

# Changes in osteoporosis therapy in postmenopausal women from the RAC-OST-POL study: a 10-year follow-up

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## KEY WORDS

epidemiology,  
follow-up,  
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## ABSTRACT

**INTRODUCTION** Therapeutic regimens for osteoporosis are the key elements in the management of osteoporotic patients.

**OBJECTIVES** The aim of the study was to present data on changes in osteoporosis therapy in women during a 10-year follow-up.

**PATIENTS AND METHODS** We analyzed a population-based sample recruited in the RAC-OST-POL study. At baseline, the cohort included 978 women, of whom 541 remained in the follow-up. Mean (SD) age of the patients was 74.7 (6.6) years.

**RESULTS** The number of untreated women and those on alendronate decreased, while the number of patients receiving other forms of the antiresorptive therapy or calcium/vitamin D supplementation increased during the study. The percentage of untreated women in the rural areas and the urban areas was, respectively, 85% and 74.1% at baseline, and 74.3% and 63.3% at the end of the follow-up. The percentage of untreated women decreased significantly, both in rural and urban cohorts. It was accompanied by a significant increase in calcium/vitamin D supplementation in both subgroups. Regarding the antiresorptive therapy, there was a significant increase in the frequency of its use only in the rural cohort. The use of therapeutic strategies was determined by the level of education. The frequency of calcium and/or vitamin D supplementation increased significantly in all education-related categories during the follow-up.

**CONCLUSIONS** Changes in the therapy of postmenopausal women with osteoporosis, observed in a 10-year follow-up of the RAC-OST-POL study, indicated that the level of care did not improve in this group of patients.

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**INTRODUCTION** The study called RAC-OST-POL (from RACibórz, OSTeoporosis, POLand), was initiated in 2010.<sup>1</sup> In that study, an epidemiological, population-representative sample was recruited, involving postmenopausal women aged over 55 years. The cohort was investigated for various aspects of bone health.<sup>2-12</sup> At baseline, the health status data were collected, and factors with a potential influence on bone metabolism and bone status were identified (more than 200 variables were recorded). The data on

the osteoporosis therapy were also gathered. Our previous manuscript described our findings on the influence of education, marital status, occupation, and the place of living on the administered therapy at baseline.<sup>4</sup> It may be assumed that since 2014 the percentage of treated patients has been changed due to a number of factors, such as increasing knowledge on osteoporosis, positive changes in the perception and awareness of some medications, higher personal income, favorable reimbursement policy, or new perspectives

## WHAT'S NEW?

This report describes changes in the therapy of osteoporosis in a population-based sample of women recruited in the RAC-OST-POL study, during a 10-year (2010–2020) follow-up. The percentage of untreated patients decreased over the observation period but the number of patients on antiresorptive therapy did not change, and a general progress was observed due to increased calcium and/or vitamin D supplementation. Obviously, calcium and vitamin D supplements cannot replace antiresorptive medications with proven anti-fracture efficacy. Consequently, the level of care provided to patients with postmenopausal osteoporosis did not improve during the 10-year observation in the analyzed cohort.

on the availability of medicinal agents. In order to collect such data, a prospective observation is necessary and the current study sought to address this challenge. Consequently, the aim of this work was to approach and analyze long-term changes in osteoporosis therapy over a period of 10 years in the epidemiological, population-based sample of women with osteoporosis.

**PATIENTS AND METHODS** **Material and data collection** Our sample from the RAC-OST-POL study included women aged over 55 years, all of them recruited from the district of Racibórz in the south of Poland in May 2010, according to a population-representative model. The study cohort was described earlier.<sup>1</sup> As many as 625 women came from the baseline cohort of 1750 women invited to participate in the study (10% of all the women from the entire district, aged over 55 years, were invited). At the beginning of the study, data were also collected from 353 volunteers, for example, women who were not invited. The crucial features, such as mean age, the place of residence, occupancy, marital status, or education, did not differ between the random sample and the volunteers, therefore, in a number of subsequent analyses presented in publications, both groups (randomly recruited and volunteers) were regarded as a single population sample comprising 978 individuals. The number of participants decreased with time, and we ended the observation with a group of 541 women with complete data. The drop out causes included phone contact loss ( $n = 325$ ), death ( $n = 95$ ), response refusal during the follow-up ( $n = 12$ ), and a lack of meaningful data from interviews ( $n = 5$ ). Summing up, the final group at baseline included 978 women at the mean (SD) age of 65.8 (7.5) years, and at the end point of that longitudinal observation complete data were available for 541 women at the mean (SD) age of 74.7 (6.6) years.

The baseline data were collected in 2010 and the follow-up was continued with an annual frequency until 2020. The baseline data were obtained in personal interviews and the collected information was updated via phone calls. The participants were enquired about necessary details of their therapy prescribed for osteoporosis. All the data were collected by a single investigator

(WP). The study protocol was approved by the Ethical Committee at the Medical University of Silesia in Katowice, Poland (KNW/0022/KB1/9/I/10). Each woman participating in the study gave her written informed consent prior to the beginning of the study.

The whole investigated cohort was divided into the following subgroups: without therapy (subgroup 1), receiving calcium and/or vitamin D supplementation, either separately or combined but without any antiresorptive therapy (subgroup 2), on alendronate, with or without calcium and/or vitamin D supplementation (subgroup 3), and using other antiresorptive medications (strontium ranelate, ibandronate, risendronate, denosumab) with or without calcium and/or vitamin D supplementation (subgroup 4). For most analyses, the patients from subgroups 3 and 4 were combined into a subgroup 5 (using any kind of antiresorptive medication), as the number of women under therapeutic regimes in subgroups 3 and 4 were too small to analyze them separately. The patients were not receiving any anabolic agents. Evaluations were also undertaken to reveal factors potentially affecting the therapy over the observation period. The effects of the place of residence (the city of Racibórz or a rural area), education (elementary school, vocational education, high school, or university), and marital status (married, widow, divorced, or unmarried) were established, both at baseline and throughout the follow-up period. All the analyses were performed at baseline and at the end of the 10-year follow-up. At baseline and at the follow-up end, the respective number of patients in the subgroups 1, 2 and 5 was: 763, 112, 102 and 366, 132, 43.

**Statistical analysis** All the calculations were run using a Microsoft Office Excel application and Statistica 12 software (StatSoft, Inc., Tulsa, Oklahoma, United States; [www.statsoft.com](http://www.statsoft.com)). The descriptive statistics of quantitative values were presented as mean values and SD. Qualitative features were characterized by providing the number of patients and/or the percentage values in the defined subgroups. The comparisons of frequency of qualitative features were performed with the  $\chi^2$  test. All  $P$  values below 0.05 were considered significant. The Bonferroni correction was applied in the case of multiple comparisons.

**RESULTS** In TABLE 1 we present the number and percentage of women in each subgroup in the consecutive years between 2010 and 2020. In general, the number of women without therapy and of those on alendronate significantly decreased over that period, while the number of patients on other forms of antiresorptive therapy or calcium/vitamin D supplementation significantly increased. In the case of the combined subgroup on any antiresorptive therapy (subgroup 5), no significant changes were identified during the entire follow-up, which may suggest switching from

**TABLE 1** The percentage of women receiving different therapies at baseline and at consecutive follow-up time points between 2010 and 2020

Subgroup	2010 (n = 978)	2011 (n = 888)	2012 (n = 856)	2013 (n = 813)	2014 (n = 777)	2015 (n = 732)	2016 (n = 693)	2017 (n = 646)	2018 (n = 621)	2019 (n = 572)	2020 (n = 541)
No therapy	78.1	77.8	76.5	75.3	75.1	73.9	73.3	72.0	69.4	68.0	67.6 <sup>a</sup>
Calcium/vitamin D supplementation	11.5	14.0	15.1	15.1	15.4	16.0	18.2	19.2	21.9	23.8	24.4 <sup>a</sup>
Alendronate	10.3	7.9	7.9	9.0	7.7	7.8	6.3	6.5	6.3	5.9	5.0 <sup>a</sup>
Other antiresorptive therapy	0.1	0.3	0.5	0.6	1.8	2.3	2.2	2.3	2.4	2.3	3.0 <sup>a</sup>
Any antiresorptive therapy	10.4	8.2	8.4	9.6	9.5	10.1	8.5	8.8	8.7	8.2	8.0 <sup>b</sup>

Data are presented as percentage of patients.

**a** Change during the follow-up (difference between 2010 and 2020) statistically significant at  $P < 0.001$

**b** No statistically significant change during the follow-up ( $P = 0.12$ )

**TABLE 2** The frequency of therapy strategy categories in rural and urban areas, at baseline (2010) and at the end of the follow-up (2020)

Area	No therapy	Calcium/vitamin D supplementation	Antiresorptive therapy	$P$ value <sup>a</sup>
Rural (baseline)	85.0	7.5	7.5	0.001
Urban (baseline)	74.1	13.8	12.2	
Rural (follow-up)	74.3 <sup>b</sup>	17.3 <sup>b</sup>	8.4 <sup>c</sup>	0.007
Urban (follow-up)	63.3 <sup>b</sup>	29.1 <sup>b</sup>	7.7 <sup>d</sup>	

Data are presented as percentage of patients.

**a**  $P$  value in the  $\chi^2$  test comparing the therapy frequency between the rural and urban cohorts

**b** Change during the follow-up (difference between 2010 and 2020) significant at  $P < 0.001$

**c** No statistically significant change during the follow-up ( $P = 0.53$ )

**d** Change during the follow-up (difference between 2010 and 2020) significant at  $P < 0.006$

alendronate to other types of antiresorptive therapy rather than a general increase in that therapeutic strategy.

The longitudinal changes in the therapy were not influenced by the drop-out effect. The structure of the therapy at baseline did not differ between the patients with complete observation data ( $n = 541$ ) and those who were lost during the follow-up ( $n = 437$ ) ( $\chi^2$  test = 0.89;  $P = 0.82$ ). We therefore concluded that the type of therapeutic approach at baseline did not affect the probability of completing the follow-up.

The structure of the therapeutic strategies differed significantly in women from the urban and rural areas, with a higher percentage of untreated women in the rural area, both at baseline (85% vs 74.1% in the urban area) and at follow-up (74.3% vs 63.3%, respectively). More detailed data for other therapy categories are provided in [TABLE 2](#). Regarding the longitudinal changes, the percentage of untreated women decreased significantly, both in the rural and urban cohorts. It was accompanied by a significant increase in calcium/vitamin D supplementation, also in both

subgroups. In the case of antiresorptive therapy, there was a significant increase in its frequency in the rural cohort, while no significant changes were observed in the patients from the urban area.

The frequency of received therapies was also determined by the level of education, with a significantly different structure in a cross-sectional analysis, both at baseline ( $P < 0.001$ ) and at follow-up ( $P = 0.009$ ). Detailed data presenting the relationship between the openness to therapy and the education level are shown in [TABLE 3](#). The lower was the education level, the higher was the percentage of women receiving no therapy. However, during the 10-year observation, the percentage of women without therapy significantly decreased for all the education-related categories. The frequency of calcium and/or vitamin D supplementation was significantly different in the education-related categories. It was the lowest in women with elementary education and the highest in university education category, both at baseline ( $P < 0.001$ ) and at the follow-up ( $P < 0.01$ ). On the other hand, the frequency of antiresorptive therapy remained stable during the follow-up in the majority of education-related categories, except for a significant drop in women with university education (from 21.4% to 7.5%), which was compensated by the highest increase in calcium and/or vitamin D supplementation in that subgroup (from 14.3% to 40.0%).

The marital status did not affect the choice of therapy, either at baseline or at the follow-up (data not shown), thus no long-term changes in the therapy frequency were analyzed with regard to this variable.

To exclude any confounding influence of drop-out on the study outcomes, the relation between complete or incomplete observation and analyzed grouping variables (place of residence, education, and marital status) was also checked by the  $\chi^2$  test. We found that all the mentioned grouping variables did not significantly correlated with drop-out effect ( $\chi^2$  test = 3.1,  $P = 0.08$ ; 5.4,  $P = 0.25$ ; and 7.5,  $P = 0.11$  for place of residence, education, and marital status, respectively).

**TABLE 3** The frequency of therapy strategy categories in women with different education levels, at baseline (2010) and at the end of the follow-up (2020)

Therapy category	Elementary school			Vocational education			High school			University		
	Baseline	Follow-up	<i>P</i> value	Baseline	Follow-up	<i>P</i> value	Baseline	Follow-up	<i>P</i> value	Baseline	Follow-up	<i>P</i> value
No therapy	83.7	77.3	0.002	80.6	67.8	<0.001	76.3	65.4	<0.001	64.3	52.5	<0.001
Calcium/vitamin D supplementation	8.0	14.7	<0.001	11.8	24.4	<0.001	13.8	26.4	<0.001	14.3	40.0	<0.001
Antiresorptive therapy	8.3	8.0	0.84	7.5	7.8	0.83	9.9	8.2	0.27	21.4	7.5	<0.001

Data are presented as percentage of patients.

Differences between baseline and follow-up were assumed significant at  $P < 0.05$ .

**DISCUSSION** To our knowledge, the current study was the first one to provide a longitudinal insight into therapeutic regimens for osteoporosis in a Polish population-based sample. The most important result of this work was that the percentage of patients without any therapy decreased over the period of observation. However, the number of women on antiresorptive therapy did not change and the observed general progress was due to an increased calcium and/or vitamin D supplementation. Obviously, calcium and vitamin D supplementation cannot replace antiresorptive medications with a proven antifracture efficacy. Therefore, the level of care in postmenopausal osteoporosis did not in fact improve during the 10-year observation in the analyzed cohort.

Several studies performed in various countries assessed the implementation of osteoporosis therapies.<sup>13-18</sup> In general, only a small fraction of the affected patients are treated across different countries and continents. In a study covering 8 countries across Europe, about 75% of elderly women at high risk of osteoporosis-related fractures did not receive appropriate medication.<sup>13</sup> In an observation performed in Austria, 1 out of 10 men, and less than 2 out of 10 women received an adequate treatment for osteoporosis at the time of fracture.<sup>15</sup> In a large sample of 5704 patients in Canada, the major fracture history was not followed by osteoporosis medication.<sup>16</sup> In a Norwegian study, the undertreatment with antiosteoporotic drugs was observed in individuals at high risk of fracture.<sup>17</sup> In contrast with the presented data, in Japan a high percentage of osteoporotic patients (87.9%) received medications soon after their high fracture risk diagnosis.<sup>18</sup> The number of women taking any antiosteoporotic medication was also low in our study and reached 22% and 32% at baseline and at the follow-up, respectively. However, any antiresorptive therapy was administered to only 10.5% and 8% of the patients at baseline and at the end of the observation, respectively, and that slight drop was not statistically significant. Of course, our data collected from an epidemiological sample cannot be directly compared with patients at high fracture risk or being close to it.

The current study was designed as an epidemiological, longitudinal investigation, therefore, the most important aspect was a comparison of its data with the prospective data of other authors. Many studies present longitudinal changes in the therapy for osteoporosis.<sup>14,15,19-28</sup> Due to different design and duration of observations, the most reliable comparisons with our results may be provided either by studies showing epidemiological data, or those based on a huge nationwide databases.<sup>19,20,22,25-27</sup> In general, the number of patients treated for osteoporosis was low in our study. On the other hand, the data, given by various authors, are not uniform. In an Australian study, women from a population-based cohort were followed with respect to the intake of antifracture medication over 2 decades. The use of these agents increased over time but remained suboptimal, while the use of any osteoporosis-related medication increased over 3 time points (1993–97, 2004–2008, and 2011–2014) by 25.9%, 32.5%, and 35.9%, respectively.<sup>19</sup> A similar improvement was also presented in another Australian study for the years 2008–2011.<sup>22</sup> In a long prospective observation, performed in women in the United Kingdom (1990–2012), the annual rates of the first prescription of any antiosteoporotic medication increased from 1990 to 2006 and were followed by a plateau, and a 12% decrease in the last 3 years.<sup>23</sup> Also, the trends in the use of oral and intravenous bisphosphonates in the United States, analyzed for the years 2002–2012, indicated a decline after an initial increase.<sup>24</sup> In Belgium, a growing trend was observed in the number of prescriptions for antiosteoporosis medications in women during the years 2000–2007.<sup>25</sup> According to the data from the Korean National Health Insurance Database, the 2008–2012 drug treatment rates were stable in 2008, 2009, and 2010 (34.1%, 31.1%, and 33.5%, respectively).<sup>26</sup> The percentage of patients taking antiresorptive medications was generally higher than in our population. An increase in annual trend for calcium and vitamin D supplements was observed in a 10-year study (2000 to 2009), performed in the United States<sup>28</sup>, and this was similar to our results.



Some studies identified factors influencing the prevalence of and the willingness for particular therapeutic options.<sup>29,30</sup> In a Swedish study, individuals with university education were more likely to receive osteoporosis drug treatment than patients, particularly women, with lower educational levels.<sup>29</sup> In a study from Norway<sup>30</sup>, previous marriage lowered the odds of adherence to osteoporosis treatment as compared with present marriage in both sexes, while education played a role only in men. In our analysis, the percentage of antiresorptive therapy was the highest in the university education subgroup at baseline but it was not influenced by the level of education at the end of the follow-up. Generally, the frequency of antiresorptive medication administration remained stable over the observation period. The unexpected drop in the use of such medications noticed in the university education subgroup requires further analysis. The marital status did not affect the adherence to the therapy in our study, either at baseline or at the end of the follow-up.

The presented variety of therapeutic strategies shows that a number of factors not included in the therapeutic recommendations affect the treatment in everyday practice. Also, the recommendations are subject to periodic changes, for example as a result of developing new diagnostic tools for osteoporosis.<sup>31</sup>

The current study has some limitations. A significant part of the baseline patients were lost during the follow-up, and the phone interviews could have been less informative than personal talks. The study was limited to women only. It was also not possible to establish indications for therapy at the follow-up because the investigators did not know all necessary details. Therefore, possible precise assessment of indications for therapy at baseline cannot be compared with adequate reliable data at the follow-up. In order to use the same method of patient evaluation during the whole period of observation, we did not establish baseline indications for therapy using available tools, such as Fracture Risk Assessment Tool or POL-RISK. However, the study design allowed us to gather a population-based epidemiological sample close to 1000 participants at baseline. The long-term follow-up and the collected data on several factors, potentially influencing changes in the therapy for osteoporosis, provided useful insights and promising perspectives for further research.

To conclude, the changes in the therapy of postmenopausal osteoporosis, observed in the 10-year follow-up in an epidemiological sample of postmenopausal women, indicated that the level of care in postmenopausal osteoporosis did not improve between 2010 and 2020. In order to avoid an epidemic of osteoporotic fractures, there is a need for wide introduction of osteoporosis screening programs as well as educational programs for general practitioners and patients improving the general knowledge about osteoporosis therapy options.

## ARTICLE INFORMATION

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**CONFLICT OF INTEREST** None declared.

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