

## General

# Quality of Life in osteoporotic patients

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### Background

Osteoporosis is responsible for fragility fractures, which are associated with impaired quality of life (QoL) and disability.

### Objective

The aim of the study was to evaluate the QoL in patients affected by osteoporosis and possible determinants.

### Methods

One-hundred thirty-four subjects followed at the osteoporosis outpatient clinic at our institution completed the QUALEFFO-41 questionnaire for quality of life. All subjects had undergone bone densitometry measurement and the FRAX index, summarizing the risk of fragility fracture, was calculated for each of them. The QoL in these subjects and its possible determinants were investigated with univariate and multiple linear regression analysis.

### Results

Subjects with osteoporosis had lower scores in the domains of physical and social function of the QUALEFFO questionnaire in comparison with subjects with normal bone mineral density. Main factors associated with impairment in QoL were high FRAX score and body mass index (BMI).

### Conclusion

Physical and social function is reduced in osteoporotic subjects. High BMI and an increased risk of fragility fracture were main determinants of impairment in the QoL in this study.

## INTRODUCTION

Osteoporosis is the most common metabolic disease of the skeleton, affecting approximately two-hundred million individuals worldwide.<sup>1</sup> This condition is often clinically silent until fragility fractures occur. Osteoporotic fractures represent one of the most common causes of disability and constitute one of the largest items in the health care budget of many countries.<sup>2</sup>

The aim of the study was to evaluate the quality of life (QoL), pain, and limitation in functional and social activi-

ties in subjects with osteoporosis. A further aim was to analyze possible predictors of the QoL in these subjects.

## MATERIALS AND METHODS

This cross-sectional study included a group of one-hundred thirty four subjects (mean age = 65.5 ± 10.4 years, range 34 – 90 years; 126 females (94%)), followed at the outpatient clinic of Orthopedic and Traumatology Department at Federico II University Hospital Napoli Italy were enrolled for this study. Sixty-four patients (47.8 %) had a previous

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fragility fracture. Informed consent was obtained from each subject. Bone Mineral Density (BMD) T-score calculated by femoral and lumbar by Dual X-ray Absorptiometry (DXA) performed less than one year earlier was obtained for all patients. In accordance with the World Health Organisation (WHO) criteria,<sup>3</sup> participants were categorised as having osteoporosis if they had T-scores lower than  $-2.5$  SD in the femur and/or in the lumbar spine. Patients with secondary osteoporosis or cognitive deficit were excluded from the study. All subjects completed the Italian version of 41-item Quality of Life Questionnaire of the European Foundation for Osteoporosis (Qualeffo-41) for the evaluation of QoL.<sup>4</sup> The Qualeffo-41 consists of five domains including pain (5 items), physical function (17 items), social function (7 items), general health perception (3 items), and mental function (9 items). In total, the lowest possible score is 0, and the highest possible score is 100. Higher scores reflect lower QoL. Furthermore, each subject enrolled in the study underwent a structural medical interview and the measurement of height and weight to calculate the FRAX score. The FRAX index is an algorithm designed by Kanis et al. aimed to calculate the absolute risk of global and hip osteoporotic fracture in the next 10 years in persons aged 40-90 years.<sup>5,6</sup> The FRAX questionnaire includes 12 items: age, sex, weight, height, previous fragility fracture, parent fractured hip, current smoking, use of glucocorticoids, association of rheumatoid arthritis, presence of conditions related to osteoporosis, such as type 1 diabetes, hyperthyroidism, chronic liver disease, and premature menopause (prior to age 45), consumption of alcoholics, and BMD.

#### STATISTICAL ANALYSIS

An independent sample t-test was performed to assess any differences in quality of life scores between osteoporotic and non osteoporotic patients. An age-adjusted univariate linear regression analysis was used to assess the association of independent variables (age, sex, body mass index (BMI), cigarette smoking, FRAX score (hip fracture and /or osteoporotic fracture), lumbar BMD T-score, femoral BMD T-score, and positive history of previous fragility fracture) with the Qualeffo-41 total and single domain scores. All explanatory variables that showed either an association or a trend toward an association (i.e.,  $P < 0.10$ ) with the outcome of interest in the univariate analysis were included in the multiple regression models. A value of  $P \leq 0.05$  was considered significant. Data were analyzed using SPSS software version 23.0 (SPSS, Chicago, IL, USA).

#### RESULTS

The characteristics of subjects enrolled in the study are reported in the [table 1](#). In the study group, seventy-one patients (53%) were diagnosed with osteoporosis. The [table 2](#) shows Qualeffo 41 total and single domain scores in osteoporotic and non-osteoporotic subjects. Osteoporotic patients had significantly higher scores in Physical Function and Social Function domain. Results of the age-adjusted univariate and multiple linear regression analyses are re-

**Table 1. Characteristics of the subjects in the study (N = 134)**

Patient data	Mean $\pm$ SD (range) or N (%)
Age (years)	65.5 $\pm$ 10.4 (34, 90)
Sex	
Females	126 (94.0)
Males	8 (6.0)
BMI	24.6 $\pm$ 3.7 (16.8, 39.5)
Smoking habit	90 (67.2)
Non-smokers	44 (32.8)
Smokers	
Serum 25-hydroxyvitamin D level (ng/mL)	32.1 $\pm$ 16.9 (5.7, 98.0)
BMD T-score - FN	-2.5 $\pm$ 0.9 (-6.4, -1.2)
BMD T-score - LS	-2.9 $\pm$ 1.1 (-7.0, -0.7)
FRAX score osteoporotic fracture %	19.3 $\pm$ 11.2 (4.1, 58.0)
FRAX score hip fracture %	9.9 $\pm$ 14.2 (0.3, 95.0)
Qualeffo 41 Total Score	41.8 $\pm$ 17.8 (6.5, 90.0)
Pain	43.3 $\pm$ 22.2 (0.0, 85.0)
Physical Function	30.4 $\pm$ 20.6 (0.0, 94.0)
Social function	47.0 $\pm$ 27.6 (0.0, 100.0)
General health perception	59.1 $\pm$ 23.5 (5.0, 100.0)
Mental function	42.8 $\pm$ 16.6 (3.0, 72.0)
Previous fragility fracture	
No	70 (52.2)
Yes	64 (47.8)

BMI = Body mass index; BMD = Bone mineral density; FN = Femoral neck; LS = Lumbar spine; FRAX = Fracture Risk Assessment Tool

ported in [tables 3](#) and [4](#). An increased risk of hip fracture assessed by FRAX score as well as a higher BMI were independent determinants of the total Qualeffo-41 score and accounted for 5 % and 4 %, respectively, of the variance in this outcome in the model of multivariate analysis. Unexpectedly, the positive history of fragility fracture was inversely related with the pain domain of QUALEFFO questionnaire. No relationships between BMD and QUALEFFO scores were found.

#### DISCUSSION

In the last decade there has been growing interest in the assessment of predictors of quality of life and personal autonomy in both young and elderly trauma patients.<sup>7,8</sup> Skeletal conditions such as osteoporosis and related complications may also negatively impact on physical, mental, social, and emotional health with consequent deterioration in QoL.<sup>9</sup> Indeed, fragility fractures and the fear for falling can lead to reduced mobility, reduced independence in daily

**Table 2. Qualeffo 41 total and single domain scores in osteoporotic and non-osteoporotic subjects**

	Osteoporosis		p
	No (N = 63)	Yes (N = 71)	
	Mean ± SD		
Qualeffo 41 Total Score	41.3 ± 17,1	43.4 ± 19.4	0.072
Pain	44.3 ± 22.9	45.2 ± 22.1	0.882
Physical Function	25.4 ± 17.1	35.4 ± 24.0	0.036
Social function	42.6 ± 23.6	51.2 ± 30.8	0.005
General health perception	56.6 ± 22.9	62.9 ± 25.0	0.386
Mental function	41.3 ± 17.1	45.0 ± 15.1	0.409

**Table 3. Determinants of Qualeffo 41 total and single domain scores at the age-adjusted univariate linear regression analysis**

Explanatory variable	c	p
Total score		
Age	0.44	0.001
BMI	1.05	0.013
FRAX score hip fracture	0.26	0.030
Pain		
BMI	1.36	0.009
Previous fragility fracture	- 9.20	0.020
Physical function		
Age	1.06	< 0.001
FRAX score osteoporotic fracture	0.57	0.001
FRAX score hip fracture	0.37	0.004
Previous fragility fracture	7.50	0.027
Social function		
Age	1.00	< 0.001
FRAX score osteoporotic fracture	0.66	0.011
FRAX score hip fracture	0.56	0.002
General health perception		
Male sex	-33.61	0.004
BMI	1.53	0.007
FRAX score osteoporotic fracture	0.79	0.001
FRAX score hip fracture	0.35	0.032
Mental function		
Male sex	-18.92	0.026
BMI	1.03	0.011
FRAX score osteoporotic fracture	0.45	0.004
FRAX score hip fracture	0.37	0.001

BMI = Body mass index; FRAX = Fracture Risk Assessment Tool

living activities and even social isolation of elderly subjects.<sup>10</sup> The results of this study, where osteoporotic patients showed worse QUALEFFO-41 scores when compared to non-osteoporotic subjects, concur with these literature data. Previous studies have found that other factors, including high BMI, previous spinal fractures fractures, and

low BMD of the total neck can negatively influence QoL.<sup>11</sup> In the current study, BMI was directly associated with impaired QoL in different QUALEFFO-41 domains, including the total score as well as the pain, general health perception, and mental function domains. Limited to the sample size of the current study group, no relationships between BMD and QoL were found. One previous study<sup>12</sup> also failed to find significant differences in quality of life among cohorts of subjects stratified by different BMD (T-score). Moreover, the QUALEFFO 41 questionnaire has not been specifically validated so far in patients with silent vertebral fractures or in nonfractured patients with low BMD.<sup>13</sup> In the study group, possible relationships between low BMD and QoL may have been clouded by the overwhelming association between BMI and QUALEFFO-41 scores, since BMD is higher in obese patients.<sup>14</sup>

The present study also found an inverse relationship between FRAX score and QoL. Specifically, an increased odd of fracture (higher FRAX index) directly correlated with increased scores in physical function, social function and general health perception QUALEFFO-41 domains. This data is consistent with the literature data. In a study by González Silva et al<sup>15</sup> the Barthel index, a scale that evaluates daily life activities, was inversely related to the FRAX index.

We acknowledge some limitations of the present study. This being a cross-sectional study, it was impossible to infer the causal relationship between QoL and the explanatory variables under investigation. Also the sample size of the present study is smaller in comparison with previous larger studies in the literature. This limitation may have decreased the statistical power of some tests. In spite of this, significant influences on QoL were nevertheless found for several variables. On the other hand, the multivariate analysis represents a strength of the present study. It permitted us to accurately evaluate the effects of several variables of interest on the QoL, while simultaneously controlling for the possible influences of multiple covariables.

## CONCLUSION

This study demonstrates that several aspects of QoL are reduced in osteoporotic subjects. High BMI and an increased

**Table 4. Determinants of Qualeffo 41 total and single domain scores at multiple linear regression analysis**

Explanatory variable	c	95% CI	p	Total R <sup>2</sup> %	R <sup>2</sup> Change %
Total score					
FRAX score hip fracture	0.33	0.09 – 0.56	0.007	5	5
BMI	0.91	0.04 – 1.78	0.041	9	4
Pain					
BMI	0.71	1.72 – 2.70	0.001	6	6
Previous fragility fracture	-10.69	-18.10 – -3.29	0.005	11	5
Cigarette smoking	7.76	0.05 – 15.46	0.049	14	3
Physical function					
Age	0.70	0.30 – 1.10	0.001	18	18
FRAX score osteoporotic fracture	0.57	0.22 – 0.92	0.001	25	7
Social function					
FRAX score hip fracture	0.56	0.21 – 0.91	0.002	10	10
Age	0.59	0.05 – 1.12	0.032	14	4
General health perception					
FRAX score osteoporotic fracture	0.88	0.49 – 1.27	< 0.001	12	12
BMI	1.77	0.69 – 2.85	0.002	21	9
Male sex	-25.99	-46.69 – -5.29	0.014	25	4
Mental function					
FRAX score hip fracture	0.40	0.20 – 0.60	< 0.001	10	10
BMI	0.95	0.20 – 1.69	0.013	16	6
Male sex	-17.41	-31.69 – -3.14	0.017	20	4

C = coefficient; CI = confidence interval; FRAX = *Fracture Risk Assessment Tool*; BMI = *Body mass index*

odds of fragility fracture negatively predict some aspects of QoL.

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**CONFLICT OF INTEREST**

The authors declare that there are no conflicts of interest.

**AUTHOR CONTRIBUTIONS**

Author contributions: the authors contributed equally

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None

**ETHICAL APPROVAL**

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**INFORMED CONSENT**

Informed consent was obtained from all individual participants included in the study

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