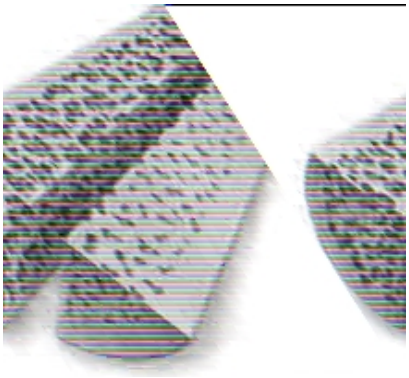

BONE DENSITY & OSTEOPOROSIS:

An Update for Manitoba Physicians

No. 3: April 30, 2001

Re: BONE ULTRASOUND TESTING IN MANITOBA PHARMACIES

Use of ultrasound may give misleading results

The members of Manitoba Health's Bone Density Program Committee have concerns over the use of ultrasound bone testing as practiced by some of the private companies. In one recent case, a child was diagnosed as having abnormal bones because the operator was unaware that measurements in children are normally much less than in adults. Such mistakes, while the exception, clearly speak for the need for better ultrasound operator education and accountability.

Ultrasound & DEXA results frequently are in disagreement

This alternative form of bone density testing using ultrasound is being offered by private companies and the service is paid for by either the patient or by a sponsor (such as a pharmacy). Although ultrasound bone measurement has some potential advantages, such as the lack of radiation and the low cost of the devices, the findings from use of ultrasound and dual X-ray absorptiometry (DEXA) are usually not the same. The results between the two are frequently not in agreement.

The scientific community remains divided on the role that such devices should play in assessing the bone density of individuals. For example, the Osteoporosis Society of Canada (OSC) has been cautious in endorsing the use of ultrasound until adequate standards, training qualifications, and physician education materials have been developed. The OSC has not and does not endorse mass testing of bone density healthy individuals.

…no requirements that private ultrasound operators have formal training

Currently there is no requirement that operators of ultrasound equipment have formal training in measuring bone density or participate in any formal quality assurance programs. Indeed, none of the private companies offering this service that we have spoken with have had training or accreditation through the International Society for Clinical Densitometry (ISCD) or have developed an ultrasound program that meets the minimal OSC recommendations.

…no guarantee that ultrasound

Therefore, there is no guarantee to you that measurements are being performed correctly and accurately. Even in the hands of experts, there is uncertainty over how to address the high

measurements are accurate

disagreement rates between the two tests. Ultrasound of the heel detects far fewer cases of osteoporosis than does DEXA and many people (probably the majority) who have had ultrasound testing will require additional DEXA testing. This duplication in testing is inconvenient for patients and generates additional costs. Finally, there is still no scientific consensus on how to use ultrasound measurements in defining fracture risk or diagnosing osteoporosis.

Manitoba no longer has an unacceptable waiting list for individuals needing DEXA measurements

Currently in Manitoba we are fortunate that a provincial bone density program assures a uniform approach to DEXA testing, quality assurance and reporting. At one time, it was difficult to obtain DEXA testing in Manitoba due to an unacceptably long waiting list. Fortunately, since Manitoba Health approved major funding increases to operate testing programs in Winnipeg and Brandon, this is no longer the case.

Guidelines have been developed to ensure that testing is directed towards individuals most likely to benefit from identification and treatment of osteoporosis. Individuals who do not qualify for testing under these guidelines are usually at low risk of osteoporotic fracture. Women who qualify for testing according to the Manitoba guidelines can obtain timely DEXA testing through Medicare and should not pay for ultrasound testing. These criteria are not inflexible, and if doctors feel that testing is justified on other grounds then this rarely refused.

Individuals can have normal heel ultrasound results while having significant bone loss in the hip and spine

Given the poor agreement between the heel ultrasound measurements and DEXA measures of the spine and hip, it is common to find individuals with ultrasound measurements that are normal or only slightly below normal while having severe bone loss in the spine or hip (as shown by DEXA). In part, this reflects the more rapid loss in bone mass from the central sites like hip and spine than from the peripheral skeleton (which the heel ultrasound measures). Experts have suggested that when ultrasound is used for screening prior to DEXA that a liberal threshold must be used to avoid missing cases with osteoporosis in the central skeleton (hip and spine). A heel ultrasound T-score threshold of -1.0 has been proposed.

If all individuals with a heel ultrasound T-score of less than -1.0 need to be referred for DEXA testing then this probably affects the majority of the population at risk and calls into question whether ultrasound screening is efficient or cost-effective. A heel ultrasound T-score of less than -2.5 usually predicts osteoporosis in the central skeleton, but the opposite is not true: heel ultrasound measurements not in the osteoporotic range may (and frequently do) show central skeletal osteoporosis.

Diagnostic thresholds for DEXA cannot and should not be applied to heel ultrasound

A recent advisory panel (as published in the journal Osteoporosis International 2000;11:192) has emphasized that the World Health Organization (WHO) definition of osteoporosis based upon DEXA (more than 2.5 standard deviations below average for a young adult) should be restricted to central sites. The message is clear:

diagnostic thresholds for DEXA cannot and should not be applied to heel ultrasound.

Currently the precision of heel ultrasound is insufficient for the monitoring of individuals to assess their response to treatment or loss of bone mass in the absence of treatment. Even DEXA has difficulty detecting short-term changes. It usually requires about three years for DEXA to detect a change (an increase) in bone density density.

RECOMMENDATIONS

The following recommendations are offered to family physicians encountering patients in their offices who bring results of heel (calcaneus) ultrasound testing:

Recognize that discordance between DEXA and ultrasound is common, with ultrasound underestimating the prevalence and severity of osteoporosis as defined from central sites.

Patients should understand that DEXA is still the gold standard for bone density testing, and that ultrasound is remains investigational. They should also understand that private ultrasound operators rarely have formal training and accreditation in bone densitometry.

Discordance between DEXA and ultrasound is particularly likely in the presence of medical factors (organ transplant, steroid therapy, amenorrhea) or when there is overt clinical evidence of skeletal fragility (low-trauma fractures).

In the absence of the above:

- a calcaneus ultrasound T-score above -1.0 can be taken as good evidence that central skeletal osteoporosis is unlikely (though osteopenia is still quite possible),
- a calcaneus ultrasound T-score below -2.5 usually predicts central skeletal osteoporosis, but may warrant DEXA testing for confirmation and/or as a baseline if follow-up testing is desired, and
- intermediate cases with a calcaneus ultrasound T-score between -2.5 and -1.0 are very common and probably require DEXA testing since a substantial fraction will be found to have central skeletal osteoporosis.

This newsletter and other program information are available through the Manitoba Health web site (http://www.gov.mb.ca/health/programs/mbd/index.html).