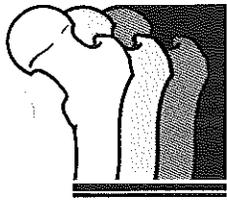


March 6, 1991



MULTI CENTER
STUDY OF
OSTEOPOROTIC
FRACTURES

University of California, San Francisco
Prevention Sciences Group

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SOF Memorandum #343

Date: 2/6/91

To: SOF Clinic Coordinators and Project Directors

From: Michael Nevitt

Re: Lateral scan selection protocol

Enclosed is the protocol for selecting subjects to receive lateral and AP spine and hip scans. I made one change from the last version. The first alternate subject should be the second subject scheduled for a session (to allow maximum time) or the second lowest ID number if subjects come in groups (for consistency). See attached.

You can start doing lateral scans next week, or as soon as your scheduling permits.

Also enclosed is a packet containing comments from Tajalli. Spencer on the lateral scans you sent to Peter and us.

**Study of Osteoporotic Fractures
Subject Selection for Lateral Spine Scan Study**

BACKGROUND

Extravertebral calcifications (osteophytes and vascular calcification) affect the accuracy of measurement of bone mineral density of the spine in elderly subjects when these measurements are made in the antero-posterior plane (Orowell 1990). BMD measurements made with lateral scanning techniques may reduce this source of error.

The purpose of this study is to determine which of three measures of BMD is more strongly associated with prevalent vertebral fractures: spinal BMD measured with lateral scanning techniques, spinal BMD measurements made in the AP plane, or hip BMD measurements.

We will randomly select participants who are attending the third clinic visit and perform the three types of scans on these subjects using the Hologic QDR 1000 scanner equipped with lateral spine scanning software. Prevalent vertebral fractures will be identified from the lateral spine xrays obtained at Visit 3.

SUBJECT SELECTION

1. Exclusions

- a) subject refuses lateral spine xrays
- b) medical or health problems which making lateral scan impossible (i.e. subject unable to hold lateral position)

2. Number of subjects

Scan two subjects per day, one from your first (AM) and one from your second (PM) session.

If scheduling or other problems make it necessary, scan one subject per day for discrete periods (e.g. a week or two now and then, as needed). When scanning one per day, alternate between morning and afternoon subjects on a week by week basis.

3. Identify a primary and an alternate subject from each session. Recruit the primary subject for scanning.

Recruit the alternate if the primary:

- a) declines to participate,
- b) is accompanied by someone who doesn't want to, or can't, wait for the extra time required, or
- c) cancels or doesn't show up.

4. Define primary and alternate subjects either

- a) in terms of their order in the session, or
- b) in ID order.

a) If subjects are given clinic appointments for different times, the first subject scheduled for a session would always be the primary and the second subject would always be the alternate. If the primary and alternate decline, then ask the next subject scheduled for that session.

b) If a group of subjects are scheduled to start a session at the same time, then arrange their IDs in numerical order. Identify the lowest number as the primary, the second lowest as the first alternate, etc.

5. Discuss the procedures entailed in the lateral scan with the subject. If in the judgment of the scan operator a medical, health or other problem is will almost certainly prevent the subject from maintaining the lateral position long enough to obtain a scan, exclude the subject and recruit an alternate. ✓

6. If a lateral spine has to be redone because the subject moves substantially, attempt to rescan the spine once. If movement requiring a rescan occurs a second time, drop the subject from the study. ✓

When a subject is dropped for recurrent movement problems, attempt to recruit an alternate if there is sufficient time to complete the scans.

7. Perform AP spine and hip scans only on subjects for whom you have obtained usable lateral scans.

8. Keep a log of the following for all subjects approached:

- ID number, date
- Exclusion status (if excluded, give reason)
- Accept or refuse? (if refuse, give reason)
- Lateral scan completed?
- Exclusion for recurrent movement?
- Hip and AP spine completed?

9. It may be best to obtain the xrays prior to performing the scans, particularly if a participant is frail or is expected to have trouble maintaining the lateral position. We don't want to miss getting an xray because the subject feels they cannot lie down for an xray due pain or other problems from the lateral scan. However, this approach may not be feasible in some clinics. ✓

10. Stick to your predefined selection protocol. It is important to scan older, frail and disabled participants as well as cooperative and healthy ones.