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On behalf of the working group on osteoporosis of the Spanish Society of Internal Medicine
(See Annex 1)

The prevalence of vertebral fractures in patients attending Internal Medicine outpatient clinics

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Summary

Background: Fractures are a clinical complication of osteoporosis, and among them vertebral fractures (VF) are the most frequent. This type of fracture is often asymptomatic or happens unnoticed and is not diagnosed.
Objective: To study the prevalence of previously non-diagnosed vertebral fractures in a population of post menopausal women over 50, who have attended an Internal Medicine outpatient clinic because of chronic back pain.
Material and methods: 273 women participated in the study, which comprised a group of cases (Group I) and a control group (Group II). Group I consisted of 202 post-menopausal women who had chronic back pain at the time they attended one of 13 Internal Medicine outpatient clinics across Spain. Group II was made up of 71 women who did not have back pain, and who were used as controls. To register any risk factors for osteoporosis, and any clinical symptoms, a questionnaire, previously validated and used in other similar clinical studies by SEIOMM members, was completed for all the female patients. A lateral thoracic and lumbar X-ray was also carried out on all female patients. The interpretation of the X-rays was done centrally. The Genant criteria for vertebral deformity were used for the diagnosis of the vertebral fractures.
Results: The post-menopausal women with chronic back pain were shorter in height than those who did not have back pain (154 ± 7.7 cm compared with 157 ± 7.7 cm, p= 0.005), they had a greater prevalence of kyphosis (54% vs 32.4%) and a higher prevalence of VF (15.8% vs 2.8%, p= 0.004). No statistically significant differences in the prevalence of fractures in total, hip fractures, Colles fractures and other fractures, were found between the two groups. BMI, VFs and kyphosis showed an independent and statistically significant association with back pain.
Conclusions: At the time of the study 15.8% of post-menopausal women with chronic back pain presented with at least one VF. In addition, they had a higher prevalence of kyphosis, and were on average 3cm shorter, than the women without back pain. Given that these fractures were not previously diagnosed, we suggest carrying out a lateral thoracic-lumbar X-ray on these patients, in order to establish a diagnosis and to start treatment as soon as possible.

Key words: *Vertebral fracture, Osteoporosis, Prevalence, Back pain.*

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Introduction

Osteoporosis is a very common disease which predominantly affects older women, although it can affect both sexes[1,2]. It is estimated that from the age of 50 white women have a risk of osteoporotic fracture of almost 50% for the rest of their lives[3].

Fractures are a clinical complication of osteoporosis[4] and among them vertebral fractures (VF) are notable for their frequency, while notable for their seriousness are fractures of the proximal extremity of the femur – or fracture of the hip[3,5].

VFs, being the osteoporotic fracture most prevalent, often occur unnoticed and are not diagnosed. This is because on the one hand diagnosis requires a lateral X-ray of the spinal column, with the application of criteria for vertebral deformity which often don't coincide[6,7], while on other hand VFs can be asymptomatic[8]. In addition, back pain, which can be a symptom of VF, is often attributed to other diseases, or even to age.

Because of this we have carried out this study in a population of women who attended an Internal Medicine clinic suffering from chronic back pain, with the objective of studying in these patients the prevalence of undiagnosed VF.

Material and methods

This work is a prospective study, with cases and controls, in which the cases were post-menopausal women over 50 who attended an Internal Medicine outpatient clinic, presenting with chronic back pain. The following criteria for including patients in the study were used: a) having back pain, located in the dorsal and/or lumbar spinal column; b) that the pain was present for at least 3 months and; c) that there was no already-known cause for the pain. Back pain located in the dorsal and lumbar spinal column was included, while pain in the cervical spinal column was excluded. The control group was made up of women of the same age with no back pain, friends, but without family connections, invited by the patients themselves, not having had dorsal or lumbar back pain for at least 6 months before the consultation, and not having taken any treatment for this condition during the same period of time.

The patients were informed of the objectives of the study and their consent requested. For all subjects a questionnaire, previously validated and used in other similar clinical studies[9-11], was completed to gather clinical data on osteoporosis. A basic physical examination was also conducted, including measurement of height and weight in light clothing. Lastly, a lateral thoracic-lumbar X-ray was carried out on the subjects. All the X-rays were brought together and studied by two radiologists (PA and RFP, see Annex 1). In cases of discrepancy an assessment was requested from a specialist in bone mineral metabolism (MSH). For the diagnosis of VF the Genant criteria[12], were used. The study was carried out with approval of the Committee on Medical Trials of the Island University Hospital of Gran Canaria.

The data collected were entered into a database already set up in the statistical programme SPSS (Statistical Package for the Social Sciences), for which we had the necessary legal licences. For the analysis of the data the Kolmogorov-Smirnoff test was applied to establish the goodness of fit to normality for the variables studied. For each group studied, the variables categorised were summarised in frequencies and percentages and the numericals in averages and standard deviations. The percentages were compared using the chi–square test and the averages using the t-test. Those variables which showed a significant association with the final objective (endpoint) were subjected to a multidimensional logistic analysis. A retrospective selection of variables based on the test of ratio of verisimilitude was carried out. The association of each variable selected with the final objective was expressed through the p-value deduced from the final logistical model and the *odd-ratio*, which was estimated with a confidence interval (CI) of 95%. A contrast of hypothesis was considered significant when the corresponding p-value was less than 0.05.

Results

A total of 273 post-menopausal women, 202 cases and 71 controls participated in the study, recruited by a total of 13 working groups across Spain. In Table 1 the basal characteristics of the population studied are shown. The average age of the participants was in the region of 70 years (69.7 ± 11.0 years in the cases and 71.3 ± 11.3 years in the controls) with no statistically significant difference between the two groups. Neither was their any difference in the weight (66.3 ± 14.0 Kg as opposed to 65.5 ± 12.6 Kg, p= 0.687) nor in the body mass index (28.0 ± 5.5 Kg/m² as opposed to 26.7 ± 4.8 Kg/m², p= 0.081). The women who had back pain were shorter in height than the controls (154 ± 7.7 cm as opposed to 157 ± 7.7 cm, p= 0.005).

Table 2 shows the prevalence of other concomitant diseases and lifestyle determinants in both groups in the study. One can see that more than half (54%) of those women who have back pain also have kyphosis, a sign which is seen in less than a third of the women who do not have back pain (32.4%), p= 0.002. The distribution of the other diseases - diabetes, chronic renal failure, obesity and dyslipidemia – as well as some lifestyle and risk factors – alcohol consumption and family history of osteoporotic fractures – were similar in both groups.

In Table 3 we observe the distribution of fractures in both groups. 15.8% of post-menopausal women with back pain have, at least one VF, whilst in the control group we see that the prevalence is 2.8%, p= 0.004. The distribution of other fractures was similar in both groups: all fractures, Colles fracture, hip fracture and other fractures.

Finally, a multidimensional logistic analysis was carried out to discover which factors show an independent association with back pain. The results of this analysis, set out in Table 4, show these factors as being the body mass index, the existence of VFs and Kyphosis, with VFs being the variable which shows the strongest independent association (OR 6.325, CI: 1.450; 27.6, p= 0.014).

Discussion

Fractures due to fragility constitute the principal clinical complication of osteoporosis, and among these VF has a special importance. A broad epidemiological study carried out in Europe demonstrated that between 20% and 25% of the population over 50 of both sexes have a VF[13], which often occurs unnoticed, since it is the only fracture in which there is neither a line of fracture nor a break in continuity between the extremes. VF can consist of a deformity, or crushing, of its morphology, requiring for its correct diagnosis, in addition to a lateral thoracic-dorsal X-ray, the application of what are known as criteria of vertebral deformity[6], of which there are many, few of which coincide[7,12]. This was observed in EVOS study, which found almost double the prevalence of VF whether they applied the deformity criteria of Eastell or McCloskey[13]. Another factor which leads to VFs being underestimated is the fact that they are sometimes asymptomatic, or are experienced as short term back pain[4,14].

VF is in itself a risk factor in suffering a new fracture, be it vertebral or hip[15,16]. A study has been published which states that 20% of women with VF without treatment suffer a new VF within a year[17], without forgetting that VF, as with the remaining osteoporotic fractures, carries a higher morbidity[5] and leads to an increase in mortality[18,19]. Hence the importance recognising this.

Our study was carried out with a population of patients who attended an Internal Medicine outpatient clinic because of back pain, or in whom this was confirmed when their clinical history was taken, this not having been the explicit reason for their attendance at the clinic. Our aim was to make a first attempt at understanding the prevalence of VF in these ambulatory patients, a study motivated by the results we obtained from other work carried out by the working group on osteoporosis of SEMI, in which we found a higher prevalence of VF, 62.6%, in those patients who were admitted and treated for a hip fracture[11]. Although in this population of high risk for osteoporosis this result was no surprise, it was surprising that in the control group in this study, who were chosen from among patients admitted to the Internal Medicine wards for other processes unrelated to OP and without apparent high risk of osteoporosis, showed a prevalence of VF of 50%. In the current study 15.8% of postmenopausal women with back pain have at least one VF, whilst in the control group this prevalence was only 2.8%. Previously, another co-operative European study confirmed that up to 25% of postmenopausal women have at least one VF[12], however, the same study clearly stated that many of these fractures were asymptomatic. However, all the patients in our study should be considered as having symptomatic fractures since they attended precisely for back pain. We do not know the reasons why the prevalence of vertebral fractures in the control group was so low.

We did not find statistically significant differences in the distribution of other diseases such as diabetes, obesity, chronic renal failure and dyslipidemia, or in the distribution of some lifestyle and risk factors such as tobacco and alcohol consumption, or family history of osteoporotic fractures. As was expected, women with VF had a higher prevalence of kyphosis than the controls. On the other hand we did not find any statistically significant differences in other fragility-related fractures, neither in general, nor independently in hip fractures, Colles fractures or other fractures, including fractures of humerus, tibia and ribs.

By carrying out a multidimensional logistic analysis we found an independent association between back pain and the variables BMI, VF and kyphosis. We interpreted these results as being interrelated. We

Table 1. Basal characteristics of the population studied

	Back pain		
	Yes N = 202	No N= 71	Value of p
Age (years)	69.7 ± 11.0	71.3 ± 11.3	0.294
Weight (kg)	66.3 ± 14.0	65.5 ± 12.6	0.687
Height (cm)	154 ± 7.7	157 ± 7.7	0.005
BMI (kg/m^2)	28.0 ± 5.5	26.7 ± 4.8	0.081

Body Mass Index (BMI): Weight (kg)/height^2 (cm)

Table 2. Prevalence of concomitant diseases in the groups of the study

	Cases Number (%)	Controls Number (%)	Value of p
Number	202 (100)	71 (100)	
Diabetes	37 (18.3)	18 (25.7)	0.184
Obesity	65 (32.3)	16 (22.9)	0.136
Chronic renal failure	19 (9.9)	4 (6.1)	0.340
Tobacco	13 (6.4)	6 (8.5)	0.566
Alcohol	6 (3.0)	3 (4.3)	0.601
Dyslipidemia	76 (38.4)	27 (39.7)	0.847
Family history of osteoporotic fractures	44 (22.0)	16 (20.6)	0.807
Kyphosis	107 (54.0)	22 (32.4)	0.002

Table 3. Prevalence of fractures by group studied

	Cases Number (%)	Controls Number (%)	Value of p
Presence of any fracture	90 (44.6)	28 (39.4)	0.454
Vertebral fracture	32 (15.8)	2 (2.8)	0.004
Hip fracture	16 (7.9)	11 (15.5)	0.066
Colles fracture	20 (9.9)	10 (14.1)	0.332
Other fractures	32 (15.8)	12 (16.9)	0.835

Table 4. Multidimensional logistic analysis: factors having an independent association with back pain

Factor	Value of p	Odd Ratio (CI – 95%)
BMI (Por Kg/m²)	0.030	1.066 (1.005 ; 1.130)
Vertebral fractures	0.014	6.325 (1.450 ; 27.6)
Kyphosis	0.008	2.246 (1.237 ; 4.077)

believe that the higher the BMI, the greater back pain is observed in patients who already have at least one VF, which in turn influences the development of kyphosis.

In conclusion, VF is found in 15.8% of post-menopausal women who have back pain, as well as a higher prevalence of kyphosis. Given that up to 20% of women who have a VF and have not had treatment suffer a new VF within one year[16], it is advisable to take into account this fact with a view to indicating the most appropriate therapeutic measures at the time.

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Annex 1: Members of the working group on osteoporosis of SEMI (GTO-SEMI)

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