



Original Article

Primary and secondary osteoporotic fractures prophylaxis: evaluation of a prospective cohort[☆]



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ABSTRACT

Objective: To measure the prevalence of primary drug prevention of fractures due to osteoporosis in patients admitted to a tertiary teaching hospital, in a medium-sized city, admitted with osteoporotic fractures. Moreover, to identify the incidence of prescribing secondary prophylaxis after the first fracture event. At the same time, the prevalence of risk factors for such fractures as described in the literature was measured.

Methods: This longitudinal prospective study was based on a cohort of patients admitted in a tertiary teaching hospital from October 2015 to January 2016. Patients with low energy or fragility fractures were included in the study regardless of gender or race, over the age of 50 years. All patients who did not have these characteristics were excluded. The follow-up lasted four months. Serial questionnaires were applied at admission and in the follow-up consultations at four to eight weeks and at 16 weeks.

Results: Only one patient reported receiving treatment with specific drugs for the disease before hospital admission, resulting in a prevalence of primary chemoprophylaxis of only 2.27%. No patient was prescribed medication for the treatment of osteoporosis after the fracture. The prevalence of risk factors was similar to those found in the literature review.

Conclusion: In the present study, the frequency of primary and secondary osteoporosis chemoprophylaxis in patients who were admitted with fragility fractures was low, as well as the early indication of drug treatment after the first fracture. The prevalence of fragility fracture risk factors is similar to those reported in the literature.

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Profilaxia primária e secundária de fraturas osteoporóticas: avaliação de uma coorte prospectiva

R E S U M O

Palavras-chave:

Osteoporose/epidemiologia
Osteoporose/terapia
Fraturas ósseas/epidemiologia
Fraturas ósseas/prevenção & controle
Prevenção primária
Prevenção secundária
Fatores de risco

Objetivo: Medir a prevalência da profilaxia medicamentosa primária de fraturas por osteoporose em pacientes internados em um hospital terciário de ensino, em uma cidade de médio porte, admitidos com fraturas osteoporóticas. Além disso, identificar a incidência de prescrição de profilaxia medicamentosa secundária após o evento da primeira fratura. Paralelamente, medimos a prevalência de fatores de risco para fratura por osteoporose descritos na literatura.

Método: Estudo longitudinal de uma coorte prospectiva de pacientes admitidos em hospital terciário de ensino de outubro de 2015 a janeiro 2016. Foram incluídos pacientes com fraturas de baixa energia ou por fragilidade, independentemente do gênero ou etnia, acima de 50 anos. Todos os pacientes que não apresentavam essas características foram excluídos. O seguimento foi de quatro meses. Foram aplicados questionários seriados na admissão, no retorno com quatro a oito semanas e com 16 semanas.

Resultado: Somente um paciente referiu ter recebido tratamento com drogas específicas para a doença antes da internação hospitalar, o que revela uma prevalência de quimioprofilaxia primária de apenas 2,27%. Nenhum paciente recebeu prescrição para tratamento da osteoporose após a fratura. A prevalência dos fatores de risco de fratura se assemelha àquela encontrada na literatura.

Conclusão: A frequência de quimioprofilaxia primária e secundária da osteoporose em pacientes admitidos com fraturas por fragilidade é baixa em nosso meio, assim como a indicação precoce de tratamento medicamentoso após a primeira fratura. A prevalência dos fatores de risco de fratura por fragilidade é semelhante àquela citada na literatura.

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Introduction

Osteoporosis (OP) is a chronic, progressive, osteometabolic disease characterized by a decrease in bone mineral density (BMD), and due to the deterioration of bone microarchitecture, leading to mechanical fragility and predisposition to spontaneous and traumatic fractures.^{1,2} The estimated world predominance is 7% in males and 17% in females.³ In Brazil, it accounts for about 10 million cases per annum.³⁻⁵ The risk of fractures due to osteoporosis is higher in females, and increases with age; they are associated with high rates of morbidity and mortality.⁶

The most common sites of involvement are the distal end of the radius, vertebrae, proximal femur, proximal humerus, proximal tibia, ankle, and pelvis.⁷ Diagnosis and therapeutic planning are performed and based on BMD, which is the best predictor of fractures.⁸

Most patients presenting with osteoporotic fractures have never previously undergone BMD measuring, a surprising fact if we take the epidemiological data of OP into account, and because it is an easily preventable complication.⁹ The early diagnosis and consequent treatment of the disease reduce the rate of morbidity and mortality.¹⁰

Although there is no consensus as to who is responsible for initiating secondary prophylaxis after the first fracture, any physician who evaluates this patient should consider the

multiple treatment options.^{10,11} The timing for hospitalization due to a fracture is a great opportunity for patients and their families to be aware of the disease and of the importance of the therapeutic intervention, since the presence of a fracture in a fragile bone is a sufficient factor for the diagnosis of OP, regardless of other tests.¹⁰ Secondary pharmacological prophylaxis (prevention of new fractures) can be performed with the use of different drugs, with some being available in the Brazilian Public Health System (SUS).¹¹

The objectives of this study were to measure the prevalence of primary drug prophylaxis of osteoporosis in patients admitted to a tertiary teaching hospital in a medium-sized city, admitted with osteoporotic fractures. In addition, to identify the incidence of prescription for secondary prophylaxis of fractures after the event of the first fracture. At the same time, we measured in our sample the prevalence of known fracture risk factors in the literature.

Methodology

This is a prospective longitudinal study based on a cohort of consecutive patients admitted to a tertiary teaching hospital from October 2015 to January 2016. The present study was approved by the Ethics and Research Committee (CAAE 46809015.1.0000.5103). We included all patients with fractures, regardless of gender or ethnicity, who were older than 50 years and had a diagnosis of low-energy or fragility

Table 1 – Demographic characteristics of patients attended with osteoporotic fracture.

Characteristic	Type	Prevalence
Gender	Female	31 patients
	Male	13 patients
Age		69.09 ± 10.93 years
Ethnicity	White	30 patients
	Black	5 patients
	Brown	9 patients
BMI		25.12 ± 4.83
History of smoking		18 patients (40.9%)
History of alcoholism		11 patients (25%)
Bone affected	Femur	12 patients (27.2%)
	Radius	10 patients (22.7%)
	Humerus	9 patients (20.4%)
	Tibia	5 patients (11.3%)
	Ankle	4 patients (36.4%)
	Ulna	2 patients (4.5%)
	Fibula	1 patient (2.3%)
	Scaphoid	1 patient (2.3%)

fractures. Patients who did not fit this description were excluded. The follow-up was of four months. However, the patients are indefinitely followed at the medical facility.

At admission, a questionnaire was used to evaluate the sociodemographic data, the factors described in the literature as risk for OP, and prior use of drugs to treat OP (Table 1). In addition, the Brazilian version of the Quality of Life Questionnaire - SF 36, the Tegner Activity Level Scale, the Osteoporosis Assessment Questionnaire - Physical Function, and the Fall Risk Score were applied.

The patients were reassessed in two moments: between four and eight weeks, and in the 16th week after hospital discharge. On these occasions, questionnaires developed by the researchers were applied with the objective of evaluating the frequency of medical recommendation for secondary prophylaxis of fractures. Additionally, on the ultimate visit, we repeated the application of the SF-36 questionnaire.

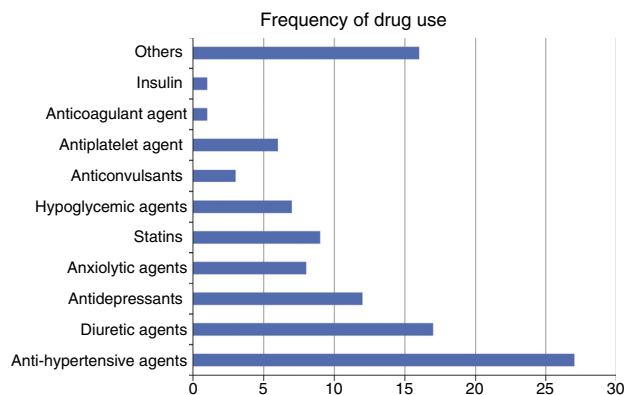
The results are presented as descriptive statistics after they were tabulated and treated on Microsoft Excel 2013 and compared on GraphInstat 3.0.

Results

Table 1 shows the main characteristics of the sample of the 44 patients studied, 31 females and 13 males. The mean age was 69.09 years ($sd = \pm 10.93$), the body mass index was 25.12 kg/m^2 ($sd = \pm 4.83 kg/m^2$) and, according to the self-declared ethnic group, 30 were white, five black and nine brown; 18 had a history of smoking (40.9%), and 11 had a history of alcoholism (25%). Among the women evaluated ($n = 31$), 30 (96.8%) had already reached menopause, eight (25.8%) reported use of hormonal contraceptive during menacme, and three (10%) underwent hormone replacement therapy.

When questioned about physical activity practice, according to the Tegner Activity Level Scale (0–10), four were ranked at level 0, six at 1, 15 at 2, 11 at 3, 1 at 4 and 5 at 5 (mean = 2.3, $sd = \pm 1.4$, $n = 42$) (Fig. 1).

On admission, the patients were classified according to the level of difficulty to perform activities seven days before

**Fig. 1 – Drug use prevalence in patients.****Table 2 – Average score of the osteoporosis assessment.**

OAQ-SF	Dimensions	Mean (standard deviation)
Level of difficulty to develop activities	Mobility	8.79 (6.82)
	Physical position	11.47 ± 8.15
	Transfer	6.84 ± 5.16

having an osteoporotic fracture, according to the scale of Osteoporosis Assessment Questionnaire - Physical Function (OAQ-PF), in a scale of 15 to 90, where lower values indicate greater function. Three items are considered: mobility (scale from 5 to 30), physical position (from 6 to 36) and transfer (from 4 to 24). The OAQ-PF was on average 24.7 ($sd = \pm 16.9$) and the scores on these subitems are presented in Table 2.

Regarding ambulation, 37 were social (community) ambulators, four were household ambulators, one was a non-functional ambulator, and two were bedridden. Regarding household, 35 lived with their family, nine alone, and none were institutionalized.

Regarding the Fall Risk Score (0 to 10, increasing according to severity), a questionnaire assessing the risk for falls to which the patient is exposed, the mean was 2.45 ($sd = 1.83$); 18 participants reported frequent falls and 16 reported having suffered previous fractures.

Comorbidities were reported by 38 patients (92.6%), the most prevalent being systemic arterial hypertension (59%), dyslipidemia and depression (20.4% each). The drugs in use by the patients are listed in Fig. 2.

Regarding the diagnosis and previous investigation of OP, only four patients had performed bone densitometry, the diagnosis of which was osteopenia in two cases (2.5%) and osteoporosis in the other two (2.5%) (Fig. 3).

Before the fracture, seven subjects were supplemented with calcium and/or vitamin D, and of these, only three kept supplementation during the follow-up period. Following the fracture, five people started using calcium and vitamin D supplementation (Fig. 4).

When addressed in relation to the use of drugs for the treatment of osteoporosis, only one patient confirmed the drug treatment (with oral bisphosphonate). After four months of follow-up, no participant initiated secondary drug fracture prophylaxis with anti-osteoporotic drugs. However, four

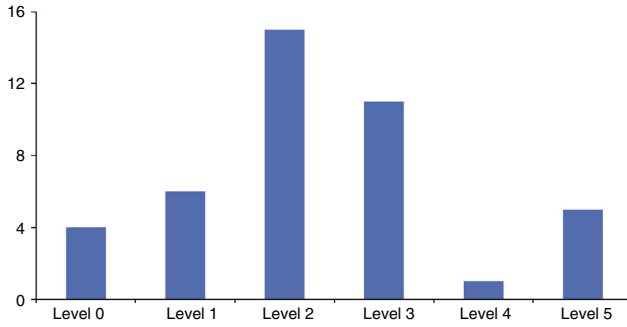


Fig. 2 – Frequency distribution of physical activity levels according to Tegner Activity Scale.

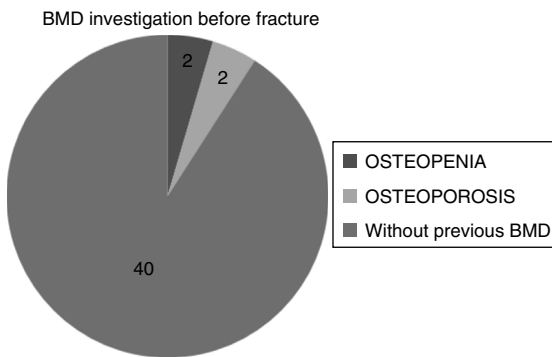


Fig. 3 – Frequency of previous investigation and diagnosis of osteoporosis with BMD.

patients reported being advised about the disease and three on the need for BMD investigation.

Of the 44 patients, one did not complete the last follow-up, due to clinical complications, with prolonged hospitalization in a Intensive Care Unit (ICU), which prevented him from answering the questionnaires. There were also seven cases of death, all over 60 years of age, six hospitalized for femur

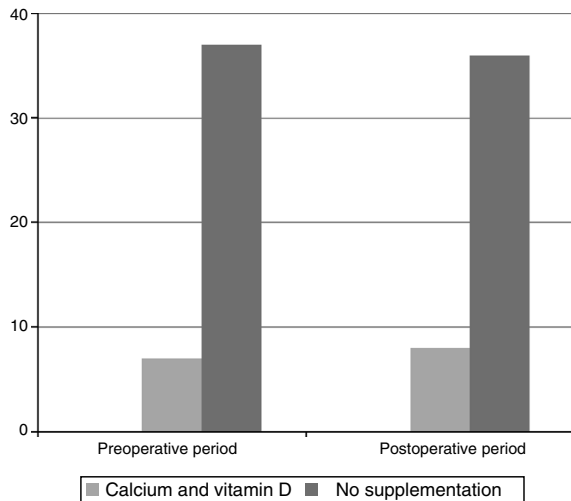


Fig. 4 – Prevalence of the use of calcium and vitamin D before and after the fracture.

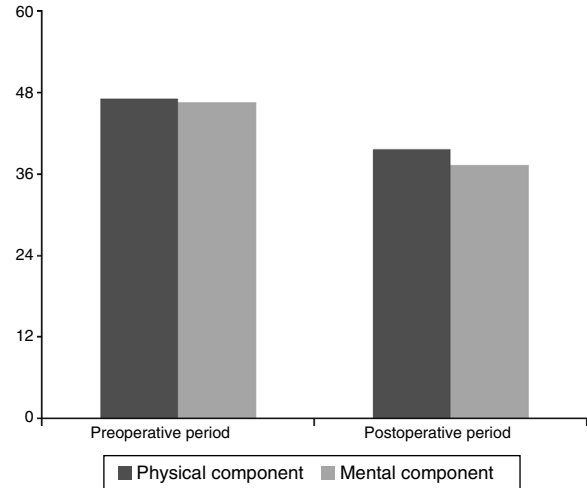


Fig. 5 – Graphic comparing quality of life by the SF36 before the fracture and after 16 weeks.

fracture and one for distal radius fracture. Thus, the mortality rate after fragility fractures in the present study was 15.9%.

The scores of Quality of Life Questionnaire – SF 36 on admission to the hospital were 47.11 (sd = 7.55) for the physical component, and 46.56 (sd=6.76) for the mental component. At the ultimate visit, the physical component was 39.69 (sd = 18.33) and 37.37 (sd = 18.68) for the mental component. Therefore, fracture treatment provided improvement in patients' quality of life ($p = 0.019$) in a short period of time (four months) (Fig. 5).

Discussion

Bone fragility fractures can be considered a public health problem, with an estimated annual incidence of 3% in women aged at least 85 years, in the proportion of 3:1 compared to men,^{11,12} with a direct cost to Brazil's Public Health System of approximately 30 million dollars annually.^{3,13} This disease prevention is of paramount importance, since it can improve a patient's quality of life, as well as reduce morbidity and mortality.¹⁴ In addition, the epidemiological transition to the Brazilian population, with the increase in the number of elderly people, implies the need to create strategies to control the risk of primary and secondary fractures.¹⁵ Our study evaluated a specific population and found an epidemiological profile similar to others in the literature. Baron et al.¹⁶ found a predominance of this type of fracture among those between 50 and 70 years, especially in females after menopause. The incidence of non-vertebral fractures in several studies is higher in the femur, radius and humerus,¹⁷ similar to our study.

While studying proximal femoral fractures in the elderly in a Brazilian cohort, Daniachi et al.¹⁴ observed the predominance of women in a 3:1 ratio, with a mean age of 79 years, a result that is close to what we found. Our study obtained a higher prevalence of fractures in patients self-reported as white (68%). This proportion differs from the demographics of the Brazilian population.¹⁵ Other authors

have also reported this observation, attributing the risk factor for fragility fractures to this aspect.¹¹

Other recognized risk factors for fragility fractures are: smoking, sedentary lifestyle, low weight, previous fractures, alcohol, frequent falls, among others.⁵ In fact, our findings show a higher prevalence of smoking among our patients compared to the Brazilian average.¹⁵ Likewise, frequent alcohol use was reported by 25% of the patients, differently from the national average, which according to Brazilian Institute of Geography and Statistics (IBGE) was 14.2% in 2013.¹⁵

To assess the level of physical activity of the patients before the fracture, a validated scale of level of physical activity – Tegner Activity Level Scale – was used, and according to the result, sedentary lifestyle was demonstrated in the admitted patients. Pinheiro et al.⁴ show that sedentary lifestyle is among the main risk factors for low impact fractures in both genders, which may be related to poor bone quality, as well as lower neuromuscular control (with a higher incidence of falls).¹⁷

The use of multiple medications in elderly patients was related to a higher incidence of fractures.¹⁸ The incidence of falls, which may be influenced by the use of certain medications and associated diseases, was 40.9% in our study. According to Pluijm et al.,¹⁹ even after drug adaptations to reduce dizziness, vertigo and postural hypotension, such as antiverigos, anticonvulsants, antidepressants and benzodiazepines, the number of falls continues to be a predictive factor for the occurrence of fractures.

A recent meta-analysis to determine the risk of fractures in psychotropic drug users has shown that benzodiazepines, antidepressants, non-barbiturate anticonvulsants, barbiturate anticonvulsants, antipsychotics, hypnotics and opioids are associated with increased risk of fractures.¹⁸ According to these data, we recorded 18% of anxiolytic drug use, 27.27% of antidepressants use, and 6.81% of anticonvulsants, or 86.36% of patients with associated diseases or in chronic use of some medication. We also observed a high prevalence of patients taking antihypertensive drugs (61.36%) and diuretics (38.63%). Oates et al.²⁰ state that some antihypertensive drugs have a negative inotropic heart effect, which is usually compensated by an increase in adrenergic cardiac stimulation to compensate hypotension. In elderly individuals, this reflex is usually reduced, and may lead to an increased risk of hypotension, and increase the risk of falls.²⁰ The relation between the use of diuretics and the increased incidence of fractures is still controversial.²⁰ While LaCroix et al.²¹ defend a possible protective effect of thiazide diuretics due to a reduction in urinary calcium excretion, with consequent increase in bone density, Cummings²² attributes the highest risk of falls to hypokalemia, arrhythmias and postural hypotension. In general, our findings corroborate those of Daniachi et al.,¹⁴ that found a frequency of 85.84% for associated diseases, and 80.53% for chronic use of medication.

The prevention of fractures due to osteoporosis should begin at puberty through the encouragement of sports and balanced nutrition, aiming to reach an adequate peak of bone mass.^{23,24} However, the screening for bone mass loss through bone densitometry is indicated in premenopause for women, and in elderly men, since the treatment of osteopenia and osteoporosis can reduce the incidence of fractures due

to fragility, that is, it functions as primary drug fracture prophylaxis.^{25,26}

In our study, in a convenience sample, probably representative of the cases of fracture in our city, we observed that the prevalence of primary prophylaxis of fractures is minimal (one patient).

We observed a low frequency of indication of secondary fracture prophylaxis (beginning of treatment after the first fracture) in our cohort. Stolnicki and Oliveira¹³ say that a second episode of fracture may occur within a short interval, especially during the first year. The earlier the secondary drug prophylaxis is established, the better, because the risk of recurrence decreases 30% to 60%.¹³ Initially, the aim of the study was to identify possible factors related to the eventual failure of this indication. For this, we calculated a sample of 100 patients and a follow-up of one year. However, because the intermediate analysis of the data demonstrated that the patients did not receive the necessary care, there was a need to interrupt the study for ethical reasons, and we implemented measures to correct this distortion. In our hospital, the measures included a series of educational lectures for orthopedists and residents involved, as well as the creation of a reference clinic for the prevention of secondary fractures, inspired by programs such as Prevfrat.¹³ The impacts of these measures will be evaluated in future studies. Nevertheless, we have decided to publish our findings, because we believe that this scenario is probably present in several hospitals in the country. It is possible that studies like ours, repeated in other centers, will find similar results and encourage them to adopt measures that, according to the literature, can help avoid 60% of new fractures, significantly reduce mortality, and reduce the cost for SUS of the treatment of fractures due to bone fragility.¹³

Experiments in other centers around the world seem promising. The Healthy Bones Program, considered the largest bone fragility fracture prevention program in the world, and aims to reduce the incidence of cases by 20% within five years, is one of the most important projects in the field of primary prophylaxis.¹³ In the scope of secondary prophylaxis, the Refractive Prevention Program (Prevrefrat) stands out, a project developed in Brazil four years ago, a world reference point for the prevention of new fractures. Since its implementation, a fall of more than 97% of new fractures has been observed in the group that was being followed.¹³

Regarding the limitations of the study, the number of patients, that had to be reduced during follow-up, and time, are highlighted.

Conclusions

The frequency of primary and secondary OP chemoprophylaxis in patients admitted with fragility fractures is low in our country, revealing the need to develop specific strategies to address this disease. The prevalence of fragility fracture risk factors is similar to that reported in the literature.

Conflicts of interest

The authors declare no conflicts of interest.

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