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Original Article

Epidemiological Data on Osteoporosis in Women From the RAC-OST-POL Study

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Abstract

In the RAC-OST-POL study, epidemiological data were presented concerning osteoporosis in 625 women older than 55 yr coming from the District of Raciborz in Poland. The mean age was 66.4 ± 7.8 yr. All the women fulfilled a questionnaire, gathering data on clinical risk factors of osteoporosis. Femoral neck (FN) and total hip (TH) were measured. The mean value of bone mineral density for FN was 0.862 ± 0.129 g/cm^2, T-score -1.25 ± 0.92, and Z-score 0.039 ± 0.78, whereas the respective values for TH were 0.945 ± 0.149 g/cm^2, -0.47 ± 1.19, and 0.52 ± 0.98. T-score for FN below -2.5 was noted in 59 women (9.5%) and for TH in 23 women (3.7%). One hundred seventy six women reported prior osteoporotic fracture(s) (28.2%). Falls were the most common clinical risk factor. The number of clinical risk factors was significantly higher in subjects with fracture history than in those without fracture records. The only first-line antiresorptive medications, used in the therapy for osteoporosis, included alendronate—42 subjects (6.7%). Estrogen therapy was prescribed in 135 women and 7 were treated with calcitonin. Calcium was administered in 94 patients and vitamin D in 84 women. In all the women on therapy, Z-score values were significantly lower than in untreated women. Concluding, the results of our epidemiological study demonstrate low treatment rate in women with history of low trauma fracture. Effective strategies are needed for prevention, especially in regard to falls, and management of this disease, in particular for improvement of the treatment rates in affected women with prior fracture, in general.

Key Words: Bone mineral density; epidemiology; fracture; fracture risk factors; therapy.

Introduction

Osteoporosis is one of the most important chronic diseases in elderly population. Because of its clinically silent course, it is called ''a silent bone thief'' and, because of the number of affected subjects, the term ''silent epidemics'' has also been used. Clinical characteristics and the great number of osteoporotic patients worldwide brings forward the importance of epidemiologic data, including fracture prevalence, the presence of risk factors, bone densitometry values, and administered therapy. No long-term health policy can be established without precise problem description and reliable data and it is the epidemiological studies, which may provide the most reliable data, regarding the incidence of disease, its therapy, and prophylactics against its occurrence. Important aspects of osteoporosis, including fracture prevalence *(1−15)*, risk factors *(1,4−6,9,13,15,16)*, bone densitometry values *(1−3,15)*, and administered therapy *(1,2,5,17−26)* have been presented and discussed in several studies. Reports

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from those studies provide a wide range of details and various characteristic features of osteoporosis. This broad and complex information makes us aware of the magnitude of osteoporosis when approached from the medical perspective.

The aim of the epidemiological study was to establish several data on osteoporosis in a group of Polish women aged older than 55 yr.

Material and Methods

Table 1 presents the clinical characteristics of patients in the studied group. The enrolled women were randomly recruited from the general population aged older than 55 yr at the District of Raciborz, South of Poland. The total number of women at the district was 57,357, and the total population of qualifiable women (≥55 yr), inhabiting the Region at the time of enrollment into the study was 17,500; and 1750 subjects were randomly selected and invited by regular e-mail to participate in the study. The blind list of women selected for the study was provided by local government and each women received a number without showing her name.

A group of 625 women responded positively to the invitation and declared their intention to take part in the study, which was performed on May 2010. We performed additional statistical analyses to confirm that our population might be treated as representative subsample. We verified whether mean age in our subpopulation matches with mean age in general population. We used data from national statistical book *(27)* and age subgroups 55−59, 60−64, and older from district of Raciborz were taken into consideration. In population, the subsequent age subgroups constitute 29.8%, 14.3%, and 55.9% of total, respectively. In our group, we had 27.0%, 19.8%, and 53.2%, respectively. For first and last subgroup, the percentage did not differ when compared with population percentage and for second one we had more women than expected, as was shown by Chi-square test (data not shown).

Each woman fulfilled a questionnaire providing data on clinical risk factors for osteoporosis (prior fracture, family history of hip fracture, prolonged diseases, chronic medication, smoking, alcohol intake, falls). For further evaluations, only those fractures were considered osteoporotic which resulted from low energy traumatic event, such as a fall from standing - or lower-position, and which occurred at the age after 40. Time since fracture till present study was 11.6 ± 8.9 yr. Only falls in previous last 12 mo were considered. The questionnaire was validated and qualified as an important source of input data. Among women, 6 were still menstruating. Skeletal status was assessed by bone densitometry on a Lunar DPX (GE Healthcare, Madison, WI), and femoral neck (FN) and total hip (TH) were evaluated. Densitometric variables were presented as bone mineral density (BMD), T-score (the number of SD from young adults), and Z-score (the number of SD from age-matched subjects). All the measurements were performed by 1 operator. The percentage of coefficient of variation (CV%) was 1.6% for FN and 0.82% for TH. CV% was calculated on the basis of 50 measurements (2 for each patient with reposition). The Ethic Committee at the Medical University of Silesia in Katowice, Poland, approved the study protocol, while also each woman gave an informed written consent before participation.

Table 1
Clinical Characteristics of Studied Women, n = 625

Parameter	Mean ± standard deviation
Age (yr)	66.4 ± 7.8
Height (cm)	155.5 ± 6.0
Weight (kg)	75.5 ± 14.2
Body mass index (kg/m^2)	31.2 ± 5.5
Menarche (yr)	14.1 ± 1.7
Menopause (yr)[a]	49.0 ± 4.8
Years since menopause (yr)[a]	17.4 ± 9.0

[a]Data obtained in 619 postmenopausal women.

Statistics

All calculations were done, using the Microsoft Office Excel application and the Statistica program (StatSoft, Inc., 2008, Tulsa, OK; STATISTICA, version 8.0, www.statsoft.com), run on a PC computer. Descriptive statistics for quantitative values was presented as mean values and standard deviations (SDs). The distribution of analyzed data was checked by the Shapiro-Wilk test. Among statistical evaluations, the *t*-test for independent samples or the Mann-Whitney *U*-test was performed for the comparison of parameters between subgroups (in case of normal and abnormal distribution, respectively). Difference of DXA results between fractured and nonfractured women was also verified by the analysis of covariance (ANCOVA). Correlation analysis was done by Pearson's or Spearman's correlation, whichever appropriate. Presentation of qualitative features was done by providing the number of subjects and the percentage value in defined subgroups. Comparisons of those subgroups were performed by the Chi-square test. All p values <0.05 were considered statistically significant.

Results

Bone Densitometry

At TH measurements, 167 women (27.02%) had T-score between −1 and −2.5 and 23 below −2.5 (3.72%), whereas the respective values for FN were 312 (50.48%) and 59 (9.54%).

Fractures

Nontraumatic fractures, resulting from a fall from standing height or less, which had occurred after the age of 40 yr, were taken into account in the study. One hundred seventy six women reported prior osteoporotic fracture (28.2%)—the most common fracture site was forearm (108 cases in 94 women). Other fractured skeletal sites included ankle,

Table 2
Comparison of Selected Clinical Features and DXA Results for FN and TH in Fractured and Nonfractured Women

Parameter	Women with previous fracture (n = 176)	Women without previous fracture (n = 449)	*p* Value
Age (yr)	68.5 ± 8.3	65.6 ± 7.5	$p < 0.0001$*
Years since menopause (yr)	20.2 ± 9.5	16.3 ± 8.6	$p < 0.00001$*
Body height (cm)	154.5 ± 6.2	155.8 ± 5.9	$p < 0.05$*
Body weight (kg)	74.4 ± 14.1	75.9 ± 14.2	ns*
FN BMD (g/cm^2)	840.1 ± 123.4	871.0 ± 130.3	$p < 0.01$*
			ns**
FN Z-score	−0.01 ± 0.78	0.05 ± 0.78	ns*
TH BMD (g/cm^2)	917.6 ± 141.8	956.8 ± 151.3	ns**
TH Z-score	0.44 ± 0.91	0.56 ± 1.01	ns*

Abbr: DXA, dual-energy X-ray absorptiometry; FN, femoral neck; TH, total hip; BMD, bone mineral density; ANCOVA, analysis of covariance.

*p value in t-test for independent samples.

**p value in ANCOVA analysis with age, years since menopause, and body height as covariates.

45 women; feet, 29; arm, 9; rib, 6; spine, 4; hip, 3; femoral shaft, 2; and other, 9. One hundred forty subjects had 1 fracture, 27 had 2 fractures, 8 had 3, and 1 woman had as many as 5 fractures. The selected clinical features with possible influence on BMD (age, years since menopause, body height, and body weight), and DXA results separately for fractured and nonfractured women are presented in Table 2. Direct comparison for BMD values shows that women with previous fracture have significantly lower results. However, when Z-scores for FN and TH are used instead of BMD and compared (which is proper due to difference in mean age between fractured and nonfractured women), the differences are no longer significant. This issue was also verified by ANCOVA analysis. When BMD values for FN and TH are compared between women with and without previous fracture including into analysis age, years since menopause, and body height as covariates, the analysis reveals a significant influence of age ($p < 0.05$ for both FN and TH BMD), years since menopause ($p < 0.05$ for both FN and TH BMD), and body height ($p < 0.00001$ for FN BMD and $p < 0.01$ for TH BMD), whereas the influence of former fracture on BMD value is not significant.

We have also checked the possible influence of time since fracture on DXA results in fractured women. The mean time since fracture was 11.6 ± 8.9 yr, so most of the reported fractures occurred long ago before the study. Only in 9 patients, the time since fracture was shorter than 6 mo and in consecutive 7 women it was between 7 and 12 mo. We did not find any correlation between time since fracture and DXA results, expressed both by BMD value and Z-score, regardless the analysis was carried out in the whole fractured subgroup or limited to the short period since fracture (1 or 2 yr) (data not shown).

Fractures occurred in 30.5% of women with FN T-score equal or below −2.5 and in 27.9% of those with T-score above this level. Respective values for TH T-score were 43.5% and 27.6%. The occurrence of fracture did not differ significantly between women with or without osteoporosis diagnosed according to DXA criteria. Only 10.3% women with previous fracture had the T-score for FN equal or below −2.5. Similarly, only 5.7% women with previous fracture had the T-score for TH equal or below −2.5. This clearly shows that the occurrence of osteoporotic fracture was much more frequent than densitometric diagnosis of osteoporosis. Chi-square test has shown that the prevalence of fractures was comparable in women with osteoporosis, osteopenia, and normal DXA measurement (data not shown).

Clinical Risk Factors

The prevalence of clinical risk factors (except for prior fracture) for fracture occurrence in the whole group is presented in Table 3, whereas Fig. 1 illustrates their prevalence in the subgroups with or without fracture history. Most commonly reported were falls, followed by early menopause (earlier than at 45 yr), actual smoking, hip fracture history in parents, and rheumatoid arthritis. The rarest indicated risk factor was alcohol abuse. One hundred sixty nine (27.0%) women demonstrated no risk factors and 456 (73.0%) had, at least, 1 risk factor. One risk factor was identified in 211 patients (33.8%), 2 in 155 (24.8%), 3 in 60 (9.6%), and >3 risk factors were revealed in the other patients. BMD for FN and TH did not correlate with the number of clinical risk factors (data not shown). The number of clinical risk factors (excluding fractures in the past) per person was 0.99 among the individuals without fracture, while amounting to 1.22 in subjects with diagnosed fracture and differed significantly ($p < 0.05$). The major role of falls was demonstrated and confirmed by the Chi-square test. Having compared the percentage of women with prior fracture among subjects without falls (n = 414, 66.2% of the whole group) and with falls (n = 211, 33.8% of the whole group), we noted more frequently fractures in those with falls (34.6% of the subgroup

Table 3
Clinical Risk Factors

Risk factor	Number of subjects	Percent
Falls	211	33.8
One fall	137	21.9
Two falls	51	8.2
Three or more falls	23	3.7
Early menopause	92	14.7
Smoking	71	11.4
Hip fracture in parents	47	7.5
Rheumatoid arthritis	40	6.4
Secondary reasons[a]	38	6.1
Steroid use	30	4,8
Alcohol abuse	4	0.6

[a]Secondary reasons for osteoporosis are diabetes mellitus type 1, nonstabile thyroid disease, hyperparathyroidism, renal failure, and long-term immobilization.

vs 24.9% of the subgroup without falls; $\chi^2 = 6.52$, df = 1, $p < 0.05$).

Therapy

The only first-line antiresorptive medication used in therapy for osteoporosis was alendronate—42 subjects (6.7%). Other bisphosphonates, raloxifen or strontium ranelate, were not used. At the time of the study, denosumab was then not yet available. Estrogen therapy was prescribed in 135 women (21.6%). The number of women with fractures did not differ between estrogen users and nonusers (data not shown). Seven women were treated with calcitonin (1.1%). Calcium was administered in 94 (15.0%) and vitamin D in 84 women (13.4%). One could expect that those with fracture(s) should have been treated more frequently than subjects without fracture, but we failed to confirm this thesis (data not shown). For final comparison between treated and untreated women, we assumed that bisphosphonates, calcitonin, and hormone replacement therapy constitute the therapeutic interventions of possible significant influence on skeletal status. The number of women taking one of above listed medication was 179, with their age being 65.2 ± 7.5 yr and differed significantly from women without therapy (n = 446, aged 66.9 ± 7.9 yr, $p < 0.05$). Because of the mean age difference, Z-score values instead of BMD values were compared for FN and TH between treated and untreated women, and mean Z-score values for both DXA localization were significantly lower in the treated group—0.06 ± 0.75 vs 0.08 ± 0.79 and 0.39 ± 1.0 vs 0.58 ± 0.97 for FN and TH, respectively ($p < 0.05$). This observation reflects that women with worse DXA results were more often qualified for therapy with the use of bisphosphonates, calcitonin, or estrogens.

Menstruation Duration

The duration of menstruation (the year of menopause minus the year of menarche) was calculated, giving the result of 34.9 ± 5.1 yr. We assumed that longer duration of fertile period should improve BMD and decrease the risk of fracture. A rather weak but significant correlation was noted between the duration of menstruation, and FN BMD and TH BMD ($r = 0.093$ and 0.098, $p < 0.05$, respectively). In women without fracture, that period was 35.2 ± 5.0 yr, whereas in

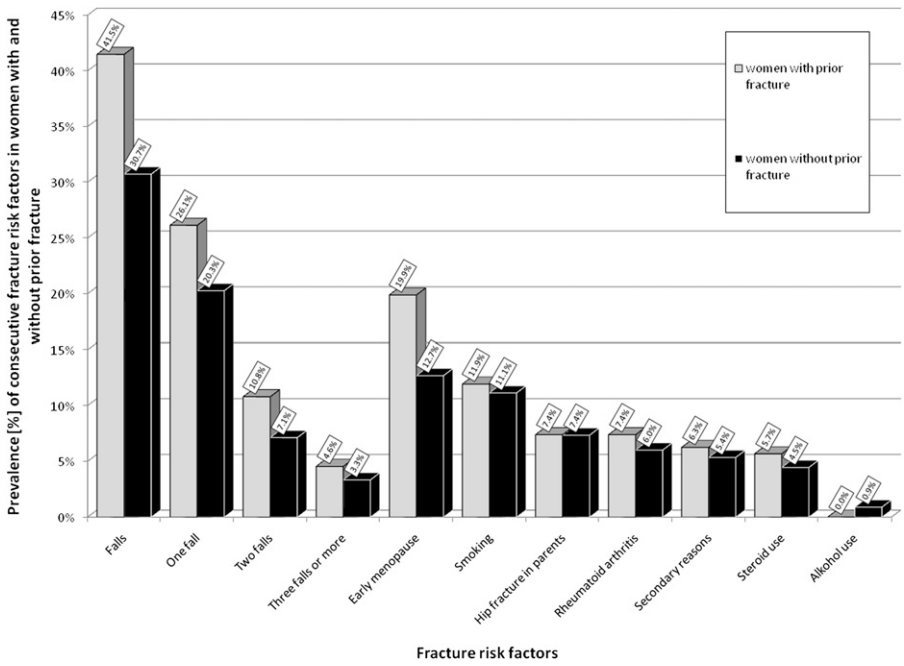

Fig. 1. The prevalence of clinical risk factors for fracture occurrence in the subgroups with or without fracture history.

those with fracture, it was 34.1 ± 5.3 yr and differed significantly ($p < 0.01$).

Discussion

Some reports, published by other authors, had an epidemiological design *(1,3,4,9,14,15,17,19,22,23,25,26)*, including studied subjects having been recruited from healthcare systems *(5,11,12,20)*, national registers *(2,6,18,24)*, or other data systems *(7,8,10,13)*. We then considered that one of the most important observation, derived from the study, was the significant role of falls as fracture risk. Falls were the most common risk factor in our study group, significantly affecting the general fracture risk. We consider that a preventive strategy should include detailed physician assessment in regard to risk of falls, and such medical specialties as opthalmology, neurology, rheumatology, or cardiology are especially important. In order to limit the falls number, enhanced physical activity improving functional status is recommended. The statement presented in a recent review *(28)* that the strongest determinant of a fracture is the actual fall rather than bone fragility is confirmed by the results of our study. In this excellent review of prevention of falls, a multifactorial program, which include several individually tailored preventive components, are especially beneficial for those who are at the highest risk *(28)*. Among women studied from our population, the highest fall risk concerns those who fell in last 12 mo and they should be treated as candidates for such preventive procedures.

Risk Factors Excluding BMD

In the present study, the most common risk factor was fall, followed by the risk factor, fracture history. Generally, the percentage of subjects with clinical risk factors in our study seems to be comparable with the values in other reports. In other studies, the number of experienced falls is usually not provided and thus, no direct comparison is possible with regard to this factor. In some reports, data were presented, regarding clinical risk factors *(1,5,6,9,13,15)*. In INSTANT Study among other risk factors, a consultation with an eye specialist and history of cardiovascular disease are, as variables, independently associated with fracture incidence *(1)*. One may expect that vision problems and cardiological diseases may increase the prevalence of falls. In another French study, the risk factors for osteoporotic fracture were identified in 2148 patients (69.4%), most frequently personal or maternal antecedents of osteoporotic fracture and a low BMI *(5)*. In contrast with these data, in the present study we noted high BMI with mean value exceeding 30 kg/m^2. In the Polish part of the EVOS Study *(9)*, smoking, secondary reasons, and steroids were indicated as risk factors. In present study, only smoking was often noted, whereas secondary reasons and steroid use were rather seldom. In our previous study in 2012 postmenopausal women, when compared with the current data, we noted a slightly smaller prevalence of falls (28%) comparable for smoking (9.4 vs 11.4%) and higher for secondary reasons (10 vs 6%) and steroid use (10 vs 5%) *(13)*. The differences may be attributed to different design patterns of the compared studies because the quoted study composed of women from the outpatient clinics. In other Polish study of 1608, the most common risk factors included low BMI (38%) and smoking (14%), followed by hip fracture in parents (11%) *(15)*. The number of falls was not presented.

Summing up this part of discussion, a very important issue in risk assessment for osteoporotic fractures is the usual lack of data, regarding the history of falls. Our data suggest that the number of falls should be always collected as being one of the most common and important risk factor for fracture.

Fracture

In some studies, performed in various European countries, the prevalence of fractures is shown *(1–3)*. In a cross-sectional epidemiological survey of osteoporosis in 2613 women older than 45 yr in the general population, 115 (4.4%) reported at least 1 previous fracture *(1)*. Vertebral fractures were reported by 101 women (3.9%) and limb fractures by 41 women (1.6%). Generally, these values reflect much lower overall fracture occurrence than in our group (28.2%), especially with regard to limb fractures (in our group 25.1%), but on the other hand, the frequency of vertebral fractures is higher than our finding (0.6%).

In a nationwide survey in Switzerland on 4966 patients, aged 50 yr or older, 32% reported 1 or more previous fractures during adulthood *(2)*, what is close to our result of 28.6%. The prevalence of vertebral fractures was established (21.4%) in 824 postmenopausal Spanish women with mean age 64 yr *(3)*, but only 1.5% of the women with vertebral fractures were aware of their condition. Probably, the low prevalence of spine fractures in our present study should be explained because of the lack of spine radiograms in our subjects.

In several reports of studies, performed in the Polish population, data were presented on fracture incidence *(7–15)*. In some of them, the prevalence of hip fractures was provided *(7,8,11,12)*, as well as that of spine fractures *(9,14)*, forearm fractures *(10)*, or of fractures in various skeletal sites *(13)*. In a group of 4834 hospital patients (women and men), there were 128 hip fractures in men and 313 in women *(8)*, whereas other authors noted 390 hip fractures in the whole voivodship population of 700,000 inhabitants *(7)*. Jaworski and Lorenc demonstrated data from National Health Service but no exact numbers were given *(12)*. Interesting data were presented by Czerwinski et al *(11)*, who, while taking into account the whole Polish population over 50 in 2005, demonstrated hip fracture prevalence at the level of 165 cases per 100 thousand women. In the present study, 3 hip fractures were identified, what—when calculated per size of our population—gives 3 times more hip fractures than reported by Czerwinski et al; however, we considered all prior fractures. The EVOS Study *(9)* recorded 10.6% subjects with spine fractures in 301 women, aged older than 50 yr, and Skowrońska et al *(14)* had even higher percentage of 20.7% in 520 females, aged 18–79 yr. We identified 4 clinical spine fractures only. In a recent cross-sectional analysis of 2012 patients from 4

outpatient osteoporotic clinics across Poland, the fracture prevalence was 36%, whereas hip fracture accounted for merely 2% only. The reported higher values than those observed in the present study may be explained by the fact that our material composed of randomly selected population. In another Polish study, performed in a group of 1608 Polish women, fractures were noted in 24% of the subjects after 50 yr *(15)*. This number was slightly lower than in our study but we took into account fractures already after the age of 40 yr.

Bone Densitometry

In the present study, we noted a relatively small number of patients with T-score below −2.5. In some other studies *(1−3,15)*, BMD values were also presented. In the INSTANT Study, the overall prevalence of diagnosed osteoporosis was 9.7% *(1)*, in the Swiss study, 46.0% of enrolled subjects had a T-score ≤−2.5 SD, and in the Spanish study, the prevalence of osteoporosis was estimated at 15.1% in the FN *(3)*. Also, greater values were shown by Badurski et al *(15)* who identified 14.8% of women with T-score below −2.5. The differences in the studied population and in the study design does not allow to make direct comparisons, and we consider that high value of BMI in present study caused a relatively low prevalence of osteoporosis.

Therapy

The mean Z-score values were significantly lower in the treated women than in those without therapy. This observation suggest that women with lower BMD results, regardless of their metrical age, were more willingly qualified as the candidates for pharmacological intervention, and obtained densitometric data were assumed as the main criterion used as an indication for therapy in our group, prevailing even the meaning of history of fracture(s).

Nonetheless, the number of treated women is rather low, which is probably because of small number of subjects with low BMD results expressed by T-score. Many studies have presented data on osteoporosis therapy *(1,2,5,17−26)*, bisphosphonates being the most commonly used protocol, just as in the present study *(1,2,5,21,22,24)*. Some studies have documented that hormone replacement therapy (HRT) is still relatively often used in osteoporotic patients *(17,19)*. In our study, the number of women on HRT was unexpectedly high but prior fracture(s) among the HRT users did not differ with regard to the number of fracture(s) in other women, what suggests that an indication for that particular therapy was other than osteoporosis. Fracture(s) in history is one of the most important indications for treatment initiation. In the present study, this factor was not often sufficiently taken into consideration. In some studies, the authors analyzed relationships between prior fracture records and the applied therapy *(2,18,25,26)*, and the general view was similar to that in our study, while prior fracture was not sufficiently used as an indicator for therapy.

The above results from medical literature indicate that generally the number of patients treated for osteoporosis is low. Also current observations suggest that women from a district of Raciborz obtained osteoporosis treatment not sufficiently often. Especially prior fracture should be taken into consideration as an independent indication for therapy initiation. Probably, the most important direction of future management should be the assessment of the risk of falls and an increasing of physical activity.

The present study has got certain limitations. The percentage of enrolled women was rather low, no longitudinal observations were performed, and only 1 skeletal site was measured. Despite these limiting circumstances, many data were obtained on the fracture risk and fracture occurrence, and on the skeletal status and applied therapeutic protocols to obtain current epidemiological data of osteoporosis in the population of Polish women aged older than 55 yr. We consider that our population should be treated as representative subsample despite some differences of our population and general female population for 1 age subgroup.

Concluding, the results of our epidemiological study demonstrate low treatment rates in postmenopausal women with history of low trauma fracture. Effective strategies are needed for prevention, especially in regard to falls and management of this disease, in particular, and for improvement of treatment rates in the affected women, in general.

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