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Osteoporosis: AACE/ACE Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (2020)

About the Guideline

- The evidence for this guideline was obtained through MEDLINE searches and other reference sources.
- Experts evaluated the available literature, and references were graded for relation to evidence level, evidence analysis, and subjective factors based on methods established by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) in 2004 and clarified in the 2010, 2014, and 2017 protocols for standardized production of clinical practice guidelines.

Key Clinical Considerations

Become familiar with the recommendations and best-practice statements provided in this guideline, especially if you work in an acute care setting.

Fracture Risk Assessment

- Evaluate postmenopausal women ages 50 or older for osteoporosis risk including a history, physical exam, and the use of an approved risk assessment tool such as the Fracture Risk Assessment Tool (FRAX®).
- Based on clinical fracture risk profile, consider bone mineral density (BMD) testing using axial dual-energy X-ray absorptiometry that includes hip and spine measurements for all women ages 65 years or older.
- Osteoporosis may also be diagnosed in patients with osteopenia and an increased fracture risk as determined by FRAX® country-specific thresholds.
- Osteoporosis should be diagnosed based on the presence of fragility fractures in the absence of other metabolic bone disorders, or a T-score of -2.5 or lower in the lumbar spine, femoral neck, and total hip, and/or a 33% radius even in the absence of a prevalent fracture.

Osteoporosis Diagnosis and Evaluation

- Evaluate the patient for causes of secondary osteoporosis and for prevalent vertebral fractures.
- Consider using bone turnover markers (BTMs) in the initial evaluation and follow-up of osteoporosis patients. A higher fracture risk and rapid rates of bone loss can be predicted by elevated levels.
- The AACE agrees with the proposed new clinical diagnosis by the National Bone Health Alliance (NBHA) that osteoporosis may also be diagnosed in patients with osteopenia and increased fracture risk as determined by using FRAX® country-specific thresholds.
- All postmenopausal women ages 50 and older should undergo clinical assessment for osteoporosis and fracture risk, including a detailed history and physical examination.
- Fracture is the single most important manifestation of postmenopausal osteoporosis.
- BMD testing is the gold standard for diagnosing osteoporosis.
- NBHA, working in association with the American Association for Clinical Chemistry, has established that the preferred resorption marker is serum C-terminal telopeptide (CTX).

Fundamental Measures for Bone Health

- Measure and maintain serum 25-hydroxyvitamin D, and supplement with vitamin D3 if needed.
    - Higher doses may be necessary in the presence of certain factors (e.g., obesity, malabsorption, certain ethnicities, older individuals).
- Counsel patients ages 50 and older to maintain a dietary and supplemental intake of 1,200 mg of calcium per day, limit alcohol intake to two drinks per day, participate in smoking cessation, and maintain an active lifestyle that includes weight-bearing, balance, and resistance exercise.
- Provide counseling on falls prevention, especially in the elderly. Consider hip protectors for those at a high risk for falls.
- Patients with osteoporosis may benefit from physical therapy or other activities and nonpharmacological measures to improve strength, reduce discomfort, and reduce the risk of falls and fractures.

Pharmacologic Therapy

- Strongly recommended for patients with low bone mass or osteopenia and a history of fragility fracture of the spine or hip.
- Strongly recommended for patients with a T-score of -2.5 or lower in the spine, total hip, 33% radius, or femoral neck.
- Strongly recommended for patients if the FRAX® 10-year probability for major osteoporotic fracture is 20% or more, if the patient has a T-score between -1.0 and -2.5, or if the patient's 10-year probability of hip fracture is 3% or more in the United States, or above the country-specific threshold in other countries or regions.

Medication for Those with Osteoporosis

- Approved agents with proven efficacy to reduce hip, nonvertebral, and spine fractures include the following: alendronate, risedronate, zoledronic acid, and denosumab. All are appropriate as initial therapy for most patients at high risk of fracture.
- Teriparatide, denosumab, romosozumab, or zoledronic acid should be considered for patients unable to use oral therapy and as initial therapy for patients at especially high fracture risk.
- Raloxifene or ibandronate may be appropriate initial therapy in cases where patients require drugs with spine-specific efficacy.
- Orally administered bisphosphonates should be used with caution in patients with active esophageal disease.
- In women more than 5 years past the onset of menopause, calcitonin produces a slight increase in BMD in the spine.

Treatment Monitoring

- Acquire a baseline axial (spine and hip) dual energy X-ray absorptiometry (DXA) and repeat every 1 to 2 years until stable.
- Monitor serial changes in the lumbar spine, femoral neck, or total hip BMD.
- Follow-up testing should be conducted at the same facility using the same diagnostic systems.
- Significant reductions in BTMs are seen with antiresorptive therapy.
- The frequency of testing should be individualized depending on the patient's clinical state.

Osteoporosis Treatment

- Consider alternative therapy or reassess for the causes of secondary osteoporosis in patients who have recurrent fractures or significant bone loss while on therapy.
- Pharmacologic and nonpharmacologic treatments are used for osteoporosis.
- Larger increases in BMD may result in increased reduction of fracture risk.
- Goal of treatment is fracture prevention.
- The risk of fracture is highest after a recent fracture and diminishes over time.
- Any recent vertebral fractures, as well as the number and severity of the fractures, are directly correlated with future fracture risk.
- Two rare risk factors of treatment include osteonecrosis of the jaw (ONJ) and atypical femur fracture (AFF).
    - Advanced cancer patients receiving high-dose osteoporosis therapy may be at risk for ONJ due to the following: dental pathologic conditions, invasive dental procedures, and poor dental hygiene.
        - Stopping treatment should be considered for patients undergoing extensive invasive dental procedures (e.g., extraction of several teeth).
    - AFF occurring in the subtrochanteric region is a risk that is increased with long-term bisphosphonate therapy (more than 5 years).

Length of Treatment

- Treatment with teriparatide or abaloparatide should be limited to 2 years, and then followed with denosumab or a bisphosphonate.
- Treatment with romosozumab should be limited to 1 year, and then followed with denosumab or a bisphosphonate.
- If taking oral bisphosphonates, a “bisphosphonate holiday” should be taken after 5 years for stable moderate-risk patients and after 6 to 10 years of stability for higher-risk patients.
- For individuals receiving intravenous (IV) zoledronic acid, consider a “bisphosphonate holiday” after 3 annual doses in moderate-risk patients and after 6 annual doses in higher-risk patients.
- Teriparatide or raloxifene may be used for a high-risk patient during a “bisphosphonate holiday.”
- Caution and close monitoring are advised among elderly patients with preexisting cardiovascular disease, especially when IV bisphosphonates are used.

Combination Therapy versus Single Therapy

- The guideline does not recommend concomitant use of agents for prevention or treatment of postmenopausal osteoporosis.
- If estrogen is being given for treatment of menopausal symptoms, or if raloxifene is administered to reduce the risk of breast cancer, an additional agent may be considered in high-risk patients.
- Some combinations may enhance the rapidity of BMD changes.
- The most substantial additive BMD effect is seen with the combination of teriparatide and denosumab, which results in a larger increase in BMD.
- Combination therapy raises the cost and potentially increases the risk for side effects.

Therapeutic Agents

- Treatment with teriparatide or anabolic therapy should always be followed by antiresorptive agents to prevent bone density decline and increase in risk of fracture.

Compression Fractures

- Kyphoplasty and vertebroplasty are not recommended as first-line treatment of vertebral fractures given their limited benefit in reducing overall pain and the potential increased risk of vertebral fractures in adjacent vertebrae.

Provider Referrals

- Referral to a clinical endocrinologist or osteoporosis specialist may be important for patients with the following conditions:
    - Normal BMD and a fracture without major trauma
    - Recurrent fractures
    - Continued bone loss while receiving therapy
    - Less common secondary conditions (i.e., hyperthyroidism or hyperparathyroidism)
    - Those with osteoporosis as well as an additional condition that complicates management (i.e., chronic kidney disease or malabsorption)

Reference

Camacho, P. M., et al. (2020). American Association of Clinical Endocrinologists and American Colleges of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis – 2020. *Endocrine Practice, 26*(Suppl. 1), 1–46. Accessed March 2021 via the Web at https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice