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Recommendations

2012 update of French guidelines for the pharmacological treatment of postmenopausal osteoporosis

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ABSTRACT

Objectives: To update the evidence-based position statement published by the French National Authority for Health (HAS) in 2006 regarding the pharmacological treatment of postmenopausal osteoporosis, under the auspices of the French Society for Rheumatology and Groupe de Recherche et d'Information sur les Ostéoporoses (GRIO), and with the participation of several learned societies (Collège National des Gynécologues et Obstétriciens Français, Groupe d'Étude de la Ménopause et du Vieillissement hormonal, Société Française de Chirurgie Orthopédique, Société Française d'Endocrinologie, and Société Française de Gériatrie et de Gérontologie).
Methods: A multidisciplinary panel representing the spectrum of clinical specialties involved in managing patients with postmenopausal osteoporosis developed updated recommendations based on a systematic literature review conducted according to the method advocated by the HAS.
Results: The updated recommendations underline the need for osteoporosis pharmacotherapy in women with a history of severe osteoporotic fracture. In these patients, any osteoporosis medication can be used; however, zoledronic acid is the preferred first-line medication after a hip fracture. In patients with non-severe fractures or no fractures, the appropriateness of osteoporosis pharmacotherapy depends on the bone mineral density and FRAX® values; any osteoporosis medication can be used, but raloxifene and ibandronate should be reserved for patients at low risk for peripheral fractures. Initially, osteoporosis pharmacotherapy should be prescribed for 5 years. The results of the evaluation done at the end of the 5-year period determine whether further treatment is in order.
Conclusions: These updated recommendations are intended to provide clinicians with clarifications about the pharmacological treatment of osteoporosis.

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1. Objectives and methods

These recommendations are intended for all physicians providing care to postmenopausal women who have osteoporosis or risk factors for osteoporosis. The objective is to discuss the principles of osteoporosis pharmacotherapy based on current data about indications, effectiveness, and safety. The content of these recommendations was discussed and drafted in accordance with the method propounded by the French National Authority for Health (Haute Autorité Sanitaire, HAS) then validated by a multidisciplinary task force. When published data were inadequate or incomplete, the recommendations were based on a professional consensus to take into account both current practice and expert opinion.

These recommendations cannot provide detailed guidance for every specific situation, co-morbidity, or hospital management protocol. They neither presume to cover all possible management options nor diminish the physician's individual responsibility toward the patient.

These recommendations were drafted by a project manager and a scientific committee then discussed and reviewed by a multidisciplinary task force in accordance with the AGREE method [1].

The following learned societies contributed to review the recommendations: Collège National des Gynécologues et Obstétriciens Français, Groupe d'Étude de la Ménopause et du Vieillissement Hormonal, Fédération nationale des gynécologues médicaux, Groupe de Recherche et d'Information sur les Ostéoporoses, Société Française de Chirurgie Orthopédique et de Traumatologie, Société Française d'Endocrinologie, Société Française de Gériatrie et Gérontologie, and Société Française de Rhumatologie.

2. Epidemiology and diagnosis of osteoporosis

Osteoporosis is a generalized bone disease characterized by diminished bone strength with an increased risk of fractures [2]. Osteoporosis is a major health concern, both because of the risk of potentially serious fractures and because its prevalence is increasing as the population ages. The present recommendations are intended only for postmenopausal patients who have none of the other metabolic, malignant, or genetic causes of decreased bone strength.

2.1. Epidemiology

Osteoporotic fractures can occur at any site except the skull, facial bones, cervical spine, first three thoracic vertebras, hands, and toes (where trauma and tumors explain the overwhelming majority of fractures). Osteoporotic fractures occur in response to low-energy trauma (e.g., a fall from standing height). Severe osteoporotic fractures are associated with a significant increase in mortality; they include proximal femoral fractures, proximal humeral fractures, vertebral fractures, pelvic fractures, distal femoral fractures, fractures simultaneously involving three ribs, and proximal tibial fractures [3]. Non-severe fractures, such as forearm fractures, may have a variable impact on morbidity but are not associated with increased mortality.

2.2. Diagnosis of osteoporosis by absorptiometry

2.2.1. Measurement technique

Dual-energy X-ray absorptiometry (DXA) is the reference standard for measuring BMD at the lumbar spine and proximal femur. Bone strength depends heavily on BMD. In postmenopausal women, BMD measurements are interpreted using the T-score, computed as the difference between observed BMD and same-site BMD in young healthy women. The T-score is expressed in standard deviation (SD) units. The World Health Organization defines osteoporosis as a T-score ≤ -2.5 [4]. However, this diagnostic cutoff is not a treatment decision cut-off (professional consensus). In France, DXA has been reimbursed in patients meeting specific criteria since July 1, 2006 (Table 1). Quality-control procedures for DXA machines are required to ensure that the measurements are reliable. In addition to initial training, DXA machine operators must receive specific training in the DXA measurement technique and result interpretation. Thorough familiarity with radiological protection procedures is mandatory.

Table 1
Uses of dual-energy X-ray absorptiometry (DXA) reimbursed by the French public health insurance system.

First DXA

In the general population, regardless of age and sex

Patient with evidence of osteoporosis: identification or radiological confirmation of a vertebral fracture (vertebral body deformity) in the absence of clear signs of trauma or tumor; previous low-energy peripheral fracture (not counting fractures of the skull, toes, fingers, or cervical spine)

Patient with a disease or treatment known to induce osteoporosis: systemic glucocorticoid therapy (preferably at treatment initiation) prescribed for at least 3 consecutive months in a dosage > 7.5 mg/day prednisone equivalent

Documented history of a disease or treatment potentially responsible for osteoporosis: prolonged hypogonadism (including androgen deprivation therapy by orchiectomy or prolonged Gn-Rh therapy), active untreated hyperthyroidism, hypercorticism, primary hyperparathyroidism, and osteogenesis imperfecta

In postmenopausal women (including those taking hormone replacement therapy in dosages lower than those recommended for bone protection), DXA is indicated as in the general population and in patients meeting the following criteria

History of low-energy femoral neck fracture in a first-degree relative

Body mass index < 19 Kg/m^2

Menopause before 40 years of age, for whatever reason

History of glucocorticoid therapy for at least 3 consecutive months in a dosage > 7.5 mg/day prednisone equivalent

Second DXA

At discontinuation of osteoporosis therapy, except for early discontinuation because of an adverse event in a postmenopausal woman;

In postmenopausal women with no fractures who were not treated after a first DXA showed normal values or osteopenia, a second DXA can be performed 3 to 5 years later depending on whether new risk factors have developed.

2.2.2. Choosing the measurement site and curve

BMD should be measured at two sites, the lumbar spine and proximal femur. An absorptiometry diagnosis of osteoporosis is made if the T-score is less or equal to −2.5 at one or more of the following sites: lumbar spine, femoral neck, and total hip [5,6]. According to the International Osteoporosis Foundation, if preference must be given to a single site, the total hip or femoral neck should be chosen and the results interpreted using only the NHANES III reference curve [7,8].

3. Evaluation of the fracture risk and treatment decision

The decision to initiate osteoporosis pharmacotherapy rests on the routine evaluation of three variables associated with fracture risk, namely, age, prior fractures, and fall risk, together with BMD values.

3.1. Prior low-energy fractures

A history of one or more low-energy fractures is the strongest predictor of future vertebral and non-vertebral fractures at any site (spine and other sites) [9–12]. The time since the previous fracture should be taken into account: the risk of further fractures is greatest