Could the FRAX® index modify the treatment of osteoporosis?

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Summary

Introduction: The FRAX® index is an algorithm devised by the WHO which, by evaluating risk factors, calculates the absolute risk of suffering any osteoporotic fracture or hip fracture in the subsequent 10 years. The aim of this work is to ascertain the risk of fracture in patients with suspected osteoporosis, using the FRAX® tool, and to ascertain how therapeutic decisions would be modified if these criteria were used.

Patients and method: The patients were drawn from a list of densitometries (DXA) carried out in the Hospital of Torrevieja during the first quarter of 2009. Using simple random sampling 110 women were selected, of whom 90 participated in this study. The FRAX® tool was applied to all of them, recording the treatment for osteoporosis which they were following, and the service which had initiated the prescription. A value of >10% for the principal fracture, and a value of 3% for a hip fracture, were considered to indicate a high risk of fracture.

Results: Fifteen patients (16.66%) had a FRAX® index with a high risk of fracture. Only 23% of patients in treatment had a FRAX® index with a high risk of fracture. 40% of those patients with a high risk FRAX® index were not taking any specific treatment.

Conclusions: The use of the FRAX® tool may change the indication for treatment in many patients in whom the decision had been based only on bone densitometry.

Key words: FRAX® index, treatment, osteoporosis.
Introduction

The objective of all treatment for osteoporosis is the prevention of fractures both in the hip, due to the fact that they result in higher rates of mortality and disability, as well as osteoporotic fractures in other part of the skeleton due to their frequency and relationship with a reduction in survival rates and in the quality of life of the patient.

For many years, the main reference used to take therapeutic decisions has been the evaluation of densitometric values, given that on these have been based the guides which we have used since recently.

However, although bone densitometry continues to be considered as the test of choice for the diagnosis of osteoporosis and the principal predictor of fractures, it is unquestionably the case that it has limitations, making its use as the single factor in establishing treatment for the disease inadvisable.

Without a doubt, a fracture is a multifactorial outcome in which are involved factors which, along with age, influence the bone mass and architecture, in short bone resistance, such as the body mass index, history of other fractures, genetics, intake of pharmaceutical drugs, alcohol and other bone-related factors, which may be related to increased risk of falls, such as functional or visual deficiencies, intake of hypnotics, etc.

After significant clinical trials and major cohort studies, different combinations of these factors have generated the appearance of scales of risk: the National Osteoporosis Foundation (NOF) index, the Fracture Index, the Osteoporosis Risk Assessment Instruments (ORAI) test, etc. However, in each case the diversity of factors and the lack of a hierarchy within them has resulted in them seldom being used in normal clinical practice.

To facilitate the use of risk factors a team from the University of Sheffield, led by Professor Kannis and under the auspices of the WHO, created FRAX® (Fracture Risk Assessment Tool), a tool accessible over the internet which measures the absolute risk of suffering an osteoporotic fracture in the next ten years. FRAX® is the result of a study of significant risk factors from a study of nine prospective populational studies, which analysed data from thousands of people.

The following risk factors are used in the calculation of the risk of fracture, although not all have the same strength of association: age, sex, body mass index, parental history of hip fracture, being an active smoker, treatment with glucocorticoids for more than 3 months, suffering rheumatoid arthritis, suffering metabolic disorders which provoke secondary osteoporosis, daily intake of more than three units of alcohol, to which may be added bone mineral density (BMD) measured in the femoral neck. Using this data FRAX® will provide us with two values of absolute risk of fracture: Hip Fracture (HF), absolute risk of suffering a hip fracture in the next ten years; and Major Fracture (MO), for the combination of fractures in the humerus, wrist, vertebrae and hip; the quantitative value of the risk should be an essential element for the indication of a specific treatment for osteoporosis.

In spite of its limitations, the possibility of having available a tool which is easy to use, available on the web and capable of quantifying levels of risk, could be a great help when taking therapeutic decisions for patients with osteoporosis.

The objective of this study is to discover the risk of fracture in a group of patients of the Torrevieja Health Department with suspected osteoporosis, using the FRAX® tool in a simulated way, and to confirm whether the professionals in our department have adjusted to the recommendations extracted from the FRAX® values for the initiation of the treatment.

Patients and method

The patients were identified through bone densitometries (DXA) carried out in the radiological service of our hospital during the first quarter of 2009. During this period 1,108 tests were performed for the department, and, using a simple random sample of those performed in women, 110 patients were selected.

Between the months of May and June of 2009, the patients were contacted by telephone to ask their oral authorisation to participate in the study and an appointment made in the rehabilitation service for the completion of a questionnaire.

Five patients (4.54%) declined to participate in the study, two (1.81%) had an insoluble language barrier (they spoke neither English or Spanish), and thirteen (11.81%) could not be located.

In total, ninety patients made up the sample, fifty four of whom (60%) attended the hospital, with thirty six having problems of availability or transport, so the questionnaire was completed over the telephone (40%). In all the cases the following variables were recorded:

- Antiresorptive-osteoformative treatment for osteoporosis, with the possibility of their taking the following active compounds being evaluated: etidronate, alendronate, risedronate, ibandronate, raloxifene, calcitonin, strontium ranelate, teriparatide and PTH 1-84.

- The service to which the professional who initiated the treatment belonged.

- Risk of fracture using the FRAX® index, complementing this in all cases with the BMD in the femoral neck. The risk was considered to be high for a hip fracture when the HF value had levels equal to or higher than 3, and for a major fragility fracture, when the MO was higher than or equal to 10.

The study was authorised by the Research Committee of the Hospital of Torrevieja.

Statistical method

A descriptive statistical analysis was carried for each variable, obtaining the frequency distribution for the quantitative variables, the characteristic parameters were calculated: mean, standard deviation, maximum and minimum.
Results
The patients had an average age of 64.22 years (40-88 years), with a standard deviation of 11.24.

Thirty nine patients (43.33%) were receiving specific antiresorptive/osteofromative treatment.

With regards to the prescribing service, primary care was the service which indicated the treatment on most occasions, 20 (53%); followed by rehabilitation, 9 (23%); rheumatology, 8 (20%); the gynaecology and traumatology services having initiated the prescription on one occasion (2.5%).

Fifteen patients (16.66%) had a high risk of fracture according to the FRAX® index, with high parameters for HF and MO (Table 1).

In analysing the treatment adjusted to the risk factors according to FRAX® it was found that 23% of the patients treated had a FRAX® level indicating a high risk of fracture, and 40% of patients with a high risk of fracture did not receive treatment (Table 2).

Discussion
Our study is a simulation of how therapeutic decisions may have been modified had the FRAX® tool been used before the initiation of treatment for osteoporosis, and, while it has clear limitations, such as the size of the sample and the fact that we applied the FRAX® tool in patients who had already initiated treatment, we believe that it reflects the reality of normal clinical practice.

In the results we obtained we can observe that if the criteria were to have been based on the FRAX® tool only 23% of the patients treated would have had to have initiated therapy; which is to say that 77% of the prescriptions would have been of dubious justification: figures much higher than those found by other authors, although it is possible that in some cases the presence of earlier fractures may have been the determining factor at the time of prescribing the treatment. What seems to us even more worrying is that 40% of patients with high risk of suffering an osteoporotic fracture according to the FRAX® index did not receive any antiresorptive/osteofromative treatment.

In short, if FRAX® had been taken as a reference the number of prescriptions would have been reduced significantly. However, we must admit that FRAX® is not a perfect tool and, from its inception, it has been accused of having some defects, such as not evaluating the BMD in the spinal column, the intake of calcium, levels of vitamin D, or the frequency of falls, among other factors, which may result in it underestimating the risk of fractures. In addition, there is not yet a single clinical trial published which demonstrates that the tool is useful in the prevention of fractures.

Another difficulty, of a local nature, is that there is no recognised cut off point for therapeutic intervention for Spain. In our study we have used the values of 3% for absolute risk of hip fracture and 19% for major osteoporotic fractures, since it is the lower cut off value communicated by Spanish authors.

In spite of its limitations, we are of the opinion that the introduction and dissemination of FRAX® will provide a good tool to support therapeutic decision-making, since it is able to quantify the weighting of the different risk factors. Its ease of use, accessibility on the web and clarity could result in its rapid inclusion in normal clinical practice, something which has not happened with other indices, and the more than 55,000 daily visits is indicative of its massive use.

In addition, this tool is able to correct an anomaly caused by the excessive weight given to densitometry when prescribing antiresorptive/osteofromative drugs, which tends to concentrate treatment on younger patients, where the risk of suffering fractures, in spite of their having osteoporotic values, is low.

This situation could cause a range of problems, one of which would be the cost to the health system, due to a significant change in cost-benefit, or the possible abandonment of treatment in older age, precisely when the risk of fracture is highest, either by boredom or by potential adverse effects provoked by prolonged periods of therapy, such as a deterioration in bone quality and the appearance of atypical fractures, which are attributable to long periods of treatment with bisphosphonates.

The work of disseminating the importance of risk factors, and in particular the use of the FRAX® tool should be carried out in all specialisms which usually treat patients with osteoporosis, especially among primary care doctors, since in some health regions, as in our case, they play a major role in this pathology.
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Bibliography