



Original article

Sensitivity, specificity, positive and negative predictive values of the criteria for indicating a bone densitometry in the Evaluation of Medical Techniques and Research in Cataluña

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ARTICLE INFO

Article history:

Received March 17, 2010

Accepted August 4, 2010

Keywords:

Bone densitometry

Sensibility

Specificity

Positive predictive value

Negative predictive value

Indication

Criteria

ABSTRACT

The Catalan Agency for Health Technology Assessment and Research (AETIM) proposed, in 2001, criteria for performing a bone densitometry (BD) for use in the consultations of the public health system.

Objective: To determine the sensitivity, specificity, positive predictive value and negative predictive value of the criteria to indicate BD.

Material and methods: Five groups of volunteers (premenopausal women aged 46 to 65 years, postmenopausal women aged 46 to 65 years, postmenopausal women aged >65 years and men 46 to 65 years and >65 years) underwent BD and a questionnaire on risk factors. The results obtained with the AETIM criteria are related to criteria for indication of BD proposed by the World Health Organization (1999 and 2003 criteria), the National Osteoporosis Foundation (1998 and 2010 criteria) and the International Committee of Clinical Guidelines on Osteoporosis.

Results: Criteria from the Catalan Agency have low sensitivity to detect both low bone mass (T index <-1) and osteoporosis (T index <-2.5), specificity varied according to the group. The positive predictive value is low, but the negative predictive value for osteoporosis is high in all groups (except for postmenopausal women aged >65 years). The remaining criteria have a high negative predictive value and, in women, good sensitivity and low specificity, especially for identifying patients with osteoporosis.

Conclusion: Catalan Agency criteria are useful for selecting patients who would not need BD, but lack sufficient sensitivity to identify individuals with low bone mass. The other criteria also have a high negative predictive value for osteoporosis, and a better sensitivity.

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Sensibilidad, especificidad y valor predictivo positivo y negativo de los criterios de indicación de densitometría ósea de la Agencia de Evaluación de Tecnologías e Investigación Médicas de Cataluña

RESUMEN

Objetivo: La Agencia de Evaluación de Tecnologías e Investigación Médicas (AETIM) de Cataluña propuso en 2001 unos criterios de indicación de densitometría ósea (DO) para su uso en las consultas del sistema sanitario público. El objetivo fue conocer la sensibilidad, la especificidad, el valor predictivo positivo (VPP) y valor predictivo negativo (VPN) de los criterios de indicación de DO de la AETIM.

Palabras clave:

Densitometría ósea

Sensibilidad

Especificidad

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Valor predictivo positivo
 Valor predictivo negativo
 Indicación
 Criterios

Material y método: Cinco grupos de voluntarios (mujeres premenopáusicas de 46 a 65 años, posmenopáusicas de 46 a 65 años y posmenopáusicas de > 65 años, y varones de 46 a 65 años y de > 65 años) a los que se realizó DO y una encuesta sobre factores de riesgo. Se calcularon la sensibilidad, la especificidad, el VPP y el VPN de los criterios de la AETIM, y los resultados se compararon con los criterios de indicación de DO propuestos por la Organización Mundial de la Salud (en 1999 y 2003), la National Osteoporosis Foundation (en 1998 y 2010) y el Comité Internacional de Guías Clínicas en Osteoporosis.

Resultados: Los criterios de la AETIM tienen una baja sensibilidad tanto para detectar baja masa ósea (índice $T < -1$) como osteoporosis (índice $T < -2,5$); la especificidad varía según el grupo. El VPP es bajo, pero el VPN para osteoporosis es alto en todos los grupos (excepto el de mujeres posmenopáusicas > 65 años). El resto de los criterios tienen un VPN alto y, en mujeres, buena sensibilidad y muy baja especificidad, especialmente para identificar pacientes con osteoporosis.

Conclusiones: Los criterios de la AETIM son útiles para seleccionar pacientes a los que no sería necesario realizar una DO, pero carecen de sensibilidad suficiente para identificar individuos con baja masa ósea. El resto de criterios tienen también un VPN alto para osteoporosis y una sensibilidad algo mejor.

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Introduction

Bone mineral density (BMD) is one of the parameters to gain better insight into the risk of fracture¹⁻³ and bone densitometry with dual energy X-ray (DXA) is the technique of choice to measure it. Although risk of fracture estimation appears to be the best way to establish an intervention, DXA is still the most commonly-used tool in clinical practice to start treatment. The indication for DXA has been based on identifying low bone mass and osteoporotic fracture risk factors. Different guides have been based on this proposal, although only a few have been validated.⁴⁻¹³ So as to rationalise the use of DXA in our community, the *Agencia de Evaluación de Tecnologías e Investigación Médicas* (AETIM) (Agency for Health Technology Assessment and Research) proposed a model based on a combination of high- and medium-risk fracture factors to establish a cut off point for BMD indication.¹⁴ Although this model tries to identify individuals at a high risk of fracture, in clinical practice it is being used to identify individuals with DXA indication.

The aim of this study was to ascertain the clinical use of the AETIM guide in selecting individuals with low bone mass. Likewise, results obtained from the guides of the National Osteoporosis Foundation (NOF) from 1998,¹⁵ the International Committee for Osteoporosis Clinical Guidelines (ICOCC)¹⁶ and the 1999 World Health Organisation (WHO) from 1999¹⁷ in the same population group were compared. New criteria from NOF (NOF 2010)¹⁸ and WHO (WHO 2003)¹⁹ were presented subsequent to the study design and were also analysed with the data collected.

Material and method

A transversal, multi-centre study to ascertain the sensitivity, specificity, positive predictive value (PPV) and the negative predictive value (NPV) of the indication criteria for bone densitometry by AETIM (Table 1). These data were used to identify patients with low bone mass, carried out on a random sample of patients who were over 45 years old and who attended programmed visits at primary care surgeries and out-patient departments for rheumatology in the metropolitan area of Barcelona. Results were compared to the indications of other guides (Table 2, Table 3, and Table 4).

So as to avoid any deviations due to age, gender or (in women) menstrual state, the volunteers were divided into 5 groups: males from 46 to 65 years old, males older than 65 years old, pre-menopausal females from 46 to 65 years old, post-menopausal females from 46 to 65 years old and females over 65 years old. Patients were included into each group between the months of February and July, until there were at least 40 volunteers in each of them. The number of volunteers for

Table 1

AETIM indication criteria for bone densitometry

High risk	Moderate risk
Age>70-80 years	Female
Body mass index<20-25 kg/m ² or low body weight (<40 kg)	Smoking (only active smokers)
Loss of weight>10% of the usual weight when young or adult, or loss of weight in the last few years	Low or no sun exposure
Physical inactivity: do not regularly carry out physical activities such as walking, going up stairs, lifting weights, doing housework or gardening or others	Family history of osteoporotic fracture
Corticoids (except inhaled or dermal)	Idrogenic menopause. Produced by bilateral oophorectomy, radiotherapy, chemotherapy or hormonal therapy
Anticonvulsant treatment	Early menopause (before 45 years old)
Primary hyperparathyroidism	Fertile period<30 years old
Type I diabetes	Late menarche. Produced after 15 years old
Anorexia nervosa	No breastfeeding
Gastrectomy	Calcium intake<500-850 mg daily
Pernicious anaemia	Hyperparathyroidism (unspecified)
Prior osteoporotic fracture	Hyperthyroidism
	Diabetes mellitus (type II or unspecified)
	Rheumatoid arthritis
Densitometry indication: 2 high-risk factors, or 1 high-risk factor and 2 moderate-risk factors, or 4 moderate-risk factors	

each group was calculated from two previous studies on the prevalence of bone densitometry indication for each criteria, carried out in the same care areas.^{20,21} Therefore, in primary care, bone densitometry indication was 36.3% for people over 18 years old who went for consultation and 45.0% for the rheumatology out-patient department (for males from 46 to 65 years old in primary care and rheumatology consultations, 11.3% and 14.5% respectively; for males>65 years old, 35% and 59.3%; for women from 46 to 65 years old, 35.4% and 43.6%; and for women>65 years old, 63.6% and 67.5%).

The first person over 45 years old who attended the consultation each day was considered eligible. This individual would be surveyed and afterwards would be asked for his/her agreement to carry out a bone densitometry. If they accepted, no further people would be surveyed until the next day. If they rejected a bone densitometry, then the next one on that day's list would be questioned and so forth until one of them agreed to participate. Due to the study logistics,

Table 2

ICOCG indication criteria for bone densitometry

Vertebral fracture confirmed by X-ray
Osteoporotic fracture after age 45
Maternal history of hip fracture
Age \geq 65 years
Early menopause
Prolonged amenorrhoea
Thin body build
Chronic treatment with glucocorticoids
Diseases predisposed to osteoporosis (malabsorption, hyperparathyroidism, hyperthyroidism, chronic inflammatory diseases, alcoholism, immobilisation)
Concern of osteoporosis by the patient

ICOCG, International Committee for Osteoporosis Clinical Guidelines.

Bone densitometry indication: presence of a risk factor.

The last factor was not considered in this study.

It applies only to women.

with a delay in notification of the volunteers included, groups with greater attendance had more volunteers.

The data for each volunteer were collected at the time of consultation, by an interview and clinical history review, and these were completed when the densitometry was carried out. A normalised questionnaire was used with the risk factors included in each bone densitometry indication guide (which was completed with the available data at the time of consultation). To make uniform interpretation of the criteria easier, a consensus meeting was held with all the study participants, where criteria to interpret the variables without very clear definitions according to the assessed guides were established, and which have been previously published.^{20,21} No additional tests other than bone densitometry were carried out, so only those factors known at the time of the interview were taken into account.

There were a total of 437 people surveyed and 311 agreed to have a BMD determination by densitometry (the rest declined and were excluded from the study). Three females were excluded as their hormonal state was unknown. At the end of the recruitment period, there were 46 pre-menopausal females aged 46 to 65 years old, 103 post-menopausal females aged 46 to 65 years old, 58 females older than 65 years old, 59 males aged 46 to 65 years old and 42 males older than 65 years old. Out of all the patients, 224 (72.7%) were recruited in primary care surgeries and the rest in rheumatology out-patient departments.

The bone densitometry was carried out at the Bone Metabolism Unit of Hospital Universitario de Bellvitge, using Hologic QDR-1000 apparatus. The spinal column (segment L2-L4) and femoral neck

Table 3

World Health Organisation (WHO) indication criteria for bone densitometry

WHO 1999
Radiological evidence of osteopenia and/or vertebral deformity
Loss of height and/or kyphosis
Previous fracture due to a low energy trauma (e.g. falling from the standing position)
Prolonged corticoid treatment
Hypogonadism (possibly to include the majority of postmenopausal women)
Chronic diseases associated with osteoporosis (e.g. hyperparathyroidism and hyperthyroidism)
Maternal history of hip fracture
Body mass index $<$ 19 kg/m ²
Low calcium intake
Densitometry indication: presence of a risk factor.
WHO 2003
The same as WHO 1999, excluding low calcium intake

Table 4

National Osteoporosis Foundation (NOF) indication criteria for bone densitometry

NOF 1998
Age \geq 65 years
Family history of osteoporotic fracture after age 40
Family history of a proximal femoral fracture, distal radial and/or ulna or vertebral fracture, in a first degree relative, from the age of 50 years old
Weight \leq 57.6 kg
Active smoker
Some of these factors must be present for bone densitometry indication
Only applicable to females
NOF 2010
Post-menopausal women $<$ 65 years old with \geq 1 risk factor for osteoporosis
Females \geq 65 years old
Males 50-70 years old with \geq 1 risk factor for osteoporosis
Males \geq 70 years old
Males or females with bone fractures after 50 years old
Menopausal women with certain risk factors
Post-menopausal women who end hormonal treatment
Other reasons: certain drugs (corticoids, anticonvulsants, aromatase inhibitors and other treatments for breast cancer, treatments for prostate cancer), hyperthyroidism, hyperparathyroidism, fracture or osteopenic appearance on an x-ray, thoracolumbar pain with a suspected fracture, significant loss of height, loss of sex hormones at an early age (including early menopause, presence of a disease or condition that causes bone mass loss)
Some of these factors must be present for bone densitometry indication
Applicable to males and females

^aRisk factors: family history, low weight, family history of bone fractures, low concentrations of sex hormones, some foods, life styles (smoking, alcohol), drugs or diseases or situations that could produce bone mass loss.

BMD were measured, and the T index was calculated in relation to the normal Spanish population values²² for each location. The worst of the two values was used to classify the volunteer as normal, osteopenic or osteoporotic according to the WHO classification criteria.²³ The same classification criteria were used for all groups. The sensitivity, specificity, PPV and NPV for each of the guides and different T-score values were calculated from the results obtained.

Informed written consent was requested from each patient to carry out bone mass determination by DXA. The study was accepted by the ethics committee of Fundaci3n Jordi Gol i Gorina.

Results

There were 308 people included in the study. The mean age \pm standard deviation (SD) of pre-menopausal females from 46 to 65 years old was 49.8 \pm 2.9 years, that of post-menopausal females from 46 to 65 years old was 56.4 \pm 4.8 years, that of females over 65 years old was 72.1 \pm 4.8 years, that of males from 46 to 65 years old was 56.5 \pm 5.3 years and of males over 65 years old it was 72.7 \pm 5.2 years. The mean age \pm SD of the 3 females aged 46 to 65 years old whose menstrual state was unknown was 53.5 \pm 2.6 years old.

In Table 5, sensitivity, specificity, PPV and NPV for each group and guide are presented.

The indications from NOF, WHO and ICOCG include an age above 65 years old to carry out a densitometry. For this reason, the sensitivity in the post-menopausal female group $>$ 65 years old is 100% and the specificity, 0%. The PPV corresponds to the proportion of females with a T-score $<$ -1 and -2.5, with sensitivity and specificity of 82.76% and 50.00% respectively. In a similar way, WHO indications include menopause among the criteria to carry out a bone densitometry. It is for this reason that in the two groups of post-menopausal females sensitivity is 100% and specificity 0%, while PPV is 52.43% in females $<$ 66 years and 82.76% females $>$ 65 years old for a T index $<$ -1, and 16.50% and 50.00%, respectively, for a T-score $<$ -2.5. It is not possible to calculate the NPV in any of these cases.

Table 5
Sensitivity, specificity, PPV and NPV for the different guides relating to gender and age (% [CI 95%])

	Sensitivity		Specificity		PPV		NPV	
	T<-1	T≤-2.5	T<-1	T≤-2.5	T<-1	T≤-2.5	T<-1	T≤-2.5
<i>Pre-menopausal females 45-65 years old (n=46)</i>								
AETIM	28.57 (15.52-41.63)	0	71.79 (58.79-84.80)	71.11 (58.01-84.21)	15.38	0	84.85	96.97
NOF	57.14 (42.85-71.44)	100	64.10 (50.24-77.97)	62.22 (48.21-76.23)	22.22	5.56	89.29	100
NOF 2010	28.57 (15.52-41.63)	0	82.05 (70.96-93.14)	80.00 (68.44-91.56)	22.22	0	86.49	97.30
WHO	71.43 (58.37-84.48)	100	58.97 (44.76-73.19)	55.56 (41.20-69.91)	23.81	4.76	92.00	100
WHO 2003	57.14 (42.84-71.44)	100	76.92 (64.75-89.10)	73.33 (88.14-63.37)	30.77	7.69	90.91	100
ICOCCG	42.86 (28.56-57.16)	100	76.92 (64.75-89.10)	75.56 (63.14-89.97)	25.00	8.33	88.24	100
<i>Post-menopausal females 45-65 years old (n=103)</i>								
AETIM	37.04 (27.71-46.36)	52.94 (43.30-62.58)	73.47 (64.94-80.00)	72.09 (64.43-80.56)	60.61	27.27	51.43	88.57
NOF	42.59 (33.04-52.14)	47.06 (37.42-56.70)	73.47 (64.94-82.00)	67.44 (58.39-76.49)	63.89	22.22	53.73	86.57
NOF 2010	87.04 (80.55-93.52)	94.12 (89.57-98.66)	30.61 (21.71-39.51)	24.42 (16.12-32.71)	58.02	19.75	68.18	95.45
WHO	100	100	0	0	52.43	16.50		
WHO 2003	100	100	0	0	52.43	16.50		
ICOCCG	61.11 (51.70-70.53)	82.35 (74.99-89.72)	53.06 (43.42-62.70)	51.16 (41.51-60.82)	58.93	25.00	55.32	93.62
<i>Post-menopausal females >65 years old (n=58)</i>								
AETIM	72.92 (61.48-84.35)	76.67 (68.89-89.74)	60.00 (47.39-72.61)	42.86 (32.03-57.63)	89.74	58.97	31.58	63.16
NOF	100	100	0	0	82.76	50.00		
NOF 2010	100	100	0	0	82.76	50.00		
WHO	100	100	0	0	82.76	50.00		
WHO 2003	100	100	0	0	82.76	50.00		
ICOCCG	100	100	0	0	82.76	50.00		
<i>Males 45-65 years old (n=59)</i>								
AETIM	18.18 (8.34-28.02)	60.00 (47.50-72.50)	92.31 (85.51-99.11)	90.74 (83.34-98.14)	75.00	37.50	47.06	96.08
NOF 2010	78.79 (68.36-89.22)	100	38.46 (26.05-50.88)	31.48 (19.63-43.33)	61.90	11.90	58.82	100
WHO	75.76 (64.82-86.69)	100	38.46 (26.05-50.88)	33.33 (21.30-45.36)	60.98	12.20	55.56	100
WHO 2003	68.00 (56.10-79.90)	80.00 (29.79-90.21)	67.65 (55.71-79.58)	55.56 (42.88-68.24)	60.71	14.29	48.39	96.77
<i>Males >65 years old (n=42)</i>								
AETIM	43.33 28.35-58.32	66.67 52.41-80.92	75.00 61.90-88.10	66.67 52.41-80.92	81.25	25.00	34.62	92.31
NOF 2010	96.67 91.24-100	100	16.67 5.40-27.94	8.33 0-16.69	74.36	13.16	66.67	100
WHO	83.33 72.06-94.60	83.33 72.06-94.60	41.67 26.76-56.58	25.00 11.90-38.10	78.13	15.63	50.00	90.00
WHO 2003	46.67 31.58-61.75	50.00 34.88-65.12	75.00 61.90-88.10	61.11 46.37-75.85	82.35	17.65	36.00	88.00

AETIM indicates Agency for Health Technology Assessment and Research; ICOCCG, International Committee for Osteoporosis Clinical Guidelines; NPV, negative predictive value; PPV, positive predictive value; T, T-score; WHO, World Health Organisation.

Discussion

The results obtained using the AETIM guide show low sensitivity in all groups for osteoporosis detection and variable specificity according to the groups. This means that it does not comply with the requirements for an efficient test, which must have high sensitivity (to detect all positive cases) and high specificity (to reduce the number of false positives). The NPV for osteoporosis is high in all groups, except in post-menopausal women who are older. In contrast, PPV for osteoporosis is low in all groups. These results indicate good ability to select individuals who would not need to have a bone densitometry, especially in the less usual groups (pre-menopausal females and males) and coincides with the results observed in other studies and other decision guides²⁴ and metaanalyses.²⁵

This study also shows the results of other densitometry indication guides in scientific literature used at the time of the AETIM guide publication, as well as later guides. The values obtained in post-menopausal females in our sample are similar to those obtained by Mauck et al,²⁶ except for the sensitivity and specificity of the

population <65 years old. This difference could be explained by the different origin of the sample. Mauck et al²⁶ is based on the general population, while in our case we use only that fraction that consult with their doctors.

Guides have appeared in the last few years with criteria for bone densitometry indication, so as to optimise the performance of this technique in its clinical application. The criteria include risk factors of low bone mass or fracture that relate them to a decrease in bone mass or with a greater prevalence of breakages in epidemiological studies. However, there are no validation studies for many of the proposed criteria.

This study assessed the AETIM guide and related the results to the ones that would have been obtained by using NOF, ICOCCG and WHO guides in the same population. The study was carried out on a sample population where the only limitation was age. This was applied as an exclusion criterion due to the low prevalence of densitometry indication in people <46 years old obtained in previous studies^{20,21} and the study was performed with the same indication criteria for the technique; this exclusion criterion was also chosen for the low

prevalence of bone mass and osteoporotic fractures in this age group observed during epidemiological studies. The sample was divided into subgroups to include representation of the population of both sexes and at any age above 45 years old. This differentiates it from other studies, mainly centred in post-menopausal women, or that exclude individuals that have any diseases that can influence bone.^{6,27} The distribution in subgroups, which although it does not reflect the general population structure or that going to medical consultations, allows us to understand the capability of the different guides in identifying, in a stratified manner, patients who would benefit from determining bone mass.

The age interval and inclusion of males and females constitute a study limitation, as they oblige us to reduce sample size. However, they allow us to better define the sensitivity and specificity of each guide in each group.

The study population came from medical consultations from primary care and rheumatology. This fact could make us think of a different distribution in the risk factors. However, a previous study on risk factor prevalence did not show such distribution differences in the most important risk factors.^{20,21}

The clinical guides are designed to be used with the general population, but they are usually applied only to a population with access to health service. The population that visits a health service centre comes from the general population, although it makes up a subgroup that probably has a greater number of risk factors of low bone mass or fracture. Applying guides designed for the general population to this subpopulation should make it possible to identify individuals with a risk of having lower bone mass more often than if they were directly applied to the general population. For this reason, a low performance in this population subgroup makes us think that its use in the general population would be low.

Only if the health system is sufficiently large to be able to periodically review all its population would the general population then correspond to the population to which the guide is applied. This circumstance only occurs if the population is very small or when the health system is disproportionately very important. Although the sample study does not exactly correspond to the general population, more than 90% of the people > 65 years old consult the doctor at some stage during the year in our environment, which is why the bias is probably small in this age group. In other groups, there is an attendance bias.

The authors are unaware of any studies that exist that analyse the use of these guides in identifying males with low bone mass, despite some guides not restricting them to just female use. This study allows us to compare the behaviour of these guides in both genders. The AETIM guide has low sensitivity but high specificity in identifying males less than 66 years old with low bone mass and is not very useful above this age. The WHO and NOF 2010 guides have even worse results. In all cases, the NPV is high for osteoporosis.

The results indicate that the criteria analysed are not sufficient to discriminate between patients with normal BMD, osteopenia or osteoporosis from clinical risk factors. It is not possible to predict the state of bone mass in an individual patient with sufficient reliability, except in extreme situations (absence of risk factors or presence of multiple factors), which are not very significant in the population. The criteria that require various risk factors to indicate bone densitometry, such as those of AETIM, are restrictive (high specificity but low sensitivity in detecting osteoporosis). In contrast, those that require only one risk factor are not very specific, although more sensitive. It can therefore be suggested that patients who do not comply with the AETIM densitometry indication criteria do not require a bone densitometry.

It was necessary to define more precisely some of the risk factors included in the guides when designing this study. For example, the AETIM defines age >70-80 years old or the body mass index < 20-25 as a high risk factor. In the WHO criteria, kyphosis is an indication

criterion (without making the degree clear), as well as low calcium intake. This lack of definition gives an assessment at the time of application that could be different from one clinician to another, giving rise to differing results.

To conclude, the AETIM criteria, the same as other criteria assessed, are useful to select patients for whom it would not be necessary to perform a densitometry. The sensitivity of the AETIM criteria in identifying patients with low body mass (index $T < -1$) or osteoporosis is low, except for the group of post-menopausal women > 65 years old, where all the criteria are sensitive, although with low specificity.

Financing

This study was financed with a grant from the Societat Catalana de Reumatologia.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

We thank the members of the Unitat de Suport a la Recerca de Costa de Ponent for their comments on the manuscript.

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