STANDARDS FOR DIAGNOSTIC IMAGING

BONE DENSITOMETRY

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BONE DENSITOMETRY (DEXA)

OUTLINE

1. Definitions
2. Preamble
3. Qualifications of Personnel
4. Indications for Obtaining Bone Densitometry
5. The Anatomic Site
6. Documentation and the Written Report
7. Equipment Specifications
8. Equipment Quality Control
9. Follow-up

1. DEFINITIONS

Bone Mineral Density (BMD):

The mineral content of bone divided by its volume when measured by QCT. Such measurements should be reported in $mg.mm^{-3}$. Measurements made by BONE DENSITOMETRY (or other methods) are reported in g/cm^2, which is representative of areal bone density. BMD is reported for most areas of the body as spine BMD, hip BMD, total body BMD, wrist BMD, and so on.

DEXA:

Dual energy x-ray absorptiometry, (also referred to as Dual X-ray Absorbtiometry (BONE DENSITOMETRY); a radiation technique that employs X-rays of two different energies to distinguish between absorption due to bone and that due to soft tissue. The result is a precise and accurate measure of bone mass or BMD.

Osteopenia:

An early definition was a reduction in bone mass noted on radiographs. Now osteopenia has been defined in terms of bone mineral density by the WHO (see the definition above).

Osteoporosis:

Osteoporosis has been defined as a chronic progressive disease characterized by low bone mass and microarchitectural deterioration of bone tissue, which leads to bone epidemiological purposes in terms of bone mineral density (BMD) as a BMD more than 2.5 S.D. below young normal (T-score <2.5)

Quantitative computed tomography (QCT):

Quantitative computed tomography measurements of true bone density (mineral/volume) are usually performed in the spine or wrist at which site it may be qualified as peripheral QCT (pQCT).

Quantitative ultrasonometry (QUS):

Quantitative measurement of bone properties obtained by transmitted ultrasound energy, often at the calcaneus. The findings may be reported in terms of broadband ultrasound attenuation(BUA), speed of sound (SOS), and a non-standardized mathematical combination of two called “stiffness” or the quantitative ultrasound index (QUI). Increasing evidence suggests that QUS may be used in predicting fracture risk.

Single photon absorptiometry (SPA):

A technique largely superseded by BONE DENSITOMETRY. A single-energy radiation source is used to determine bone at the distal radius and ulna. In such machines the radiation source was either iodine-125 or amerinuium-241.

T-scores:

Units of standard deviation from the mean for BMD compared with the presumed peak bone mass in given individuals. A T-score value (-5 to +5) is reported on most if not all densitometers at the time of bone density acquisition.

WHO classifications of osteopenia and osteoporosis:
Osteopenia and **osteoporosis** have been defined for epidemiological purposes in menopausal women by a Working Group of the World Health Organization in terms of bone mineral density (i.e. before fracturing necessarily occurs) as follows:

a) NORMAL: A value for BMD or bone mineral content (BMC) within 1 SD (1 T score) of the young adult reference mean.
b) LOW BONE MASS (OSTEOPENIA): A value for BMD or BMC more than 1 SD (<1.0 T) below the young adult mean but less than 2.5 SD (<2.5 T) below this value.
c) OSTEOPOROSIS: A value of BMD or BMC 2.5 SD or more (<2.5 T) below the young adult mean.
d) SEVERE OSTEOPOROSIS: A value of BMD or BMC 2.5 S.D. or more(<2.5T) below the young adult mean value in the presence of one or more fragility fractures.

Z-scores:

Units of standard deviation from the mean represented by age-, sex-, and height-matched controls. Z-scores tend to be higher than T-scores in a given individual and may underestimate the true extent of osteoporosis and fracture risk, since aging itself is associated with a significant reduction in BMD. It is possible to have a low T-score and still have a normal Z-score if the person being measured is elderly. Furthermore, a normal Z-score does not protect the individual from a future hip fracture.

2. PREAMBLE

It is recognized that osteoporosis is a major health problem in Saskatchewan due to an aging population and consequent increase in hip fracture incidence. Methods of diagnosing and treating osteoporosis as well as strategies for preventing osteoporosis and its associated fractures should be high priority in health care.

Bone densitometry by dual x-ray absorptiometry (DEXA) is a clinically proven and accurate method of measuring bone mineral density (BMD). It is the single best method for predicting fracture risk and its high precision is particularly useful for follow-up studies. DEXA is typically applied to the central skeleton (lumbar spine, proximal femur or even the whole skeleton). Other peripheral technologies have emerged, such as peripheral dual-x-ray absorptiometry (pBONE DENSITOMETRY) and peripheral quantitative computed tomography (pQCT). Not all are equally effective and further evaluation is needed.

The measurement of bone densitometry and the assessment of fracture risk is not a static process. For example, a technique has been patented to estimate fracture risk by mechanical techniques. If this is successful it may well replace DEXA. In addition, it is now possible to image apoptotic cells by Nuclear Medicine techniques. A group from Stanford University predicts it will be possible eventually to image apoptotic osteoblasts in vivo and select patients for specific therapy.

Quantitative ultrasound (QUS) which assesses bone in the calcaneus, tibia, or patella has shown promise in osteoporosis risk assessment where geography or machine availability may limit access to DEXA. QUS appears comparable to hip DEXA in predicting risk of hip fractures in

women over 65, however data concerning follow-up are conflicting and given the limited precision of instrument, it is not recommended for use in follow-up studies.

The goal of DEXA is to accurately and reproducibly measure a patient's bone mineral density, and compare that measurement to reference population standards. This comparison contributes to the referring physician's diagnosis of osteoporosis in asymptomatic people, assessment of the patient's risk of sustaining fracture, and a possible need for appropriate therapy and fracture prevention programs for the patient. It is also useful in evaluating the effectiveness of prior or current therapy.

In order to obtain reliable results, a high standard of quality control is essential. Expertise in the performance of densitometry must be assured, including supervision by qualified medical personnel, input from a medical physicist, and experienced technologists.

Because the at-risk group for osteoporosis is large, implementation of strategies for osteoporosis control is potentially very costly. It is vital that strategies utilized for osteoporosis control be cost effective so that our limited resources be used to the best advantage.

Because of the above, and because of the experience in other provinces where DEXA has rapidly expanded, resulting in overuse, the Advisory Committee on Medical Imaging of the College of Physicians and Surgeons of Saskatchewan feels the use of DEXA in Saskatchewan must be carefully evaluated and stringently controlled. Usage must be limited to indications with good support in the literature, and expertise in the performance of densitometry must be assured.

3. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A) PHYSICIAN:

1. The examination must be performed and interpreted by a licensed physician with specialty certification by the Royal College of Physicians and Surgeons of Canada in Nuclear Medicine or Radiology.

   (a) For those physicians with documented bone density training, it is the expectation that the training programs would include, but not be restricted to:
   - Knowledge and understanding of bone structure, metabolism, and osteoporosis.
   - Documented training and understanding of the physics of X-ray absorption and radiation protection, including the potential hazards of radiation exposure to both patients and personnel and the monitor requirements.
   - Knowledge and understanding of the processing of DEXA data and image acquisition, including proper patient positioning and placement of regions of interest, and artifacts and anatomic abnormalities which may falsely increase or decrease bone mineral density values.
   - Knowledge and understanding of reporting perimeters including, but not limited to; bone density measurements, percent of mean, T-score, Z-score, fracture risk, and World Health Organization (WHO) classification system.

- Knowledge and understanding of the criteria for accurate and precise comparison of serial measurements, including limitations of comparing measurements made by different techniques and different devices.
- Knowledge and understanding of the utility of the entire spectrum of bone density techniques, such as pDEXA, DEXA, SXA, QCT, RA, and QUS. This ensures that the physician is able to fulfill a consultative role in recommending further bone density studies, future serial measurements, or diagnostic procedures to confirm suspected abnormalities seen on DEXA images.
- The physician must be familiar with the methods of statistical analysis necessary for the determination of site and machine specific precision.

(b) Radiologists or Nuclear Medicine Physicians must have two weeks documented training in bone densitometry in a teaching center recognized by the Royal College of Physicians and Surgeons of Canada.

(c) All Physicians responsible for bone densitometry programs should obtain certification by the International Society for Clinical Densitometry.

(d) Participation in Maintenance of Certification and Continuing Professional Development program for specialists of the Royal College of Physicians and Surgeons of Canada is required.

(e) The supervising physician shall be responsible to oversee the DEXA facility and equipment quality control program. The physician accepts final responsibility for quality of all DEXA scans used in reporting and shall be available for consultation and quality control during the performance of the procedures.

B) TECHNOLOGIST

The Director of the Imaging Facility shall ensure that:

1. The technologist shall be certified in radiographic or nuclear medicine technology by the Canadian Association of Medical Radiation Technology and comply with that association's requirements for continuing education.
2. The technologist must obtain two weeks formal training in the use of the DEXA in a dedicated bone densitometry unit.
3. The technologist must perform all manufacturers specified quality assurance procedures.
4. The technologist should have the responsibility for patient comfort and safety, preparing and properly positioning the patient, and of placement of regions of interest for assessment of bone mineral density measurements, monitoring the patient during the measurements, and obtaining the measurements performed by the supervising physician.
5. The technologist must read, be familiar with, and have accessible, the manufacturer's operating manual for the specific scanner model being used.

4. INDICATIONS FOR OBTAINING BONE DENSITOMETRY

Bone densitometry measurement is indicated whenever a clinical decision to intervene will be directly influenced by the result of the test. BD should not be used as a routine screening procedure.

Indications for densitometry include, but are not limited to:

a) Menopausal women who are not on estrogen.
b) Premature menopause (<45 years old) or long-standing premenopausal hypogonadism.
c) Pharmacologic glucocorticoid therapy (>7.5 mg prednisone or equivalent) for longer than three months or Cushing's syndrome.
d) Family history of osteoporosis (in first-degree relatives).
e) Previous fragility fracture (fracture with minimal trauma).
f) Long standing malabsorption or malnutrition
g) Long standing use of anticonvulsant drugs
h) Primary hyperparathyroidism
i) Chemotherapy exposure (assuming long-term survival is expected)
j) Low body weight (BMI<20) or weight under 57 kg (125 lbs).

It is also reasonable to do a baseline BMD in postmenopausal women if two or more of these general risk factors are present:

a) cigarette smoking
b) a history of clinical hyperthyroidism requiring medical or surgical intervention
c) low calcium intake
d) alcohol excess

Contraindications to DEXA include:

a) recent barium or radionuclide studies should be considered in scheduling;
b) severe arthritic or fracture deformity or other degenerative changes at the site measured;
c) Radio-opaque implants in a measured area, most commonly at the hip;
d) patient's inability to maintain correct position and/or remain motionless for the duration of the measurements;
e) both extreme obesity and extremely low BMD may compromise measurements and the capacity to obtain accurate and precise measurements.

All imaging facilities must have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential risks to the fetus and clinical benefits of the procedure must be considered before proceeding with the study.

All patients should receive an explanation of the procedure, particularly with respect to ionizing radiation, before the procedure is commenced.

5. FOLLOW-UP

The supervising and interpreting physician shall ensure that repeated examinations should be not performed any more frequently than is recommended.

The sensitivity of BMD measurements by DEXA is such that it may take longer than two years before significant changes in BMD can be reliably detected in an individual patient. Initial follow-up measurements should be performed at one year to exclude continued bone loss. If a patient is not losing bone mass, a second follow-up measurement to assess therapy should be obtained at two-three years, or on cessation or change of therapy.

For following a patient without pharmacologic intervention, the earliest consideration of a follow-measurement should be at least two years.

Patients at risk for glucocorticoid-induced osteoporesis who are not receiving osteoporesis therapy should have a follow-up DEXA in six months to determine whether treatment is required. Those receiving treatment should have a follow-up measurement in one year to assess treatment efficacy.

Patients with primary hyperparathyroidism may also require more frequent BMD monitoring. It is suggested that a measurement be made at the time of diagnosis and (if surgery is not performed), at one year to be certain the patient is not undergoing accelerated bone loss.

Follow-up measurements for a patient should take place, whenever possible, on the same instrument used for the first scan, utilizing the same scanning procedure.

6. THE ANATOMIC SITE

a) It is recommended that bone density measurements of both lumbar spine and femoral neck be obtained unless a specific indication exists to examine a single or alternative site such as the radius and ulna when there are metal rods in the spine or the patient has had a hip replacement.
b) The images indicating the areas of bone mineral density measurement should be obtained with the DEXA device; generally radiographs are not necessary. If prior radiographs of these anatomic areas are available these should be reviewed to determine if specific sites should not be analyzed.
c) Anatomic areas of known prior fracture or prior surgery should be excluded from measurement.
d) If significant discordance is present between two areas measured with no evident explanation from patient history, DEXA images or plain radiographic correlation, additional DEXA positions (example: lateral lumbar spine, opposite proximal femur/forearm), or other bone density measurement techniques (example: QCT) should be considered.

e) Positioning and soft tissue equivalent devices issued by the manufacturer must be used consistently and properly. Comfort devices, such as pillows under the head or knee, must not interfere with proper positioning, must never appear in the scan field.

7. DOCUMENTATION AND THE WRITTEN REPORT

a) The written request for bone densitometry examination should contain appropriate clinical history and the reason for examination. The history should be obtained from the patient regarding risk factors, including family history, prior fragility fractures, and prior bone trauma/fractures or surgeries which could potentially affect the accuracy of measurement.

b) A record must be maintained, in accordance with the College Bylaws, including;
   1. Patient name, identification number, date, device serial number, facility of examination.
   2. Clinical notes of any unique history, positioning, anatomy and/or technique settings that would be important for performing serial measurements.
   3. Print outs of the images and regions of interest, if provided by the device, and the bone mineral measurement values obtained.

c) The written report shall include for each site examined;
   1. Bone densitometry in gm/cm^2
   2. A comparison with young adult control population (T-score)
   3. Comparison of age matched values (Z-score) may be reported at the discretion of the physician.
   4. Comparison to prior available comparable studies including a statement whether a change in BMD is statistically significant.
   5. The report should classify the patient according to World Health Organization criteria.
   6. If needed, recommendations for conclusive radiograph and interval follow up BD (bone mineral densitometry) scan shall be provided.

8. EQUIPMENT SPECIFICATIONS

Multiple equipment designs are available which can accurately and precisely measure bone density using dual-energy X-ray absorptiometry. The equipment should provide the following:

a) Normal young adult and age-matched control population standards matched for sex applicable to the equipment being used must be available. Some devices also provide standards matched for ethnicity, weight, and body mass index.

b) A phantom or other standard must be provided in order to evaluate the accuracy, precision and linearity of response of BMD measurement.

c) A permanent recording of labeled images of the anatomic site measured and measurement results for patient records

d) Precision error of measurements of the phantom or standard should not exceed the specifications or recommendations of the manufacturers and should be less than 1%. In vitro

(phantom) precision should not be equated with in vivo (patient) short-term precision, as the role of the technologist in positioning and scan analysis is critical.

9. EQUIPMENT QUALITY CONTROL

Bone densitometry equipment quality control is extremely important for long-term monitoring of the effectiveness of therapy or progression of disease. The importance of bone densitometry quality control cannot be overstated.

a) Quality control procedures should be performed and permanently recorded by a trained technologist. These procedures are generally required on a daily basis and always before the first patient measurements of the day. They should be interpreted immediately upon completion according to the guidelines provided by the manufacturer to ensure proper system performance. If a problem is detected according to manufacturer guidelines, the service representative should be notified and patients should not be scanned until the equipment has been cleared for use.

b) Each imaging facility should have documented policies and operations for monitoring and evaluating the effective management, safety, and operation of imaging equipment. The quality-control program should be designed to minimize patient, personnel, and public radiation risks and to maximize the quality of the diagnostic information.

c) At least annually, equipment performance should be monitored and a quantitative dose determination should be conducted by a qualified medical physicist.

SOURCES

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