



THE QUALITY OF LIFE IN WOMEN WITH POSTMENOPAUSAL OSTEOPOROSIS AND THE IMPACT OF FALLING

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Introduction. Postmenopausal osteoporosis is associated with an increased risk of fragility fractures and secondary morbidity, which can significantly impair the health-related quality of life (HR-QoL).

Objective. To analyse the HR-QoL in a group of postmenopausal women with osteoporosis compared to an age-matched group of women without osteoporosis and to assess the impact of falling and fractures.

Methods. The study group consisted of 92 women with postmenopausal osteoporosis. The control group consisted of 68 age-matched women without osteoporosis. We assessed the HR-QoL using both a generic (EQ-5D) and a disease-specific [the osteoporosis assessment questionnaire (OPAQ)] QoL instrument. The serum concentration of 25 hydroxy-vitamin D (25OHD) was measured by electrochemiluminescence. Fragility fractures and falling episodes status was assessed.

Results. Vitamin D (VD) deficiency was markedly prevalent in both groups (68% of all women had serum 25OHD concentrations <20 ng/ml). The patients with osteoporosis had significantly worse scores on bodyimage and pain, borderline significance for lower visual assessment score (VAS).

In the osteoporotic group, patients with falling episodes in the previous year had worse scores for the fear of falling, bodyimage and global QoL. If corrected for the falls number, the number of prevalent fractures was not significantly correlated to any of the QoL items.

Conclusions. Women with postmenopausal osteoporosis have impaired HR-QoL compared to age-matched women. The presence of a positive falling history is particularly associated with affected QoL subscores.

Key words: postmenopausal osteoporosis, quality of life, falls, fractures.

INTRODUCTION

Postmenopausal osteoporosis is a disease with increased worldwide prevalence, associated with an increased risk of fractures and subsequent morbidity¹. Chronic pain, disability, muscle mass loss, frailty, avoidance of physical activity due to fear of falling – all can progressively become part of the life of a postmenopausal woman with osteoporosis. Therefore, health-related quality of life (HR-QoL) has become an important outcome criterion in the assessment and follow-up of osteoporotic patients.

Various studies have documented that women with postmenopausal osteoporosis have reduced generic HR-QoL compared with the age-matched

female general population². Prevalent fragility fractures have been particularly associated with an impaired HR-QoL in osteoporotic women^{3,4}. Frequent falls, even if they are not followed by fragility fractures, also have a detrimental impact on the QoL⁵. The pathogenetic correlations are insufficiently characterized.

The objective of the present study was to examine several dimensions of the HR-QoL using both a generic QoL instrument (designed to assess the HR-QoL in all populations, with and without medical conditions, broadly used for comparisons across diverse groups of subjects) and a disease-specific QoL tool (targeted at the evaluation of patients with osteoporosis) in a group of postmenopausal women with osteoporosis compared to a group of age-matched women with normal bone mass.

MATERIAL AND METHODS

We studied 180 postmenopausal women, recruited from the cases referred to a tertiary endocrinology center, the Department of Pituitary and Neuroendocrine diseases of the “C.I. Parhon” National Institute of Endocrinology. All patients had been referred by the general practitioner for the evaluation of the bone mass, for the management of already diagnosed low bone mass or for the clinical suspicion of thyroid disease. We excluded from the study the patients with active malignancies, inflammatory or metabolic bone disease, severe arthritis with disabling pain, chronic inflammatory rheumatoid disease, clinically significant endocrine disorder. The study was approved by the Ethics Committee of our institution and all patients signed an informed consent.

Baseline assessments of anthropometric data, medical history, and prevalent fracture status were obtained from all participants. For the assessment of possible unrecognized vertebral fractures, a radiography of the dorsal spine was performed in all patients complaining of dorsal pain.

The history of falling episodes was assessed in all women. Subjects who had at least one fall episode in the previous year were defined as “fallers”, as opposed to “non-fallers” (those who did not have a fall in the previous 12 months).

In all cases the evaluation included the serum concentration of 25-hydroxy vitamin D (25OHD) by electrochemiluminescence method (Cobas e601) in order to assess the VD status. We defined the VD status as follows: 25OHD ≥ 30 ng/ml – VD sufficiency, $20 \leq 25\text{OHD} < 30$ ng/ml – VD insufficiency, $10 \leq 25\text{OHD} < 20$ ng/ml – VD deficiency, < 10 ng/ml – severe VD deficiency.

All women were also assessed by central X-ray absorptiometry (DXA) (lumbar spine L1-L4 and hip) using a GE Healthcare Lunar Prodigy machine. For the diagnosis of osteoporosis we used the criteria devised by the World Health Organisation (WHO, 2004).

After the complete baseline evaluation we included 180 postmenopausal women in the study. The study group consisted of 92 women with postmenopausal osteoporosis (defined by central DXA densitometry). The control group consisted of 68 age-matched women without osteoporosis

(defined by DXA), without positive history for fragility fractures).

We recorded the quality of life in both groups using two widely validated questionnaires: European Quality of Life 5 Dimensions Index (EQ-5D; former EuroQoL) and the short version of the osteoporosis assessment questionnaire (OPAQ-SV).

EQ-5D is a standardized, generic measure of health-related QOL. The first part evaluates 5 items (mobility, self-care, usual activities, pain and anxiety). Each item is divided into three levels (level 1: no problem, level 2: moderate problems, level 3: severe problems). For each item we estimated the percentage of subjects reporting each of these levels. The second part of the questionnaire asks the subject to rate his/her overall perception of the own health on a visual scale (VAS, visual analogue scale) from 0 to 100 (worse to best possible health)⁶.

The OPAQ-SV questionnaire is a validated disease-targeted instrument that assesses three dimensions of the HR-QoL: physical function (walking/bending, daily activities transfer), emotional status (fear falls, body image) and back pain⁷. OPAQ is scored such that a high value indicated better health status.

STATISTICAL ANALYSIS

The statistical analysis was performed using the SPSS programme, version 17.0 for Windows (SPSS Inc., Chicago, IL). Comparisons among the two groups as well as among subgroups of subjects were done using the Mann-Whitney U-test. Linear regression analysis was used to assess independent variables affecting certain QoL items. Spearman correlation coefficients were obtained to assess the correlation between non-parametric variables. P values < 0.05 were considered as statistically significant.

RESULTS

The selected cases were 55–83 years old, with a median age of 62 years; there was no statistical difference between the age of osteoporotic cases and that of the women in the control group (Table 1).

Table 1

General characteristics of the women in the study group and control group

	All cases	Study group (N = 72)	Control group (N = 48)	P
Age (Mean \pm SD)	64.04 \pm 7.12	65.06 \pm 7.2	62.5 \pm 6.77	0.052
At least one fall episode in the previous 12 months	21	17	4	0.031*
Prevalent fragility fractures (no of cases)	45	45	0	0.000*
Serum 25OHD (Mean \pm SD)	16.82 \pm 7.94	19.07 \pm 8.16	13.43 \pm 6.29	0.005*

Of the 92 cases with osteoporosis, 45 were under antiosteoporotic treatment with oral bisphosphonates at the time of the study (for the last 1–3 years), while 47 were naïve to antiosteoporotic treatment. 58 patients in the study group received cholecalciferol (800–1000 IU daily) at the time of the study while 34 received no VD supplementation. Only 25 of the postmenopausal women in the control group received cholecalciferol; none received bisphosphonates.

Overall, the serum 25OHD concentration ranged between 4.49–46.45 ng/ml, with a median concentration of 15.97 ng/ml. There was a marked predominance of low VD status (20.8% severe VD deficiency, 47.5 % VD deficiency, 25.83% VD insufficiency, only 5.83% of all cases had normal

VD status). The serum level of 25OHD was significantly higher in the study group compared to the control group (Table 1 and Figure 1).

Fractures were present only in the osteoporotic group: 45 cases had at least one prevalent fragility fracture (32 had only one fracture, 10 had 2 fractures, 2 with 3 fractures and one woman had sustained 5 fragility fractures). Also the number of fallers was significantly higher in the study group compared to the control group (Table 1).

The patients with osteoporosis had significantly worse scores on bodyimage (OPAQ) and pain (EQ-5D), borderline significance for lower visual assessment (VAS) score (EuroQoL) – see Tables 2 and 3.

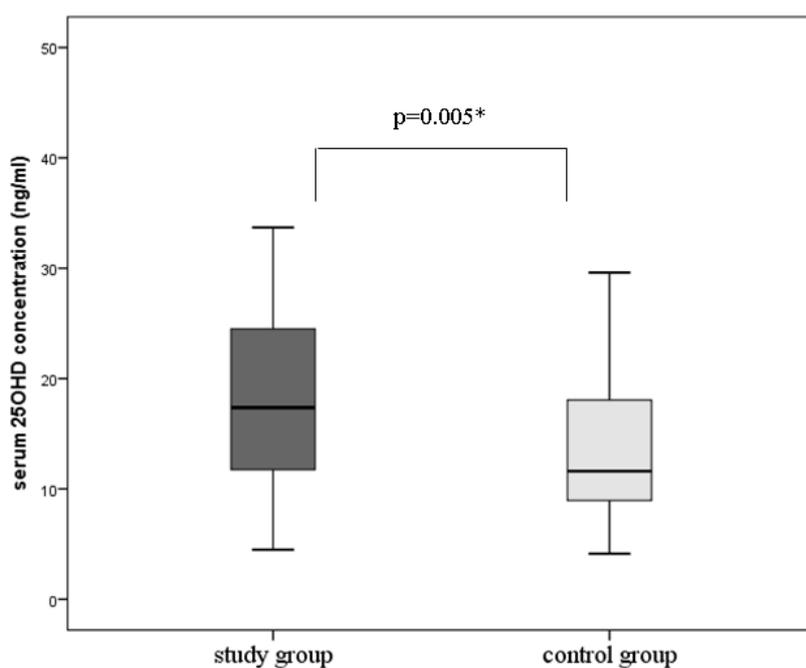


Figure 1. Serum concentration of 25OHD in the study group and control group.

Table 2

Comparison of EQ-5D results among groups

Dimension of health	%cases reporting problems in the study group			% cases reporting problems in the control group			p
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	
Mobility	63.4	36.6	0	64.6	35.4	0	0.894
Selfcare	84.5	12.7	2.8	81.3	18.8	0	0.698
Usual activities	64.8	33.8	1.4	64.6	35.4	0	0.974
Pain	22.5	70.4	7	37.5	62.5	0	0.029*
Anxiety	56.3	36.6	7	56.3	43.7	0	0.751
VAS	66.78 ± 14.24			72.97 ± 15.92			0.049*

Table 3

Comparison of OPAQ results among groups

Dimension of HR-QoL	Study group	Control group	p
Bending	54.69 ± 11.78	59 ± 10.61	0.165
Usual activities	72.09 ± 11.15	74.66 ± 7.76	0.361
Transfer	33.63 ± 17.18	34.88 ± 7.94	0.524
Fear of falling	31.15 ± 8.23	31.83 ± 6.41	0.746
Pain	25.66 ± 8.26	29.44 ± 6.85	0.079
Bodyimage	22.42 ± 6.08	26.77 ± 4.45	0.006*
Independence	22.72 ± 6.11	24.22 ± 5.08	0.345
Global score	76.97 ± 13.4	76.02 ± 21.43	0.800

In the osteoporotic group, the fear of falling and bodyimage score were significantly worse in patients with falling episodes in the previous year (Figure 2). Also the global QoL score of OPAQ was lower in fallers compared to non-fallers – see Table 4.

The impact of prevalent fractures on QoL items was lower. The fear of falling was the only QoL parameter globally correlated with the number of prevalent fractures. However, the partial correlation obtained after correction for the number of falls (which was, as expected, significantly higher in patients with fractures) was no longer statistically significant. In a multiple regression model including as dependent variables the age, the number of falls and fractures, the number of falls was an independent predictor for a worse score in the fear of falling item of the OPAQ (beta coefficient – 0.327; $p = 0.045$), data not represented.

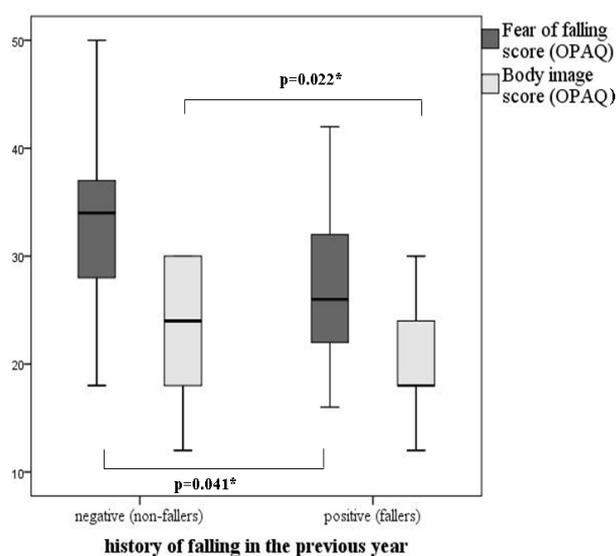


Figure 2. The fear of falling and bodyimage score were significantly worse in fallers (patients with falling episodes in the previous year).

Table 4

The difference in QoL scores in osteoporotic women with and without falling episodes or fractures

	Fallers	Non-fallers	p	Prevalent fractures	No fractures	p
OPAQ						
Bending	50±12.92	56.32±11.03	0.051	52.43±11.86	56.82±11.46	0.082
Usual activities	68.94±14.85	73.18±9.5	0.284	70.25±12.21	73.82±9.93	0.098
Transfer	32.35±7.81	34.08±6.98	0.394	32.68±7.3	34.52±7.07	0.182
Fear of falling	27.17±8.63	32.53±7.71	0.024*	30.21±7.69	32.02±8.74	0.022*
Back pain	23.76±7.51	26.32±8.48	0.266	24.75±7.84	26.52±8.67	0.271
Body image	20.82±5.47	22.97±6.23	0.048*	21.43±5.81	23.35±6.26	0.161
Independence	20.70±6.66	23.42±5.81	0.130	22.12±6.32	23.29±5.94	0.481
Global OPAQ score	71.34±14.66	78.88±12.53	0.041*	74.49±13.46	79.23±13.13	0.091
EQ-5D %cases reporting problems level1/level2/level3						
Mobility	52.9/47.1	66.7/33.3	0.309	55.9/44.1	70.3/29.7	0.212
Self care	76.5/17.6/5.9	87/11.1/1.9	0.283	79.4/17.6/2.9	89.2/8.1/2.7	0.272
Usual activities	58.8/35.3/5.9	66.7/33.3	0.465	58.8/38.2/2.9	70.3/29.7	0.283
Pain	11.8/82.4/5.9	25.9/66.7/7.4	0.354	14.7/76.5/8.8	29.7/64.9/5.4	0.132
Anxiety	52.9/41.2/5.9	57.4/35.2/7.4	0.818	55.9/38.2/5.9	56.8/35.1/8.1	0.969
VAS	66.42 14.93	67.91 12.33	0.677	65.96 15.09	67.73 13.46	0.804

DISCUSSION

We investigated the HR-QoL in a group of postmenopausal women with osteoporosis and compared the results to those of age-matched postmenopausal women with normal bone mass. The group had a very high prevalence of vitamin D deficiency (68% of all subjects had serum 25OHD concentration below 20 ng/ml), in line with previous studies documenting the dimension of this problem in Romanian population^{8,9}. However, despite the fact that VD deficiency in itself might impair some QoL items¹⁰, it is unlikely that this contributed to any major extent to our results because VD deficiency was very frequent in both groups studied. In fact, the serum VD concentration was higher in the study group, as a result of the more widely prescribed (though clearly suboptimal) VD replacement in this group.

The osteoporotic group had lower results in the body image and pain scales as well as lower self-perceived health (assessed by the VAS). Global reduction of the HR-QoL has been reported in postmenopausal women with osteoporosis compared with age-matched healthy women but the possible etiologic relationship linking osteoporosis and impaired QoL, if any, is not clearly established².

Frequent falls are not only one of the most important factor for fragility fractures¹¹, but possibly important elements in the individual HR-

QoL. Our results suggest that osteoporotic women are more frequent fallers than healthy age-matched postmenopausal women. Similar results were described in a population survey performed in Germany which indicated that women with osteoporosis have a higher rate of falls compared to the general population¹².

In our study, prevalent fractures appear to have a lower impact on HRQoL compared to falls. This seems to contradict some of the results of other studies that documented that vertebral, hip and non-vertebral-non-hip fragility fractures significantly impair the QoL¹³. Relevant HR-QoL impairments have been described in the physical function as well as socio-emotional status and overall HR-QoL^{3,14,15}. Such significant reductions in QoL scores in women with previous fragility fractures have been described both with generic and disease-specific tools (including OPAQ)^{16,17}.

However, other studies using EQ-5D as an assessment tool, reported that the global QoL impairment in osteoporotic women is not dependent on the positive history of fracture², a result similar to what we obtained.

Our relative small study sample does not allow us to draw definite conclusions on this aspect. However, it is possible that frequent falling exerts a more deleterious effect on the chronic patient's perception of his/her own health than fractures themselves. Women frequently view the fragility fractures as accidents and do not perceive the

increased further fracture risk¹⁸. On the contrary, our results show that falls are associated with increased fear of further falling as well as a global decrease of HR-QoL. Other studies have also documented that falls are negatively associated with the quality of life independent of other comorbidities⁵. The causal relationship is again elusive, but fear of falling probably plays a significant role. Fear of falling impairs balance and postural stability¹⁹, can lead to further avoidance of activity and conceivably impairment of HR-QoL. Indeed in a large study assessing the factors that influence the HR-QoL in postmenopausal women, high fear of falling was among the most important factors associated with impaired HRQoL⁴.

All these results suggest that frequent falling can contribute on its own to the decreased psychological well-being of women with postmenopausal osteoporosis and falling prevention should become a crucial intervention not only in fracture prevention programmes but also in our combined efforts to increase the well-being and the confidence of postmenopausal women with osteoporosis to independently perform their tasks.

In the future effort to better delineate the etiological connections between various characteristics of the postmenopausal osteoporotic female population and impaired HR-QoL items, it is essential to further develop adequate QoL research instruments. The use of generic QoL instruments is probably not optimal in this population, especially in the older age. With advancing age the risk of comorbidities, physical limitation, reduced muscle mass and performance (sarcopenia) increases and this is likely to specifically affect certain QoL items. Therefore, the use of disease-specific instruments specifically designed for frail patients is probably ideal²⁰.

CONCLUSIONS

Women with postmenopausal osteoporosis have impaired quality of life compared to age-matched postmenopausal women. The global quality of life score as well as certain subscores (fear of falling, body image) are significantly worse, especially in patients with positive history for falling compared to non-fallers.

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