

Bone Mineral Density Assessment Understanding the Value of BMD Testing in the Primary Care Setting

Charles Cantoni
Diane King
Alara, Inc.

Abstract

In a paper published in December, 2001, Siris, et al describe the results of the National Osteoporosis Risk Assessment (NORA) study, which revealed that half of post-menopausal women over the age of 50, with no previous osteoporosis diagnosis, had undetected low bone mineral density (BMD).¹ The study concluded that, “Given the economic and social costs of osteoporotic fractures, strategies to identify and manage osteoporosis in the primary care setting need to be established and implemented.” Gallagher, et al report in a study of 1500 female members of a Connecticut independent practice association that, “...only a small minority (12% to 34%) had their BMD tested.”² This paper examines the feasibility and value of establishing practical, cost-effective testing for low BMD in the primary care setting. We conclude that such testing is feasible using low cost peripheral radiographic absorptiometry (RA) techniques.

Introduction

Hip and spine fractures are serious, debilitating injuries that dramatically reduce quality of life. Early detection of osteoporosis can lead to interventional therapies that can reduce the probability of hip or spine fracture.³ Such therapies include:

- a. Adequate intake of dietary calcium;
- b. Regular weight bearing and muscle-strengthening exercise;
- c. Drug therapies such as alendronate, risedronate, raloxifene and calcitonin.

The motivation for establishing BMD testing in the primary care setting is established in part by the paper presented by Siris, et al regarding results of the NORA study.¹ In this study, a cohort of 200,000 post-menopausal women aged 50 years and older with no previous diagnosis of osteoporosis was tested using peripheral techniques. Almost 50% of the subjects had low BMD including 7.2% with osteoporosis. The subjects were then followed for 3 years to determine actual osteoporotic fracture outcomes. Those found to be osteoporotic based on peripheral measurements had a fracture rate approximately 4 times that of normal BMD subjects and osteopenic patients were associated with a 1.8-fold higher fracture rate. The study concludes that “Peripheral BMD results were highly predictive of fracture risk.” and that “Given the economic and social costs of osteoporotic fractures, strategies to identify and manage osteoporosis in the primary care setting need to be established and implemented.”¹

In an editorial in the *Journal of Bone and Mineral Research*, Kleerekoper and Nelson state, “Among the clinical and scientific community, there is almost universal agreement that measurement of bone mineral density (BMD) in seemingly healthy individuals is the only means of assessing skeletal status and fracture risk. Even in persons with other identifiable risk factors for fracture (personal or family history of fragility fracture, corticosteroid use, etc.) measurement of BMD adds substantially to the assessment of fracture risk in the individual.”⁴

Given these facts, the goal should be to expand BMD testing in the primary care setting.

Practical Implementation of BMD Testing

The primary goal in introducing BMD testing to your primary care setting is to provide a very important service to your patients, namely to test or screen for low BMD. With the many therapies available today, testing for low BMD is the critical element in reducing the economical and social costs of osteoporotic fractures in general, and specifically to the benefit of your patients.

Implementing BMD testing in the primary care setting should be done in a practical way. Practical considerations include:

- Motivation for testing BMD,
- Efficacy of the testing system utilized, including such measures as sensitivity, specificity, negative predictive value and positive predictive value,
- Regulatory considerations for the instrument used (facility and operator requirements),
- Volume of tests to be performed over time,
- Costs to acquire the system and continuing operational costs, and
- Reimbursement expectations.

We will discuss each of these in turn in the remainder of this paper.

Motivation for Testing

In the Introduction above, we have discussed the need for BMD testing as a means to identify those at risk for osteoporotic fracture. Without in-house peripheral BMD testing, primary care physicians must refer patients to a facility with a central DXA (Dual Energy X-ray Absorptiometry) system for assessment of BMD. This process involves scheduling the patient for a hospital or clinic outpatient visit. Time is then required to get the report back to the referring physician. In all, the process is time consuming and is considered inconvenient by many patients. The end result, we believe, is that many patients that should have BMD screening do not receive it. The primary care setting represents that place where most individuals can be conveniently tested for low BMD.

There are well-defined criteria for those that should be screened. These include:⁵

- Being female
- Thin and/or small frame
- Advanced age
- A family history of osteoporosis
- Postmenopausal, including early or surgically induced menopause
- Abnormal absence of menstrual periods (amenorrhea)
- Anorexia nervosa or bulimia
- A diet low in calcium
- Use of certain medications, such as corticosteroids and anticonvulsants
- Low testosterone levels in men
- An inactive lifestyle
- Cigarette smoking
- Excessive use of alcohol
- Being Caucasian or Asian, although African Americans and Hispanic Americans are at significant risk as well.

BMD measurement in the office setting can result in a very convenient, effective testing process for patients. In particular, a test requiring little or no preparation on the part of the patient, performed on an easily operated BMD measurement system, can provide convenient access for all appropriate patients. Convenient testing means that

you, as the physician, can track changes over the years and identify patients with low BMD. Based on your preferences and local resources, you may then use the peripheral results as a screening tool to refer for central (hip /spine) DXA testing, or you may use the peripheral results directly for diagnosis and treatment.

☑ Efficacy

To get right to the point, one needs a BMD testing system with proven efficacy in order to implement an office BMD screening program. The lower cost peripheral measurement alternatives include QUS (Quantitative Ultrasound) of the heel and RA of the phalanges. In a separate white paper¹¹, Alara presents an overview of studies done to-date that quantify the characteristics of the available systems. You, as a physician, must be comfortable with the technology being employed. RA of the phalanges turns out to be an attractive approach to solving the problem. In a poster presented at the ASBMR (American Society of Bone and Mineral Research) meeting in Minneapolis in 2003, Boonen, et al⁶ evaluated Calcaneal Ultrasound, RA of the Phalanges (MetriScan[®]) and Metacarpal Digital X-ray Radiogrammetry as potential means to get BMD measurement into the primary care setting. They concluded that RA of the phalanges was the most accurate method of doing so.

When using peripheral bone density testing as a screening test for risk of fracture, it is important to understand the relationship between peripheral and central measurements. It is also important to understand the overall context of the diagnosis of fracture risk. Miller, et al⁷ have written an excellent article on the subject in the *Journal of Clinical Densitometry*. They correctly pointed out that BMD measurement is an important factor but not the whole story in deciding on therapeutic courses of action for patients with low BMD.

In the end, all diagnostic or screening tests may be evaluated by their sensitivity, specificity, negative predictive value, positive predictive value, and/or odds ratio. Evaluation of these parameters will depend on whether the test is used for screening or diagnosis. We will begin our discussion of efficacy with a little background on BMD measurement, and move into the question of screening vs. diagnosis.

Background

Special purpose instruments for the measurement of bone mineral density became available commercially in the U.S. in the late 1970's. These instruments used radioactive sources or x-ray sources to make projection images on the forearm, femur and spine in an attempt to develop a means of prediction of bone fracture due to osteoporosis.

In 1979 the World Health Organization (WHO) conducted a study of healthy young women to determine the relationship of osteoporotic fracture risk to bone mineral density (as measured in the peripheral skeleton.) Based on the results of the study, the T-score metric was defined as the number of standard deviations from the mean bone density of young (20 – 39 years), healthy Caucasian females. Based on fracture rates in the study population, subjects with T-scores in the range of -1 to +1 were defined as “normal,” those with T-scores between -1 and -2.5 were defined as osteopenic, those with T-scores below -2.5 were deemed osteoporotic.

From these beginnings, a number of devices have been developed which assess BMD. Measurements of healthy young populations provide a reference database, allowing the systems to calculate T-scores for patients. One method, known as dual-energy absorptiometry (DXA), can be used to estimate the bone density in the central skeletal sites such as the hip or spine. Central DXA has become a consensus standard for the assessment of osteoporosis. While central DXA is generally a good predictor of fracture risk, the machines are typically large, expensive, and require a trained, certified operator. Central DXA exams are time consuming. Moreover, central DXA machines are not typically installed in the primary care setting; thus an appointment must be made with a separate facility for a central DXA exam.

For these reasons, and to provide greater access to BMD testing, manufacturers have developed smaller and less expensive BMD measurement systems which are easier to use, usually involving BMD estimation at a peripheral

site, such as the heel, forearm, or phalanges of the hand. These systems are good candidates for installation in the primary care setting. They are typically much lower in cost to purchase and can be easily operated by the physician's staff. Such systems include:

- DXA of the heel, forearm, or phalanges
- Photo Densitometry (PD) or Radiographic Absorptiometry (RA) of the phalanges
- Quantitative Ultrasound of the heel or forearm

Peripheral BMD measurements have been the basis for several definitive research studies, which have shown the techniques to be excellent predictors of osteoporotic fractures. Mussolino, et al⁸ found that RA measurements of phalangeal bone density were predictive of hip fracture. Thus the value of these measurements has been well proven.

Screening vs. Diagnosis

The question is often asked, how does a peripheral device such as MetriScan (Phalangeal RA) compare to central DXA in measurement of BMD? Should it be used as a screening device or as a testing device? The diagram illustrates the question.

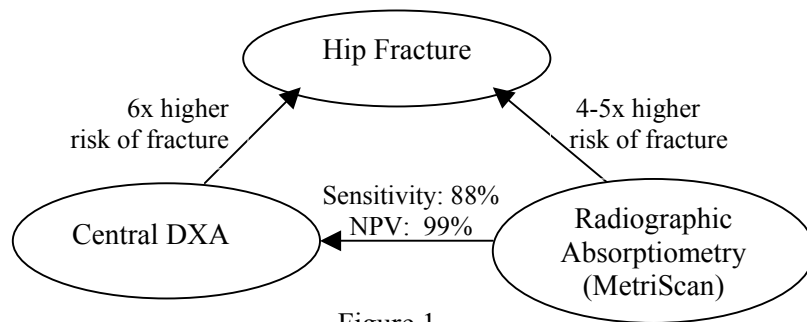


Figure 1

Research has shown that peripheral BMD testing may be used effectively either for screening prior to considering central DXA, or as a means of directly estimating fracture risk, given that peripheral measurements have been shown to be excellent predictors of hip fracture.

Assessments of diagnostic or screening tests evaluate how well the test is able to correctly classify a patient as “normal” or “diseased”. It is important, therefore, to understand how the true disease state is defined.

Direct Diagnosis: Prediction of Hip Fracture

As we shall discuss below, both central DXA and peripheral devices such as MetriScan are predictive of fracture risk, and of course determination of osteoporotic fracture is the primary purpose for BMD measurement. In determining the ability of central DXA or RA to predict hip fracture, we define the true disease state to be the actual occurrence of hip fracture.

Siris, et al.¹ examined fracture rates for patients tested with peripheral BMD devices. Patients diagnosed as osteopenic (T-score < -1) were found to have a 1.8-fold higher fracture rate than those diagnosed as normal (T-score > -1). Those found to be osteoporotic (T-score < -2.5) had a 4-fold higher fracture rate than normals. Grampp et al.⁹ found an odds ratio of 2.0 for RA of the phalanges for prediction of hip fracture. The odds ratio for hip DXA was only slightly better at 2.5. Both authors conclude that BMD measurement of the phalanges is an excellent predictor of hip fracture.

Peripheral RA for Screening and Referral to DXA

If the peripheral BMD test is used as a screening tool upon which to base referrals to central DXA, we consider the true disease state to be a classification of osteoporosis based on central DXA. Studies such as that reported by

Boonen, et al.¹⁰ looked at the correlation between phalanges RA and central DXA and concluded that phalangeal RA was the most accurate of various peripheral techniques in referring to central DXA. Alara, Inc. is sponsoring a study at Radiological Associates of Sacramento, CA involving 1000 patients tested on central DXA and MetriScan. Preliminary results indicate that a reasonable threshold can be set which results in a sensitivity of 88% (88% of all patients that would be classified by DXA as osteoporotic are referred by MetriScan) and negative predictive value of 99% (99% of all patients who test normal on MetriScan would also test normal on central DXA). From these data it is clear that MetriScan can be used very effectively as a testing device to determine patients with low BMD who should be further tested and possibly treated. See Miller et al.¹⁴ for a discussion of the use of peripheral BMD for screening and referral to central DXA.

Deciding Between Diagnosis and Screening

As discussed above and illustrated in Figure 1, MetriScan may well be used either for diagnosis or for screening and referral to central DXA. The choice remains with the physician based on preferences and local resources. Some points to consider:

- Availability of central DXA in your community
- The likelihood of patient compliance with a referral
- Accuracy of treatment monitoring; current recommendations are to monitor drug treatment with central DXA (see the section on Frequently Asked Questions).

Alara's white paper on phalangeal RA¹¹ provides further information on the use of Alara's MetriScan system and cites numerous references showing the validity of the phalangeal RA technique.

Regulatory

Regulatory requirements for the various systems that can be employed vary from state to state and country to country. In general, x-ray based systems seem to offer better short-term precision in measurement, but the regulatory requirements for x-ray systems are greater. Alara has published a compendium of regulatory requirements for the 50 states in the U.S. Most are not difficult to implement.

Expected Patient Volume

In deciding whether BMD screening is appropriate for your facility in today's cost containment environment, economics clearly must be considered. The economic analysis starts with the expected patient volume. Following is an example of a computation that is designed to get at the expected patient volume for a family practice with *two practicing physicians*. Clearly, in doing this analysis, you must decide on your screening criteria. Which patients fall into the "should be screened" category?" The assumptions in the analysis are highlighted in *italics*.

Physicians in the group:	2	
<i>Total patient</i> population (from A.M.A. data):	3,000	
Estimated percent over the <i>age of 50</i> :	40 %	
Percent <i>Female</i> :	50 %	
<u>Resulting female population to screen:</u>		<u>600</u>
<i>Percent of male</i> population to be screened (subjective):	20 %	
<u>Resulting male population to screen:</u>		<u>120</u>
<i>Patient turnover</i> , per year:	10 %	
<i>Screening Frequency</i> :	Every 2 years	
<u>Resulting total population to be screened.</u>		<u>396 per year</u>

From the analysis the group could be expected to screen an average of approximately 33 patients per month. This number helps determine the cost effectiveness of implementing screening in your office.

☑ Reimbursement Expectations

The Bone Mass Measurement Act, passed by Congress and signed by the President in 1997, mandated Medicare coverage for bone density testing beginning July 1, 1998.

All Medicare carriers and most private insurers cover biannual bone density testing for the following beneficiaries (CPT Code 76078):

- A woman who is estrogen-deficient and at clinical risk for osteoporosis
- An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia or vertebral fracture
- An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to greater than or equal to 7.5 mg of prednisone per day for more than 3 months
- An individual with primary hyperparathyroidism
- An individual being monitored to assess the response to or efficacy of an FDA approved osteoporosis drug therapy

As of January, 2004 the average Medicare reimbursement rate for RA BMD measurement was \$41.20. Rates vary from state to state. One may also expect to have a percentage of patients who will self-pay, perhaps at rates closer to \$25 per test.

☑ Costs to Acquire and Operate

Systems for BMD measurement, such as the Alara MetriScan, are available from the manufacturer's representative. Usually, systems may be leased or purchased outright.

☑ Resulting Economic Decision

From the patient volume analysis and cost estimates one can derive the economic factors that go into the decision as to the feasibility of doing in-office BMD screening. One should include the cost of the system, supplies, and once out of warranty period, service contract costs.

Costs for labor for performing the testing when using the MetriScan system are not significant. That is because of the minimal time required. Testing on an individual can be accomplished in approximately 2 minutes, mostly consumed in entering patient data. At 26 patients per month, this equates to 52 minutes per month, a minor workload increase on existing staff.

For practically priced systems, such as MetriScan, assuming reimbursement levels outlined above, and with the test volumes anticipated, the placement of BMD measurement systems in the primary care setting is quite cost effective.

Summary and Conclusions

In this paper we have examined the value of BMD testing in the Primary Care setting. From various published papers, we see considerable evidence that extending BMD testing beyond the central DXA reach can be of great value in identifying patients with low BMD that can be treated to lower the probability of future hip or spine fracture. Further, various studies have shown the long-term predictive value of peripheral measurements of BMD in assessing hip and other fracture risk. These valuable peripheral techniques include RA of the Phalanges, such as performed by Alara's MetriScan system.

Finally, we have explored the financial feasibility of using MetriScan for BMD measurement in the Primary Care environment and conclude that for moderate sized practices, MetriScan is cost effective.

Frequently Asked Questions

- **Does Medicare reimburse uniformly in all states?**
No, reimbursement by Medicare varies by location, even within states. The average reimbursement is \$ 41.20.
- **Do all insurance companies reimburse for MetriScan tests?**
No, this is quite variable. Some reimburse as a screening test, others do not. Those that reimburse for screening do not necessarily reimburse for follow-up testing during therapy.
On the other hand, several states have taken a strong public health stand on osteoporosis and either mandate coverage for diagnosis and treatment or require private insurers to at least offer such coverage.
- **Can MetriScan be used for therapy follow-up?**
MetriScan is cleared for monitoring changes over time, but realistically, two factors must be considered. First, for the drug being given, what is the expected rate of change of bone density in the phalanges as compared to the spine or femur? Second, what is the precision capability of MetriScan? The precision capability of MetriScan is better than 1.2 %, comparable to or better than DXA precision. But some drug companies state that when being treated, the rate of change in the phalanges is significantly slower compared to the rate of change in the spine.¹² In that case, following therapy with MetriScan involves a longer sampling interval than might be used with DXA techniques.
- **Is MetriScan radiation safe?**
Yes. The skin entrance dose to the patient for a single measurement is ≤ 10 mrem, less than 5% of that received during a typical dental x-ray.
- **Is MetriScan safe for the technologist/doctor?**
Yes. With a patient load of 25 patients per month, the annual dose to the operator is less than 0.3 mrem compared to a typical annual occupational dose limit of 5,000 mrem, and can be further reduced by using the remote cable switch and stepping back from the system.
- **Will the MetriScan BMD result agree exactly with a central DXA machine?**
Not necessarily. Within the same patient, bone density varies from one anatomical site to another as seen in the discordance in many hip and spine studies.¹³ Bone density at the phalanges is as well-correlated with the hip and spine as the hip and spine are correlated with each other. Studies have shown, however, that testing at the phalanges is an excellent predictor of hip fracture.

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Charles Cantoni is President and CEO and Diane King is VP Regulatory Affairs of Alara, Inc., the manufacturer of the MetriScan BMD measurement system. Reprints of this paper are available from Alara, Inc. 47505 Seabridge Drive, Fremont, CA 94538