Exercise Protocol: Bone Mineral Density (DXA Scan)

Applications

Dual-energy x-ray absorptiometry (DXA) measurements are used to measure bone mineral density (BMD) and body composition. The National Osteoporosis Foundation recommends bone density scans for the following persons:

* All postmenopausal women under age 65 who have one or more additional risk factors for osteoporotic fracture (besides menopause);
* All women aged 65 years and older regardless of additional risk factors;
* Postmenopausal women who present with fractures (to confirm diagnosis and determine disease severity);
* Women who are considering therapy for osteoporosis, if BMD testing would facilitate the decision; and
* Women who have been on hormone replacement therapy for prolonged periods.

Additional populations that may be studied are athletes and children, as well as men. In addition, studies of body composition use the DXA technique as the new “gold standard” for determining lean tissue and fat mass.

**Exclusion/Inclusion Criteria**. Criteria specific to each new protocol will be provided by the investigator. The only general exclusion criterion is that pregnant women will not be scanned.

Test Description

Bone mineral density (BMD, will be assessed by dual-energy x-ray absorptiometry (DXA) using a Lunar DPX-NT densitometer (Lunar/GE Corp). All scans will be conducted in the fitness lab at the Center for Behavioral Epidemiology (C-BEACH), 9245 Sky Park Court, San Diego, CA. The scan sites most often assessed include the spine (L1-L4), hip, and total body. The DXA total body scans will be used to determine both total body BMD as well as body composition and regional fat distribution. The average scan time for each of these is approximately 3, 4, and 10 minutes for the spine, hip, and total body, respectively. The total time required for subject positioning and scanning is approximately 5, 8, and 12 minutes for the spine, hip, and total body, respectively. A typical appointment, therefore, requires approximately 30 minutes per subject for all 3 scans, or approximately 20 minutes for spine and hip only.

Quality assurance (QA) tests will be performed each morning of use. QA will be conducted using a standard with tissue-equivalent material with three bone-simulating chambers of known bone mineral content. In vivo BMD precision is 0.6-1.2% for the spine, 0.6-1.7% for the femoral neck, 0.6-0.8% for total-body mineral, and less than 1.5% for total body soft tissue mass (Mazess, Br J Radiology 70:109-110, 1997).

Subjects are instructed, prior to the day of their scan, to dress with clothing free of any metal and not to wear jewelry. Women are encouraged to wear a halter-top or something similar. If subjects arrive with any metal on their clothing, they are asked to change into shorts and t-shirt. A supply of these are kept in the fitness lab and laundered as needed. The subject is shown the DXA machine and told that the scan arm will move above them while he/she lies on the table. They are instructed to lie still and not to talk while the machine is scanning. The following is a description of how the subject is positioned for each of the three scans:

**Spine:** The subject lies supine with his/her hands on their shoulders (to keep the arms away from the lumbar spine). The technician first straightens his/her body by gently pulling from the ankles (this is not done with older subjects or those who, when asked before proceeding, report back pain). The scan arm is then brought to the start position. The technician then asks the subject to bend his/her knees while a box is place beneath the lower legs. This is done to insure that the spine is positioned correctly and kept in contact with the table. The technician then locates the anatomical site for starting the scan, which is vertically aligned with the navel and 3-5 cm below it. Prior to touching the subject, the technician tells him/her to point to their navel. This is done to minimize the amount of palpation required by the technician. The subject is then asked to remain still while the machine scans.

**Hip:** The subject lies supine with his/her arms crossed over their chest. The feet are strapped to a plastic device such that the hip joints are medially rotated. The technician then locates the anatomical site for starting the scan, which is vertically aligned with the mid-thigh and approximately 7 inches below the anterior, superior iliac crest. The subject is then asked to remain still while the machine scans.

**Total Body**: The subject lies supine with his/her arms by their sides. Velcro straps are secured around the knees and ankles to hold the legs together. The subject is then asked to remain still while the machine scans.

*Females who are minors will be accompanied by a parent or another adult when scanned by a male technician. The parent will sit just outside the door to the DXA room, but within clear view of the subject. California law does not permit anyone other than the technician and patient in the room during scanning.*

Training/Supervision Needed

All scans will be conducted by experienced technicians certified by the state of California. A copy of the certification should be included in the IRB application. California law requires all DXA facilities to be supervised by an M.D. Greg Gastaldo, M.D. and Medical Director of the Center for Optimal Health & Performance, will serve as the C-BEACH medical advisor and licentiate. He has ultimate responsibility for insuring safe and effective procedures regarding bone densitometry testing. He is available to assist investigators in interpreting scans, should this be requested. He is not required to be present during the scanning procedures. Technicians certified by the state of California will conduct all preliminary analyses of scans, unless the Principal Investigator of a particular project indicates that he/she wants to receive unanalyzed data. Some studies may have a designated reader at another site, but for analyses done at C-BEACH, any abnormal or questionable scans will be reviewed by both Dr. Gastaldo and the technician, with Dr. Gastaldo making the final interpretation.

Risks

Skin entrance dose of radiation is approximately 20 µSv for a spine and hip scan, and 0.2 µSv for total body. In practical terms, this is equivalent to the amount of radiation to which one is exposed during a cross-country airplane flight. Since long-term effects of exposure to a fetus are not known; pregnant women will not be scanned. There are no other known risks associated with this procedure.

Risk Management

Only experienced and certified technicians are permitted to conduct scans. Given the extremely low dose of radiation, the benefits far outweigh the risks for any population tested. Young adults will have a baseline report for future comparison. Menopausal women and older adults will have objective data regarding their risk for osteoporosis, thus allowing them to discuss with their physicians possible preventive treatment. Since most insurance policies do not cover routine osteoporosis screening for persons younger than 65 years of age, participation in a research project in which BMD is assessed provides the participant with information that would otherwise cost between $150-300. For studies involving female subjects, the investigator will include relevant screening questions (see below) as part of the consent content.

Screening for Pregnancy:

To insure that a pregnant woman is not scanned, a female will be scheduled for testing within 14 days of her last period. By including the following question in the screening process, relevant information can be obtained and used for scheduling without asking intrusive questions such as whether the subject is using birth control or whether she is sexually active.

Are you having menstrual cycles? Yes No

If yes, what is the date of the first day of your last period? \_\_\_\_\_\_\_\_\_\_

If you are in menopause, when did your periods stop completely? \_\_\_\_\_\_\_\_\_\_\_\_

Are you pregnant, or could you possibly be pregnant? Yes No

The use of a pregnancy test is also an option for screening purposes.

Adult women (18 years and older) will be asked only the following question: “Are you pregnant or could you possibly be pregnant?” A negative answer will suffice for proceeding with the scan. If the participant is unsure, or if requested, a pregnancy test will be conducted. For studies of postmenopausal women, the technician will ask the participant to confirm that she is in menopause.

Potential Benefits

The primary benefit is for women, particularly postmenopausal women, to assess and monitor bone mineral density and their risk of osteoporosis. However, testing may also benefit males who are at risk. Moreover, testing can detect the presence of fractures and determine the severity of osteoporosis.

Confidentiality of Data and Room Security

When not in use, the room in which the DXA is located is kept locked. Other than Drs. Hovell and Nichols and the C-BEACH administrative assistant, only persons trained in DXA operation have keys to the room. Data collected each day are removed from the hard drive and stored on diskettes, which are kept in a locked file in each investigator’s office. Data transferred to a database for statistical analysis are coded; no identifying information will be used in data analysis.

Consent Content “What Will Happen in this Research?” section

Dual-energy x-ray absorptiometry (DXA) measurements are used to measure bone mineral density (BMD) and body composition. For the DXA measurement, it is necessary to dress with clothing free of any metal and not to wear jewelry. We recommend that female participants wear a halter top or swim suit top, or something similar. If you forget and arrive with any metal on your clothing, we will have spare pairs of sweat pants and several t-shirts that you can wear while being scanned.

The DXA machine consists of a table with a scan arm that moves over your body while you lie on the table. The technician will position you for each scan. You will be asked to lie still and not talk while the machine is scanning. The entire procedure takes 10-20 minutes, depending on which scans are conducted.

Consent Content “What are the Risks or Discomforts Involved in the Research?” section

The amount of radiation exposure from a DXA scan is low. The actual amount of radiation emitted for a total body scan is 0.2 uSv, which, in practical terms, is much less than the amount received during a cross-country airplane trip. However, the long-term effects of exposure to a fetus are not known, therefore, pregnant women are not scanned. For females: To ensure that you are not pregnant, we will ask you to schedule your appointment within two weeks of your last period. If you are unsure or cannot remember your last period, we will conduct a pregnancy test to confirm that you are not pregnant. For this we will have you collect a few drops of urine and we will use an over-the-counter test kit to determine pregnancy status.

Parental consent text if the subject is a minor female child: The assent form explicitly states that if your daughter is pregnant or could possibly be pregnant she cannot participate. To avoid embarrassing your child we have indicated on the assent form that she should simply tell us she does not want to participate, without giving us a reason. If your daughter qualifies for the study, we will ask her to tell us the date of her last menstrual period (if she has begun menstruating). We will then schedule her for her scan and other measurements within 2 weeks of her last period, thus ensuring that she could not possibly be pregnant when she is scanned.

Consent Content “Will My Information be Private?” section

When not in use, the room in which the DXA is located is kept locked. Other than Drs. Hovell and Nichols and the C-BEACH administrative assistant, only persons trained in DXA operation have keys to the room. Data collected each day are removed from the hard drive and stored on diskettes, which are kept in a locked file in each investigator’s office. Data transferred to a database for statistical analysis are coded; no identifying information will be used in data analysis.