

*Guidelines for the Diagnosis and Management of Osteoporosis in Greece*.  
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***English-language abstract***

**CLINICAL GUIDELINES OF OSTEOPOROSIS DIAGNOSIS AND TREATMENT**

**Risk Factors**

**CONCLUSIONS**

The presence of multiple vertebral fractures increases the risk of a new vertebral fracture (E1).

The presence of one osteoporotic increases the risk of future fractures, independently of bone mineral density (E2).

**RECOMMENDATIONS**

Immediate evaluation and initiation of therapy for patients with multiple vertebral distortions associated with height loss and kyphosis (Grade A).

Immediate evaluation and initiation of therapy, for patients with clinical evidence of fracture (Grade B).

**Bone Densitometry**

**RECOMMENDATIONS**

Bone Mineral Density (BMD) measurement by Dual Energy X-Ray Absorptiometry (DEXA) is the best way to estimate fracture risk in postmenopausal women (Grade A).

BMD, as expressed by T-score, is useful in decision making for determination of treatment, taking into account patient's age (Grade B).

Postmenopausal women, without indications for initiation of therapy, should repeat the measurement every two years (Grade D).

Postmenopausal women receiving treatment should repeat the measurement every year.

BMD low values raise suspicions for the existence of secondary osteoporosis.

If BMD measurement assists in decision making for determination of treatment, it should be considered as an indication for persons of any age and either sex.

## **Biochemical Markers of Bone Turnover**

### **CONCLUSIONS**

Their determination is potentially useful for recognition of women at high risk for fracture among the elderly. There is insufficient data for the young, men and non whites (E2).

The combination of elevated biochemical markers of bone turnover (BMBT) and low BMD has probably greater prognostic value where fracture risk is concerned with each parameter separately (E2).

Early decrease of BMBT during antiosteoporotic treatment has probably prognostic value for the future increase of BMD (E2). Nevertheless, there are no data correlating specific levels of BMBT during therapy with fracture risk.

### **RECOMMENDATIONS**

Measurement of one marker of bone resorption and one of bone formation before treatment and 3–6 months after initiation of treatment (Grade A).

## **Treatment**

Who needs treatment?

- Postmenopausal women sustaining multiple vertebral fractures (having excluded other disorders).
- Postmenopausal women with T-score  $< -2.5$  SD with or without fracture.
- Elderly people with history of low energy fracture of the peripheral skeleton.
- Men diagnosed with osteoporosis by DEXA measurement, with or without previous osteoporotic fractures.
- Patients receiving corticosteroids (for more than 3 months).

## **Bisphosphonates**

- Absorption of bisphosphonates is poor. Typically, only 05–5% of the administered dose is absorbed. Ideal absorption requires empty stomach,

one glass of water with the drug and avoidance of food for at least 30 minutes after ingestion of the bisphosphonate.

- All bisphosphonates can cause side effects from the gastrointestinal tract. For aminobisphosphonates like alendronate and risedronate, these side effects are rare and may present as ulcerative esophagitis. The risk decreases if the patient does not lie down for 30 minutes after ingestion of the drug.
- Etidronate administered continuously for long periods of time can cause disorders of mineralization, like osteomalacia and for that reason is administered for two weeks every three months, usually at a dose of 400 mg/day.
- Given the strict directions for bisphosphonate administration it is doubtful whether this treatment is indicated for patients that do not comply with instructions, like elderly demented patients who live alone or patients with an increased risk for developing esophagitis, like patients with gastroesophageal regurgitation.

#### RECOMMENDATIONS

- Aminobisphosphonates are first choice preventive treatment for menopausal women with low bone density: alendronate (Grade A), risendronate (Grade A), etidronate (Grade A).
- Bisphosphonates are first treatment choice for menopausal osteoporotic women, especially those with prior vertebral fractures: alendronate (Grade A), risendronate (Grade A), etidronate (Grade B).

#### Calcitonin

- The only absolute contraindication to the administration of intranasal or subcutaneous calcitonin is sensitivity to the substance or to its additives.
- Subcutaneous administration has more side effects. Nausea or vomiting, hot flushed and skin irritation at the site of puncture are among the usual.
- Both ways of administration cause the development of antibodies and the phenomenon is dose-dependent. It does not affect however the effectiveness of the drug and it is not associated with side effects.

#### RECOMMENDATIONS

- Intranasal calcitonin is second treatment choice for menopausal women with osteoporosis (Grade B).
- Intranasal or parenteral calcitonin administration if first choice treatment for pain due to acute vertebral fractures for a period of 2–3 months (Grade A).

### **Selective Estrogen Receptor Modulators (SERMs)**

#### RECOMMENDATIONS

- Raloxifene is first choice treatment for the prevention of further bone mass loss in menopausal women with low BMD (Grade A).
- Raloxifene is first choice treatment for menopausal women with osteoporosis with or without vertebral fracture (Grade A).

### **Hormone Replacement Therapy (HRT)**

#### RECOMMENDATIONS

- HRT is first choice preventive treatment for menopausal women with low BMD. When administered only for osteoporosis prevention, risk may outweigh the benefits (Grade A).
- HRT is second choice treatment for menopausal women with osteoporosis (Grade B). In long term HRT administration for osteoporosis treatment the risk of breast cancer, cardiovascular and cerebrovascular episodes may outweigh the benefits.

### **Calcium–Vitamin D**

#### RECOMMENDATIONS

- Calcium (1.000–1.200 mg/day) and vitamin D administration (800 IU/day) to elderly patients reduces fractures of the femoral neck (Grade A).

## **Parathyroid Hormone**

### **RECOMMENDATIONS**

- rhPTH (1–34) is first choice treatment for menopausal women with severe osteoporosis and fractures (Grade A).
- The recommended duration of treatment is 18 months, followed by another antiosteoporotic therapy in order to maintain the beneficial effect.

## **Non-pharmacological interventions**

### **RECOMMENDATIONS**

#### **Exercise**

The elderly, men and women alike, should be encouraged to participate in long term exercise programs, to maintain their bone density (Grade B for women, Grade C for men).

To maintain bone density, programs should include medium to high intensity weight-bearing exercises ((Grade B for women, Grade C for men).

For men and women in high risk of falls or those that already fall often, exercise should be tailored to each patient's needs according to the findings of the evaluation and should include exercises that increase strength, improve balance and neuromuscular coordination and reduce reaction time to external stimuli (Grade A).

#### **Nutrition**

- Daily recommended intake of calcium:
  - Children (4–8 years old): 800 mg/day (Grade B).
  - Teenagers (9–18 years old): 1300 mg/day (Grade B).
  - Premenopausal women (18–50 years old): 1000 mg/day (Grade A).

- Menopausal women or women over 50: 1500 mg/day (Grade A).
- Men (18–50): 1000 mg/day (Grade C)
- Men over 50: 1500 mg/day (Grade C)
- Pregnant or lactating women over 18: 1000 mg/day (Grade C)
- Pregnant or lactating women over 18: 1300 mg/day (Grade C)
- Daily recommended intake of vitamin D:
  - Men and women below 50: 400 IU (10 µg)/day (Grade D)
  - Men and women over 50: 800 IU (20 µg)/day (Grade A)
- Protein intake should be in the range of 1–1.5 gr/kgr BW and not below 0.8 gr/kgr BW (Grade B).
- Vitamin K supplementation reduces the risk of fracture (Grade C).
- Calcium/phosphorus intake should ideally be 1:1 (Grade C).
- Sodium intake >2.100 mg/day should be avoided, especially by menopausal women (Grade C).
- Caffeine intake (up to 3 cups/day) is allowed as long as calcium intake is adequate (Grade C).
- Scientific data about alcohol intake is not sufficient to allow recommendations to be made.
- There is no strong evidence supporting magnesium, copper, zinc, iron, essential fatty acid supplementation as part of the prevention or treatment of osteoporosis.

#### **Prevention or treatment of corticosteroid–induced osteoporosis (CIO)**

- Patients about to receive or receiving corticosteroids in daily dose equal of higher than 7.5 mg of prednisolone for a period greater than 3 months. These patients should be evaluated as possible candidates for antiosteoporotic treatment (Grade A).

- Patients receiving corticosteroids in daily dose lower than 7.5 mg of prednisolone for a period greater than 3 months. These These patients should be evaluated for osteoporosis risk and their BMD should be measured, given the fact that corticosteroid dose greater and 2.5 mg prednisolone daily for a long period of time is correlated with increased fracture risk (Grade B).

## **Calcium–Vitamin D**

### **RECOMMENDATIONS**

Calcium alone or vitamin D alone are not recommended for prevention and treatment of CIO (Grade A).

All patients on corticosteroid therapy should receive 1.200–1.500 mg/day of calcium and 400–800 mg/day of vitamin D (Grade B).

## **Estrogens**

### **RECOMMENDATIONS**

- HRT is not recommended as first choice treatment for prevention and therapy of CIO in menopausal women due to lack of data (Grade A).
- In spite of lack of data, estrogens can be administered to pre-menopausal women with amenorrhea or oligoamenorrhea (Grade D).

## **Testosterone**

### **RECOMMENDATIONS**

- In spite of lack of sufficient data that does not allow testosterone to be characterized as first choice treatment (Grade B), testosterone can be administered to men with hypogonadism for prevention and treatment of CIO (Grade D).

## **Biphosphonates**

### RECOMMENDATIONS

- Biphosphonates are the treatment of choice for prevention and therapy of CIO (Grade A).
- Cyclical administration of etidronate, daily administration of 10 mg of alendronate or 5 mg of risedronate is recommended (Grade A).

## **Calcitonin**

### RECOMMENDATIONS

- Salmon calcitonin should not be our first choice treatment for the prevention and therapy of CIO (Grade A).

## **Parathyroid Hormone**

### RECOMMENDATIONS

- Because of lack of data where parathyroid hormone's effect on fractures is concerned, rhPTH (1-34) should not be first choice treatment for prevention and therapy of CIO, at least at this stage (Grade B).

## **Osteoporosis in Men**

### RECOMMENDATIONS

- Data on BMD measurements in men is poor. Given the fact that, after the age of 65, the fracture risk increases as much in men as in women, BMD measurement after that age is justified (Grade B).
- The few existing clinical trials concern etidronate (Grade D), alendronate (Grade A), calcitonin (Grade A), parathyroid hormone (Grade A) and for men with hypogonadism testosterone (Grade A). The effect of risedronate has been evaluated in osteoporotic men receiving corticosteroid treatment.

