Diagnostic criteria for primary osteoporosis: year 2000 revision

Osteoporosis Diagnostic Criteria Review Committee: Japanese Society for Bone and Mineral Research

Hajime Orimo, Yasufumi Hayashi, Masao Fukunaga, Teruki Sone, Saeko Fujiwara, Masataka Shiraki, Kazuhiro Kushida, Shigehito Miyamoto, Satoshi Soen, Junji Nishimura, Yasuo Oh-hashi, Takayuki Hosoi, Itsuo Gorai, Hiroyuki Tanaka, Tetsuo Igar, and Hideaki Kishimoto

1 Tokyo Metropolitan Geriatric Centre, 35-2 Sakae-cho, Itabashi-ku, Tokyo 173-0015, Japan
2 Tokyo Metropolitan Tama Geriatric Hospital, Tokyo, Japan
3 Kawasaki Medical School, Kurashiki, Japan
4 Radiation Effects Research Foundation, Hiroshima, Japan
5 Research Institute and Practice for Involutional Diseases, Nagano, Japan
6 Hamamatsu University School of Medicine, Hamamatsu, Japan
7 Kinki University School of Medicine, Osaka-sayama, Japan
8 Medical Institute of Bioregulation, Kyushu University, Fukuoka, Japan
9 Faculty of Medicine, University of Tokyo, Tokyo, Japan
10 Yokohama City University School of Medicine, Yokohama, Japan
11 Okayama University Medical School, Okayama, Japan
12 Department of Rehabilitation, Tokyo Metropolitan Rehabilitation Hospital, Tokyo, Japan
13 Department of Orthopedic Surgery, Tottori Medical School, Yonago, Japan

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Preamble

In 1995, the Japanese Society for Bone and Mineral Metabolism (now the Japanese Society for Bone and Mineral Research) established The Osteoporosis Diagnostic Criteria Review Committee, which consisted of representatives from the fields of orthopedics, internal medicine (geriatrics), gynecology, radiology, and sports medicine who were involved in clinical research or the medical care of patients with osteoporosis. Following discussions held at the 13th scientific meeting of the Society in 1996, the Committee, with the consensus of its members, proposed diagnostic criteria for primary osteoporosis. The Committee revised those criteria in 1998 (Journal of Bone and Mineral Metabolism, 16:139–150, 1998) and again in 2000. In this article we present a summary of the year 2000 revisions.

Definition of osteoporosis

Osteoporosis is a disease characterized by low bone mineral density and altered bone microstructure which causes bone fragility. It is generally classified as primary or secondary.

Basic concepts for establishing diagnostic criteria for primary osteoporosis (1996)

Primary osteoporosis should be diagnosed by the examination of X-ray images of the spine or by measurements of bone mineral density (BMD) preferably of the lumbar spine: Three basic concepts were presented:

1. Reduced bone mass can be determined either by the examination of X-ray images of the spine or by bone densitometry, depending on the patient.
2. For patients with a traumatic spinal fracture or when BMD falls below 70% of the young adult mean (YAM), diseases other than osteoporosis that cause low BMD and secondary osteoporosis should be excluded by differential diagnosis.
3. Primary osteoporosis is diagnosed according to established criteria after a differential diagnosis is made and is therefore based on exclusion.

Problems with the 1996 diagnostic criteria for primary osteoporosis

Table 1 shows the 1996 diagnostic criteria for primary osteoporosis. The main problems that have been pointed out since those criteria were proposed are the following:

1. The criteria have not been validated.
2. Bone densitometry appears to be superior to X-ray images as a diagnostic tool and should therefore be used routinely.
3. Evaluation of osteopenia by means of X-ray images of the spine is neither objective nor quantitative.
4. Diagnostic criteria are needed for hip fracture patients which is frequent in the aged.
5. It is not known whether the diagnostic criteria which were based on data from women are applicable to men as well.

The Committee discussed the above questions, collected the necessary data and revised the criteria for the year 2000.

Validity of the 1996 diagnostic criteria

The 1996 diagnostic criteria determined BMD cutoff value using cross-sectional study data, that differentiated patients with and without spine fracture efficiently on the basis of sensitivity and specificity. The validity of these cutoff values has since been tested in a longitudinal study. The study subjects were 1539 women (average age, 63.1 ± 10.0 years) who met all of the following criteria: (1) They were examined at either Yokohama City Medical School, the Radiation Effects Research Foundation, Kawasaki Medical School, or the Research Institute and Practice for Involutional Disease; (2) they were followed up for 2 years or more (mean, 3.3 years) after BMD of the lumbar vertebrae was measured by dual X-ray absorptionometry (DXA); (3) information was provided on the presence or absence of spine fracture; and (4) they had not taken medication that affected bone or calcium metabolism during the follow-up period. Table 2 shows the distribution of subjects by age and incident fractures.

### Table 1. Diagnostic criteria for primary osteoporosis (1996)

<table>
<thead>
<tr>
<th>X-ray film of spine</th>
<th>Lumbar BMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>No radiographic osteopenia</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>Grade I radiographic osteopenia</td>
</tr>
<tr>
<td></td>
<td>70%–80% of YAM</td>
</tr>
<tr>
<td>Osteoporosis</td>
<td>Grade II or more severe radiographic osteopenia</td>
</tr>
<tr>
<td></td>
<td>Less than 70% of YAM</td>
</tr>
</tbody>
</table>

YAM, young adult mean (age, 20–40 years)

*a In principle, BMD means bone mineral density of lumbar spine, but if lumbar BMD is difficult to assess, that of the radius, second metacarpal bone, femoral neck, or calcaneus may be used.

### Table 2. Study subjects by age (women)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>No. of subjects</th>
<th>No. of patients with incident fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤39</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>40–49</td>
<td>146</td>
<td>5</td>
</tr>
<tr>
<td>50–59</td>
<td>384</td>
<td>20</td>
</tr>
<tr>
<td>60–69</td>
<td>598</td>
<td>50</td>
</tr>
<tr>
<td>70–79</td>
<td>318</td>
<td>82</td>
</tr>
<tr>
<td>≥80</td>
<td>83</td>
<td>34</td>
</tr>
<tr>
<td>Total</td>
<td>1539</td>
<td>191</td>
</tr>
</tbody>
</table>

### Fig. 1. Incidence of spine fracture (women without spine fracture at baseline). BMD, bone mineral density.

As shown in Fig. 1, spine fracture incidence was strongly affected by age and BMD and, at a given BMD, the risk of bone fracture increased with age. As shown in Fig. 2, the cutoff value of the lumbar BMD obtained from the longitudinal study was 0.737 g/cm² (72.9% of YAM). The difference between these values and the values obtained in the cross-sectional study of the same subjects (0.760 g/cm²; 75.2% of YAM) was within the