

Original Article

Osteopenia in Primary Health Care Patients: Do We Need to Be More Rigorous?

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ABSTRACT

Aim: To describe the treatment prescribed to osteopenic women seen at an urban primary health care centre and the treatment compliance of those patients with a prescription of calcium and/or vitamin D.

Materials and method: Cross-sectional study, osteopenic women diagnosed by bone densitometry between February 2005 and January 2006 (n=121). Clinical history review: demographic information; previous clinical history of bone fracture, type of fracture; parental history of fractures; tobacco use; osteoporosis-related medication or disease; dietary and sun exposure assessment; calcium, vitamin D and raloxifene/biphosphonates prescription; mean daily dose of calcium and vitamin D supplements collected at the pharmacy by patients. Analysis of treatment prescription and compliance according to the information collected was performed.

Results: Mean age, 61.9 (9.1) years; 90.7% post-menopausal. The dietary assessment was performed in 30.5% of the women included in the study. The drug prescription was as follows: calcium 74.6%, vitamin D 68.6%, and raloxifene/biphosphonates 16.1%. All drug prescriptions were associated with lower T-score values. The patient's compliance of calcium supplements has been calculated as mean of 423.8 (321.7) mg/day, and 343.1 (225.9) IU of vitamin D; with no association with any of the studied variables.

Conclusions: We identified greater drug prescription in those patients with a lower T-score. The clinical history of previous fracture did not show association with drug prescription nor a better compliance. There was a lack of information about relevant issues in the clinical history of the osteopenic women included in the study. The patient's compliance of calcium and vitamin-D supplements is very variable.

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Osteopenia en atención primaria: ¿debemos ser más rigurosos?

RESUMEN

Objetivo: Describir el tratamiento prescrito a mujeres osteopélicas atendidas en un centro de atención primaria urbano y el cumplimiento de las pacientes que reciben prescripción de calcio o vitamina D.

Material y métodos: Estudio transversal en mujeres con osteopenia diagnosticada por densitometría ósea (DMO) entre febrero de 2005 y enero de 2006 (n = 118). Comprobación en la historia clínica de: información demográfica; antecedentes de fractura, tipo; antecedentes familiares de fractura; hábito tabáquico; toma de fármacos o antecedente de enfermedad crónica relacionados con disminución de DMO; valoración/consejo dietético, valoración de exposición solar; prescripción de calcio, vitamina D y raloxifeno/bisfosfonatos; dosis diaria media de calcio y vitamina D recogida por las pacientes de la farmacia. Análisis de la prescripción de fármacos y del cumplimiento en función de las variables recogidas.

Resultados: Media de edad, 61,9 ± 9,1 años; el 90,7% posmenopáusicas. La valoración/consejo dietético se encontró en el 30,5%. La prescripción de fármacos fue: calcio, 74,6%; vitamina D, 68,6%, y raloxifeno/bisfosfonato, 16,1%. La prescripción de todos los fármacos se asoció a valores más bajos de T-score. El cumplimiento medio de las mujeres se estimó en 423,8 ± 321,7 mg Ca/día, y 343,1 ± 225,9 UI de vitamina D, sin relación significativa con ninguna de las variables estudiadas.

Conclusiones: Se identifica una mayor prescripción de los tratamientos farmacológicos en pacientes con valores de T-score menores. El antecedente personal de fractura no se asocia a la prescripción de fármacos ni al mejor cumplimiento por las pacientes. En la historia clínica de las mujeres osteopélicas hay una falta

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de registro de aspectos relevantes. El cumplimiento de los suplementos de calcio y vitamina D es muy variable.

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Introduction

Osteoporosis is a reduction in the bone mass with deterioration of the bone tissue micro-architecture, increase in bone frailty and an increased risk of fracture. The World Health Organization (WHO) has established some operative definitions based on bone mineral density (BMD).¹ Osteopenia is a densitometric term defined by a T-score between -1 and -2.5 . Values of T-score superior to that are considered normal while those inferior to that define osteoporosis.

Prevalence of osteopenia in our country has been estimated by very few studies.^{2,3} In women from 20 to 44 years, it is estimated to be 13.1% in the lumbar spine and 17.9% in the femoral neck, numbers that increase progressively to 50% and 31.1% respectively in women aged 60 to 69 years. In more recent studies, similar estimates have been obtained.⁴

The pathological meaning of osteopenia has not been clearly established. It has been observed that a BMD on the lumbar spine with a T-score <-1 supposes a relative risk (RR) for vertebral fracture of 2.3 (95% confidence interval [CI], 1.9-2.8) and a RR for hip fracture of 2.6 (95% CI, 2-3.5).⁵

As for diagnosis, the program of preventive activities and health promotion (PAPPS)⁶ does not recommend a systematic search for osteoporosis or osteopenia. And, regarding treatment, it states that there is no justification to carry out drug treatment in women with osteopenia. Interventions to be carried out should be the promotion of a healthy lifestyle, an adequate consumption of calcium and vitamin D, exercise, and tobacco avoidance.

The WHO recommends the realization of a densitometry in the presence of risk factors.⁷ In addition, a recent document, one performed after the study, recommends treatment for osteoporosis taking into account clinical risk factors for fracture.⁸ It has published the FRAX[®] model, which estimates the risk for fracture at 10 years, with the objective of helping primary care physicians in osteoporosis treatment decision making.

Once the prescription has been decided upon based on a significant risk for fractures, treatment compliance is fundamental for an adequate prevention of the risk for fracture.

There are doubts, based on the observation in daily clinical practice, on whether the primary care physicians undertake treatment of osteopenic women based on the integral evaluation of multiple risk factors, as well as on the compliance that patients with osteopenia carry out when they have been prescribed with a calcium or vitamin D supplement.

The objective of this study is to describe the drug treatments (calcium supplements and vitamin D, raloxifene, bisphosphonates) as well as non-pharmacologic treatments (diet, sun exposure) prescribed to osteopenic women in an urban primary care center (CAP), and compliance with treatment based on calcium and/or vitamin D supplements.

Material and Methods

Transversal study performed at the Primary Care Center of Les Corts, Barcelona. This center, in a health study performed in 2007, had an assigned population of 31 812 inhabitants (distributed by age and gender as is shown on Figure 1), attended by 16 family physicians, apart from other health personnel (family and community medicine residents, nursing, pediatrics, gynecology, and other specialties).

All of the women selected for this study were treated at this center and had osteopenia registered by BMD, studied between february 2005 and january 2006. Premenopausal women with a minimal Z-score >-1.0 were excluded and 3 women were eliminated from the initial total of those in which no assurances could be made that they indeed were osteopenic, as has been exposed.

Variables studied through review of clinical history were: age, smoking habit, a history of fractures, type, family history of hip fractures, BMD, chronic use of drugs related to a reduced BMD, diagnosis of a metabolic or systemic disease related to a reduced BMD, presence in the clinical history of dietitians evaluation/advice, exposure to sunlight, calcium prescription, vitamin D, raloxifene, or bisphosphonates.

For estimating compliance with treatment with calcium and/or vitamin D supplements prescribed, the pharmacy reviewed the filling of the prescription at the health office, something which is registered on a card. The number of bottles, in any commercial format, of said supplements were counted for each patient with a prescription, between February 1, 2005 and January 31, 2006. To determine the mean daily consumption, a quotient between total dose in the period and the number of days of treatment was calculated. For the calculation of the numerator, the total dose of calcium in milligrams or vitamin D in international units was added. To determine the denominator, the sum of total days from the day of treatment prescription until the final day of the study period was performed. In those cases in which the last prescription was filled by the pharmacy less than 60 days before the end of the period (for bottles with 60 pills), the denominator was lengthened in a number of days equivalent to the number of pills left over in the last bottle.

Data analysis was performed with the SPSS v.11.0 statistical package. A descriptive analysis was done and the association of drug prescription in relation to the studied variables was evaluated, through a bivariate analysis using the χ^2 test for categorical variables, Fisher's exact test if the application conditions were not met and Student *t* or Mann Whitney *U* for quantitative variables. The level of statistical significance was defined as a *P* value of $<.05$. In addition, a multivariate analysis (logistical regression) was done, considering the prescription of the drug (yes/no) as a dependent variable and, as independents, variables considered relevant and of interest for the study, as well as those which showed a statistically significant association in the bivariate analysis. The variation in the daily mean dose of calcium and vitamin D prescription filled out by the patients at the pharmacy was also performed, in relation to the same variables, in addition to the prescription of raloxifene/bisphosphonates. For that, the same analysis plan commented was employed, adding a correlation analysis to study the association between quantitative variables.

Results

During the study period, 118 registries of a BMD with a T-score ≤-1.0 and ≥-2.5 were found, in other words, osteopenia, which were analyzed. In a latter search before the publication of this study, in February 2008 (2 years after the end of the study), 474 registries of BMD corresponding to the study period were found, of which 65 were normal, 182 corresponded to osteoporosis, and 227 to osteopenia. The difference between these 227 found in 2008 and the 118 found at the end of the study in 2006 was explained by the retrospective registry of BMD of those that had not been registered

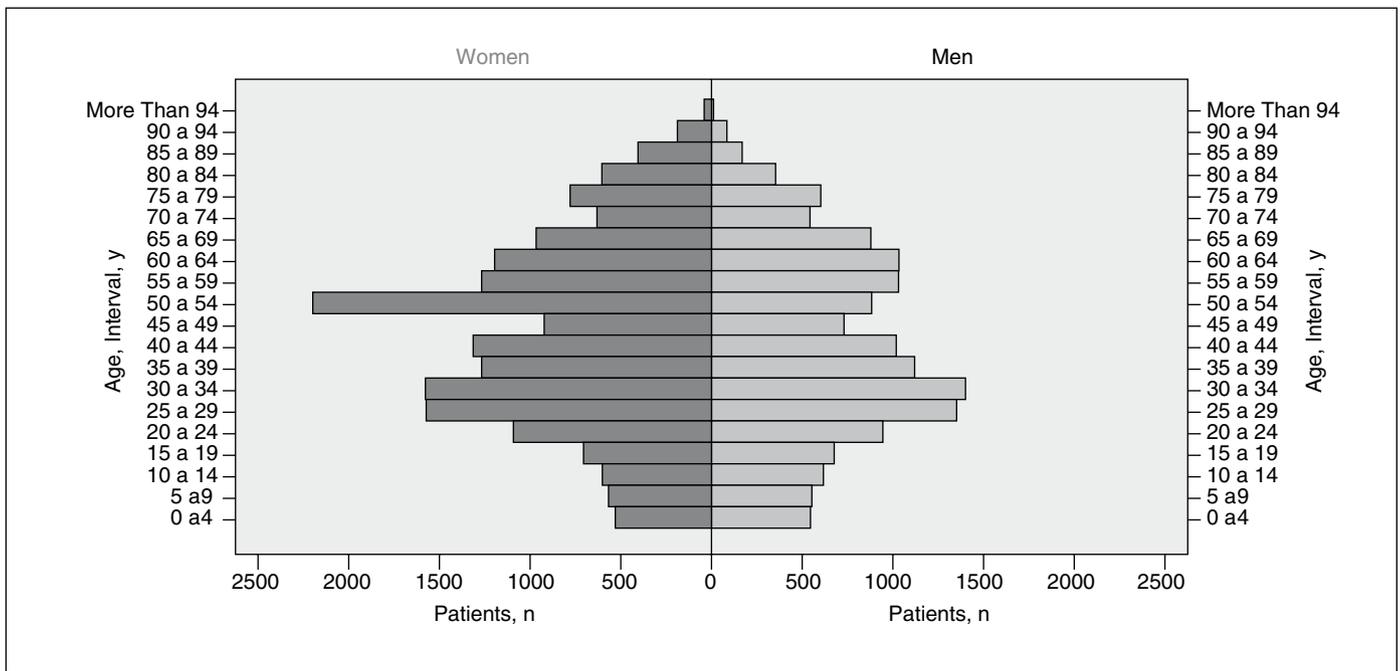


Figure 1. Distribution by age and sex of the population corresponding to the Primary Care Center (Les Corts, Barcelona).

previously during the study period or those reported by patients at a later date. From now on we will refer to the 118 BMD analyzed initially as the total.

The registries corresponded to the 16 family physicians of the CAP, with a mean of 7.3 (interval, 1-14) BMD per physician.

Fifty-six point eight percent of the BMD were solicited by the family physicians; 14.4% by a gynecologist; and in 23.7% the requesting physician was not registered. There were 2 BMD which had been solicited by a rheumatologist.

The motive for soliciting the BMD was not stated in 52 (44.1%) cases. Of the 66 cases in which it was stated, 31.8% was for control of an already diagnosed osteopenia; 22.7% for the study of radiologic osteopenia; 15.1% for a search of postmenopausal osteopenia; 7.6% for the study after a fracture; and 7.6% for study in cases of premature menopause; 2 BMD (3%) were solicited on the bases of a family history of osteoporosis; and the same number by patient request. Other motives were less frequent (1 BMD) and were: control of patients with osteopenia-inducing treatments, control of the patient with osteopenia-related systemic disease, a low-calcium diet, bone pain, search for osteoporosis at 65 years of age, and part of the study protocol due to osteoporosis risk factors.

Mean (standard deviation) of the women's age was 61.9 (9.1) years. Ninety point seven percent was found in a postmenopausal state, 2.5% were premenopausal, and unclassifiable in 8 (6.8%) women in none of the 2 groups by data from the clinical file. Nine point three percent were smokers, in 12.7% no mention was made on smoking habits. In 5 (4.2%) women, there was a family history of fracture. In 88.1% of cases there was no data concerning such a history.

Twenty-seven (22.9%) women had a history of fractures. There was some difficulty to determine which were pathological using the information on the clinical history, opting to evaluate them as a whole. Their distribution according to localization is shown in Figure 2.

Nine women were undergoing drug treatment related to a reduction in BMD: 6 with steroids, 2 with L-tiroxine, and 1 with chemotherapy; 2 women were diagnosed with an osteoporosis related metabolic/systemic disease: one with polymyalgia rheumatica and the other with Cushing's syndrome. Dietitians evaluation/advice was sought by 30.5%, and sun exposure was not

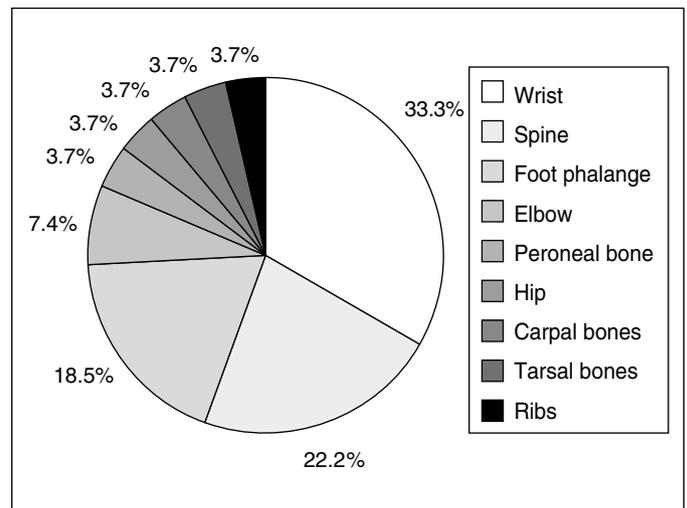


Figure 2. Localization of previous fractures in osteopenic women (27/118).

demonstrated in any case. Drug prescription was: calcium, 74.6%; vitamin D, 68.6%, and raloxifene/biphosphonate, 16.1%. In the bivariate analysis of biphosphonate/raloxifene, calcium, and vitamin D prescription, there was a statistically significant association between these and reduced values on the T-score (Table), something that was not seen with the rest of the variables under study (age, menopause, personal history of fracture, smoking habit, osteopenia-inducing drug chronic use, diet evaluation). This association was maintained in the multivariate analysis. The mean dose of prescribed calcium and/or vitamin D filled out by the osteopenic women at the pharmacy was 430.5 (321.8) mg Ca/day and 312.6 (240.3) IU of vitamin D, but no association was seen with any of the variables under study.

Discussion

The main limitation of this study is that it is based on a review of clinical files and histories and, probably, many of the observations

Table

Comparison of the Minimal T-score According to Drug Prescription in Patients Diagnosed With Osteopenia

	Minimum T-score, Mean (SD)	
	With Treatment	Without Treatment
Biphosphonates/raloxifene ^a	-2.02 (0.29)	-1.75 (0.37)
Calcium ^a	-1.84 (0.37)	-1.63 (0.34)
Vitamin D ^a	-1.84 (0.37)	-1.68 (0.36)

^aP<.05 (T-score of calcium and/or vitamin D vs biphosphonates/raloxifene).

and recommendations made by the physicians are not recorded. It is necessary to improve these aspects of the registry, elaborating specific computer applications for this purpose (protocols), used in many primary care attention processes. In fact, in the 2 years after the study there has been an increase in the reporting of BMD values in the established space in the computerized clinical history.

As for the sample, selection was limited between both the dates in a 1 year period, obtaining a convenient sample without performing sample size calculations. This did not limit obtaining findings, relevant in our opinion, useful for recommending that modify the common clinical practice of family physicians regarding treatment of women with osteopenia.

In the analysis of pharmacologic treatment of osteopenic women, apart from calcium and vitamin D, biphosphonates, and raloxifene were chosen because they are the bone resorption modifying drugs more frequently prescribed in osteoporosis in our environment during the study period.

The main finding of the study is that, for all of the pharmacologic treatments of osteopenia, the factor most often associated to their prescription by family physicians is the T-score. The rest of the fracture risk factors do not show significant differences in their analysis. For example, it does not appear that the presence of prior fractures is considered by physicians as an aggravating component, independent of densitometric findings. It must be taken into account that the presence of fractures would be the main clinical factor which could justify the prescription of anti-resorptive treatments to women with osteopenia. In a study carried out in primary care, the predictive value of a history of fracture in women over 65 was a predictor of osteopenia or osteoporosis.⁹

The lack of reporting of pathologic fracture (those that occur without trauma or after minimal trauma) also stands out. Greater motivation is necessary to improve such reporting and take this into account for decision taking. The main risk factors for osteoporotic fracture which cannot be left out are: BMD, a personal history of fractures, a family history of fractures, thinness, and active tobacco use,^{10,11} with the most important being a personal history of fractures.

The WHO in 2007 has provided primary care physicians with a calculator for the risk of fracture after 10 years, Frax[®] (available from: <http://www.shef.ac.uk>), in order to facilitate decisions regarding treatment prescription. Apart from those already mentioned, the rest of the risk factors that this tool takes into account are: age, gender, steroid use, rheumatoid arthritis, secondary osteoporosis, and alcohol consumption >30 g/day. Its use probably helps in the integral evaluation of the risk for fracture in primary care clinics.

Other risk factors for bone mass loss must be remembered,¹² many of them modifiable, for its early correction and a primary prevention of osteoporosis in the general population: lack of exercise, poor calcium intake, protein-rich diets, and excess coffee consumption, as well as other drug treatments and other systemic diseases related to a loss in bone mass.

The fact that only 2 of the 118 BMD of osteopenic patients were solicited by rheumatologists also stands out. We interpret this finding as a difficult communication and the existence of barriers in the flow of information between different levels of care. The

availability of DXA would also play a role in the fact that some family physicians would not refer the patient to another level of care in order to solicit such a test.

As for compliance by the patients in taking the prescription of calcium and vitamin D, our study shows variability between subjects, without relationship to the severity of the disease or the presence of past fractures. In another study in the primary care environment, the total consumption of calcium in a general population of women, including supplements, was evaluated, and compliance was evaluated according to data offered by the patients themselves. Variable consumption was also seen; for example, in women over 65, 1704 (855) mg/day. Larger consumption was seen in diagnosed cases of osteopenia and osteoporosis, as well as in caucasians and non-smokers, without a significant relationship with other variables (for example, a family history of osteoporosis).¹³ This leads us to question the effectiveness that prescribing calcium or vitamin D supplements to women with osteopenia can have if compliance was so irregular and without any trials that evaluate the effectiveness on the prevention of fractures through calcium and vitamin D supplementation in this specific group. Two recent meta-analysis of the Cochrane Collaboration have shown erratic variations in BMD when systematically treating all postmenopausal women with calcium¹⁴ or vitamin D,¹⁵ respectively. In the case of combined treatment with calcium and vitamin D, a certain effectiveness in the prevention of hip and non-spinal fractures was seen, an effect limited to institutionalized patients.

Regarding sunlight exposure, the deficit of which is associated to a reduction in vitamin D levels,¹⁶ and which has shown to be effective in the prevention of fractures,¹⁷ it should be thoroughly evaluated in future studies on its usefulness in the treatment of patients with osteopenia or osteoporosis.

In conclusion, an improvement in reporting important data is needed, both of risk factors as well as non-pharmacologic treatment plans, in the clinical history of osteopenic women. Studies that evaluate the effectiveness of the prescription of calcium and/or vitamin D in the prevention of fractures in osteopenic women are also needed. In addition, interventions are needed to improve compliance with the prescribed treatments to women with a risk for fractures.

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