

Predictors of quality of life in women with postmenopausal osteoporosis

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Summary

Aim. The aim of the study was to assess the predictors quality of life (QoL) in women with postmenopausal osteoporosis.

Method. The study was an outpatient, questionnaire-based poll, carried out from June 2018 to May 2019. The study included a group of 198 women, aged 72.31 ± 8.59 years, with diagnosed postmenopausal osteoporosis, treated in two osteoporosis clinics in the city of Lodz (Poland). The inclusion criteria were as follows: a diagnosed osteoporosis in the patients' medical records according to the ICD-10 – M81.0 and no chronic diseases which would require systematic treatment. The paper utilized the following tools: the Polish version of the QUALEFFO-41 quality of life scale, the visual analogue scale (VAS) and the author's own survey. The data were analyzed with the use of the multiple linear regression. Statistical analysis was performed using Statistica 13.0 software.

Results. The average result of the QUALEFFO-41 was 40.26 ± 16.92 points. An analysis of particular QUALEFFO-41 domains revealed the lowest quality of life in the mental function domain (48.49 ± 18.06 points). The domain of activities of daily living was assessed twice as well compared to the domain of mental functions. Marital status, education and financial situation had a statistically significant impact on the quality of life ($p < 0.05$). The analysis showed that the pain expressed on the VAS scale, pain waking from sleep, taking sleeping pills, and older age of the respondents deteriorate the quality of life.

Conclusions. The analysis showed that Polish women with postmenopausal osteoporosis enjoy an average quality of life. The quality of life of chronically ill patients and pain severity on the VAS scale are not routinely or commonly assessed in Poland.

Key words: QUALEFFO-41, quality of life, postmenopausal osteoporosis

Introduction

The World Health Organization reports that people aged 60 years or older make up more than 11% of the world's population and it is estimated that by the year 2050,

this number will have increased up to about 22% [1]. As life expectancy increases, the number of osteoporosis cases also continues to increase. This observation is disturbing for countries with ageing populations, including Poland. 30–40% of postmenopausal women in Poland are estimated to struggle with osteoporosis [2].

The most serious complications of osteoporosis are bone fractures. They are painful and limit physical fitness and social functions, which are indicators of health-related quality of life (HRQoL). Kanis et al. [3] assume that due to demographic changes in the world's population, the annual number of bone fractures in people with osteoporosis will increase from 3.5 million in 2010 to 4.5 million in 2025, which corresponds to a 28% increase. A recently published study by Glinkowski et al. [4] demonstrates that femoral neck fractures in Polish people with osteoporosis aged over 50 years are more and more common. In many people, bone fractures contribute to loss of independence, increased pain and deterioration of HRQoL, which may affect the mental condition of the patient and limit their social life.

The International Costs and Utilities Related to Osteoporotic Fractures Study (ICUROS) results revealed that the quality of life substantially deteriorates immediately after a bone fracture and the mental condition improves only after about 18 months. However, it still remains lower than before the fracture [5]. Moreover, a bone fracture is associated with development of other harmful complications such as disability, depression, cardiovascular disease, stroke, and increased mortality.

The increasing number of bone fractures in the course of osteoporosis, particularly observed in developed countries, poses a serious health and economic problem [6]. It is estimated that by 2025, the cost of osteoporosis treatment in Poland (i.e., costs in the first year and in the years following the fracture, pharmacological interventions, convalescence period, including administration costs) will have increased by 27% [7] and in European Union countries – by 25% (i.e., from €37.4 billion in 2010 to €46.8 billion in 2025) [7, 8].

Curtis et al. [8] note that osteoporosis, compared to other non-communicable diseases, is rarely adequately funded by the government and healthcare providers, unfortunately we can also observe this trend in Poland. Analyzing the individual countries of the European Union (EU), there are 4.3 densitometric devices in Poland (DXA – dual-energy X-ray absorptiometry) per million inhabitants, only Lithuania (3.4 DXA/million), Luxembourg (2.0 DXA/million) and Bulgaria (1.2 DXA/million) have fewer devices [8]. On the other hand, the largest number of DXA testing devices per million inhabitants in the EU, as many as 53, is in Belgium, which shows the scale of the problem of difficulties in accessing diagnostics, adequate monitoring and treatment of this disease [8].

It should be remembered that sleep problems affecting the quality of life in the elderly, which in women are related to menopause, also increase with age [9]. Polo-Kantola [10] reported that 25% of women aged 50–64 years had sleep issues and 15% of them suffered serious sleep disorders, which significantly affected their quality of life.

There are many detailed questionnaires used to measure the quality of life of people with osteoporosis, but none of them is as specific as the QUALEFFO-41 [11, 12]. Limitations related to old age (e.g., difficulty moving, loneliness, sleep disturbances),

chronic pain, problems with access to diagnostics (e.g., DXA), and an increased risk of bone fractures are just some of issues which people with osteoporosis must face every day. A great challenge is to maintain a good mental state and high quality of life. Therefore, the main objective of our study was to make a general assessment of the quality of life (QoL) of female respondents with osteoporosis, depending on their sociodemographic situation and pain assessed on the Visual Analogue Scale (VAS).

Objective

The aim of the study was to analyze the levels of quality of life in women with postmenopausal osteoporosis depending on sociodemographic factors.

Materials and method

The study was conducted from June 2018 to May 2019. The patients were examined in two osteoporosis treatment outpatient clinics in Lodz. The study included 198 postmenopausal women aged 72.3 ± 8.59 years (range: 51–90 years). The study patients were not randomly selected, but the group included women who had been diagnosed with postmenopausal osteoporosis (according to ICD 10 – M81.0) by a doctor at the osteoporosis treatment outpatient clinic.

The researcher presented information brochures about the purpose and course of the survey to all women who waited for an appointment in the clinic waiting room. The women who agreed to take part in the study were individually invited to a separate room at the clinic, where they signed an informed consent to participate in the study and filled in questionnaires (at the same time they had an opportunity to ask questions to the researcher). Then, the researcher analyzed the medical records of the respondents and purposefully selected patients with confirmed postmenopausal osteoporosis (ICD 10 – M81.0), diagnosed in their medical history (the main qualification criterion). The women who did not meet the main criterion were excluded from the study.

Other criteria for including women in the study group were as follows:

- informed consent to participate in the study;
- completion of the QUALEFFO-41 and VAS questionnaires;
- no hospitalization during the last six months.

The following women were excluded from the study:

- women with active cancer, with malignant bone metastases;
- women who failed to complete the QUALEFFO-41 and VAS, questionnaires;
- women treated with glucocorticoids;
- women with currently broken bones;
- women hospitalized in the last 6 months.

The research method was a diagnostic survey and the tools were as follows:

1. The quality of life was assessed on the basis of the Polish version of the detailed questionnaire – QUALEFFO-41, which consists of 41 questions, in which we distinguish 5 main domains: pain (5 questions), physical functions (17 questions), social functions (7 questions), general health perception (3 questions), and mental functions (9 questions) [13]. In our study, physical functions were divided into: physical activities (4 questions), jobs around the house (5 questions) and mobility (8 questions). The result was analyzed according to the algorithm proposed by the International Osteoporosis Foundation on a scale from 0 to 100. In interpreting the results of the questionnaire the principle was applied that the more points the worse the quality of life. When filling in the questionnaire, one should choose only one answer for each question. The results of each domain and the total QUALEFFO-41 result were analyzed.
2. The Visual Analogue Scale (VAS) to assess the severity of pain during the last week. Subjects choose a number on the line, with “0” indicating no pain and “10” the most severe pain one can imagine. This method of determining the severity of pain is simple and it is universally applicable in medicine.
3. The author’s questionnaire, consisting of questions on sociodemographic data (e.g., age, marital status, place of residence, financial situation).

Ethical issues

The survey was voluntary and was conducted according to principles of human research specified in the Helsinki Declaration. The respondents signed an informed consent form and were told that the study would be anonymous, according to currently applicable regulations and provisions of the GDPR. Before filling in the questionnaires, the patients were informed about the purpose of the study and instructed how to complete the questionnaires correctly. Each person qualified for the examination provided answers in the room in which they stayed together with the surveyor. Some patients asked the surveyor to read the questions aloud, then they answered the questions verbally, and the answer was circled in the questionnaires. The duration of the survey was adjusted to individual capabilities of the examined woman.

The study was approved by the Bioethics Committee of the Medical University of Lodz (Resolution No. RNN/215/18KE of June 12, 2018).

Statistical analysis

Results obtained from the questionnaires were statistically analyzed. The values of the analyzed parameters were provided with the use of: mean, median, standard deviation, minimum and maximum values. The Shapiro-Wilk test was used to test the normality of the quantitative variable distribution. Correlation coefficients between quantitative variables were calculated using the Spearman or Pearson correlation, according to the distribution of the variable.

Intergroup comparisons were performed with the use of the ANOVA and Mann-Whitney *U* test. Data were analyzed using multivariable regression analysis. The level of $p < 0.05$ was adopted as statistically significant. The statistical analysis was performed with the use of the Statistica 13 PL software (StatSoft, Tulsa, OK, USA).

Results

Characteristics of the study group.

198 women with postmenopausal osteoporosis were included in the survey. The mean age was 72.3 ± 8.59 years (range 51–90 years). The vast majority of study participants had abnormal body weight – the mean body weight was 64.5 ± 11.66 kg and the mean height was 158.6 ± 6.52 cm, which represents a body mass index (BMI) of 25.71 ± 4.73 kg/m² for the entire group of women.

Almost half of the respondents (47%; $n = 93$) were married. The vast majority of the survey participants, as many as 57% ($n = 112$) lived in a city with a population of over 100,000 inhabitants, and only 9% ($n = 17$) of women – in rural areas. Most of the respondents had secondary (35%; $n = 70$) and higher (25%; $n = 50$) education. As many as 89.4% ($n = 177$) of the respondents were retired and only 10.6% ($n = 21$) were professionally active. Over half of the respondents – 53% ($n = 105$) rated their living conditions as good.

In the study group, the mean age of diagnosed osteoporosis was 61.82 ± 9.74 years (range 43–81 years). The duration of osteoporosis among the respondents was on average 10.70 ± 8.53 years. In addition, 28.8% of the respondents ($n = 57$) reported that osteoporosis occurred in the immediate family. In 54% ($n = 31$) of cases it affected mothers and in 21% ($n = 12$) – sisters of the surveyed women. The respondents slept about 7 h on average. Sleeping pills were taken by 51% ($n = 101$) of women. Sleep problems caused by pain were reported by 49% ($n = 98$) of the respondents. Characteristics of the studied group are presented in Table 1.

Table 1. Characteristics of the study population. The levels of quality of life measured using the QUALEFFO-41 depending on sociodemographic factors

Factors		Population [n]	QUALEFFO 41 [pts ±]**	ANOVA (p-value)
BMI*	Underweight	13	44.99 ± 24.38	p = 0.251
	Normal body weight	78	37.49 ± 15.98	
	Overweight	75	41.24 ± 16.37	
	Obesity	32	42.82 ± 16.63	
Education	Primary	41	53.36 ± 15.47	p < 0.05
	Vocational	37	41.24 ± 15.18	
	Secondary	70	35.04 ± 15.88	
	Higher	50	36.11 ± 15.18	

table continued on the next page

Place of residence	Village	17	47.61 ± 14.16	p = 0.136
	City of above 50,000 inhabitants	26	35.74 ± 18.69	
	City of 50,000 – 100,000 inhabitants	112	38.79 ± 15.36	
	City of over 100,000 inhabitants	43	40.76 ± 17.23	
Living conditions	Very good	17	35.81 ± 14.13	p < 0.05
	Good	105	36.03 ± 14.40	
	Unsatisfactory	51	42.72 ± 18.61	
	Very bad	25	56.08 ± 15.19	
Marital status	Never married	14	37.91 ± 22.79	p < 0.05
	Married	93	39.45 ± 16.04	
	Widowed	72	44.74 ± 16.99	
	Divorced	19	29.03 ± 9.08	
Any fractures	Yes	137	42.05 ± 17.31	p < 0.05
	No	61	36.25 ± 15.40	
Pain awakens during sleep	Yes	98	47.28 ± 15.13	p < 0.05
	No	100	33.39 ± 15.77	
Pain during the day	Yes	156	43.15 ± 16.40	p < 0.05
	No	42	29.56 ± 14.45	

N – number of respondents; p – statistical significance level

*BMI – Body Mass Index (underweight: <18.5 kg/m², normal weight: 18.5–25 kg/m², overweight: 25–30 kg/m², obese: >30kg/m²).

** The quality of life is assessed on a scale of 0–100, where 0 indicates the highest quality of life and 100 indicates the lowest quality of life.

The surveyed women rated their quality of life as average, 40.26 ± 16.92 (median = 39), according to the QUALEFFO-41. A detailed analysis of the QUALEFFO-41 questionnaire shows that the surveyed women reported the least number of problems in the activities of daily living domain and mobility domain. The respondents assessed the mental function most negatively (Table 2).

Table 2. QUALEFFO-41 results according to domain

QUALEFFO-41 domain	Mean \pm SD	Median
Activities of daily living	24.58 \pm 19.49	25
Mobility	34.56 \pm 24.80	29
Pain	42.27 \pm 24.47	40
Jobs around the house	37.27 \pm 26.64	40
General health perception	44.61 \pm 28.34	42
Leisure, social activities	44.29 \pm 23.34	46
Mental function	48.49 \pm 18.06	50

Interpretation: A higher score corresponds to worse quality in a particular domain; SD – standard deviation.

Then, the sociodemographic features were statistically analyzed. Education, marital status and financial situation appeared to have a significant impact on the quality of life (Table 1). People with secondary and higher education enjoyed a higher quality of life, compared to people with primary education. In addition, respondents with very good financial situation as well as divorced respondents rated their quality of life as highest.

Respondents with any bone fractures in their history rated their quality of life as worse according to the QUALEFFO-41 (42.05 \pm 17.31 points), compared to those without fractures (36.25 \pm 15.40 points). The greatest drop of QoL values was observed in patients with a hip fracture (51.88 \pm 18.90 points; $p < 0.05$) followed by ankle fracture (47.85 \pm 16.53 points; $p = 0.081$), vertebral fracture (44.38 \pm 15.41 points; $p = 0.063$) and upper limb fracture (40.02 \pm 18.05 points; $p = 0.958$).

The Cronbach's alpha reliability index in the QUALEFFO-41 total domains was high – 0.90. The Cronbach's α values for the QUALEFFO-41 domains were as follows: pain – 0.87, physical functions – 0.86, leisure, social activities – 0.86, general health perception – 0.90, and mental function – 0.89.

On the VAS scale, patients rated the pain as mild. The average level obtained on the VAS scale was 4.87 \pm 2.39 points. A statistically significant positive correlation ($r = 0.54$) between the pain assessed on the VAS scale and the quality of life in the QUALEFFO-41 scale was demonstrated. The relation between the VAS scale and domains of the QUALEFFO-41 was statistically analyzed and a positive correlation was obtained in all domains. Results of this correlation were as follows: pain $r = 0.58$, activities of daily living $r = 0.48$, jobs around the house $r = 0.56$, mobility $r = 0.56$, leisure and social activities $r = 0.29$, general health perception $r = 0.14$, and mental function $r = 0.13$.

The multivariable regression analysis revealed statistically significant predictors affecting quality of life. The model turned out to be significant, and explains 45.33% of the dependent variable regarding the quality of life ($F = 40.01$; $p < 0.05$). In the multivariable regression model, where all other variables have the same particular values, the natural logarithmic QUALEFFO-41 was statistically associated with: age, pain awakening at night, pain assessed on the VAS scale, and taking sleeping pills (Table 3).

Table 3. Predictors of quality of life in women with postmenopausal osteoporosis, aged 50 years or over

	β	SD	t	p
Age	0.31	0.51	5.49	p < 0.001
VAS	0.35	0.38	5.69	p < 0.001
Pain waking from sleep	0.14	0.68	2.32	p = 0.021
Taking sleeping pills	0.15	0.86	2.42	p = 0.016

β – absolute value of the standardized β coefficient; t – significance level t; SD – standard deviation; p – statistical significance level; VAS – Visual Analogue Scale.

By analyzing particular parameters, we can conclude that with each year of life, the quality of life of the surveyed women deteriorates by 0.61% according to the QUALEFFO-41. On the other hand, occurrence of painful ailments that cause nocturnal arousals decreases the quality of life by 4.9%. Besides, an increase in the VAS scale by one point deteriorates the quality of life by 2.4%, whereas the use of sleeping pills deteriorates it by 4.9%.

Discussion

The survey showed that the level of the quality of life of the respondents was average. The obtained results are similar to those previously reported by Bączyk et al. [14] for women with osteoporosis surveyed in Wielkopolska (Poland), also assessed using the QUALEFFO-41. While analyzing the particular QUALEFFO-41 domains, we found the lowest quality of life in the mental function domain, which reveals, among others, an emotional impact of a diagnosis and evaluates the mental state of the patient. This result is consistent with a previous study on the Polish population, which indicated that women with osteoporosis suffer from low quality of life, especially in the mental function, general health perception and social activities domains [14, 15]. It is suggested that the quality of life, assessed using the QUALEFFO-41, is different for different continents and ethnic groups. In most analyzes, the quality of life was lowest in Asia and Europe and highest in North America and Oceania [16]. Further research is undoubtedly needed to understand this phenomenon.

The study shows that marital status, education and financial situation have a statistically significant impact on the quality of life. We showed that women who were divorced assessed their mental state better.

The patient's education level, being a determinant of the quality of life, is another discovery in this study. In our survey, secondary and higher education was a protective factor against poorer quality of life. Similar relations were noted by de Oliveira Ferreira et al. [17] and Abourazzak et al. [18]. This can be explained by the fact that women with higher education usually search for more information about their illness (they broaden their knowledge), so consequently, they take supplements more often (e.g., vitamin D3, calcium preparations) or introduce hormone replacement therapy [18, 19].

We have also shown that a financial situation affects the quality of life in women with postmenopausal osteoporosis. It is suggested that a state of being richer provides access to better quality medical services (e.g., DXA) [20]. Other authors confirm our results and also indicate that well-paid job improves the quality of life of women with postmenopausal osteoporosis according to the QUALEFFO-41 [17]. Literature reports show that BMI, race, education, age at menopause, and implementation of hormone therapy are factors which are significantly related to the quality of life [17]. Osteoporosis reduces the patient's quality of life by affecting all their spheres. This shows that further interventions are needed to improve psychological support and education of patients as well as long-term treatment of osteoporosis.

A study conducted by Janiszewska et al. [2] among 292 women aged 51–83 in Lublin (Poland) showed that better educated female city dwellers who enjoy very good or good social and welfare conditions demonstrated a much higher level of knowledge about osteoporosis prevention. In addition, the same authors concluded that women who undergo bone densitometric testing also do not have sufficient knowledge about osteoporosis prevention. A low level of women's knowledge of prevention, diagnosis and treatment of osteoporosis additionally causes stress, triggers negative emotions and decreases their quality of life.

Results of this study showed that the total QoL in women with a bone fracture in the medical records was lower than among respondents without fractures. Bączyk et al. [14], Lesnyak et al. [21] and Gold et al. [22] showed the same relationship. Interestingly, we found that women with a femoral neck fracture assessed their quality of life more negatively than people with fractures of other bones and the value was statistically significant. A similar relationship was observed in Russia among patients with osteoporosis aged over 50 years, where a lower quality of life was demonstrated in patients with a hip fracture compared to fractures of the spine, humerus or ankle [21]. After one-year observation of women with osteoporosis and a femoral neck fracture, Hagino et al. [23] concluded that the deteriorated QoL was not restored to the level observed prior to the bone fracture and was more severe than after a wrist fracture. However, so far, a vertebral fracture has been reported as one of factors deteriorating the quality of life in women with postmenopausal osteoporosis [15].

On the other hand, it should be noted that regardless of bone fractures, women with osteoporosis show a reduced quality of life in different QUALEFFO-41 domains. This is confirmed by the reports of, e.g., Hopman et al. [24], Ciubean et al. [25] and Bianchi et al. [26]. Perhaps it is related to increased chest kyphosis, decreased lean muscle mass and generalized muscle weakness [27]. Therefore, the authors suggest that the HRQOL should be tested before any bone fracture in order to develop appropriate interventions for all stages of the disease [24]. Hence, it would be advisable to increase the size of the study group so as to analyze this issue more closely.

This study indicates that one of factors associated with general health perception is sleep. Poor quality of sleep (sleep disorders) affects the bone micro architecture, which might lead to osteoporosis [28, 29]. It is known that a good night's sleep is a key factor in maintaining quality of life [9].

In the current study, we have noted that taking sleeping pills deteriorates quality of life. These observations correspond to an earlier study, which implies that the use of sleeping pills in women may be associated with worse bone condition and should be considered when examining older patients [29]. Moreover, pain waking from sleep affects the mental state of patients. According to Svensson et al. [30], Swedish women who experienced a spinal compression fracture complained about nocturnal sleep problems, woke up with severe pain, and many of them took sleeping pills to rest better.

We have not shown a statistically significant relationship between the sleep length and QUALEFFO-41 results. Literature reports confirm that short sleep time (shorter or equal to 5 h) was associated with a lower bone mineral density (BMD) and a higher risk of osteoporosis [31]. Ochs-Balcom et al. [31] found that short sleep time (5 hours or less) was associated with lower BMD and a higher risk of osteoporosis in a group of 11,084 postmenopausal women. Other authors emphasize that both short and long sleep time in middle-aged and elderly people is associated with a significantly increased risk of osteoporosis, whereas an appropriate sleep time may help in delaying or preventing osteoporosis [32, 33]. However, the appropriate length of sleep in people with osteoporosis has not been specified as yet and is still debatable and discussed.

Pain deserves special attention in this study because it was associated with poor quality of life. There was a good correlation in this aspect between the VAS and QUALEFFO-41 in all domains. A similar relationship in women with osteoporosis in Norway was observed by Stanghelle et al. [34]. Hubscher et al. [35] suggest that pain intensity negatively affects HRQoL in women with osteoporosis with or without a vertebral fracture. Moreover, chronic pain contributes to unbalanced gait, which increases the risk of falls in older people [36]. Albayrak et al. [37] found no statistically significant differences in total VAS and QUALEFFO-41 results. It would be advisable to assess the pain at the beginning of therapy and then monitor its level during treatment.

As the life extended, we observed a deterioration of the quality of life, and this results are similar to other studies using the QUALEFFO-41. In many publications, the authors highlight that fractures and age have a significant impact on HRQL in people with osteoporosis [15, 22]. Only counseling, support and psychological care for the elderly can help patients develop effective strategies for accepting and managing the disease [26]. In addition, improving medical care in Poland would require the implementation of a national fracture prevention program.

In our work, we used the Polish version of the QUALEFFO-41 questionnaire. The Cronbach's alpha reflecting the reliability of the Polish version of the QUALEFFO-41 for all domains was satisfactory and fell within the scope of internal consistency. Our Cronbach's alpha values are similar to those presented for the Polish population in the study by Bączyk et al. [14].

Our study has some limitations that should be mentioned. The results of the study concern women with postmenopausal osteoporosis from one city, it would be advisable to conduct a study in another city to verify the obtained results. After extending the duration of the study, the same respondents could be reexamined after two or three

years, and the individual stages of osteoporosis treatment and the history of fractures could be analyzed. After expanding the research group, it would be advisable to analyze the factors influencing the hygiene and quality of sleep of the respondents. In addition, an analysis could be made depending on the current bone mineral density.

To sum up, the level of the quality of life of women with postmenopausal osteoporosis in the Lodz Province is average. An unfavorable trend observed in this study, manifested with a deteriorated mental condition, is associated with the occurrence of pain, which should be considered a serious health problem. Pain waking from sleep and taking sleeping pills have the greatest impact on the quality of life. It would be advisable to introduce new methods of psychological assistance and sleep testing (hypersomnia), as well as to implement more effective methods (pharmacotherapy, physiotherapy) aiming at reducing pain and improving sleep quality in this group of patients.

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