosis (defined as  $T$ -score  $\leq -2.50$  at the femoral neck or total femur), treatment for osteoporosis, a past history of a hip or clinical vertebral fracture, or a follow-up DXA study was not available for review. All women studied were ambulatory with

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For another Viewpoint on this topic, please see Gourlay et al. (*J Bone Miner Res.* 2012;27:743–746. DOI: 10.1002/jbmr.1585).

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normal BMD (*T*-score  $\geq -1.00$  or higher at the femoral neck or total hip) or osteopenia (*T*-score between  $-1.00$  and  $-2.50$  at the femoral neck or total hip); age was  $\geq 67$  years and  $>99\%$  were white. The primary outcome measure was the estimated interval for 10% of participants to make the transition from normal BMD or osteopenia at baseline to osteoporosis, before a hip or clinical vertebral fracture occurred or before treatment for osteoporosis was started. As would be expected, the authors found that a higher baseline BMD was associated with a longer time to develop osteoporosis and that women with normal bone density at the age of 67 years were unlikely to have subsequent rapid bone loss. In women with normal baseline BMD, the mean adjusted interval for 10% of study participants to develop osteoporosis was 16.8 years (95% confidence interval [CI], 11.5–24.6). In individuals aged 67 years who had low baseline BMD values, the time to develop osteoporosis was shortened, with participants having “advanced osteopenia” (baseline *T*-score between  $-2.00$  and  $-2.50$ ) having an adjusted interval of only 1.1 years (95% CI, 1.0–1.3) for 10% to develop osteoporosis. The findings are consistent with other studies showing an age-related bone loss of about 1% per year in women with similar characteristics.<sup>(16)</sup> Based on such data, a recommendation for extended BMD retesting intervals in older white women with favorable baseline BMD values and low risk of rapid bone loss or fracture is reasonable.

The authors correctly identified limitations of the study that preclude its applicability to a wider patient population. The study cohort was restricted to preselected women  $\geq 67$  years of age and did not include men or younger postmenopausal women. It is particularly important to note that women in their early postmenopausal years are likely to experience accelerated bone loss that may require short testing intervals (eg, 1–2 years) to assess. Also excluded from the trial were nearly 50% of the SOF study participants who had a previous diagnosis of osteoporosis (based on a prior hip or clinical vertebral fracture or densitometric evidence of osteoporosis) or who were already on treatment for osteoporosis.

Other limitations to the trial were not noted by the authors. Only clinical vertebral fractures were considered in the analysis, although undiagnosed morphometric vertebral fractures are common in patients with densitometric evidence of osteopenia and are associated with high morbidity.<sup>(17)</sup> In a prospective cohort study of 671 postmenopausal women undergoing periodic spine imaging, 48% of vertebral fractures were found in women with *T*-scores between  $-1.0$  and  $-2.5$ . With a morphometric vertebral fracture, they would be reclassified as having a clinical diagnosis of osteoporosis.<sup>(18)</sup> Many of these patients would not have been identified in the study of Gourlay and colleagues.<sup>(15)</sup> In making treatment decisions in clinical practice, it is imperative to consider risk factors for fracture in addition to the femoral neck and total hip *T*-score. Gourlay and colleagues, for example, did not measure lumbar spine BMD. Low lumbar spine BMD is associated with increased fracture risk at all skeletal sites.<sup>(19)</sup> Moreover, lumbar spine *T*-score may be  $\leq -2.5$  even if the femoral neck or total hip *T*-score is  $> -2.5$ . Without tracking lumbar spine BMD, Gourlay and colleagues may have underestimated the number of individuals who progressed to osteoporosis during the study. Most importantly,

with its singular focus on BMD, the study did not capture those patients with osteopenia who by FRAX fracture risk assessment would have been at high risk for fracture and therefore warrant drug therapy.

Not unexpectedly, the study by Gourlay and colleagues<sup>(15)</sup> generated considerable media attention, suggesting that DXA was an expensive test that was overused and abused by physicians,<sup>(20,21)</sup> and that Medicare will save money if fewer DXA studies are performed.<sup>(22)</sup>

In reality, overtesting with DXA is not a problem. The real problem is that far too few patients are being screened for osteoporosis. The annual Medicare Part B testing rate for women 65 years of age and older is only 14%, with a decline in the annual rate of testing in 2010.<sup>(23)</sup> A recent Medicare claims analysis by King and Fiorentino<sup>(23)</sup> during the 7-year period from 2002 to 2008 demonstrated that 48% of elderly women had not had a single DXA study. Only 25% had one test, 15% had two tests, 8% had three tests, 2% had four tests, and  $<1\%$  had five or more tests. Importantly, the claims data also included women already diagnosed with osteoporosis and those on drug therapy, patients who were excluded from the study by Gourlay and colleagues.<sup>(15)</sup>

Although concerns have been raised that some screening prevention programs for other chronic diseases do not result in healthcare savings,<sup>(24)</sup> that is not the case for BMD testing in appropriately selected patients. The experience of healthcare systems suggests that increases in BMD testing reduce fracture rates and save money. A 5-year observational study evaluated the clinical and fiscal outcomes of the Geisinger Health System Osteoporosis Disease Management Program from 1996 to 2000.<sup>(14)</sup> It was found that implementation of osteoporosis guidelines that included increases in BMD testing and treatment was associated with a significant decrease in the age-adjusted incidence of hip fractures and an estimated \$7.8 million reduction in healthcare costs during this 5-year period. At Kaiser Southern California, an osteoporosis disease management program (“Healthy Bones Program”) was fully implemented in 2002, with a goal of reducing hip fractures by increasing BMD testing rates and treatment in patients at high risk of hip fracture.<sup>(25,26)</sup> It was estimated that in 2006, 935 hip fractures, with an average cost of \$33,000 each, were prevented, resulting in savings of over \$30.8 million for Kaiser.<sup>(13)</sup> Multiple osteoporosis screening strategies have been found to be clinically effective, and cost-effective as well.<sup>(12,27,28)</sup>

Osteoporosis is a major public health concern.<sup>(10)</sup> More than 200 million women and men are estimated to have osteoporosis worldwide, including about 10 million Americans.<sup>(29,30)</sup> There are about 2 million osteoporotic fractures each year in the United States, resulting in over 432,000 hospital admissions, almost 2.5 million medical office visits, and increased risk of disability and death,<sup>(31,32)</sup> with healthcare costs exceeding \$18 billion.<sup>(33)</sup> Despite the availability of DXA to diagnose osteoporosis and the use of FRAX to assess fracture risk, osteoporosis remains a disease that is underdiagnosed.<sup>(34)</sup> Although FDA-approved therapies that are proven to reduce fracture risk are widely available, the disease is still, in 2012, undertreated.<sup>(35–40)</sup> Recent declines in Medicare DXA reimbursement in the United States to levels that are below the cost of providing the procedure have

been associated with a reduction in BMD testing.<sup>(23)</sup> Failure to appreciate the limitations of the study reported by Gourlay and colleagues<sup>(15)</sup> may have adverse consequences that further reduce BMD testing due to a negative impact on policy formulated by CMS, legislators, and insurers. This negative scenario could result in fewer patients tested for osteoporosis, fewer patients treated, more fractures, and higher healthcare costs.<sup>(41)</sup>

More BMD testing, not less, is needed to screen for osteoporosis. This is good clinical practice, cost-effective, and will reduce the burden of osteoporotic fractures. Current evidence-based guidelines for BMD testing should be followed. The National Osteoporosis Foundation,<sup>(30)</sup> the International Society for Clinical Densitometry (ISCD),<sup>(42)</sup> and the USPSTF<sup>(11)</sup> all recommend BMD testing for women  $\geq 65$  years of age and for younger women who may be at high risk for fracture according to prespecified parameters. Monitoring for treatment effect is recommended 1 to 2 years after starting or changing therapy,<sup>(30,42)</sup> with consideration of longer testing intervals once a favorable treatment effect is confirmed. The ISCD Official Positions state that intervals between BMD testing should be determined according to each patient's clinical status<sup>(42)</sup>; the USPSTF suggests screening intervals of at least 2 years in women with normal baseline BMD.<sup>(11)</sup> Both of these recommendations are consistent with the findings of Gourlay and colleagues.<sup>(15)</sup> When screening shows that BMD is normal or slightly low in women age  $\geq 67$  years, and there are no clinical risk factors for fracture or rapid bone loss, a long interval until repeat testing is appropriate. For younger patients, for those with BMD values substantially below normal, for those with prior fracture or clinical risk factors for fracture, and for those started on osteoporosis drug therapy, a repeat BMD test should be done after a much shorter time interval.

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