

The Management of Postmenopausal Osteoporosis: A Position Paper of the World Health Organization Collaborating Center on Public Health Aspects of Rheumatic Diseases

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The World Health Organization Collaborating Center on Public Health Aspects of Rheumatic Diseases convened a Consensus Experts Meeting on the Management of Postmenopausal Osteoporosis on May 18, 2004 in conjunction with the International Osteoporosis Foundation World Congress on Osteoporosis held in Rio de Janeiro, Brazil by the International Osteoporosis Foundation. The focus of this task force was to develop guidelines for the management of osteoporosis, and strategies for maintaining postmenopausal bone health in light of emerging information on bone quality.

Osteoporosis is a continuum of disease and is currently defined as a skeletal disorder characterized by compromised bone strength predisposing a person to increased risk of fracture. Bone strength is further defined as prima-

rily reflecting the integration of bone density and bone quality¹. Several risk factors for developing osteoporosis have been identified and include low bone mineral density, family history, previous fracture, low body weight, and smoking. Of these factors, low bone mineral density is the best predictor of fracture risk in postmenopausal women who do not have any other signs or symptoms of the disease^{2,3}. Age can also be used as predictor of fracture risk, independent of BMD, in individuals over the age of 65⁴. The economic impact of osteoporotic fractures is also increasing as the world population continues to age⁵.

It has been established that the presence of a vertebral fracture significantly increases an individual's lifetime risk of sustaining a subsequent fracture⁶, and clinical vertebral or hip fractures are associated with an increase in mortality^{7,8} and morbidity⁹. It has also been demonstrated that a patient with one or more vertebral fractures is often unable to participate in simple activities of daily living¹⁰. It is imperative that criteria are established to identify patients that are at the highest risk for sustaining a first fracture, thus preventing a negative cascade of fracture risk and diminishing their overall quality of life¹¹. It is now possible to calculate the ten-year probability a patient has for sustaining an osteoporotic fracture based on age and T-

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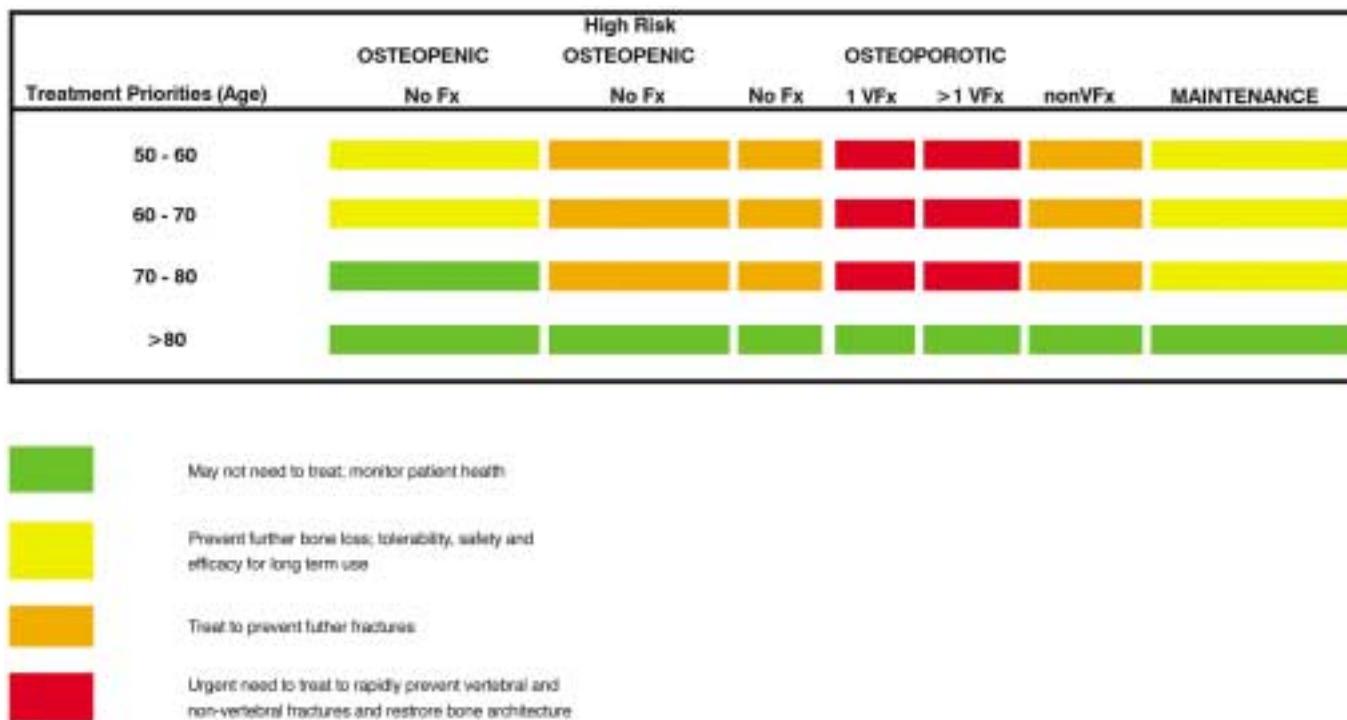


Figure 1. Osteoporosis Treatment Paradigm.

score¹². The development of these types of tools will also assist in establishing risk stratification for individuals with low bone mass or osteopenia. Several studies have clearly demonstrated an increased incidence of new vertebral and non-vertebral fractures in patients with a prevalent vertebral fracture¹³⁻¹⁶, which can be independent of their BMD^{13,16,17}. In addition, patients with one or more vertebral fracture are at a 5-fold increased risk of sustaining an additional vertebral fracture in the year immediately following their first fracture⁶. However, the urgent need to treat patients who have sustained an osteoporotic fracture has yet to be fully realized. Several studies have recently reported that even when patients are known to have sustained an osteoporotic fragility fracture, they are not treated with an anti-osteoporosis drug¹⁸⁻²⁰.

With this background, it is appropriate to recommend an approach to the treatment of osteoporosis that focuses on pharmacological and non-pharmacological interventions that will prevent bone loss, or increase bone mass, and decrease the incidence of vertebral and non-vertebral fragility fractures by interrupting the cascade of osteoporotic fracture incidence^{6,21}. The National Osteoporosis Risk Assessment (NORA) has recently confirmed what had been suspected for several years, the widespread underdiagnosis of low bone mass and osteoporosis^{22,23}. Of the approximately 200,000 women involved in the NORA evaluation, 46% had undiagnosed osteopenia or osteoporosis.

Within the previously undiagnosed NORA population there was a 4-fold and 1.8-fold increase in fracture rate for women with osteoporosis or osteopenia, respectively²². In addition, of the women participating in NORA who sustained a new osteoporotic fracture, only 6.4% had a baseline T-score ≤ -2.5 ²⁴ based on a peripheral bone mass measurement. The Study of Osteoporotic Fractures (SOF) also demonstrated the need for identifying patients diagnosed with low bone mass that are at high risk of fracture and need to be treated. In the SOF study, more than 50% of osteoporotic fractures occurred in patients with a baseline BMD T-score > -2.5 ²⁵. The results of the Rotterdam Study, which related the incidence of non-vertebral fracture to BMD, found only 44% (women) and 21% (men) of non-vertebral fractures occurred in patients with a BMD T-score below -2.5 ²⁶.

Treatment Recommendations

During the Consensus Experts Meeting, treatment scenarios for the patient with osteopenia and osteoporosis were discussed. The scope of the patient profiles were designed to be representative of the patient groups that clinicians are most likely to encounter in their daily practice, and a comprehensive review of the clinical factors that influence the choice of an osteoporosis treatment regimen were reviewed by the participants.

Patients with Osteopenia

For postmenopausal women, ages 50-70 who have not sustained an osteoporotic fracture, the primary focus should be on preventing further bone loss and subsequent risk of a vertebral fracture, as this younger patient with low bone mass has a low risk of hip fracture over the next 10 years. Treatment should maintain a normal (physiologic) quality bone and be safe over the long term. For older individuals >70 years of age with low bone mass, who are at an increased risk for both vertebral and non-vertebral fracture, especially at the hip, the focus should be on preventing future bone loss, and implementation of a treatment regimen that will be tolerable to the patient.

Early detection and intervention will play a key role in the long-term bone health of the patient with osteopenia. Patient intervention following diagnosis may take the form of dietary changes, including an increase in calcium intake, and exercise. Studies have shown that muscle weakness and increased body sway independently predict an increase in fracture risk²⁷. Adequate vitamin D levels are also important for muscle function and the prevention of falls in older individuals²⁸⁻³⁰. An anti-osteoporotic drug, shown to be effective in preventing vertebral fracture in patients with low bone mass or osteopenia, may also be recommended if the absolute risk of fracture is substantially high due to the presence of risk factors other than osteoporosis.

Patients with Osteoporosis

In a postmenopausal woman diagnosed with osteoporosis, the primary treatment objective is to improve bone strength and prevent the first or subsequent vertebral and non-vertebral fractures. In most of these patients, an anti-resorptive therapy should be recommended to decrease the risk of fracture in a patient with osteoporosis. Patients with low bone mass and additional risk factors should also be considered for treatment with an anti-resorptive therapy. There is an increased emphasis on pharmacologic intervention and an urgent need to treat a patient who has suffered >1 vertebral, or an atraumatic non-vertebral fracture. For patients with more severe osteoporosis, including those with several fragility fractures, a bone anabolic agent may be recommended to build new bone, to increase bone mass and restore adequate bone strength.

The Role of Rehabilitation

When a patient with osteopenia or osteoporosis suffers a fragility fracture there is a spectrum of clinical outcomes that may occur including: full recovery, chronic pain, disability or death. As a measure to help alleviate the disability a patient may experience, the National Osteoporosis Foundation of the United States has recently emphasized the role of rehabilitation for the patient with osteoporosis.

The recommendations include taking measures to assist in the reduction of chronic pain, improvement of overall health and function in activities of daily living for the patient^{31,32}. Rehabilitation may include physical therapy as well as specific exercises, systemic muscle training, or the use of orthosis specifically designed for patients with osteoporotic vertebral fractures³². Lifestyle modification including exercise is advised following not only hip fracture, but also after sustaining a vertebral or Colles' fracture.

Maintaining the Benefits of Bone Building

There is no definitive clinical guidance on how to best maintain the improved bone strength achieved by treatment with an osteoporosis therapy. Some osteoporosis treatments may be limited to a fixed duration due to their specific label, or physicians may impose an arbitrary limitation on duration of use in an individual patient. Independent of the initial duration of therapy, it is recommended that physicians maintain the improvement in their patient's bone health with an osteoporosis therapy that has been shown to prevent long-term bone loss, and has a favorable safety profile. In younger patients with less severe osteoporosis this is particularly relevant. Younger postmenopausal women should receive, and be maintained, on treatment that achieves normal physiologic bone health, and that the physician feels comfortable prescribing long-term.

Conclusion

The recommendations presented in this document are intended as a resource for clinicians to enable the best possible patient care. The emphasis is clearly to foster an increased awareness of the impact of osteoporosis on our aging population, and communicate the urgency of identifying and treating patients with low bone mass at high risk of fractures. There are still uncertainties about the optimal duration of most treatments and about the best approach to maintain and improve bone strength that is gained through osteoporosis treatment. Finally, with the overall life expectancy of our population increasing, the incorporation of a rehabilitation regimen is suggested to improve the overall quality of life of individuals who have sustained an osteoporosis-related fracture.

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