REVIEW ARTICLE

Polish guidelines for the diagnosis and management of osteoporosis: a review of 2013 update

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ABSTRACT

To decrease the risk of osteoporotic fractures in Poland, the Multidisciplinary Osteoporotic Forum has set up a joint Working Group including the representatives of the Polish Associations of Orthopedics and Traumatology, Rehabilitation, Gerontology, Rheumatology, Family Medicine, Diabetology, Laboratory Diagnostics, Andropause and Menopause, Endocrinology, Radiology, and the STENKO group as well as experts in the fields of rheumatology, obstetrics, and geriatrics to update the Polish guidelines for the diagnosis and management of osteoporosis in men and postmenopausal women in Poland. The assessment of fracture risk and intervention thresholds was made using the FRAX® calculation tool for Poland. The strength of recommendations was evaluated according to the principles of the Scottish Intercollegiate Guidelines Network and the results have been approved by national consultants. Finally, the Working Group has formulated the updated guidelines and recommended two-step diagnostic and therapeutic procedures. The first stage applies to family physicians or general practitioners and involves the assessment of fracture risk using the FRAX®-BMI to identify patients at high risk of fractures. An osteoporotic fracture remains an absolute indication both for the general practitioner and specialist to implement treatment. At the second stage, the specialist (in an osteoporosis or other specialty clinic) should review the primary or secondary causes of fracture risk, confirm the diagnosis, and introduce an appropriate treatment and monitoring. In patients (men aged >50 years and postmenopausal women) without low-energy fractures, the absolute risk of fractures exceeding 10% should be considered an indication for treatment. The Polish guidelines were compared with other international guidelines in terms of diagnostic measures, pharmacotherapy, as well as calcium and vitamin D supplementation.

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INTRODUCTION Osteoporosis is a common disease characterized by reduced bone tissue density and deficient microarchitecture, which makes bones fragile and more prone to fractures. Clinical manifestations of osteoporosis include bone fractures resulting from minor traumas that reflect reduced mechanical strength of the bone. Vertebral fractures occur first and are the most common. Even though only from 25% to 30% of osteoporotic vertebral fractures manifest themselves clinically with severe pain, all of them lead to reduced body height, body deformation with thoracic kyphosis, reduced lung volume, hindered venous outflow from the lower body, and increased mortality. Nonvertebral fractures mostly occur in the femur, radial bone, pelvis, and tibia. Hip fractures are the most serious consequence of osteoporosis; in 50% of the cases, they make the patient unable to move independently, resulting in death of every fifth woman and every third man owing to complications during the first year after the fracture.[1-3] Therefore, the primary objective of osteoporosis management is to reduce the risk of fractures and prevent their recurrence.

The 2013 guidelines for the diagnosis and management of osteoporosis[2] are an update of the 2007 Polish recommendations on the diagnosis and treatment of osteoporosis and are available on the website of the International Osteoporosis Foundation (IOF) at http://www.iofbonehealth.org/guideline-references. The guidelines include current epidemiological data from Poland regarding bone fractures as well implementation of the Polish version of the FRAX® tool.[4,5] They further implement the basic principles of management used in Europe in postmenopausal[1,6] and glucocorticosteroid-induced osteoporosis,[7] with due regard for the advantages and limitations of the FRAX® tool.[8,9]

The two-step diagnostic and therapeutic procedure suggested in Poland recommends a thorough evaluation of patients at risk of osteoporosis to be made by primary care units first (family practitioners), and, subsequently, to be complemented by comprehensive diagnostic procedures, selection of adequate management, and monitoring by specialized health centers and osteoporosis clinics. Detailed guidelines have been published in Polish,[2] while this paper summarizes the guidelines in English.

Methods

Systematic literature reviews The national epidemiology of fractures and economic health policy including reimbursement of treatment were reviewed. The assessment of fracture risk and intervention thresholds was made using the FRAX® tool for Poland (http://www.shef.ac.uk/FRAX/tool.aspx?country=40).

Consensus process The Multidisciplinary Osteoporotic Forum (MOF) has set up a joint Working Group including the representatives of the Polish Associations of Orthopedics and Traumatology, Rehabilitation, Gerontology, Rheumatology, Family Medicine, Diabetology, Laboratory Diagnostics, Andropause and Menopause, Endocrinology, Radiology, STENKO group, and 3 additional experts in the fields of rheumatology, obstetrics, and geriatrics. A consensus was reached after 1 in-person meeting, multiple e-mails, and phone calls. The MOF Subcommittee received written comments from experts; reliability of data and the strength of recommendation were evaluated according to the principles of the Scottish Intercollegiate Guidelines Network grades of the recommendations from the highest A to the lowest D (www.sign.ac.uk)[10,11]; and the reviewed document has been approved by national consultants (in endocrinology, gynecology, orthopedics, rheumatology, gerontology, diabetology, nephrology, medical rehabilitation, and family medicine).

Definitions

Osteoporosis Osteoporosis is a condition of the skeleton characterized by an increased risk of bone fracture resulting from deficient mechanical resistance. The mechanical resistance of bones is conditioned by bone mineral density (BMD) and the quality of bone tissue. Osteoporosis criteria according to the World Health Organization[12] are based on the BMD evaluation of the proximal end of the femur (hip) (or vertebrae) in postmenopausal women, given as the T-score expressed as the number of standard deviations (SD); the baseline is the maximum bone mass:

1. >–1 SD: normal value
2. from –1 to –2.5 SD: osteopenia
3. <–2.5 SD: osteoporosis
4. <–2.5 SD and osteoporotic fracture: advanced osteoporosis.

The Z-score should be considered in children and young adults; the baseline is the BMD value for the relevant sex and age.[1,3]

The initiation of treatment depends on whether lowered BMD and, in particular, a fracture are observed. Increased fracture risk (e.g., FRAX® with body mass index [FRAX®-BMI]) is mainly an indication for the introduction of preventive measures and extensive diagnostic workup.[1,2]

Fracture risk In untreated postmenopausal women and men older than 50 years, an important factor to be considered when making a decision on initiation of therapy is the evaluation of a 10-year fracture risk. The absolute fracture risk is estimated based on the analysis of clinical risk factor, using the FRAX® calculation tool for the Polish population.[2,5] The FRAX® tool integrates densitometry data with selected clinical risk factors to increase sensitivity without decreasing specificity of evaluation, provided that an existing low-energy fracture is always an indication for treatment.[1,2,5]

Osteoporotic fracture Osteoporotic fracture is a term used to define a low-energy fracture (not proportionate to the force causing it) of the hip (femoral neck, pertrochanteric fracture, subtrochanteric fracture), ribs, vertebrae, humerus, radial bone, or tibia following a fall from the standing position, or compression fracture, in the absence of other causes. In view of the position of the Polish Osteoarthrology Society, it seems advisable to use 2 terms: the common "hip fracture" and anatomical "proximal femur fracture", both consistent with the ICD-10 classification – S72.[2,5] Importantly, a low-energy fracture may be caused by other factors than postmenopausal osteoporosis, such as tumors, bone cysts, or osteomalacia.[1,7]

The recommended management strategy is presented in the FIGURE. The first stage, primarily provided by family physicians or general practitioners, includes selected screening tests based on the results of a physical examination and patient's medical history and evaluation of fracture risk factors (body height, risk of falling, medical conditions, and use of medication). They are performed to identify patients who should receive preventive care or undergo further diagnostic procedures and treatment. At this stage, the FRAX® algorithm for the Polish population in a table or electronic format can be used, with the inclusion

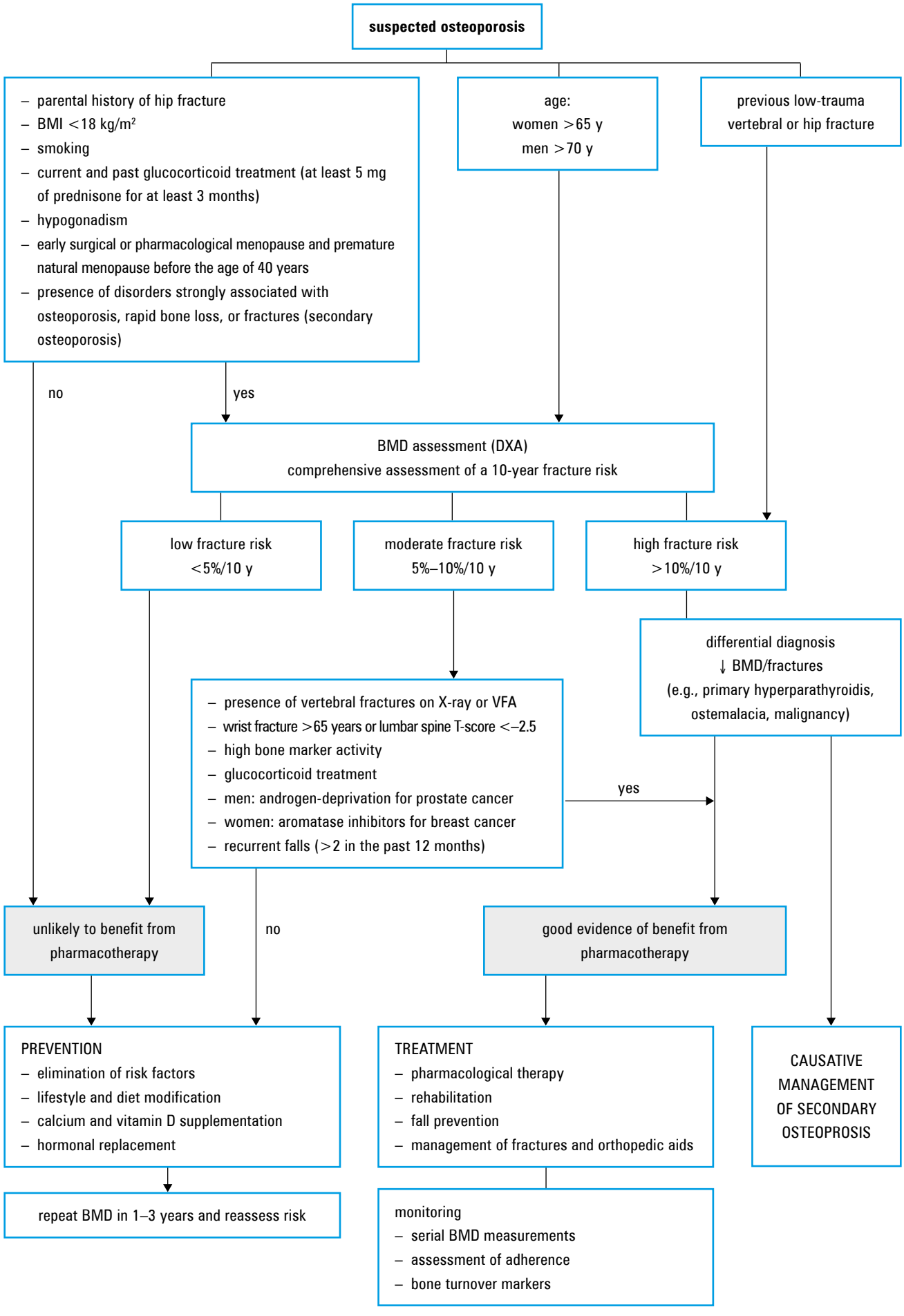

FIGURE General algorithm for osteoporosis management (M80/M81)
BMD – bone mineral density, BMI – body mass index, DXA – dual-energy X-ray absorptiometry, VFA – vertebral fracture assessment

of BMI (FRAX®-BMI). A low-energy fracture is an absolute indication for an antiosteoporotic treatment, which should be introduced by general practitioners and specialists.

The second stage includes verification of the diagnosis by specialists from an osteoporosis clinic and selection of relevant pharmacological treatment and other treatment modalities. The diagnosis relies on a comprehensive analysis of the patient's condition, including evaluation of clinical risk factors (including the risk of falling), X-ray scan, and, whenever possible, densitometry and morphometry, as well as the measurement of bone metabolism markers. A differential diagnosis of secondary osteoporosis plays an important role in the diagnostic procedure.

Any asymptomatic osteoporotic vertebral fracture with radiological, densitometric, or morphometric documentation (X-ray or vertebral fracture assessment [VFA]), similarly to symptomatic fractures of the vertebrae or hip should be considered as an equivalent to a diagnosed high risk of fractures and represents an absolute indication for the introduction of pharmacological treatment. The differentiation between primary and secondary causes of low-energy fractures is an important issue in the diagnostic workup. A suspected pathological fracture not related to osteoporosis requires the exclusion of other causes, mainly tumors (e.g., multiple myeloma), primary hyperparathyroidism, or osteomalacia, and continued specialist management, all of which do not necessarily preclude the need for pharmacological intervention.

In postmenopausal women and men over 50 years of age without documented low-energy fractures, a 10-year fracture risk is assessed with the FRAX® calculation tool for the Polish population with the recommendation of measuring the BMD of the femoral hip.

The risk thresholds for fracture over 10 years based on the local epidemiology data are lower in Poland than in many European countries. The selected values for Poland are as follows: high fracture risk at >10% (drug treatment is recommended); moderate fracture risk at 5%–10% (additional diagnostic workup is required); low fracture risk at <5% (an indication for fracture prevention). Any decision on the introduction of medication must be made on the basis of a comprehensive evaluation of the patient. A lowered T-score for the lumbar vertebrae (<–2.5 SD) must be viewed as an equivalent to at least moderate fracture risk, regardless of the patient's age. Prolonged glucocorticosteroid treatment (over 3 months) and accelerated bone metabolism in postmenopausal women (assessed as the concentration of bone turnover markers) increase to fracture risk by 1 (i.e., from low-to-moderate and from moderate-to-high). The goal of osteoporosis prevention and treatment is the reduction of the risk of fracture. The therapeutic management consists of 2 integral components: nonpharmacological management (nutrition, rehabilitation, fall prevention, lifestyle modification) and pharmacological treatment. They improve mechanical strength of the bones, prevent the first fracture, and limit the risk of any subsequent fractures. Drug selection is based on registered indications for use supported by the findings of clinical trials assessing their effect on fracture risk.

The terms "treatment of osteoporosis" and "reduction of risk of fractures" as used in the current guidelines should be considered equivalent. Other important factors are as follows: patient's age and sex, fracture risk, potential fracture site (vertebral vs. nonvertebral), benefit-to-cost ratio, contraindications, practical considerations (oral or parenteral route of administration), mechanism of action, price of the drug, its reimbursement status, and patient preferences (TABLE). Drugs used in osteoporosis treatment are classified as anticatabolic (bisphosphonates, denosumab, hormone replacement treatment [HRT]), selective estrogen-receptor modulators [SERMs]), proanabolic (teriparatide), or with dual mechanism of action (strontium ranelate).

Secondary osteoporosis treatment depends on the management of the underlying disease. The monitoring of efficiency of treatment and patient compliance requires biochemicals and densitometric measurements. The monitoring should be provided by primary health care units (general practitioner, nurse) and specialists.

Summary of detailed recommendations

1 The diagnosis of osteoporosis in postmenopausal women and men over 50 years of age is based on the evaluation of BMD, 10-year absolute fracture risk, and previous osteoporotic fractures [B].

2 10-year absolute fracture risk is estimated based on the BMI, clinical risk factors, including (whenever available) BMD measured at central sites, as well as other independent risk factors [B]. Based on the epidemiological data, the following risk groups have been established for Poland: high risk, >10% (being an indication for treatment); moderate, 5%–10%; and low, <5%.

3 Routine management is divided into 2 stages. In the first stage, the primary physician or general practitioner should screen and classify patients (based on the FRAX®-BMI algorithm for the Polish population) into those requiring fracture prevention and those who must receive osteoporosis treatment and undergo further diagnostic procedures at specialized clinics.
Follow-up and monitoring of osteoporosis treatment by a specialist are recommended [B].

4 The main tasks of the specialist who treats osteoporosis (stage II) should be the differential verification of the initial diagnosis, assessment of fracture risk, comprehensive evaluation of a 10-year fracture risk [B], and decision making with regard to all identified risk factors, together with the introduction of comprehensive management including drug therapy consistent with evidence-based medicine [A] and defining the terms of monitoring.

TABLE Pharmaceutical treatment of osteoporosis

First-line treatment	
oral bisphosphonates: therapy of choice in the prevention of osteoporotic fractures: 1) in postmenopausal women (alendronate, risedronate, ibandronate, zoledronate) 2) in men with osteoporosis (alendronate, risedronate, zoledronate) 3) in patients with glucocorticoid-induced osteoporosis (alendronate, risedronate, zoledronate) Intravenous administration is a viable option in the treatment of patients with contraindication to the use of oral drugs: immobilized (directly following a vertebrae or proximal femur fracture of brain stroke), with gastrointestinal conditions, and not tolerating oral bisphosphonates.	alendronate: 70 mg/wk p.o. (alternatively, 10 mg/d) risedronate: 35 mg/wk p.o. (alternatively, 5 mg/d) ibandronate: 150 mg/mo p.o. or 3 mg IV every 3 months zoledronate: 5 mg IV every 12 months
denosumab: an alternative for postmenopausal women (regardless of the baseline bone turnover value), also with renal insufficiency, and for men with hypogonadism in the treatment of prostatic cancer.	60 mg s.c. every 6 months
strontium ranelate: can be used in postmenopausal women and men with osteoporosis, regardless of the baseline concentration of bone turnover markers. It can be the therapy of choice in women: 1) with low concentration of bone turnover markers 2) at high fracture risk and osteopenia (T-score from –1 to –2.5 SD) 3) older than 80 years of age	2 g/d p.o.
second-line treatment – to be used in patients with contraindications to the use of first-line treatment drugs, with poor drug tolerance, or unable to comply with administration requirements	
raloxifene: reduces solely the risk of vertebral body fractures	60 mg/d p.o.
teriparatide: demonstrates high efficacy in the reduction of osteoporotic fracture risk in men and women with severe osteoporosis; for safety reasons, therapy is limited to 24 months (EMA, UE, FDA, USA); continuation of treatment with bisphosphonates is required to maintain therapeutic effects	20 μg/d s.c.

Abbreviations: EMA – European Medicines Agency, FDA – Food and Drug Administration, SD – standard deviation, EU – European Union, USA – United States

5 The key point of diagnosis is the differentiation between primary and secondary causes of a low-energy fracture or abnormally low bone mass [A]. Before the introduction of any pharmacological intervention for secondary osteoporosis, a precise diagnosis and treatment of the underlying disease are required. In all fractures unrelated to primary osteoporosis, or in any other case BMD is reduced, a specialist treatment is required. An increased fracture risk may be the result of comorbidities or the medication used, e.g., glucocorticosteroid treatment for at least 3 months [A].

6 In the prevention of osteoporosis, optimization of calcium salt intake (according to recommendations), protein (1.2 g/kg body weight/day), potassium (>3500 mg/d), and magnesium (>300 mg/d) [B] is of vital importance. An adequate supply of vitamin D (800–2000 IU/d) reduces the risk of fractures by acting directly on the skeletal system, improves the function of the muscular and nervous systems, and reduces the risk of falls. A sufficient supply of calcium and vitamin D is the cornerstone of prevention and an indispensable element of pharmacological intervention [B].

7 The general principles of osteoporosis prevention apply to all patients. People with a moderate 10-year fracture risk (5%–10% in Poland) are advised to change their lifestyle, prevent falls, improve musculoskeletal function through appropriate physical rehabilitation and nutritional regime, and to assess their risk of fracture on regular basis [D].

8 Any existing osteoporotic fracture or serious fracture risk (>10%) is an indication for drug therapy. The decision on starting pharmaceutical treatment must be preceded by confirmation of fracture by an X-ray or VFA scan of the vertebra. This can be done independently of BMD assessment [A].

9 Antiresorptive drugs are recommended in patients with osteoporosis confirmed by dual-energy X-ray absorptiometry (DXA). Proanabolics (teriparatide) and drugs of dual action (strontium ranelate) are efficient in reducing the risk of fractures, regardless of the baseline BMD and bone metabolism score [B].

10 The efficacy of bisphosphonates in the prevention of fractures has been documented in patients with a T-score of less than –2.0 SD (vertebrae) and less than –2.5 SD (hip), subject to adequate vitamin D supply. Therefore, treatment with bisphosphonates should be preceded by BMD assessment and elimination of any vitamin D deficits [A]. Long-term clinical studies have shown that bisphosphonates containing nitrogen significantly reduce the risk of vertebral and nonvertebral fractures, including hip fractures [A]. Therefore, they are widely used in the treatment of osteoporosis in men and postmenopausal women.

11 According to the approved indications, osteoporosis in men should be treated with alendronate, risedronate, zoledronate, teriparatide, and strontium ranelate. The European Union approval of denosumab is pending. [A].

12 Intravenous bisphosphonates (ibandronate, zoledronate) are recommended for patients unable to take drugs orally: immobilized (e.g., following a stroke) or suffering from some gastrointestinal disorders [A].

13 Denosumab (fully human monoclonal antibody against RANK ligand activity) demonstrates fast and efficient reduction of the rate of bone resorption, reducing fracture risk in postmenopausal women within a broad age group, and in men receiving anti-androgen therapy in the treatment of prostate cancer [A]. It can also be administered in patients with renal insufficiency [C].

14 Antifracture efficacy of strontium ranelate has been documented regardless of the baseline fracture risk (FRAX®) in women with osteopenia, with osteoporosis in a broad range of age groups, also those over 80 years [A], and in men with osteoporosis [B]. It should be used with caution in patients at a high risk of cardiovascular diseases.

15 Parathormone analogs (teriparatide and rhPTH1-84) demonstrate high efficacy in reducing the risk of all types of fracture in severe osteoporosis in postmenopausal women and in men, as well as in glucocorticosteroid-induced osteoporosis. For safety reasons, administration of the drug should not exceed 24 months [B]. An antiresorptive should be used after discontinuation of parathormone analog to maintain the therapeutic effect [D].

16 HRT can prevent the development of osteoporosis and fractures after menopause. Osteoporosis is not among primary indications for HRT in postmenopausal women [B].

17 Administration of raloxifene (SERM) may be considered in postmenopausal women with hyperlipemia, and especially in those with an increased risk of breast cancer [B].

18 Specific antianalgesic effect of salmon calcitonin may be temporarily used in symptomatic (painful) vertebral fractures and in patients suffering from pain related to other osteoporotic fractures. Currently, calcitonin is not recommended for prolonged treatment of osteoporosis [B].

19 Owing to poor compliance in the case of prolonged treatment and because of possible adverse reactions, efficient cooperation of patients and doctors and monitoring of treatment efficacy become very important. It is recommended to monitor treatment by DXA (including VFA) and to assess bone metabolism [C].

20 Osteoporosis induced by prolonged glucocorticosteroid therapy (>3 months) is among the most common causes of secondary osteoporosis [A]. In patients older than 50 years who have received (or are scheduled to receive) glucocorticosteroid therapy for more than 3 months, a preliminary fracture risk assessment should be performed because even in patients at moderate fracture risk (and/or BMD T-score <–1.5 SD), the use of corticosteroids longer than 3 months leads to high risk of fractures. Osteoporosis prevention or treatment should be implemented as soon as possible [B].

In patients over 65 years of age treated with prednisone (or equivalent) at a dose of 7.5 mg/d and higher for over 3 months, preventive (antifracture) therapy should be applied, even in the absence of any other fracture risk factors [C]. Drugs approved for glucocorticosteroid-induced osteoporosis include alendronate, risedronate, zoledronate, and teriparatide [B]. In women in reproductive age, the decision to introduce treatment is at the descretion of the patient and the treating physician [D].

Discussion The development of the Polish guidelines for the diagnosis and management of osteoporosis[2] is a long-term process—a result of the multicenter program of the Ministry of Health and the State Committee for Scientific Research "Early risk identification and effective prevention of osteoporosis based bone fractures in Polish population EPOLOS" (# 4 P05D 004 98 C/3959) and 2 implementation programs, as well as the international cooperation of the Central and Eastern European countries.[13,14] The results of the Polish part of the program led to the development of the Polish version of the FRAX® algorithm[2,5] and an algorithm for using bone turnover markers to identify postmenopausal women at a risk of fracture due to an increased rate of bone metabolism (a risk factor independent of BMD),[15] as well as recommendations on short-term (bone turnover markers) and long-term (BMD) therapy monitoring, evaluation of the response to treatment, and decision to change the therapy.[15,16] Vitamin D supplementation in the optimization of osteoporosis treatment is an important part of the Polish guidelines and a result of vitamin D supplementation recommendations for Central Europe developed as the initiative of Polish and international experts.[17]

In 2013, Kanis et al.[1] stressed the need for recommendations adapted to individual European countries. Despite rapid population aging, Poland ranks among countries with a relatively low fracture risk—nearly 2-fold lower than that in Denmark or Sweden.[1] Epidemiology of fractures and the introduction of the FRAX® tool for Poland made it necessary to define proper thresholds for therapeutic decisions. Therefore, Polish experts agreed that a 10-year absolute risk of fracture of 10% or higher assessed by FRAX® should be considered as a high risk requiring therapeutic intervention. Looking further, the threshold can be subjected to future modifications. The British Group headed by Juliet Compston,[6] who developed osteoporosis guidelines for the United Kingdom recognizing the cost/efficiency ratio of the available procedures, established age-based intervention thresholds: in the case of patients over 80 years, it is a ≥30% risk of major osteoporotic fractures as established by FRAX®-BMD, while for 50-year-old patients, the threshold was set at 6%. In their paper, Kanis et al.[1] provided a broader discussion (compared with 2008) on the limitations of the FRAX® algorithm, which

fails to recognize certain significant risk factors for fractures, such as falls, vertebrae BMD measurement, or the number of fractures. Kanis et al.[1] also noticed that different algorithms are used in other countries, e.g., the Australian Garvan Institute calculator.

Based on all the above facts, and considering the local conditions in Poland (limited availability of densitometers, organization of the health care system, cost of drugs, etc.) and our gradually gained experience, we decided to recommend a 2-stage osteoporosis management system implementing FRAX®--BMI at primary health care units in order to identify patients at high risk of fractures for further diagnosis with DXA and laboratory tests, and to define the course of further treatment by specialized osteoporosis clinics. The weakest link of the system in Poland, and in many other countries,[18] is the absence of an adequate pharmacological treatment of osteoporosis following surgical treatment of fractures. In our guidelines, we have repeatedly stressed that every low-energy fracture represents an indication for pharmacotherapy, regardless of whether the patient is under the care of an orthopedist, family doctor, general practitioner, or rheumatologist. Since one of the most common risk factors are falls and injuries, we provide detailed recommendations on assessing the risk of falls as well as on diagnostic procedures (such as get up and go) and rehabilitation programs.

The routine pharmacological management strategy (choice of medications) is determined by the drug reimbursement system in Poland favoring generic oral bisphosphonates. Intravenous bisphosphonates, teriparatide, raloxiphene, and strontium ranelate are not reimbursed in Poland. Denosumab is covered by partial reimbursement for patients in whom earlier use of bisphosphonates proved to be ineffective or bisphosphonates are contraindicated.

The pharmacological treatment offering the best efficacy should be selected with a focus on causal treatment. Treatment with anticatabolics is recommended in patients with fast bone turnover, while proanabolics and mixed--action drugs are effective regardless of the bone turnover rate. Anticatabolics and proanabolics require more accurate evaluation of bone turnover, as stressed repeatedly in the Polish guidelines, both from the point of view of therapy selection and monitoring of its efficacy. In Hungary, it has been recommended that drugs be selected to match the metabolic condition of the bone tissue to ensure a tangible improvement in treatment efficacy.[19,20]

Slightly different osteoporosis management recommendations have been adopted in Germany, Austria, and Switzerland,[21,22] where a high intervention threshold has been set at a fracture risk of more than 30% estimated using the Dachverband Osteologie (DVO) calculator, which provides for vertebral fractures diagnosed by morphometry (FRAX® only covers clinical fractures and does not recognize the number and grading of fractures). DVO recommends pharmacological intervention in patients with a T-score of –2 and lower (and not –2.5) and at high fracture risk, or even without DXA assessment in patients with pertrochanteric fractures or with at least 2 vertebral fractures. In patients without fractures or additional risk factors, DVO recommends pharmacological treatment based on DXA assessment, depending on the T-score in individual age groups. Solely for Switzerland and based on FRAX®, Lippuner et al.[22] set a cost-effective intervention threshold at an absolute fracture risk of 15%. In France, and in some other European countries, in patients with an existing osteoporotic fracture, the selection of drugs is based on the site of the fracture (e.g., bisphosphonates, denosumab, strontium, and teriparatide in the case of hip fractures; in women with vertebral fractures, raloxifene may be considered; HRT is also listed), while in patients without fractures or with nonsevere peripheral fractures, the strategy of management is based on a T-score value of –3 or lower, being an indication for pharmacotherapy. A T-score of less than –3 is an indication for FRAX® assessment and, depending on the severity of risk in each age group, for further therapeutic decisions.[23,24] The Hungarians[19,20] also recommend a DXA scan, only supplemented with additional diagnostic procedures and FRAX® assessment in patients with a T-score of less than –2. In the 2010 guidelines,[23] the Belgian Bone Club provided a detailed analysis of the results of clinical studies of individual drugs, based on which it indirectly gives indications for their effective use. The Belgian paper does not mention the FRAX® or any other fracture risk calculator. The US National Osteoporosis Foundation[3] recommends the introduction of pharmaceutical therapy in postmenopausal women and men over 50 years with existing hip or vertebral fractures (even without calculating the BMD, owing to "the t-score being not so important"),[3] in patients (with or without fractures) with a T-score of –2.5 or lower in the femoral neck, total hip, or lumbar spine. In patients with osteopenia (T-score, <–1 >–2.5), the fracture risk calculated with FRAX® determines the further course of treatment. According to the Polish guidelines,[2] which are partly similar to British[6] and Canadian[25] recommendations, in patients without fractures, the estimation of risk with the FRAX®-BMI calculator precedes further diagnostic procedures, including densitometry, and any therapeutic decisions.

It seems that the two-stage approach is advisable in a country with limited access to densitometry facilities and specialist treatment. However, drug prices and current reimbursement policy determine the preferred or any secondary lines of treatment in Poland. The issues of monitoring, evaluation of efficacy, and duration of treatment with individual drugs are yet to be addressed. As in the United Kingdom[6] and IOF,[1] we recommend

to verify treatment efficacy at 5 years and decide whether it should be continued.

Secondary osteoporosis and, in particular, the need for prevention of fractures in the case of prolonged glucocorticosteroid treatment, are frequently overlooked. In line with the European recommendations[7] for the management of glucocorticosteroid-induced osteoporosis, we have opted for routine pharmacological prevention in patients aged over 65 years beginning with glucocorticosteroid therapy. The reimbursement of this therapy is now available in Poland (risedronate in elderly patients treated with prednisone or its equivalent >5 mg/d for over 3 months). The epidemiology of fractures and management of other forms of secondary osteoporosis are discussed in relevant scientific papers.[26,27]

The consensus on vitamin D supplementation reached in Warsaw in 2012 for the Central European countries[17] as well as American[28] and European[29,30] recommendations clearly point to the need of calcium and vitamin D supplementation (serum levels of 25[OH]D >30 ng/ml) as an indispensable standard both in prevention and pharmacotherapy of osteoporosis. Consistent with these standards, we make the following recommendations for Poland: 1) measurement of serum levels of 25(OH)D in patients and 2) adequate supplementation of calcium and vitamin D, particularly prior to inclusion of bisphosphonates. Polish recommendations regarding the prevention of falls, reduction of modifiable risk factors for fractures, and dietary advice are consistent with the IOF guidelines.[1]

Note The guideline development process in Poland was conducted without financial support from any commercial organization.

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ARTYKUŁ POGLĄDOWY

Polskie zalecenia postępowania diagnostycznego i leczniczego w osteoporozie: omówienie aktualizacji z 2013 r.

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SŁOWA KLUCZOWE

FRAX®, leczenie osteoporozy, złamania osteoporotyczne

STRESZCZENIE

W celu zmniejszenia ryzyka występowania złamań osteoporotycznych w Polsce, Wielodyscyplinarne Forum Osteoporotyczne powołało Grupę Roboczą, składającą się z przedstawicieli Polskiego Towarzystwa Ortopedii i Traumatologii, Rehabilitacji, Gerontologii, Reumatologii, Medycyny Rodzinnej, Diabetologii, Diagnostyki Laboratoryjnej, Andropauzy i Menopauzy, Endokrynologii, Radiologii i STENKO oraz ekspertów z dziedziny reumatologii, położnictwa i geriatrii w celu uaktualnienia polskich zaleceń dotyczących diagnostyki i leczenia osteoporozy u mężczyzn oraz kobiet po menopauzie w Polsce. Określenie ryzyka wystąpienia złamania i progów interwencyjnych bazowało na kalkulatorze FRAX® Polska. Siłę rekomendacji oceniono zgodnie z zaleceniami Scottish Intercollegiate Guidelines Network, a wyniki zostały zaakceptowane przez konsultantów krajowych. Na ich podstawie Grupa Robocza ustaliła zaktualizowane zalecenia rekomendujące dwustopniową procedurę diagnostyczną i terapeutyczną. Pierwszy etap obejmuje lekarzy rodzinnych oraz pierwszego kontaktu i dotyczy oszacowania ryzyka wystąpienia złamania na podstawie FRAX®-BMI Polska, w celu identyfikacji pacjentów z wysokim ryzykiem wystąpienia złamania. Wystąpienie złamania osteoporotycznego pozostaje bezwzględnym wskazaniem do wdrożenia terapii zarówno dla lekarza podstawowej opieki zdrowotnej jak i specjalisty. Na drugim etapie lekarz specjalista (w poradni osteoporozy lub innej poradni specjalistycznej) jest zobowiązany do ponownej oceny klinicznej pacjenta, potwierdzenia rozpoznania oraz przeprowadzenia odpowiedniego leczenia i monitorowania. U pacjentów (mężczyzn >50 r.ż. i kobiet po menopauzie) bez złamania niskoenergetycznego ryzyko bezwzględne złamania >10% powinno być rozpatrywane jako wskazanie do włączenia terapii. Zalecenia polskie porównano z innymi międzynarodowymi wytycznymi w obszarze diagnostyki, farmakoterapii oraz suplementacji wapniem i witaminą D.

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