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Expanded criteria for diagnosis of osteoporosis

Poszerzenie kryteriów rozpoznania osteoporozy

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Słowa kluczowe

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S u m m a r y

Current WHO diagnostic criteria according to which the threshold for osteoporosis diagnosis is a T-score ≤ -2.5, are unsatisfactory because, according to this criterion 70% persons, who suffered fractures had excluded osteoporosis. In 2010, the National Bone Health Alliance published expanded criteria on assumption those who have elevated fracture risk shul be treated. This position has been adopted to Polish population by Group of Experts on Osteoporosis at the National Consultants for Rheumatology in 2015, and following guidelines has been proposed. Osteoporosis should be diagnosed in postmenopausal women (over the age of 50 years) and in men over the age of 65 years who fulfil one of condition:

- without fractures, DXA T-score ≤ -2.5 SD,
- low-trauma hip fracture without a BMD measurement,
- major low-trauma fracture (vertebral, hip, proximal humerus, also in some cases distal forearm fracture) and osteopenia or osteoporosis (at the spine or hip),
- without fractures (or with fractures), FRAX BMD > 10% (FRAX for polish population).

S t r e s z c z e n i e

Dotychczasowe kryteria osteoporozy WHO przyjmujące za próg rozpoznania wartość wskaźnika T ≤ -2,5 są stanowczo niewystarczające. 70% złamań dokonuje się u osób, które według tego kryterium nie mają osteoporozy. Powoduje to, że większość osób, którym grozi ryzyko złamania, nie jest leczona i zmniejszenie liczby złamań jest niewystarczające. W roku 2010 grupa robocza National Bone Health Alliance (NBHA) zaproponowała poszerzenie kryteriów diagnostycznych, wychodząc z założenia, że osteoporoza powinna być rozpoznawana u osób, którym grozi złamanie. Powyższe kryteria zostały zaadaptowane do warunków w Polsce przez Zespół Ekspertów ds. Osteoporozy przy Konsultancie Krajowym ds. Reumatologii, który w roku 2015 zaproponował poszerzenie kryteriów osteoporozy. Powinna być ona rozpoznawana u pacjentów spełniających jedno z poniższych kryteriów:

- bez złamań, DXA T-score ≤ -2,5,
- złamanie niskoenergetyczne bliższego końca kości udowej (bkku), bez badania DXA,
- złamanie niskoenergetyczne w lokalizacji głównej: kręgosłup, bkku, bliższy koniec kości ramiennej, także niektóre przypadki złamania kości przedramienia oraz osteopenia lub osteoporoza w badaniu DXA kręgosłupa lub biodra,
- bez złamań (lub ze złamaniami), FRAX BMD > 10% (FRAX dla populacji polskiej).

Powyższe stanowisko zostało przekazane Ministerstwu Zdrowia i Opieki Społecznej w Polsce.

Conflict of interest
Konflikt interesów

None
Brak konfliktu interesów

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WHO DIAGNOSTIC CRITERIA OF OSTEOPOROSIS

The existing diagnostic criteria of osteoporosis are based on the bone mineral density (BMD) results. They stem from the WHO definition of osteoporosis from 1993 according to which osteoporosis is defined as a systemic metabolic skeletal disease characterised by low bone mass and microarchitectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fractures.

According to these criteria osteoporosis should be diagnosed in patients with T-score in the proximal femur (hip) or the spine equal to or less than -2.5 SD (1). The WHO working group set the level of -2.5 SD

arbitrarily on the basis of epidemiological data indicating that 95% of fractures occur in these ranges (2). This relationship applies only to proximal femur however, after a long-lasting debate it was determined that osteoporosis can also be diagnosed based on the results of measurements in the spine.

Clinical trials carried out since the 1990s confirmed the validity of this change. The inclusion criterion in most studies was the value of T-score equal to or less than -2.5 SD in the spine or femoral neck, and in this population the antifracture efficacy of the tested medications was demonstrated.

The great advantage of the densitometric examination is the ability to quantify the degree of loss of bone mineral density by means of a very precise method (error tolerance in DXA 1-3%) (3).

PROBLEMS ARISING FROM THE CURRENT CRITERIA

It is known that the reduction of bone mineral density is one of the strongest risk factors of fractures and the decrease in BMD by 1 SD entails 2.5-fold increase in the risk of fracture (tab. 1) (4, 5). Unfortunately, as it turned out, 70% of fractures occur in individuals who do not fall under the diagnosis of osteoporosis based on the densitometry result (6).

Therefore, on the basis of DXA a person in a real risk of a fracture can be considered "healthy", despite the fact that this group of patients is most vulnerable to fractures and should be treated.

Tab. 1. The increase in risk of fracture for every 1 SD decrease in BMD (5)

Site of measurement	Foream fracture	Hip fracture	Vertebral fracture	All fractures
Distal radius	1.7	1.8	1.7	1.4
Femoral neck	1.4	2.6	1.8	1.6
Lumbar spine	1.5	1.6	2.3	1.5

The fundamental question arises: what "disease" should be diagnosed in a 50-year-old woman who sustained an osteoporotic fracture and the result of DXA excludes osteoporosis? As a consequence of this shortcoming of the WHO definition, most people with elevated risk of a fracture remain untreated. At the same time, there is no established therapy for those who have T-score greater than -2.5 SD and there is no research in this area.

DIAGNOSIS OF FRACTURE RISK USING FRAX

The introduction of the FRAX tool for the assessment of fracture risk in 2008 was a major advance in diagnostics of osteoporosis. The FRAX method allows to determine the risk of fracture based on BMD or BMI as well as known fracture risk factors, such as: prevalent low-energy fractures, family history of fractures, smoking, corticosteroid therapy, alcoholism, rheumatoid arthritis.

FRAX calculations are based on the results of a prospective study on 230,486 subjects. Currently, 62 models exist in 57 countries. It is estimated that 78% of the world's population is embraced by FRAX, and the annual number of individual calculations reaches 3.5 million (7, 8).

POSITION STATEMENT OF THE NATIONAL BONE HEALTH ALLIANCE WORKING GROUP

In 2010, the National Bone Health Alliance (NBHA) was appointed in the USA. The NBHA is a public-private partnership comprising representatives of 54 organizations, including 35 scientific societies (ASBMR, NOF, AAOS), 16 private institutions and 4 government agencies: NIH (National Institute of Health), the FDA (Food and Drug Administration), Centers for Disease Control and Prevention, NASA.

The aim of the group was, among others, to establish diagnostic criteria for osteoporosis in women over the age of 50 years. As a principle, the group has not dealt with therapeutic issues.

According to NBHA Working Group the diagnosis of osteoporosis should be established in postmenopausal women and in men over the age of 50 if any of the following factors occur:

- T-score $\leq$ -2.5 SD (at the spine or hip),
- low-trauma hip fracture without a BMD measurement,
- low-trauma fracture (vertebral, proximal humerus, pelvis, or in some cases, distal forearm fracture) in patients with osteopenia,
- elevated fracture risk based on FRAX in patients with osteopenia (level established for each country separately). In USA FRAX > 20% for major fracture (9).

These criteria were adopted by the NOS and are used in the USA.

Currently, there is a wide-ranging discussion over the legitimacy of broadening the criteria.

Prof. John Kanis maintains that fracture risk cannot be equated with the diagnosis of osteoporosis just as it is impossible to recognize a myocardial infarction based on the risk of its occurrence. This stance results from the assumption that osteoporosis is strictly a bone disease and it can be only diagnosed on the basis of the parameters evaluating the bone itself.

The non-invasive methods presently available are: densitometric examination, ultrasound, X-ray, MRI. Unfortunately, they do not provide satisfactory diagnostic capabilities. This also applies to micro X-ray. TBS (Trabecular Bone Score) offers some degree of promising potential (10).

Invasive methods include a microindentation and biopsy. Microindentation is a direct measurement method of evaluating bone mechanical properties by means of inserting a probe and reaching to a pelvis plate for indentation. This method is very rarely used (11). The most reliable method would undoubtedly be bone biopsy however, this is an invasive procedure. Bone biopsy involves morphometry of obtained bone specimens, which provides comprehensive information about the static and dynamic remodeling of bone. Regrettably,

there is no data that would allow to determine fracture risk on this basis. Therefore, we could diagnose osteoporosis without assessment of fracture risk (12).

DOES LOW-ENERGY FRACTURE INDICATE THE DIAGNOSIS?

As per the definition a low-energy fracture is recognized when a fracture is a result of a fall from own height. This clear definition is not devoid of weaknesses.

A completely different energy is involved when a 50-year women old undergoes a radial fracture when falling on concrete; quite different when a 85-year-old woman endures the same injury falling at home on a carpet. However, after each fracture the risk of subsequent fractures increases 2.5 times (tab. 2) (13). The question then arises whether osteoporosis should be diagnosed in any patient who has suffered a low-energy fracture. Given the variety of fractures and their circumstances, it seems that this could result in overdiagnosis of osteoporosis.

Tab. 2. Prior fractures and increased fracture risk (13)

Increased risk of fracture after fracture				
Location of prior fracture	Location of subsequent fracture			
	Hip	Vertebral	Wrist	Other
Hip	2.3	2.5	1.4	1.9
Vertebral	2.3	4.4	1.4	1.8
Wrist	1.9	1.7	3.3	2.4
Other	2.0	1.9	1.8	1.9

The most reasonable solution is to incorporate major fractures as in the FRAX model, that is: proximal femur, spine, proximal end of the humerus, the distal end of the radius. It should also be emphasized that every person who has sustained a low-energy fracture categorically requires preventive measures of subsequent fractures.

THE POSITION OF THE GROUP OF EXPERTS ON OSTEOPOROSIS AT THE NATIONAL CONSULTANTS FOR RHEUMATOLOGY, WARSAW 2015

According to experts (J. Badurski, M. Bolanowski, E. Czerwiński, A. Dębski, P. Głuszko, M. Jabłoński, K. Księżoposlka-Orłowska, R. Lorenc, E. Marcinowska, W. Marczynski, W. Tłustochowicz), in postmenopausal women (over the age of 50 years) and in men over the age of 65 years the decisive criteria for the diagnosis of osteoporosis should be (one of the following):

- without fractures, DXA T-score ≤ -2.5 SD,
- low-trauma hip fracture without a BMD measurement,
- major low-trauma fracture (vertebral, hip, proximal humerus, also in some cases distal forearm fracture) and osteopenia or osteoporosis (at the spine or hip),
- without fractures (or with fractures), FRAX BMD > 10% (FRAX for polish population) (14).

CONCLUSIONS

There is no doubt that the current WHO diagnostic criteria according to which the threshold for osteoporosis diagnosis is a T-score ≤ -2.5, are unsatisfactory.

According to this method as a "healthy" are considered 70% persons, which in fact suffered fractures. Thus, the revision of the criteria is an inherent need of the moment, to cover proper treatment of the population.

There is still an open question to what extent the risk of disease may be referred to as its definition.

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