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Osteopenia as a target for early therapeutic intervention in the prevention of osteoporosis

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Abstract
Background. Osteoporosis is the most common metabolic bone disease in the world, occurring primarily in postmenopausal women and older men. The disease is usually diagnosed only after a fracture has occurred, and in a significant proportion of patients, bone mineral density (BMD) values indicate only osteopenia.
Aim. The article aims to draw attention to the need for early diagnosis and appropriate intervention in people with osteopenia, to determine the appropriate moment to start treatment, and to present recommendations for prevention and treatment in different phases of the disease.
Material and Methods. A literature review has been conducted using databases such as PubMed, FRAX calculator. Particular attention was paid to the most recent years of publication.
Conclusions. Early diagnosis and prevention of bone mineral density disorders, as well as the implementation of appropriate treatment in the early stages of the disease can limit the development of osteoporosis and reduce the risk of fractures. According to current guidelines, pharmacological treatment of patients with osteopenia should only be considered in the presence of additional fracture risk factors. Effective implementation of therapy requires accurate diagnosis and proper classification of the patient into the appropriate fracture risk group.

Keywords: osteopenia, osteoporosis, risk factors, Fracture Assessment Tool (FRAX), bone mineral density (BMD), prevention, treatment

Introduction

Osteoporosis is the most common metabolic bone disease in the world, occurring mainly in postmenopausal women and older men [1]. The disease is most often diagnosed only when a fracture occurs, which means that a significant proportion of cases remain undetected at a stage when effective treatment could be implemented. This places a heavy burden on both the healthcare system and the patients themselves [1,2].

The first fracture is not the onset of the disease, but a consequence of pre-existing, undiagnosed bone metabolism disorders. The occurrence of another fracture, especially in older people, significantly increases the risk of further fractures, leading to a deterioration in quality of life, an increase in the incidence of comorbidities and an increase in mortality [2].

It is worth noting that more than half of fractures in postmenopausal women occur in patients whose bone mineral density (BMD) measurements indicate osteopenia rather than osteoporosis. This fact highlights the importance of early diagnosis and prevention of bone mineral density disorders and the implementation of appropriate treatment at an early stage of the disease, which can prevent the development of osteoporosis and the occurrence of fractures [2,3,4].

Predisposing factors for diagnosis

Osteoporosis is a disease characterized by low bone density, deterioration of bone tissue, disturbed bone microarchitecture, and impaired bone strength leading to fractures. Depending on the etiology, osteoporosis is divided into primary and secondary osteoporosis which develops in the course of other diseases or as a result of chronic use of certain medications (Table 1) [2].

Table 1. Risk factors for primary and secondary osteoporosis [5].

Type of osteaoporosis	**Risk factors**	
Primary	Early menopause Excessive alcohol intake Family history of osteoporotic fracture Low body weight (<57,6kg) Smoking	
Secondary	Medical causes: Alcoholism Ancylosis spondylitis Chronic kidney disease Chronic obstructive pulmonary disease Hyperparathyroidism Hyperthyroidism (or on thyroid replacement therapy) Malabsorption disorders Rheumatoid arthritis Type 1 or type 2 diabetes mellitus Vitamin D deficiency	Medications: Antiepileptics Aromatase inhibitors Glucocorticoids Gonadotropin- releasing hormone agents Heparin Lithium Medroxyprogesterone Proton pump inhibitors Selective serotonin reuptake inhibitors Thiazolidinediones Thyroid hormones

According to the diagnostic criteria of the World Health Organization (WHO), osteoporosis is diagnosed on the basis of BMD using the T-score (ratio of the subject's BMD to the average bone density of a young person) of the femur or lumbar vertebrae using dual-energy X-ray absorptiometry (DXA). Patients with T-scores higher than -1.0 are classified as healthy§, while patients with T-scores lower than -2.5 are diagnosed with osteoporosis. Patients with *T-scores* between -2.5 and -1.0 also have a higher risk of fractures than the average population, and this condition is called osteopenia [6].

BMD is one of the strongest predictors of fracture risk, which is why many institutions around the world have adopted BMD thresholds as the basic criterion for therapeutic intervention. However, the results of a study indicate the limitations of this approach. The use of fixed BMD thresholds does not take into account the fact that fracture risk depends not only on bone density itself, but also on age, previous fractures and other clinical factors. Thus, an identical T-score may be associated with different levels of risk in different age groups, which undermines the validity of universal intervention thresholds based solely on BMD. For this reason, even if BMD results do not allow for the diagnosis of osteoporosis, but only osteopenia, the assessment of the overall risk of fracture should be an important element of the therapeutic decision, including consideration of the need for pharmacological treatment [7].

According to the recommendations of the Bone Health and Osteoporosis Foundation, the indications for DXA testing depending on age are: in women: age ≥ 65 , age 50-64 with clinical risk factors; men: age $70 \geq$, age 50-69 with clinical risk factors; everyone: age $50 \geq$, with a fracture, condition or medication that affects bone mass reduction or loss [5].

Fracture risk stratification

An important tool to support therapeutic decisions is the FRAX (Fracture Assessment Tool) calculator, which allows the estimation of the 10-year risk of osteoporotic fractures, taking into account not only BMD but also a number of other important clinical factors (Table 2) [8]. FRAX risk assessment should be performed in all postmenopausal women and men over 50 years of age who have clinical risk factors for low-energy fractures [9].

The use of FRAX to estimate 10-year fracture risk, even without BMD data, can be a reliable and useful screening tool. An improved version of the FRAX calculator, FRAXplus, is now available, which partially eliminates the limitations of the classic model by allowing the introduction of additional clinical variables that increase the accuracy of osteoporotic fracture risk assessment: recent osteoporotic fracture, high exposure to oral glucocorticoids, type 2 diabetes, concurrent data on lumbar spine BMD, trabecular bone score, history of falls and hip axis length [10].

Densitometry data provide accurate but insensitive information, as most fractures occur in individuals with a T-score higher than –2.5. Supplementing this assessment with an analysis of clinical risk factors may increase the effectiveness of fracture prediction. The fact that BMD has only a limited impact on FRAX model predictions and that changes in BMD over time do not necessarily reflect future fracture risk also indicates that it is reasonable to consider implementing pharmacological treatment as early as the osteopenia stage [4,11].

However, it should be remembered that the FRAX calculator does not cover all possible risk factors. Therefore, the final therapeutic decision should be based on a comprehensive clinical assessment, taking into account the patient's full health context and risk factors not included in the available prognostic models [9].

Table 2. Components of the FRAX calculator [12].

COMPONENTS OF THE FRAX CALCULATOR
1. Age (40-90 years)
2. Sex
3. Weight
4. Height
5 History of low-energy fracture
6. History of proximal femoral fracture in parents
7. Current smoking
8. Use of glucocorticoids (more than 3 months at a dose of prednisolone of 5mg daily or more or equivalent doses of other glucocorticoids)
9. Rheumatoid arthritis
10. Secondary osteoporosis If the patient has a 5onditio strongly associated with osteoporosis, such as: -type I diabetes -congenital bone fragility in adults, -untreated long-term hyperthyroidism -hypogonadism -premature menopause (<45 years of age) -chronic malnutrition or malabsorption syndrome -chronic renal failure (not dependent on dialysis) -chronic liver disease
11. Alcohol 3 or more units/day
12. BMD value of the femoral neck (neck g/cm²) with indication of the type of densitometer used

When to start pharmacological treatment

Pharmacological therapy is commonly recommended for patients diagnosed with osteoporosis or who have suffered osteoporotic fractures. However, there is still debate about the appropriateness of its use in people with osteopenia [13]. Current guidelines indicate the need to consider the implementation of pharmacological treatment in patients with osteopenia, but only in the presence of additional fracture risk factors [2].

In postmenopausal women and men aged ≥50 years, osteoporosis treatment is recommended not only on the basis of low bone mineral density (T-score ≤ –2.5), but also in the presence of specific risk factors for osteoporotic fractures**,** which include:

1. a history of fracture(s) from any cause in adulthood
2. a decrease in height of approximately 4 cm (defined as the difference in height between the current value and the highest value achieved in life)
3. a decrease in height of >2 cm since the last documented measurement
4. recent or long-term use of glucocorticosteroids *(≥5 mg/day of prednisone for more than 3 months)*
5. diagnosis of hyperparathyroidism
6. T-score ≤-2.5 in the femoral neck or "whole hip", in the lumbar spine, or possibly in the distal (33%) radius
7. low bone mass (osteopenia: T-score between -1.0 and -2.5) in the femoral neck or total hip based on DXA, with a 10-year risk of femoral neck fracture ≥3% or osteoporotic major fractures ≥20% based on the FRAX®USA model (in Poland, a risk of >10% is assumed).
8. BKKU or vertebral fracture regardless of BMD value
9. proximal humerus, pelvic bone or distal forearm fracture in individuals with low bone mass (osteopenia: T-score between -1.0 and -2.5) [2,14].

Awareness of the above risk factors is crucial for assessing the appropriateness of pharmacological treatment. It is also important in the process of determining the fracture risk category to which a patient can be assigned. Correctly assigning a patient to the appropriate risk group is an important element of individualizing therapy and can significantly facilitate the selection of the optimal pharmacological treatment (Table 3) [15].

Table 3. Modified criteria for assessing fracture risk in Poland for women and men >50 years of age [15].

Risk	Criteria
Low/ medium risk	If present: **Age >50 or postmenopausal** **No fracture** and **T-score >- 2,5** and/or **FRAX: 5 to < 10% for MOF medium RF, FRAX: < 5% for MOF low RF**
High risk	At least one of the following applies : **Major osteoporosis fracture in the last 2 years** and/or **T-score ≤ 2,5** and/or **FRAX 10 to 15% for MOF or 3 to 4,5% for hip**
Very high risk	At least one of the following applies: **Newly- diagnosed MOF within past 12 months and T-score ≤ -1** or **Multiple major fractures (≥2)** or **Fractures while medication used other reasons is harmful to bone, e.g: glucocorticosteroids, aromatase inhibitors or others** and/or **Very low T-score <-3** and/or **FRAX >15% for MOF or > 4,5% for hip**

FRAX - fracture risk assessment tool; MOF-major osteoporotic fracture; RF-risk of fracture

Analysis of the data presented in Table 3 indicates that individuals with a T-score between -1 and -2.5, classified as having osteopenia, can be included in all of the risk groups described - low, medium, high and very high.

Early preventive measures in clinical practice

The basic therapeutic approach at every stage of the disease is education and lifestyle changes for the patient, taking into account the individual circumstances of each person and, if possible, treatment of the underlying disease. Preventive recommendations include a well- balanced diet rich in calcium, avoiding smoking and excessive alcohol consumption, regular physical activity, weight control and adequate exposure to sunlight/vitamin D supplementation [14,16].

Among these interventions, we should pay particular attention to physical activity, which has been proven effective in terms of its beneficial effect on bone mineral density (BMD) [16].

The form of physical activity should be tailored to individual capabilities and include aerobic and resistance exercises [14]. One study showed that alternating loads of 70% of 1 maximum repetition with loads of 50% of 1 maximum load in the same set and performing the exercise protocol twice a week can lead to an increase in lumbar spine BMD in postmenopausal women with osteopenia/osteoporosis [13].

It is also worth noting that regular physical activity not only contributes to improved bone mineral density, but also to increased muscle strength, improved motor coordination and balance. These factors play an important role in the prevention of falls, which are one of the key risk factors for fractures in people with osteopenia and osteoporosis [14].
One meta-analysis showed that supplementation with calcium or vitamin D alone did not significantly reduce the risk of hip fracture. Only their combined use was associated with a reduction in this risk - by approximately 19% [5].
The optimal serum concentration of 25-hydroxyvitamin D [25(OH)D] is between 30 and 80 ng/ml. The standard recommendation is vitamin D supplementation at a dose of 800–1000 IU per day. In cases of severe deficiency (25(OH)D < 10 ng/ml), the dose may be increased to as much as 7000 IU per day for a period of 3 months, with simultaneous monitoring of 25(OH)D concentration, serum calcium levels, alkaline phosphatase activity and urinary calcium excretion every 1–3 months. In patients with chronic renal failure, it is recommended to use active metabolites of vitamin D3, such as alfacalcidol, at a dose of 0.25–0.5 μg per day. In patients with hepatic insufficiency, it is recommended to administer calcifediol at a dose of 50–75 μg daily (equivalent to 10–15 drops) [8].
The recommended daily calcium intake is 1000 mg for men aged 50–70 and 1200 mg for women over 50 and men over 70. If possible, calcium should be taken with meals, as its absorption may be significantly reduced in cases of achlorhydria [5,8].

Therapeutic strategies depending on fracture risk
Every patient, regardless of risk group (Table 3), should have preventive measures in place. In patients with a low risk of fractures, this will be the key and only course of action [15].
Patients with moderate fracture risk should remain under further medical supervision, including regular clinical assessment and consideration of pharmacological treatment with bisphosphonates. In women in this group, hormone replacement therapy or raloxifene may also be considered. Patients treated with oral bisphosphonates should be re-evaluated after approximately five years of therapy, while those treated with intravenous preparations should be re-evaluated after three years to determine the appropriateness of continuing treatment or introducing a therapeutic break [5,15].
In patients at high risk of fractures, bisphosphonates or denosumab are recommended. Oral bisphosphonate therapy can be continued for up to 10 years, while intravenous therapy can be continued for up to approximately six years. With regard to denosumab therapy, it is advisable to reassess the appropriateness of its continuation after five and ten years of treatment [5,15].
In patients at very high risk of fractures, it is justified to use anabolic treatment, such as teriparatide or romosozumab, as a first-line treatment. After completion of anabolic therapy (1-2 years), it is recommended to implement treatment with bone resorption inhibitors, which allows for the consolidation of the therapeutic effects achieved and a further reduction in the risk of fractures [15].

However, it should be remembered that not only the determination of fracture risk but also factors such as the presence of comorbidities, the registration indications for a given preparation, potential contraindications, reimbursement options and patient preferences play an important role in the selection of appropriate pharmacological treatment. It is equally important to plan complementary treatment, including fall prevention, appropriate selection of rehabilitation methods, reduction or elimination of modifiable fracture risk factors, calcium and vitamin D supplementation, dietary adjustments and monitoring of the effectiveness of the therapy (Table 4) [15].

Table 4. Treatment algorithm for women and men > 50 years of age depending on the degree of fracture risk [15].

.	Low risk	Medium risk	High risk	Very high risk
The first-line treatment	Supplementation of calcium and vitamin D to prevent the deficiency	**Bisphosphonate orally** **In women:** HRT or Raloxifen	**Bisphosphonate**: Alendronate Risedronate Zoledronic acid **Denonsumab**	**Anabolic treatment:** Teriparatide **Only women:** Romosozumab **Antiresorptive treatment:** Denosumab Zoledronic acid
Monitoring	DXA: every 4 years or after fracture	DXA: every 2-4 years or after fracure	DXA: every 1-2 years Optimal option: bone tumover markers	DXA: every 1-2 years Preferably measurement of bone turnover markers

DXA - dual-energy X-ray absorptiometry; HRT - hormonal replacement therapy

Summary

- Identifying potential causes and risk factors for reduced bone mineral density is crucial for early diagnosis and detection of changes at an early stage.
- An approach focused on prevention, early diagnosis and intervention is a key element of effective clinical management, particularly in the context of reducing the risk of fractures.
- An important tool supporting therapeutic decisions is the FRAX calculator, which allows for the estimation of the 10-year risk of osteoporotic fractures, taking into account not only BMD, but also a number of other important clinical factors.
- Pharmacological treatment should be administered to all individuals of both sexes over the age of 50 who have suffered low-energy fractures, as well as to patients with a very high, high or moderate risk of fractures.

- The therapeutic decision should take into account individual factors affecting fracture risk, comorbidities, BMD results, available biochemical tests, registration indications and possible contraindications to the use of drugs, as well as the costs of therapy.

Disclosures and Declarations

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