

Original article

Elaboration, implementation and follow-up of a postmenopausal osteoporosis protocol: Collaboration between the Primary care and Rheumatology departments

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ABSTRACT

Objective: To improve the clinical management of postmenopausal osteoporosis, an intervention based on the implementation of a guideline agreed to between the Primary Care and Specialized departments of all centers at “Mutua of Terrassa” was carried out.

Methods: Descriptive and interventional study. The intervention consisted of the elaboration of a consensus guideline that was presented in all centers. Results were assessed from bone densitometry studies requested by family physicians over 1 year.

Results: One thousand one hundred sixty-five densitometric studies were requested, of which 689 were for the diagnosis of new patients. For the evaluation of the guidelines, details were obtained from 560. Five hundred two studies (89.6% 95%CI 87.1-92.2) complied with indication criteria established in the guideline. Of the total of patients who received bisphosphonates and other drugs affecting bone metabolism (43 osteopenic and 167 osteoporotic), 83.7% (95%CI 69.3-93.2) and 89.8% (95%CI 85.2-94.4) respectively complied with drug recommendations. Drug consumption during the year 2007 was reduced by 152,745 euros (-6.3%) although the number of patients increased in 565 (+4.9%) with respect to the previous year. 442 (78.9% 95%CI 75.6-82.3) densitometries presented a result in the osteopenia or osteoporosis category. There were statistically significant differences of the results according to the patients' age and the motive for the bone densitometry request.

Conclusions: Implementation of the guideline allowed for the effective management of the clinical process of osteoporosis in our field.

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Elaboración, implantación y seguimiento de un protocolo de osteoporosis posmenopáusica: colaboración entre Atención Primaria y el Servicio de Reumatología

RESUMEN

Objetivo: Con el objetivo de mejorar la gestión clínica de la osteoporosis posmenopáusica, se ha realizado una intervención basada en la implantación y seguimiento de un protocolo consensuado entre la Atención Primaria y la Especializada de la Mútua de Terrassa.

Métodos: Estudio descriptivo y de intervención. La intervención consistió en la elaboración de un protocolo consensuado, que fue presentado en todos los centros. Los datos se han evaluado a partir de densitometrías óseas solicitadas por los médicos de familia durante 1 año.

Palabras clave:

Osteoporosis posmenopáusica

Guía de práctica clínica

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Resultados: Se han solicitado un total de 1.165 densitometrías, de las cuales 689 son para diagnóstico de nuevas pacientes. Para la evaluación del protocolo se han obtenido datos de 560. Quinientas dos densitometrías realizadas (89,6%, IC 95%: 87,1–92,2) cumplían con los criterios de indicación marcados por el protocolo. Del total de pacientes que recibieron tratamiento con fármacos antirresortivos (43 osteopénicas y 167 osteoporóticas), el 83,7% (IC 95%: 69,3–93,2) y el 89,8% (IC 95%: 85,2–94,4), respectivamente, cumplían con las recomendaciones de primera elección. El consumo de fármacos durante el año 2007 se ha reducido en 152.745 euros (–6,3%), aunque el número de pacientes tratadas ha aumentado en 565 (+4,9%) respecto al año anterior. Cuatrocientos cuarenta y dos (78,9%, IC 95%: 75,6–82,3) densitometrías presentaron un resultado de osteopenia u osteoporosis. Se observan diferencias estadísticamente significativas de los resultados según la edad de las pacientes y el motivo de solicitud.

Conclusiones: La puesta en marcha del protocolo ha permitido gestionar de forma eficiente el proceso clínico de la osteoporosis en nuestro ámbito.

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Introduction

Osteoporosis and its complications currently represent a high volume of health care demand, with great economic impact on health services and economic.^{1,2} Approximately 40% of Caucasian women will have an osteoporotic fracture after age 50, and fractures caused by osteoporosis generate an estimated expense of \$ 30,000 million euros in Europe.³

In a cohort of patients followed in the city of Oviedo, it was observed that the incidence of vertebral fractures after 50 years of age was 9.85 per 1,000 people per year. The impact of fractures, especially hip fracture, is devastating: it is considered that 20%–30% of patients die during the first year after the fracture.²

As in many other pathologies, it is of the utmost importance that there be coordination between primary care and the specialist to optimize the management of osteoporosis in all aspects: diagnosis, treatment, rehabilitation, etc. Osteoporosis is one of the priority groups for action because of the impact it has on overall spending and the health of the population. Until late 2006, primary care physicians in our area assumed the clinical evaluation of osteoporosis in varied ways. Usually, the diagnosis was made in Specialized Care (as family doctors could not request a bone densitometry [BMD]), and monitoring of these patients varied widely.

The literature has reported that the diagnosis of patients treated in primary care consults in our country is made mainly by clinical and conventional radiology and to a lesser extent, by densitometric criteria, due to poor accessibility to the test.⁴

In order to rationalize this clinical process at the level of primary care, it is considered essential that family physicians request BMD directly. To this end, the need to plan a joint strategy between Primary Care and Specialized Care arose, that could improve overall management, allowing family doctors to request the tests while maintaining maximum quality and efficiency criteria.

The main objective of this study was to improve the clinical management of osteoporosis through a protocol based on the implementation and monitoring of actions in relation to the indication for BMD applications, on the appropriateness of the treatments and their efficiency. As a secondary objective, we have analyzed the results of BMD according to age and the criteria for requesting it included in the protocol to better match its indication in our environment.

Material and methods

We performed a descriptive and intervention study in collaboration with Primary and Specialty Care of the Mutual Terrassa system (www.mutuaterassa.cat), which operates eight primary care centers and a

referral hospital (Hospital Mutua de Terrassa) and provides assistance to a population of 240,000 inhabitants of Vallès Occidental, an area near the city of Barcelona.

During 2006, a care protocol was developed for the diagnosis, treatment and monitoring of osteoporosis.⁵ The protocol was conducted by a task group that included a rheumatologist, a family physician and a Primary Care pharmacist.⁵

The protocol included as priority sections the diagnostic recommendations based on WHO criteria, the risk factors that are indicative for the performance of BMD, outlined in the application form (Figure 1), an algorithm of treatment recommendations (Figure 2) as well as monitoring indicators. The consensus protocol was presented to each primary care center during the month of January 2007. To facilitate compliance, the application form for BMD was included in the electronic clinical history.

Simultaneously, and to strengthen the implementation of the protocol, individual monthly tracking of prescription drugs for osteoporosis was established for all physicians. The purpose of this

Bone densitometry request sheet

- Name.....
- Age..... No. history
CAP..... Date.....

The patient presents one of the following main motives for requesting a BMD measurement:

- Cause of secondary osteoporosis.
Specify.....
- A history of fragility fracture
- Menopause before 45 years of age
- Maternal history of fragility fracture
(especially femoral)
- Radiological suspicion of osteoporosis

Or the patient presents one of the following secondary motives:

- Smoking over 10 cigarettes a day
- Extreme sedentarism
- Maintained deficit in calcium consumption
- Low weight and height. Specify.....

Or it is a follow up test.
Date of last test

Figure 1. Bone densitometry request sheet. BMD indicates bone densitometry.

Results of densitometry			Recommendation of 1st choice		
Prevention	NORMAL (BMD>1)		General measures*		
	OSTEOPENIA (BMD between -1 and -2,5)	Mild or moderate osteopenia and no other risk factors	General measures*	Calcium+vitamin D when diet contribution is insufficient	
Severe osteopenia or other added risk factors		Evaluate need for antiresorptive treatment			
Treatment	OSTEOPOROSIS (BMD>2.5)	No fracture/ vertebral fracture		≤65 years	Alendronate, risedronate or raloxifene
				>65 years	Alendronate or risedronate
		Non vertebral fracture	Alendronate or risedronate		

Figure 2. Treatment recommendation. BMD indicates bone densitometry.

Avoid tobacco and excessive alcohol consumption, as well as sedentarism, carrying out a balanced diet with an adequate content of calcium and vitamin D, also avoiding falls.

monitoring was to improve efficiency following the prescription of the treatment recommendations protocol.

Twice a year the comparative data regarding the indications, motives and results of densitometries requested by all of the physicians on the team and from other centers were presented individually and through a handout.

The evaluation was conducted from the DMO requested by family physicians during the period between February 1, 2007 to January 31, 2008 for the diagnosis of new patients or those who did not have made a BMD performed in the previous 10 years.

The analysis of drug expenditure was based on prescriptions billed by all of our patients in our health area and in drug treatment for osteoporosis during the years 2006 and 2007.

Clinical data was obtained from the medical history (HCAP) of the patient. From BMD applications we obtained data such as age, date of application, requesting physician and the reason for application, in the case of the main indication, when it was "premature menopause", we collected, in addition, the age of menopause. "Radiologic suspicion" was considered when evidence of decreased bone density was seen on the simple spine x-ray (radiological strengthening of the vertebral plates and vertical trabeculae). From the HCAP, we obtained the values of BMD at the lumbar spine (L1-L4) and femoral neck levels, and data was expressed as T score. The densitometry technique used was the dual-energy x-ray absorptiometry (DXA) (Lunar® densitometer, model Prodigy). The patients were classified into three categories, depending on the findings of BMD (normal, osteopenia and osteoporosis), and these subgroups were compared with the variables described.

The indicators used were:

- Number of BMD that met the indication criteria with respect to the total.
- Number of treatments that met protocol recommendations according to the outcome of the DMO.
- Spending per patient for osteoporosis drugs from 2007 to 2006.
- Percentage of normal densitometry, osteopenic or osteoporotic in total applications evaluated.
- Percentage of normal, osteopenic or osteoporotic densitometries according to age and reason for request.

Pharmacy Unit coordinated the monitoring and evaluation of all results.

The data was collected and processed using SPSS Win version 12.0. Quantitative variables were described by calculating the mean and standard deviations (SD) and qualitative variables were calculated using proportions and confidence intervals. For mean comparisons, the Student's T test was carried out. In order to determine the association between qualitative variables (reason for request, BMD results), we used a chi square test. A P value <.05 was considered as statistically significant.

Results

During the first year of implementation of the protocol, family physicians requested a total 1,165 densitometries, of which 689 corresponded to new patients classified as postmenopausal. The rest were follow-up densitometries or were indicated in patients not included in the protocol (secondary osteoporosis and others). To evaluate the protocol, data was collected from 560 densitometries (Figure 3) and it was impossible to recover data from 129 applications. The mean age of patients was 63.3 years (SD: 10.2).

Indications for the request

Five hundred two densitometry performed (89.6%, 95%CI: 87.1 to 92.2) met the indication criteria set by the protocol; in the remaining 58 there was no motive that justified the performance of a BMD.

Adequacy of treatment

118 patients yielded a normal BMD result (21.1%). Of these, 106 patients received no drug treatment (89.8%, 95%CI: 84.4 to 95.3), according to the option recommended by the protocol, and the remainder (12 subjects) received treatments indicated by the protocol.

In 249 patients the result was osteopenia (44.5%), of which 206 patients received no drug treatment or received only supplemental calcium and vitamin D. Patients who received drug treatment were, on average, older than those that received no treatment (no statistical significance) and had a lower BMD at the lumbar and femur level ($P<.05$) (Table 1).

193 patients (34.5%) had osteoporosis (included patients with fractures, regardless of the value of BMD). 10 of those patients were not given any treatment, two were treated with dietary measures and

14 received calcium and vitamin D. These 26 patients had a higher lumbar BMD than the group of patients receiving antiresorptive treatment ($P=.001$) (Table 2).

Table 3 shows the number of osteopenic and osteoporotic patients that received treatment considered as of first choice according to their age and/or the location of the fracture.

Spending on drugs for the treatment of osteoporosis in 2007 was EUR 2,271,987 (a reduction of EUR 152 745 [-6.3%] compared to 2006), although the number of patients treated increased from 11527 to 12092 (4.9%) with respect to the previous year. Spending per patient rose from 210 euros per year to 188 euros/year. 88.4% of invoiced containers corresponded to bisphosphonates or raloxifene.

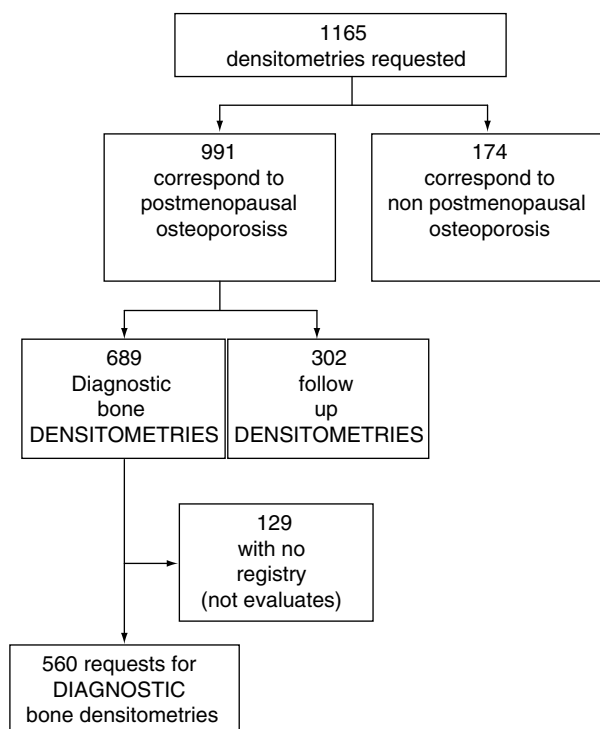


Figure 3. Number of requested and evaluated densitometries.

Evaluation of the results of bone densitometry per age and reasons for request

Of the 560 BMD's analyzed, 442 (78.9%, 95%CI :75.6-82.3) showed osteopenia or osteoporosis.

The average age of women whose BMD results were normal was 59.54 years (SD 9.4), and in the osteopenic patients it was 62.14 years (SD: 9.8), while in osteoporotic patients it was 67.16 years (SD: 9.9), these differences were statistically significant ($P<.05$).

Table 4 shows the most common reasons for requesting a BMD, as well as their results.

Statistically significant differences were observed between the subject regarding the request and the results ($P<.001$): the results of osteopenia or osteoporosis were more frequent when the request was due to a radiological suspicion. Normal results were more frequent when the reason for requesting the test was premature menopause (31.8%) or when the reasons was not given (34.5%).

In requests motivated by early menopause and with a registry of the age since the beginning of menopause ($n=94$), no statistically significant differences were seen in relation to the years since menopause (chi square: 0.874, $P=ns$).

The 86 patients who had any current or prior fracture were older (mean age: 68.4 years [SD: 10.3] vs 62.4 [SD: 9.9], $P<.05$), but not statistically significant differences were found either with the overall result of the BMD, or the value of BMD in the lumbar spine or femur. 15.1% (95%CI 8.3 to 24.5) of these patients had normal BMD values.

Discussion

Protocol implementation has contributed to an efficient management of the clinical approach and treatment of osteoporosis in our area. We have obtained good results in the three objectives that had been proposed.

First, the performance of densitometry has been adjusted, in a great proportion, to the indications contained in the protocol. About 10% of BMD were requested for patients without risk factors considered in the protocol.

The adequacy of treatment has also been high, although there is a percentage of patients with osteoporosis ($n=26$) that, according to the protocol, should have received antiresorptive treatment and did

Table 1

Type of treatment in patients with a result of OSTEOPENIA according to age and T score value of the bone mineral density

Osteopenia	n (%)	Age, years	Lumbar BMD, mean	Femoral BMD, mean
No treatment/dietary advice or treatment with calcium or calcium+vitamin D	206 (82.7%)	Mean=61.72 (SD=9.8)	-1.52	-1.28
Other treatments	43 (17.3%)	Mean=64.12 (SD=9.9)	-1.90	-1.58
T-student		ns	0.38 (95%CI: 0.13-0.63) $P=.003$	0.29 (95%CI: 0.03-0.55) $P=.027$

BMD indicates Bone Mineral Density; SD, standard deviation.

Table 2

Type of treatment in patients with a result of OSTEOPOROSIS, according to age and T score value of bone mineral density

Osteoporosis	n (%)	Age, years	Lumbar BMD, mean	Femoral BMD, mean
No treatment/dietary advice or treatment with calcium or calcium+vitamin D	26 (13.5%)	Mean=66.77 (SD=9.8)	-2.34	-2.39
Antiresorptive treatment	167 (86.5%)	Mean=67.22 (SD=9.9)	-3.11	-2.39
t-student		ns	0.77 (95%CI: 0.30-1.24) $P=.001$	No differences

BMD indicates bone mineral density; CI, confidence interval; SD, standard deviation.

Table 3
Patients with a result of OSTEOPENIA or OSTEOPOROSIS receiving the recommended antiresorptive treatment (1st choice) by the protocol

Osteopenia	n (%)	Recommended first choice treatment	Patients receiving the recommended treatment 95%CI
Age 65 years	26 (60.5%)	Alendronate Risedronate	22 84.6% (65.1-95.6)
Age >65 years Osteoporosis	17 (39.5%)	Raloxifene Alendronate Risedronate	14 82.3% (56.6-96.2)
No fracture or vertebral fracture ≤65 years	76 (45.5%)	Alendronate Risedronate	65 85.5% (75.6-92.5)
No fracture or vertebral fracture >65 years	87 (52.1%)	Raloxifene Alendronate Risedronate	82 94.3% (87.1-98.1)
Non vertebral fracture	4 (2.4%)	Alendronate Risedronate	3 75% (19.4-99.4)

CI indicates confidence interval.

Table 4
Result of the densitometry according to the reason for request

Motive for request	n (%)	Normal	Osteopenia	Osteoporosis
Radiological suspicion	176 31.4%	22 12.5%* (95%CI: 7.6-17.4)	66 37.5% (95%CI: 30.3-44.7)	88 50.0% (95%CI: 42.6-57.4)
Early menopause	110 19.4%	35 31.8%* (95%CI: 23.1-40.5)	53 48.2% (95%CI: 38.8-57.5)	22 20.0% (95%CI: 12.5-27.5)
Radiological suspicion+early menopause	36 6.4%	3 8.3% (95%CI: 1.8-22.5)	19 52.8% (95%CI: 35.5-69.6)	14 38.9% (95%CI: 23.1-56.5)
Radiological suspicion+history of fracture	28 5.10%	4 14.3% (95%CI: 4.0-32.7)	11 39.3% (95%CI: 21.5-59.4)	13 46.4% (95%CI: 27.5-66.1)
Current fracture	26 4.6%	4 15.4% (95%CI: 4.4-34.9)	9 34.6% (95%CI: 17.2-55.7)	13 50.0% (95%CI: 29.9-70.1)
History of fracture	19 3.4%	3 15.8% (95%CI: 3.4-39.6)	10 52.6% (95%CI: 28.9-75.6)	6 31.6% (95%CI: 12.6-56.5)
Other	107 19.1%	27 25.2% (95%CI: 17.0-33.5)	52 48.6% (95%CI: 39.1-58.1)	28 26.2% (95%CI: 17.8-34.5)
No record	58 10.4%	20 34.5%* (95%CI: 22.5-48.1)	29 50.0% (95%CI: 36.6-63.4)	9 15.5% (95%CI: 7.4-27.4)
Total	560	118	249	193

CI indicates confidence interval.

not and, conversely, some patients with normal densitometric results (n=December) who continued antiresorptive treatment. In the case of the osteopenic patients, as expected, the vast majority did not receive antiresorptive treatment. In addition, the profile of patients receiving treatment had lower BMD values at both the lumbar spine as well as in the femoral neck.

This result concurs with that published by Serra et al.⁶ in which it was clear that in osteopenic women, the factor associated with the prescription of drugs was the T-score.

The follow up of the recommendation for the treatment of first choice was also high.

One limitation of the study is the high number of registry losses. In 129 cases it was not possible to obtain data on the outcome of the BMD. This weakens the strength of the protocol.

One result to note is the decrease in drug spending, despite the significant increase in new patients. This result was positively affected by the introduction of reference prices which has affected the most prescribed active ingredient (alendronate). The intervention

has helped prevent a switch to other active ingredients that are not subject to such regulation. This result has an added value, since it has been calculated in all patients in the area and confirmed that the impact of the intervention has an impact on all of the prescription, not only in new patients enrolled according to the protocol.

Currently, we can not know how many new patients start treatment for osteoporosis without following the protocol, but the numbers of new applications for BMD (689) and the number of new patients who have billed drugs for osteoporosis (565) lead us to assume that they are a minority.

The normal BMD are approximately 20%, which can be considered as a very good selection of patients who had an indication for a densitometry. In other published studies addressing osteoporosis in primary care centers, the percentages of pathological BMD were lower.^{7,8}

In our study, the request based on a radiological suspicion has been that which led to more pathological results on the BMD. Moreover, in cases where the application was the result of an unknown motive,

the percentage of normal results was the highest. Many normal results were also obtained in women with premature menopause, regardless of the time since menopause.

There are many guidelines, protocols and recommendations on the strategy of prevention and treatment of osteoporosis, although there is little agreement regarding the indication for densitometry.^{9,10} Some guides recommend the realization of a densitometry based only on age criteria (>65 years), while in others, age is considered along with other risk factors. Similarly, no risk factors are common to all guidelines. For example, early menopause is a factor considered variably by them. Our results are more in line with the guidelines that do not include this risk factor among the criteria for indication of BMD. The studied factor that best predicts the presence of osteoporosis is age as considered in other recommendation sets.^{11,12}

These results confirm that the implementation of protocols, provided they are accompanied by proper monitoring, helps improve the management of clinical decision-making processes. The presentation of the results to all physicians involved keeps them constantly update on this issue.

In light of the results, proposals for the future arise: continue to monitor the new requests for BMD, adjust the indications for new BMD with the results obtained, perform a follow up of the cohort for a longer period of time in order to evaluate the long term impact and involve physicians from other specialties (gynecologists, orthopedic surgeons).

Finally, this study has helped promote the efficiency of the process in the two most controversial aspects¹²: who requests a BMD test and who establishes the drug treatment.

Disclosures

The authors have no disclosures to make.

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