REGULATION AND GUIDELINE

Clinical Practice Guideline of Traditional Medicine for Primary Osteoporosis

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BACKGROUND

Primary osteoporosis is a disease characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk(1).

Primary osteoporosis is particularly common in senile persons and in postmenopausal women. It ranks the fifth of diseases in the modern society(2). There are about two billion patients with osteoporosis all over the world. Half of them are in Asia or in the Pacific Region. The causes of primary osteoporosis are not totally clear at present. It is related to age, physiological degeneration of tissues, decreased estrogen levels in postmenopausal women, etc. Primary osteoporosis can be classified into two types, namely, postmenopausal osteoporosis (type I) and senile osteoporosis (type II)(3). The critical result of osteoporosis is fracture, which may particularly increase the risk of disablement and death for senile persons. The risk factors for osteoporosis include falling, history of previous fractures, family history of osteoporosis, smoking, and excessive alcohol intake(4). Osteoporosis is also related to factors such as age, sex, ethnicity, number of pregnancies and deliveries, body weight, exercise, and calcium intake.

Primary osteoporosis not only causes decreased life quality of the patients but also brings about major economic burdens on the national health care system; therefore, more research should focus on primary osteoporosis. World Health Organization (WHO) suggests every October 20th as the "World Osteoporosis Day", and has launched the "Bone and Joint Decade 2000–2010," which is to raise globe awareness about bone and joint diseases, including primary osteoporosis(5).

CLINICAL CHARACTERISTICS

Clinical Manifestations

Primary osteoporosis is a chronic and progressive disease. In mild cases, there may be no symptoms or slight symptoms. With the development of the disease, the clinical symptoms and signs such as pain, loss of height, kyphosis and fracture appear.

Pain is the most common symptom of primary osteoporosis in its initial phase. It is always marked by back pain, pain of the entire skeleton, or pain of hip, knees and wrist joints. The back pain may occur in a static state at the beginning, then even in a dynamic state, it gradually results in a lasting back pain, which might be worsened, long-term, taking the same posture. If the nerve is affected by a compression fracture, then several symptoms will result, such as numbness, lassitude, contracture, pain of limbs, intercostals nerve pain, or abdominal pain. In some cases, there may be no significant pain in the back region even with obvious osteoporosis.

Loss of height and kyphosis are two significant signs following back pain. Mild osteoporosis may only affect 1 or 2 vertebrae, while the severe one may cause deformities of whole spinal column. Thus, there will be shortening of the spinal column for 10–15 cm, and the ratio of height from the head to pubis to that from the pubis to heel can be less than 1.0, resulting in loss of height. Compression fractures or deformities of some vertebrae, particularly those with wilder mobility or more weight-carrying function such as T11, T12 and L3, may give rise to worsening of dorsal kyphosis with possible...
subsequent back pain. Vertebral-body compression fractures can cause deformity of thoracic cavity, further leading to increased pressure in the abdominal cavity as well as the dysfunction of heart and lungs.

The most devastating complication of primary osteoporosis is fracture, and the occurrences of fractures have certain correlation with age and menopause. Low trauma or nontraumatic collision also can induce fracture. The most common fractures related to primary osteoporosis include vertebral-body compression fracture, hip fracture, and distal radius fracture.

With the development of osteoporosis, the clinical manifestations and signs progressively become worse; especially the symptoms of skeleton pain, aching of lower back and knees, and weakness of lower limbs may lead to impaired quality of life or disability in elderly people.

**Physical and Laboratory Examination**

Bone mineral density (BMD) is the major criterion used for the diagnosis of osteoporosis.

Dual-energy X-ray absorptiometry (DEXA) scanning can be used for measuring BMD and the confirmed diagnosis of osteoporosis. Other techniques such as Single Photon Absorptiometry (SPA) or Single-energy X-ray Absorptiometry (SXA) are often used as screening methods for the monitoring.

When DEXA is not available in some areas, the assessment of bone density from plain radiographs can be referred. Since the loss of BMD is only measurable at the levels of over 30%-40% by plain radiographs, the measurement of the BMD is not precise, and many patients with mild osteoporosis would be missed. The lateral film is required to be performed only for the heel. At other sites, both anterior-posterior and lateral films should be taken. High resolution and contrast of images and fine-grain films are required for obtaining clear structure of soft tissues and bones.

Decreased blood estradiol in postmenopausal women indicates postmenopausal osteoporosis. Decreased blood testosterone in older men suggests osteoporosis.

**DIAGNOSIS CRITERIA**

**Diagnosis in Western Medicine and Differential Diagnosis**

WHO proposed a diagnostic criterion of osteoporosis by measuring BMD (the number of standard deviations by which the patient; BMD differs from the mean peak bone mass for young normal subjects of the same gender) in 1994. This criterion was considered only applicable for postmenopausal white women. There are different opinions on the application of this classification to other groups. The four diagnostic categories proposed by WHO are as follows: (1) Normal: A value of BMD within one standard deviation (SD) of the young adult reference mean (T-score ≥ -1); (2) Low bone mass (osteopenia, which refers to those individuals at the highest risk of primary osteoporosis): A value of BMD more than one standard deviation below the young adult mean but less than 2.5 standard deviations below this value (T-score < -1 and > -2.5); (3) Osteoporosis: A value of BMD 2.5 standard deviations or more below the young adult mean (T-score ≤ -2.5); (4) Severe osteoporosis (established osteoporosis): A value of BMD 2.5 standard deviations or more below the young adult mean in the presence of one or more fragility fractures.

The method of measuring the loss percentage of bone mass in lumbar vertebrae can be used for the diagnosis of persons belonging to any culture or ethnicity without taking the peak bone-mass survey or for those whom standard deviation is inapplicable.

The following revised criteria issued by Japan in 1996 can be referred: (1) Normal: > M-12%; (2) Low bone mass (osteopenia): M-13%-24%; (3) Osteoporosis: < M-25%; (4) Severe osteoporosis (established osteoporosis): < M-25% in the presence of one or more fragility fractures; (5) Severe osteoporosis (established osteoporosis): < M-37% in the absence of fractures.

Primary osteoporosis is classified as postmenopausal osteoporosis (type I) and senile osteoporosis (type II), according to the causes of bone loss and the fracture sites. Both of them are retrograde degeneration diseases.

Patterns of primary osteoporosis are determined according to the condition of excess and deficiency, Zang (腎)-fu (腑) organs, as well as qi and blood based on the theories of Chinese medicine (CM), particularly under the guidance of the yin-yang theory. "A guideline for the diagnosis and treatment of common diseases in the traditional Chinese internal medicine—osteoporosis," the results of clinical epidemiological survey, and expert consensus are referred. There are four patterns of primary osteoporosis:

- Shen (腎)-yang deficiency pattern. Cold pain of lumbar and back, general aching of the body, lassitude, kyphosis, limitation of movement, intolerance of cold and preference for warmth, symptoms of particular lower limbs deterioration by cold, frequent and profuse urine, or