Fracture risk and fracture prevalence in women from outpatient osteoporosis clinic and subjects from population-based sample: A comparison between GO Study and RAC-OST-POL cohorts

Wojciech Pluskiewicz[1,A,B,D,F], Piotr Adamczyk[2,C,D], Bogna Drozdzowska[3,A,E,F]

[1] Department and Clinic of Internal Diseases, Diabetology and Nephrology, Metabolic Bone Diseases Unit, Faculty of Medical Sciences in Zabrze, Medical University of Silesia in Katowice, Poland
[2] Department of Pediatrics, Faculty of Medical Sciences in Katowice, Medical University of Silesia in Katowice, Poland
[3] Department of Pathomorphology, Faculty of Medical Sciences in Zabrze, Medical University of Silesia in Katowice, Poland

A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of the article

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Address for correspondence
Wojciech Pluskiewicz
E-mail: osteolesna@poczta.onet.pl

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Abstract

Background. The method of recruiting the study subjects is an important element of the study design. It can have a strong influence on the results. Different recruitment schedules can give a different picture of the studied phenomenon.

Objectives. The aim of the study was to compare bone health in a group of female patients treated for osteoporosis with a population-based sample.

Materials and methods. A cohort of women from GO Study from 1 outpatient osteoporotic clinic (n = 1442, mean age 65.8 ±6.7 years) and population-based female sample of RAC-OST-POL Study (n = 963, mean age 65.8 ±7.5 years) were studied. Mean age did not differ between groups. Mean weight, height and body mass index (BMI) in subjects from GO Study and RAC-OST-POL Study were 69.5 ±13.1 kg, 157.8 ±6.1 cm and 27.9 ±5.1 kg/m^2, and 74.2 ±13.7 kg, 156.0 ±6.0 cm and 30.5 ±5.4 kg/m^2, respectively, and differed significantly ($p < 0.0001$ for each variable). Data on clinical risk factors for osteoporosis and fractures were collected. Bone densitometry at hip was performed using a Prodigy or Lunar DPX device (GE Healthcare, Waukesha, USA). Fracture risk was established using FRAX, Garvan and POL-RISK.

Results. Mean values of T-score for femoral neck in subjects from GO Study and RAC-OST-POL Study were –1.67 ±0.91 and –1.27 ±0.91 and differed significantly ($p < 0.0001$). In GO Study and RAC-OST-POL Study, there were 518 (35.9%) and 280 (29.1%) subjects with fractures, respectively. The fracture frequency was significantly higher in the GO Study group ($p < 0.001$). Among clinical risk factors, only rheumatoid arthritis ($p < 0.0001$) secondary osteoporosis ($p < 0.0001$) and falls ($p < 0.0001$) were more frequent in RAC-OST-POL Study. Fracture risk established using FRAX, Garvan and POL-RISK calculators was significantly greater in patients enrolled in the GO Study than in subjects from the RAC-OST-POL population-based sample ($p < 0.0001$ for each variable).

Conclusions. Differences noted between female patients treated for osteoporosis and population-based sample, especially in regard to fracture risk, reveal a strong influence of recruitment criteria on study results in the field of bone health and osteoporosis.

Key words: bone mineral density, females, clinical risk factors, fracture risk, fracture incidence

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Background

The most informative results describing health problems associated with widespread diseases such as osteoporosis can be obtained from representative population samples. However, in daily practice, data gathered according to different inclusion criteria are often presented. It is not clear whether bone health and many specific features such as fracture incidence, the number of clinical risk factors for fractures, and functional status expressed by the number of falls really differ between population-based samples and patients treated for osteoporosis. Such knowledge would be important and helpful for practitioners in daily practice and proper interpretation of a results of their studies. In 2010, a study called RAC-OST-POL was performed.[1] In this study, an epidemiological, population-representative female sample was recruited. This cohort was then studied in regard to various aspects of bone health.[2–12]

More recently, we presented data from a large group of female patients enrolled when attending a single outpatient osteoporosis clinic; this research was published in consecutive papers and identified with the acronym GO Study.[13–15] In recent years, methods for fracture risk assessment were developed,[12,16–18] and fracture risk assessment became an important part of the examination of patients. Nowadays, fracture risk is one of the most important criteria for the initiation of pharmacologic treatment. We consider the comparisons between clinical risk factors and fracture risk in a population-based sample and regular osteoporotic patients to be an important issue.

Objectives

This study aimed to test 2 hypotheses. The 1st is that data describing bone health, e.g., clinical risk factors for fracture, bone mineral density (BMD) and fracture risk, collected in a group of patients treated for osteoporosis, are different from those obtained from a population-based sample. The 2nd hypothesis is related to fracture prevalence in compared cohorts. One may expect the bone status in osteoporosis patients to be worse and these patients to have a higher fracture prevalence than randomly recruited subjects.

Materials and methods

Material

Postmenopausal women from the GO Study were recruited from 1 osteoporosis outpatient clinic in Gliwice in southern Poland. This cohort was previously described in detail.[13] Postmenopausal females were also selected for the RAC-OST-POL Study and recruited according to a population-representative design from the urban area of Racibórz (also southern Poland) and the surrounding rural areas.[1] In both studies, women over 55 years were enrolled. For the current analysis, to obtain reliable comparisons, age-adjusted cohorts were selected. Finally, 1442 women from the original GO Study cohort (including osteoporotic clinic patients) and 963 women from a randomly selected, population-based RAC-OST-POL sample were enrolled in the current study.

In the RAC-OST-POL study, the cohort consisted of women who positively responded to the invitation to participate in the study. The list of invited persons was prepared randomly, based on contact data obtained from the City Hall, and took into account the demographic structure of the population in the region. Health status was not a factor taken into account when recruiting; however, it was assessed during the course of the study. The GO Study included women referred to an osteoporosis outpatient clinic or who presented on their own initiative to this facility. Therefore, they were patients with suspected bone health problems, determined based on their medical or family history. Some participants also reported for an osteoporosis screening or were looking for preventive advice.

Both the GO Study and RAC-OST-POL Study were approved by the Ethics Committee of the Medical University of Silesia, Katowice, Poland. Participants from both studies gave their written consent for enrollment into the study. The study design complied with the Declaration of Helsinki.

Mean weight, height and body mass index (BMI) in subjects from the GO Study and RAC-OST-POL Study were 69.5 ±13.1 kg, 157.8 ±6.1 cm and 27.9 ±5.1 kg/m^2, and 74.2 ±13.7 kg, 156.0 ±6.0 cm and 30.5 ±5.4 kg/m^2, respectively, and differed significantly ($p < 0.0001$ for each variable).

Methods

Data on the clinical aspects influencing bone health (clinical risk factors for fractures, e.g., smoking, secondary osteoporosis, falls, rheumatoid arthritis, and hip fractures in parents) were self-reported by patients in both groups. Study participants also reported previous osteoporotic fractures. The number of falls was established regarding the year prior to data collection. Bone mineral density was measured on the non-dominant femoral neck (FN). Bone status was established using the densitometer device Prodigy (GE Healthcare, Waukesha, USA) in the GO Study and Lunar DPX (GE Healthcare) in the RAC-OST-POL Study. The precision of measurement expressed as the coefficient of variation (CV%) was 1.6% in both studies.[1,13]

Fracture risk (expressed as the probability of experiencing a fracture during a defined period) was established using FRAX™ (www.sheffield.ac.uk), the Garvan calculator (www.fracturerisk calculator.com) and the Polish algorithm POL-RISK (www.fracture-risk.pl) online tools. The FRAX

expresses fracture risk as the probability of a major osteoporotic fracture and a hip fracture in the next 10 years. Garvan presents data for fracture risk for any fracture and hip fractures over a 5- and 10-year period. The POL-RISK algorithm expresses the risk of fracture for any fracture during a 5-year period.

Statistical analyses

Statistical analysis was performed using Statistica software v. 12 (StatSoft Inc., Tulsa, USA). Absolute values and percentages were provided for qualitative variables. The mean values and standard deviations (M ±SD) were used for descriptive statistics of continuous variables. The normality of data distribution was verified using the Shapiro–Wilk test. After checking the test assumptions, the Mann–Whitney U test was applied for the comparisons of continuous variables between the groups. Comparisons of qualitative features such as frequency were performed using the χ^2 test. The significance of the results in all of the statistical analyses was assumed at a $p < 0.05$.

Results

The mean values of T-scores for the FN in subjects from the GO Study and the RAC-OST-POL Study were –1.67 ±0.91 and –1.27 ±0.91, respectively, and differed significantly ($p < 0.0001$). In Table 1, the data on clinical risk factors for fractures are presented. The incidence of smoking, hip fracture and glucocorticoid use did not differ between the compared cohorts, whereas rheumatoid arthritis and secondary osteoporosis were more frequent in subjects from the RAC-OST-POL Study.

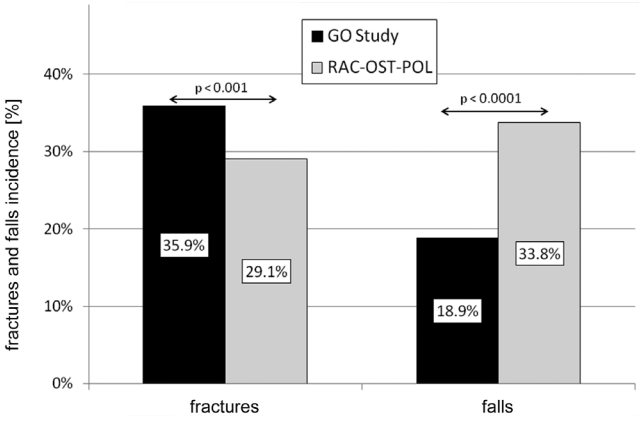

Fig. 1. Incidence of fractures and falls [%] in GO Study and RAC-OST-POL Study cohorts

In the GO Study and the RAC-OST-POL Study, there were 518 (35.9%) and 280 (29.1%) subjects who reported previous fractures, respectively. The χ^2 testing showed the fracture frequency to be significantly higher in subjects from the GO Study ($p < 0.001$). The respective total number of fractures (including multiple fractures in the same subjects) were significantly higher in GO Study patients (n = 869) compared to the population-based sample (n = 366, $p < 0.0001$).

Falls were noted more often in subjects from the RAC-OST-POL cohort (n = 326, 33.8%) than in the GO Study (n = 273, 18.9%, $p < 0.0001$). The respective total numbers of falls were 526 and 490, and differed significantly ($p < 0.0001$). The incidences of fractures and falls in both study cohorts are presented in Fig. 1.

Table 1. The incidence of clinical risk factors for fractures [%]

Fracture risk factor	GO Study (n = 1442)	RAC-OST-POL Study (n = 963)	χ^2 statistics	p-value
Smoking	13.4	10.9	3.27	NS
Rheumatoid arthritis	1.5	7.3	51.77	<0.0001
Glucocorticoid use	6.8	5.5	1.64	NS
Hip fractures in parents	5.5	6.7	1.66	NS
Secondary osteoporosis	5.5	25.3	193.98	<0.0001

NS – not significant.

Table 2. Fracture risk assessment established by fracture risk calculators (M ±SD)

Method of fracture risk assessment	GO Study (n = 1442)	RAC-OST-POL Study (n = 963)	Z value	p-value*
FRAX major fractures	7.02 ±4.91	5.85 ±4.03	6.93	<0.0001
FRAX hip fractures	2.35 ±3.80	1.55 ±2.48	8.91	<0.0001
Garvan – 5-year any fractures	12.76 ±12.04	9.85 ±9.16	7.01	<0.0001
Garvan – 5-year hip fractures	5.22 ±10.26	3.23 ±7.20	7.81	<0.0001
Garvan – 10-year any fractures	23.76 ±18.06	18.99 ±14.35	7.06	<0.0001
Garvan – 10-year hip fractures	9.13 ±14.85	5.86 ±10.69	7.57	<0.0001
POL-RISK – 5-year any fractures	13.52 ±9.40	10.96 ±7.21	7.09	<0.0001

M ±SD – mean ± standard deviation. * Mann–Whitney U test.

Data for fracture risk assessment are presented in Table 2. The values of fracture risk established using FRAX, Garvan and POL-RISK were significantly greater in GO Study patients than in patients from the population-based sample ($p < 0.0001$).

Discussion

To our knowledge, the current study is the first of its kind showing a comparison of data on fractures, clinical risk factors for fractures and falls, BMD and fracture risk assessment between female osteoporosis clinic patients and a population-based sample. Some expected and unexpected observations were noted.

First, one might expect that the incidence of fractures would be higher in osteoporosis clinic patients. Patients with prior fractures are obvious candidates for consultation from a physician, post-fracture diagnostic procedures and bone health treatment considerations. The higher fracture incidence in these patients compared to the general population was confirmed in our study and this result might be treated as an expected one.

Second, lower values of BMD expressed by FN T-scores were noted in patients from the GO Study, making it one (perhaps the most important one) of the reasons for the higher fracture incidence. One might expect that the osteoporotic clinic is visited by patients with overall worse bone health.

Third, we found the differences in anthropometric parameters very interesting. Patients from the GO Study cohort had a higher mean height, while the population-representative sample had a higher body weight and BMI. Height has been identified as a factor modifying the risk of fractures in the FRAX[16] and POL-RISK[12] calculators. Contrarily, an excessive body mass reduction, especially during the postmenopausal period, results not only in adipose tissue reduction, but also a lower lean body mass, and may have an adverse effect on bone health.[19] Thus, the higher BMI in the population-based sample from the RAC-OST-POL Study can be regarded as a protective factor in terms of fracture risk.

Fourth, the role of rheumatoid arthritis and secondary osteoporosis on fracture risk seems to be limited, despite these conditions being more frequently reported in the RAC-OST-POL Study sample, as the number of fractures was lower in this cohort. This may also reflect the impact of the data collection method on identifying relevant clinical factors. In the GO Study, complete medical records were available for each patient. Data collection in the population-based RAC-OST-POL Study was performed by filling in a questionnaire during a one-time meeting with the study participant, without verification based on medical records. Thus, the diagnosis of rheumatoid arthritis could have been overinterpreted, e.g., senile joint pain could have been declared as rheumatoid arthritis.

Fifth, the observed higher incidence of falls in the RAC-OST-POL Study sample did not cause an increased number of fractures. One may consider that, despite the poorer functional status in this population, the better bone status was a protective factor against fracture.

In our view, the most valuable point of this study is the fracture risk assessment compared between groups with different enrollment protocols. In recent years, methods of fracture risk assessment have become one of the most important elements of patient's health status evaluation. Such information is especially helpful in making decisions about the implementation of pharmacological therapy. The significantly higher fracture risk shown by all 3 calculators indicates that osteoporosis clinic patients require more attention in terms of therapy, and need treatment more frequently than subjects representing the general population.

It is not easy to summarize the obtained results. Some expected and unexpected observations suggest that the methodology used in subject enrollment and data collection may have significantly influenced the final study results. A population-based cohort had a better bone status with a lower fracture incidence despite more frequent falls, rheumatoid arthritis and secondary osteoporosis. Contrarily, osteoporosis clinic patients displayed a worse bone status and higher fracture incidence. We believe that the main factor influencing the incidence of fractures was bone health, whereas functional status, rheumatoid arthritis and secondary causes of osteoporosis were less significant than expected. Finally, the most important observation concerns the results documenting fracture risk, which indicated that special attention should be paid to osteoporosis clinic patients.

A review of the literature did not reveal many publications comparing the results from outpatient- or hospital-based cohorts with population-based studies for this topic and also in other areas of medical research. The few analyses of this type show that the research results may depend on the analyzed topic. A study assessing the quality of life depending on the method of treatment for intracranial vascular malformations found no differences in the results depending on the method of recruitment used in the study cohort.[20] On the other hand, an analysis of the relationship between psoriasis and metabolic syndrome yielded different results in a population-based sample when compared to hospitalized patients.[21] In the context of this scarce information, our analysis shows a clear difference in the clinical characteristics of patients in an osteoporosis outpatient clinic compared to a population-representative cohort, and sheds new light on osteoporosis research.

Our research strongly support the principle that the study design is a factor that "a priori" modifies the obtained results. Interpretation of the results cannot be carried out without taking into consideration the knowledge of the study design. Even a large sample size in a studied cohort does not allow one to draw conclusions regarding

the entire population unless the study sample has been properly selected. Observed differences between osteoporosis clinic patients and a population-based cohort, especially regarding fracture incidence and bone status, suggest that clinic patients cannot be treated as a representative sample.

Limitations of the study

The presented manuscript is a compilation of data from 2 separate studies. Patients came from different, although geographically close, recruitment areas. The data collection was performed only among female patients.

Conclusions

In conclusion, fracture risk and fracture incidence are higher among women treated in an osteoporosis outpatient clinic compared to the general population. While this is not a surprising observation, it is noteworthy to consider that it did not correlate with a higher incidence of multiple fracture risk factors in the clinic group. Interestingly, the incidence of falls was significantly higher in the population-based sample than among osteoporotic patients.

ORCID iDs

Wojciech Pluskiewicz https://orcid.org/0000-0003-1839-6560
Piotr Adamczyk https://orcid.org/0000-0001-9557-221X
Bogna Drozdzowska https://orcid.org/0000-0002-2287-6842

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