

## Original Research

# Screening for osteoporosis among post-menopausal women in community pharmacy

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### ABSTRACT\*

**Objectives:** To identify postmenopausal women with risk of osteoporosis through quantitative ultrasound imaging (QUI) and to value the medical intervention after the determination of the bone mineral density (BMD).

**Methods:** Cross-sectional descriptive study developed in a community pharmacy. During the month of June of 2005 the community pharmacy enrolled postmenopausal women into the study. Women in treatment with calcium, vitamin D, hormone replacement therapy, estrogen receptor modulators, calcitonin or biphosphonates were considered criteria for exclusion. To all the women that consent to participate, the pharmacist measured BMD with the device Sahara Hologic Ultrasound Bone Densitometer at right calcaneus. Following the World Health Organization, women were classified as osteoporotic if their T-Score was less than -2.5 and as osteopenic if their T-Score ranged between -2.5 and -1.0.

**Results:** Of the 100 women screened, 11 (11%) presented risk of osteoporosis and 61 (61%) of osteopenia. The 18.5% postmenopausal women with body mass index lesser than 30 presented risk of osteoporosis and the 63.0% osteopenia.

**Conclusions:** The QUI constitutes a useful tool in community pharmacy for the screening of osteoporosis and it supposes a greater integration of the community pharmacy within the health care.

**Keywords:** Osteoporosis. Osteopenia. Mass screening. Ultrasonography. Spain.

### RESUMEN

**Objetivos:** Identificar mujeres posmenopáusicas con riesgo de osteoporosis mediante ultrasonografía ósea cuantitativa y valorar la intervención médica tras la determinación de la densidad mineral ósea.

**Métodos:** Estudio descriptivo transversal desarrollado en una farmacia comunitaria mediante la selección de las mujeres posmenopáusicas que acudieron durante el mes de junio de 2005. Se consideró criterio de exclusión estar en tratamiento con calcio, vitamina D, terapia hormonal sustitutiva, raloxifeno, calcitonina o bifosfonatos. A todas las mujeres que acceden a participar se les realizó un ultrasonografía ósea en el calcáneo derecho con el dispositivo Sahara (Hologic). Se aplicaron los criterios de clasificación de la Organización Mundial de la Salud, que clasifican a los pacientes con una DMO de más de 2,5 desviación estándar inferior a la media de una adulto joven (T-Score < -2,5) como osteoporótico, y a los pacientes con T-Score entre -1 y -2,5 como osteopélicos.

**Resultados:** De las 100 mujeres estudiadas, 11 (11%) presentaban riesgo de osteoporosis y 61 (61%) riesgo de osteopenia. El 18,5% de las mujeres con un índice de masa corporal < 30 presentaba riesgo de osteoporosis y el 63% osteopenia.

**Conclusiones:** La ultrasonografía ósea cuantitativa constituye una herramienta útil en farmacia comunitaria para el cribado de osteoporosis y supone una nueva vía de integración en la atención sanitaria.

**Palabras clave:** Osteoporosis. Osteopenia. Cribado. Ultrasonografía. España.

## (English)

### INTRODUCTION

Osteoporosis is a systemic disease of the skeleton, characterised by low bone mass and alterations in the micro-architecture of the bone tissue that lead to an increase in brittleness with the ensuing predisposition to bone fractures.<sup>1</sup> In 1994 the World Health Organisation (WHO) established diagnostic criteria based on the results of bone densitometry results obtained, in which osteoporosis is considered to exist with a reduction in the mineral bone density (MBD) of 2.5 standard deviations below the mean of the bone mass peak.<sup>2</sup> Based on this commonly-accepted criterion, it is estimated

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that some 2 million women<sup>3</sup> suffer from osteoporosis in Spain.

Given the progressive aging of our society, osteoporosis is an emerging disease that has increased in prevalence over the past few years. The most important consequence is the morbidity-mortality associated to the fractures, especially among the elderly, which has a great effect on the quality of life of patients and social and health costs.<sup>4,5</sup>

Since it is a silent disease with no symptoms prior to the fracture, it is well worth putting into practice strategies aimed at preventing fractures caused by osteoporosis. For this reason, the community pharmacy role may be significant in preventing this disease. Despite the fact that community pharmacies are a health agency that is accessible for both the health and sick population, with proven capacity to performing screenings<sup>6</sup>, in Spain there is very little literature that analyses the participation of community pharmacies in strategies for preventing the risk of osteoporosis.<sup>7,8</sup>

The quantification of the MBD, determined by the quotient between the bone mass, measured in grams, multiplied by the surface area, measured in square centimetres, has become an essential element in evaluating patients at risk of suffering from osteoporosis, since it is one of the most useful factors in predicting the risk of fractures due to brittleness<sup>9</sup>. Bone densitometry by dual X-ray absorptiometry (DXA) is currently regarded as the most effective test or method for diagnosing osteoporosis.<sup>10</sup> The prediction of the risk of fractures is greater when the MBD is measured directly in the bones that are most often affected (vertebral column and hip). However, technically speaking it is easier to measure the peripheral bones. Among the peripheral methods for measuring MBD, quantitative ultrasound imaging (QUI) has been associated, both in cross-over and prospect studies, with the prevalence and risk of fractures respectively, and provides an indication of the fracture risk, irrespective of the MBD, in particular in the case of hip fractures. It is currently proposed as a fast, economic, radiation-free alternative for evaluating the bone mass.<sup>11,12</sup>

Benefiting from these advantages, the present study was proposed in a community pharmacy, with the following most important objectives:

- To identify post-menopausal women at risk of suffering osteoporosis by QUI.
- To evaluate the medical intervention after determining the MBD.
- To ascertain the degree of patient satisfaction in relation to the new prevention service provided.

## METHODS

A cross-sectional, descriptive study conducted in a community pharmacy through the selection of post-menopausal women aged over 50, who visited the pharmacy during the month of June 2005. The exclusion criteria applied were being treated with

calcium, vitamin D, substitutive hormonal therapy, raloxifen, calcitonin or biphosphonates.

All patients who agreed to participate in the study were subjected to a bone ultrasound analysis in the right heel bone with the Sahara (Hologic) device. This densitometer calculates MBD based on the ultrasound parameters measured: sound speed, ultrasound attenuation and quantitative ultrasound index. The WHO criteria were applied, classifying patients with MBD with a standard deviation of over 2.5 lower than the average for a young adult (T-Score < -2.5) as osteoporotic and patients with a T-Score of between -1 and -2.5 as osteopenic.

All participants were given 5 questionnaires or rating scales that made it possible to evaluate the individual risk of low MBD: National Osteoporosis Foundation (NOF), Osteoporosis Risk Assessment Instrument (ORAI), Age Body Size No Estrogen (ABONE), Osteoporosis Self-Assessment Tool for Asians (OSTA) and a scale arising from the data of the Californian study "Study of Osteoporotic Fractures" (SOFSTURF).

To ascertain patient satisfaction we prepared a questionnaire consisting of 3 closed questions to be responded to with an "X" in a scale rated from 1 to 5.

A descriptive analysis of the data was performed with the computer programme G-Stat, giving mean values, absolute frequencies, relative frequencies in percentages, minimums and maximums, standard deviation, regression spans, contingency tables and statistic significance ( $p < 0.05$ ) with the Chi square test.

## RESULTS

Of the 100 women participating in the screening, 11 (11.0%) showed a risk of developing osteoporosis and 61 (61.0%) a risk of developing osteopenia. The average age of the 11 women with a risk of developing osteoporosis was 65.5 years, whereas the average age of the women with a risk of developing osteopenia was 64.6 years. Table 1 shows the main characteristics of the 100 participants.

18.5% of women with a body mass index (BMI) < 30 showed a risk of developing osteoporosis and 63.0%, osteopenia. Table 2 shows the different frequencies of the MBD alterations, depending on the BMI.

Figures 1 and 2 show the regression spans estimated by square minimums (relation between the MBD-age and MBD-BMI variables). Furthermore, the prediction axis consisting of prediction curves with a prediction of under 95% for mean values and prediction curves with a prediction of 95% for individual values.

Medical intervention in the 11 patients with a risk of developing osteoporosis who advised to visit their physician is shown in figure 3, where it can be observed that in 6 patients the family physician recommended pharmacological treatment.

	Minimum	Maximum	Mean ± DE
Body mass index	20.9	41.7	29.6 ± 4.6
Age in years	50	83	64.2 ± 8.5
Years of amenorrhoea	0	36	16.2 ± 11.0
Bone mineral density	Normal 28 (28,0%) (IC95%: 19.5%-37.9%)	Osteopeny 61 (61.0%) (IC95%: 50.7%-70.6%)	Osteoporosis 11 (11.0%) (IC95%:19.5%-37.9%)
Consumption of diuretics	No 76 (76.0%)	Yes 24 (24.0%)	
Smoker	No 93 (93%)	Yes 7 (7%)	

The questionnaire was completed by 87% of participants. 64.4% of those surveyed considered that the explanation given by the pharmacist on the test results was excellent and 29.9% considered it very good. Professional treatment was rated excellent by 74.7% of the women and 20.7% rated it as very good. The convenience of the pharmacy preparing a report for the physician on the test results was evaluated with an average score of 4.5, the explanation given by the pharmacist on the test results obtained a score of 4.6 and the treatment of patients by the pharmacist, 4.7.

BMI	Normal	Osteopeny	Osteoporosis
< 25	1 (7.1%)	12 (85.7%)	1 (7.1%)
25-30	9 (22.5%)	22 (55.0%)	9 (22.5%)
30-35	11 (33.3%)	22 (66.7%)	-
35-40	6 (54.5%)	4 (36.4%)	1 (9.1%)
> 40	1 (50.0%)	1 (50.0%)	-
Total	28 (28.0%)	61 (61.0%)	11 (11.0%)

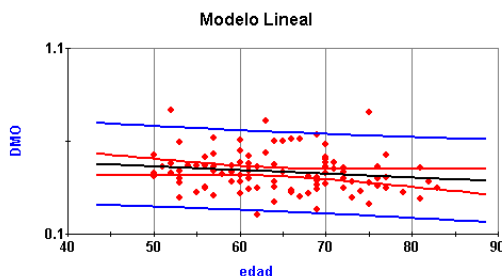


Figure 1. Single lineal regression MBD-age

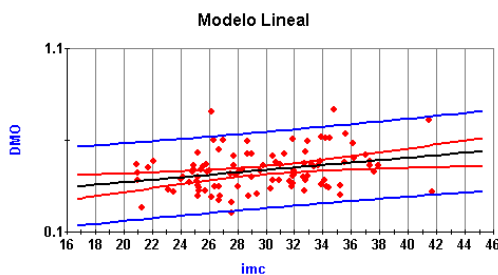


Figure 2. Single lineal regression MBD-BMI

The results after applying the different questionnaires or scales for measuring the risk of low MBD are shown in Table 3.

The mean MBD value of the women, depending on whether or not they met the criteria of the different scales for evaluating the risk of low MBD is shown in table 4.

### Medical Intervention

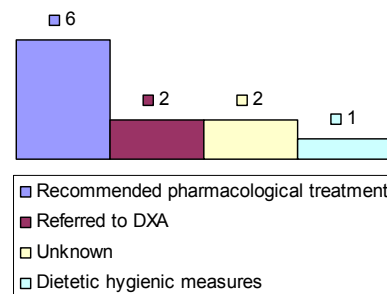


Figure 3. Medical intervention following patient referral.

In describing the association between the age>70 years and BMI <25 variables with the risk of osteoporosis (T-Score <-2.5) contingency tables and Chi square test were used. No statistically significant relation was found between the BMI<25 variable and the risk of osteoporosis (p=0.918) and neither was any statistically-significant relation found between the age>70 years variable and the risk of osteoporosis (p=0.776).

Also, when the Chi square test was applied among the risk of bone alterations (T-Score <-1.0) and the age>70 years and BMI<25 variables, a statistically significant relation was obtained between BMI<25 and the risk of bone alterations (p=0.0073). No significant relation was found for the age>70 years variable (p=0.743).

### DISCUSSION

In the document "Consenso sobre Atención Farmacéutica" (Consensus on Pharmaceutical Care) published by the Ministry of Health and Consumer Affairs<sup>13</sup>, pharmaceutical care is defined as "the active participation of the pharmacist in attending patients in the dispensing and follow-up of a pharmacotherapeutic treatment, thereby cooperating with the physician and other healthcare professionals for the purpose of achieving results that will improve the quality of life for patients. It also entails involving pharmacists in activities that will promote good health and prevent diseases". The

latter is related to the integration of community pharmacists into the development of prevention strategies through screening. Taking into account the field of activity open to community pharmacies in screening, the present study is intended to contribute an innovative practice in an attempt to benefit from new technologies in combating osteoporosis as a preventive activity. The main reasons why QUI was selected as the MBD measuring technique were as follows:

- Its use as a screening tool and for evaluating the risk of osteoporotic fractures is supported by the International Society for Clinical Densitometry.<sup>14</sup>
- It is a useful tool in predicting the risk of fractures

among women with low MBD and can therefore be used in primary care to refer patients to their physicians for more thorough assessment on osteoporosis.<sup>15</sup>

- It is a method that uses small-sized equipment without the need for employing specialist staff, in addition to being an easy technique to perform.<sup>16,17</sup>
- The QUI screening strategy can be converted into an option for situations in which the osteoporosis diagnosis is defective, due to the difficulties of gaining access to DXA equipment.<sup>18</sup>

Table 3. Results of low bone density scales.

Scale	Nº of women meeting scale criteria	Risk of OT and OP n (%)	Nº of women not meeting scale criteria	Risk of OT and OP n (%)
NOF	63	OT: 9 (14.3%) OP: 37 (58.7%)	37	OT: 2 (5.4%) OP: 24 (64.9%)
ORAI	63	OT: 8 (12.7%) OP: 40 (63.5%)	37	OT: 3 (8.1%) OP: 21 (56.8%)
ABONE	54	OT: 6 (11.1%) OP: 35 (64.8%)	46	OT: 5 (10.9%) OP: 26 (56.5%)
SOFSURF	75	OT:9 (12.0%) OP:47 (62.7%)	25	OT:2 (8.0%) OP: 14 (56.0%)
OSTA	56	OT:8 (14.3%) OP:37 (66.1%)	44	OT:3 (6.8%) OP:23 (52.3%)

OT= osteoporosis; OP=osteopenia

Table 4. Mean bone density value depending on whether or not they meet the criteria of the different scales for evaluating the risk of low bone density (g/cm<sup>2</sup>)

Questionnaire	NOF	ORAI	ABONE	SOFSURF	OSTA
Mean±DE Meet criteria	0.429±0.115	0.422±0.106	0.429±0.103	0.426±0.107	0.406±0.098
Mean±DE Do not meet criteria	0.446±0.097	0.457±0.110	0.442±0.114	0.463±0.109	0.472±0.111

The determining of MBD in the heel bone will be of great value if it leads to positive actions in influencing the risk of developing osteoporosis. For this reason, it is very important for medical staff to offer sufficient cooperation in screening performed on this pathology and for community pharmacies to be accepted as part of the multidisciplinary team dealing with the patient. If in addition to the results given in figure 3, we consider that 31 (50.8%) women with a risk of developing osteopenia consulted their physicians on the MBD determination made in the pharmacy and 21 (34.4%) received pharmacological treatment, it can be assumed that this new service is well accepted by physicians, who are willing to take clinical decisions after receiving this information. The reason for the low number of patients referred to DXA may lie in the difficulty experienced by primary care physicians in accessing the most important diagnosis technique, namely DXA.<sup>19,20</sup> This situation appears to be in line with the data shown by studies demonstrating how difficult it is to use the DXA technique in the primary care area.<sup>5</sup> For example, in Andalusia, only 5-10% of physicians surveyed were able to request densitometries. In another study performed in primary care centres all over Spain<sup>21</sup> it is affirmed that the diagnostic criteria most often used in women visiting the primary care centres suspected as having developed osteoporosis are the case history, risk factors and conventional

radiology. MBD is used in 32% of cases when diagnosing osteoporosis in primary care. Taking into account this situation, it seems only logical to expect a reduction in the number of patients for whom the DXA technique is prescribed.

The main objective of the rating scales in evaluating the risk of low MBD is to select the women prior to performing the densitometry, thereby optimising the use of this test. These scales provide information only on the risk of a low MBD without evaluating the individual risks of fractures.

Although the criterion for referral to QUI used in the present study was post-menopausal women aged 50 years without being treated with calcium, vitamin D, substitutive hormonal therapy, raloxifen, calcitonin or biphosphonates, five rating scales for evaluating the risk of low MBD have been used in the women selected (NOF, ORAI, ABONE, OSTA and SOFSURF) with the objective of describing the results that would have been obtained by applying these questionnaires (tables 3 and 4). Such scales may easily be applied in daily practice in community pharmacies for screening high-risk patients, but without forgetting their main limitation; they are instruments that relate the risk factor with the reduction in the bone mass. The low bone mass risk factors do not furnish any information on the risk of fracture in the patient after determining the MBD.<sup>22</sup> Different prospective studies have shown

that although MBD is an important predictor of bone fractures, other risk factors also exist that have been shown to have equal or greater association with the appearance of fractures than the presence of low bone mass.<sup>23</sup> Both the skeletal risk factors (bone hardness and resistance) and those related to falls (traumatism and force of impact) interact in a complex, synergic manner.<sup>24</sup> The fracture risk factors are related to the risk of falls, type of traumatism and force of the impact, and the hardness and resistance of the bone. In this regard, we propose the following practical questionnaire which consists of 15 questions<sup>22</sup>:

- Did you have your last period before the age of 45? (History of early menopause).
- Did you have your ovaries removed before the age of 50? (Ooforectomy).
- Have you ever broken a bone? (Previous history of fractures).
- Have you ever been treated with cortisone (or derivatives thereof) orally for more than 6 months, at a dose of more than 7.5 mg/day? (Cortisone treatment).
- Do you weigh less than 55 kg? (Weight < 55 kg).
- Do you have any relatives who suffer from osteoporosis or have had a bone fracture (hip, column, wrist)? (Family history of osteoporosis).
- Have you been menopausal for more than 10 years (no period)? (Menopause > 10 years).
- Have you missed any periods during a term of

over one year since the onset of your menstruation cycle and before the menopause? (Previous history of amenorrhoea).

- Since your youth, has your diet been lacking in calcium (milk and derivatives)? (Diet lacking in calcium).
- Do you consume alcohol regularly? (Alcohol intake).
- Do you smoke more than 10 cigarettes a day? (Smoking habit).
- Do you practice little physical exercise and lead a sedentary life (Many hours spent sitting down or bedridden)? (Sedentary life).
- Are you predisposed to falls (with or without fractures)? (Predisposed to falls).
- Do you have problems with your eyesight, even though you wear spectacles? (Eyesight problems).
- Do you suffer from any symptom of dementia? (Dementia symptoms).

Table 5 shows different studies using peripheral densitometries to determine the risk of osteoporosis. The studies performed in community pharmacies share the same conclusions on the fundamental role of the pharmacist in community programmes for osteoporosis screening and the high level of cooperation provided by medical professionals.<sup>27-29</sup>

Study	Participants	Location	Measuring method	Results	Cut-off point
26	115 post-menopausal women	Health Centre	Bone ultrasound scan of right heel bone with Norland McCue CUBA Clinical Device	50.4% OT 29.6% OP	T-Score WHO criterion
27	267 post-menopausal women	Health Centre	Bone ultrasound scan of heel bone with Sahara (Hologic) Device	12% OT	T-Score ≤ -2.5
28	133 women ≥65 years	Rural community pharmacies	Peripheral DXA densitometry of the heel bone with Peripheral Instantaneous X-Ray Image (PIXI) belonging to GE Medical Systems	20% OT 26% OP	T-Score WHO criterion
29	102 people >18 years	Urban community Pharmacies	Peripheral DXA densitometry of the heel bone with APOLLO Bone Densitometry System Device	11.7% OT 22.6% OP	T-Score WHO criterion
30	532 people The results are those obtained from 305 patients	Community pharmacies group	Bone ultrasound scan in heel bone with Sahara (Hologic) Device	37% high risk of OT 33% moderate risk of OT	T-Score between 0 and -1 moderate risk T-Score ≤ -1 high risk

OT=osteoporosis; OP=osteopenia

## CONCLUSIONS

Quantitative ultrasound imaging is a useful tool in community pharmacies for screening osteoporosis

and may constitute a new channel of integration into healthcare assistance.

With respect to taking future action aimed at tackling the problem of osteoporosis in our

community pharmacy, the following objectives have been defined:

- Extending the osteoporosis screening activity to men.
- Evaluating therapeutic compliance among patients with osteoporosis<sup>30</sup> for the purpose of planning interventions at a later date that will

improve matters with respect to following treatment, if necessary.

- Include an evaluation of the quality of life from the health standpoint in the process of pharmacotherapeutic follow-up of osteoporosis treatments.<sup>31,32</sup>

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