Osteoporotic women with fractures show greater therapeutic compliance than those without fractures

Correspondence: Manuel Sosa Henríquez - c/Espronceda, 2 - 35005 Las Palmas de Gran Canaria (Spain)  
e-mail: msosa@ono.com

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Summary

Background: Fractures are a clinical complication of osteoporosis. Sufficient therapeutic compliance is necessary to reduce the risk of fracture. The literature suggests that a significant percentage of patients with osteoporosis soon abandon treatment, both drugs and calcium and vitamin D supplements.

Objectives: To study the degree of compliance with osteoporosis therapy in a population of women affected by the disease, with and without fragility fractures.

Patients and method: 413 women with a diagnosis of osteoporosis already established were included in the study consecutively, as they attended a health centre, without any selection or recruitment campaign.

Results: 38.6% of the women had suffered at least one fragility fracture, the most frequent being non-vertebral fractures as a whole, followed by vertebral fractures. Fractured patients had an average age 5 years older than those without fractures. The overall proportion of patients who were taking regular treatment was 66.1%, with the proportion of compliant patients being higher in those who had a fragility fracture, at 75.9% for those taking drugs in general and 84.1% for those taking calcium and vitamin D supplements, as against 59.7% and 68.4% respectively for those without fracture (p<0.001).

Conclusions: Those women affected by fragility fractures were older and had a greater adherence to treatment, both for drugs in general and for calcium and vitamin D supplements, than patients with osteoporosis without fractures. Non-vertebral fractures were those most commonly observed fractures.

Key words: osteoporosis, Primary care, fractures, treatment, compliance, calcium, vitamin D.
Introduction
Osteoporosis is a highly prevalent disease which may be treated by different medical specialists, including family doctors.

Primary care doctors form the base of the National Health System (Sistema Nacional de Salud) and are the main point of access for patients7.

The interest in and involvement of primary care doctors in the prevention diagnosis and treatment of osteoporosis is indicated both by the existence of working groups on this disease in their scientific societies, and by the scientific documents which they generate8-14.

However, there are questions regarding the treatment of osteoporosis which have not yet been resolved. One of these is that patients affected by osteoporosis and with fragility fractures are not indicated for treatment15. Another is that once indicated, the patients abandon treatment after a certain period of time, or do not follow the treatment correctly, which is to say that they have poor persistence or adherence7-13, which leads to an increase in the risk of fracture15-17.

We carried out this study in a population of patients previously diagnosed with osteoporosis and monitored by their primary care doctors, with the aim of understanding some of their clinical characteristics and the possible differences in their adherence to treatment, depending on whether or not they have fragility fractures.

Patients and methods

Context of study and selection of patients

All primary care doctors in all the health centres in the island of Gran Canaria participated in this study between 1st March and 30th September 2013. Their relationship is shown in Annex 1. The objective was to include 500 patients of both sexes affected by osteoporosis. In the end, 439 patients who met the inclusion criteria, and who had previously been diagnosed with osteoporosis, this diagnosis having been confirmed in their electronic primary care medical record, were recruited.

This study did not try to establish, confirm or question the diagnosis of osteoporosis, but this was accepted as an assumption, the diagnosis having taken place at another medical appointment. This could either have been in the primary care clinic of the same doctor, or through a referral to a specialist, either in specialist clinics (Centros de Atención Especializada [CAEs]) or to a hospital, mainly the Bone Metabolism Unit of the Island University Hospital (Hospital Universitario Insular).

Each doctor included their patients in the study as they attended the health centre, either for monitoring or review, without any selection. After informing the patient of the objectives of the study their informed consent was requested to include their data in a questionnaire designed for this purpose, a modification of the Prochasa-Diclemente test8.

The study was approved by the ethics committee of the Mother and Baby Island Hospital (Centros de Atencíon Especializada [CAEs]) or to a specialist, either in specialist clinics (Centros de Atención Especializada [CAEs]) or to a hospital, mainly the Bone Metabolism Unit of the Island University Hospital (Hospital Universitario Insular).

Results

A total of 500 patients participated in the study. Figure 1 shows the organogram of the patients who met the inclusion and exclusion criteria for this study.

The proportion of patients who received vitamin D and calcium supplements was higher than those with fractures treated again being higher than those without fracture, p<0.001.

With respect to the distribution of fractures, the non-vertebral fractures were the most frequent...
(38.6%), followed by vertebral fractures, which made up 24.1% of the total of fractures. In this series 22.8% had had more than one fracture, whether they were vertebral or non-vertebral. Lastly, the most common non-vertebral fracture was the Colles fracture at 13.3%.

In carrying out a multidimensional logistic analysis (Table 2), we found that only 2 variables were statistically significantly associated with the presence of fragility fractures, which were age and the current consumption of calcium and vitamin D.

Discussion

Our study was aimed at trying to understand some of the clinical characteristics and degree of compliance with treatment in a population of patients of both sexes affected by osteoporosis in primary care. To achieve this, the design was intended to gather data from 500 patients diagnosed with osteoporosis, who attended the health centre for themselves. None of the patients were called to be included on the study.

We were therefore surprised by the low number of male participants, with only 20 out of a total of 500 included initially. This led us to exclude them from the subsequent statistical studies, since comparisons made between such disparate sample sizes seemed to us not to be reliable.

For us, this finding confirms one of the facts observed in the field of osteoporosis, which is that males are probably underdiagnosed and that they make up a smaller proportion of cases than women, in spite of the fact that osteoporosis affects, although not to the same extent, both sexes. The average age of all the patients with osteoporosis was 71.5 years. In addition, the women with fractures were older than those without (74 vs 69.8 years of age), all of which confirms that osteoporosis is a disease which affects older women, in whom, on our opinion, both preventative and therapeutic activities should be focused. Given that fragility fractures are a clinical complication of osteoporosis, treatment should be aimed at preventing its appearance, be it for the first time or as re-fractures. The achieve this aim, it is essential that patients carry out the treatment correctly, since no drug reduces completely the risk of new fractures and, furthermore, it has been observed that when patients do not take their medication correctly protection against fracture is reduced.

So, our findings are moderately optimistic since 66.1% of the patients with osteoporosis were receiving treatment at the time of completion of the survey, this being higher among those who had suffered a fragility fracture, reaching 75.9%, a statistically significant difference. Similar and even better results were observe with calcium and vitamin D supplements, with 74.6% of all those women affected by osteoporosis taking these supplements at the time of the interview, increasing to 84.1% in the case of patients with fractures, the difference again being statistically significant. Classically, it has been reported that patients affected by osteoporosis, in general, complied poorly with treatment, both with anti-resorptive drugs, especially the bisphosphonates, and with the anabolics, and in a more fundamental way, with calcium and vitamin D supplements. In some series it has been reported that the first thing that patients stop taking correctly is precisely calcium and vitamin D, which is exactly the opposite to what we found in our study, where 84.1% of the fractured patients took calcium and vitamin D, while only 75.9% took any other drug.

The patients had suffered a fragility fracture in 39.6% of cases (Table 3), and of these, the most common fractures were non-vertebral, which were recorded in 38.6% of these patients, followed by vertebral fractures (24.1%). We have separated the hip fractures from the non-vertebral fractures, and have grouped these in a different section since we believe that due to their mortality and morbidity they should not be included in the same group as, for example, fractures of the rib. We should highlight the fact that 22.8% of the patients had suffered various fractures, vertebral and non-vertebral combined.
Finally, the multidimensional logistic analysis, which is shown in Table 2, identified the variables associated with the existence of fractures within the population studied. We found, in first place, age, which is an all too well-known fact. Fragility fractures, even though they can be observed at any age, are more frequent the older the patient. The other data obtained was the current intake of calcium and vitamin D, which we believe is a consequence and not a cause, and that precisely due to their having suffered a fragility fracture the patients were better at taking the calcium and vitamin D treatment.

Our study has some limitations. Firstly, we could only included a small number of males, as has already been mentioned, having had, therefore, to restrict the study to women. Another limitation is not having estimated more precisely the adherence and persistence of the patients, using, for example the Morisky scale. And lastly, a description of the different drugs used was not included in the design of the study. However, one of its strengths is that we have been able to carry out one of the first co-operative studies between primary care, hospital care (Bone Metabolism Unit) and the University of Las Palmas Gran Canaria, which has enabled us to consolidate the Canarian working group on osteoporosis.

In summary, adherence to treatments for osteoporosis in the population studied, is acceptably high, and is higher in women who have suffered a fragility fracture.

**Annex 1. Members of the Working Group on osteoporosis canary**


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### Table 1. Clinical characteristics of patients included in the study, classified by the presence or absence of fractures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total N=419</th>
<th>Fractures N=166 (39.6%)</th>
<th>No fractured N=253 (60.4%)</th>
<th>Value of P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>71.5±10.2</td>
<td>74.0±9.5</td>
<td>69.8±10.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time since diagnosis of osteoporosis (years)</td>
<td>6.1±3.5</td>
<td>6.1±3.5</td>
<td>6.1±3.5</td>
<td>0.980</td>
</tr>
<tr>
<td>Currently receiving treatment</td>
<td>277 (66.1%)</td>
<td>126 (75.9%)</td>
<td>151 (59.7%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Take calcium and vitamin D today</td>
<td>309 (74.6%)</td>
<td>138 (84.1%)</td>
<td>171 (68.4%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Table 2. Multidimensional logistic analysis

<table>
<thead>
<tr>
<th></th>
<th>P value</th>
<th>OR (IC 95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, per year</td>
<td>&lt;0.001</td>
<td>1.049 (1.027;1.072)</td>
</tr>
<tr>
<td>Currently taking calcium and vitamin D</td>
<td>&lt;0.001</td>
<td>2.758 (1.651;4.610)</td>
</tr>
<tr>
<td>Fracture type</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>--------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Vertebral</td>
<td>40 (24.1)</td>
<td></td>
</tr>
<tr>
<td>Hip</td>
<td>24 (14.5)</td>
<td></td>
</tr>
<tr>
<td>Non-vertebrales*</td>
<td>64 (38.6)</td>
<td></td>
</tr>
<tr>
<td>Colles</td>
<td>22 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Humerus</td>
<td>13 (7.8)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>29 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Various**</td>
<td>38 (22.8)</td>
<td></td>
</tr>
</tbody>
</table>

* Includes patients with a vertebral fracture than hip or.
** Included patients with multiple fractures of any type: vertebral, non-vertebral or hip.

** Table 3. Distribution of fractures **

** Bibliography **