Association between generic and disease-specific quality of life questionnaires and mobility and balance among women with osteoporosis and vertebral fractures

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ABSTRACT. ***Background and aims:*** *The aims of this study were to assess correlations between two health-related quality of life (HRQOL) measurements, the Quality of Life Questionnaire issued by the European Foundation for Osteoporosis (QUALEFFO-41) and the total score of The General Health Questionnaire (GHQ-20) in a population of women living at home with well-established osteoporosis and at least one vertebral fracture, as well as the internal consistency and floor and ceiling effects of these measurements. Also examined were the mean values of these measurements, to ascertain whether they were significantly different for the group consisting of 75% of the women with the best performance on mobility and balance, compared with the other participants.* ***Methods:*** *Across-sectional study of 89 women aged 60 years or more, evaluated by QUALEFFO-41 (consisting of one total score and five section scores), GHQ-20 (one total score), maximum speed and Functional Reach (FR).* ***Results:*** *Cronbach's alpha coefficient for measurements of HRQOL ranged from 0.61 to 0.92. Significant correlations between 'QUALEFFO-41: total score' and 'GHQ-20: total score' were 0.49, and between 'GHQ-20: total score' and section scores of 'QUALEFFO-41' 0.28-0.63. Those in the 75% group with the highest maximum walking speed or longest distance on FR reported significantly better disease-specific HRQOL than the others, with poorer results on these tests.* ***Conclusions:*** *Disease-specific and generic HRQOL instruments are not redundant when applied together, and the disease-specific 'QUALEFFO-41' and generic GHQ-20 measure different aspects of HRQOL.*

(Aging Clin Exp Res 2011; 23: 296-303)

INTRODUCTION

There is increasing public health concern about osteoporosis among the elderly population, particularly in postmenopausal women (1, 2). The World Health Organization (WHO) has defined osteoporosis as a condition in which the bone marrow density (BMD) of the patient is 2.5 SD or more below the mean of gender-matched young adults. According to the WHO definition of osteoporosis, about 30% of women in the postmenopausal period have osteoporosis (3).

Vertebral fractures are the main and most common consequence of osteoporosis (4). Osteoporosis and vertebral fractures are associated with a variety of adverse consequences for health as well as for the quality of life (5). The health-related quality of life (HRQOL) covers those parts of the quality of life which directly relate to an individual's health (6, 7). As a long-term chronic disease, osteoporosis and its complications have a considerable impact on patients' quality of life, largely because of pain, reduction in physical function, and changes in mood undergone by patients (8).

Psychological distress has been consistently mentioned in association with osteoporosis in women and associated with their quality of life (1, 9-13). The physical, psychological and social consequences of osteoporotic fractures profoundly influence the health-related quality of life (HRQOL) (8, 14). This significantly affects not only individuals but also their families and communities. The results of a previous study showed that the quality of life of osteoporotic women with a fracture was significantly worse in all domains than that of healthy controls (15). Other studies have reported that, even without a fracture, the quality of life of osteoporotic women was poor compared with other subjects without osteoporosis (total score of 41 items of Quality of Life

Key words: Osteoporosis, quality of life, validation, vertebral fractures.

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Received December 31, 2009; accepted in revised form May 13, 2010.

Questionnaire issued by European Foundation for Osteoporosis: 39.5 and 25.6 respectively) (16, 17).

HRQOL: generic and disease-specific

HRQOL covers those parts of the quality of life which directly relate to an individual's health (6, 7). The concept is fundamental in healthcare, in that it recognizes the effects of illness (18) and facilitates resource decisions (19). HRQOL may be assessed using generic or disease-specific instruments (5). Generic questionnaires pose general questions on the respondent's health status, can be used to investigate the effect of various diseases, and enable comparisons between various diseases (20). These generic instruments give a general estimate of health and are not specific to any disease. They can be used to estimate the burden of disease in a population and to compare the consequences of various diseases. More recently, disease-specific instruments have been developed which may contain more relevant questions, are less time-consuming to administer, and may be more valid, in the sense that they measure the quality of life more accurately in people with that particular disease than generic instruments can (21). Examples of the generic instruments of HRQOL used to assess the quality of life in vertebral osteoporosis are the SF-36, SF-12, Sickness Impact Profile (SIP), Nottingham health profile (NHP), and EQ-5D (5, 20-24). Reginster et al. (25) examined healthy postmenopausal women to discover whether depressive symptoms, as assessed by the General Health Questionnaire (GHQ), were associated with a significant decrease in BMD. GHQ was also used in a study to assess the psychological effects of androgen therapy on men with osteoporosis (26), and was also used by Werner (13) to assess whether the GHQ score was a significant correlate with the self-reported prevalence of osteoporosis in a representative sample of 3022 Jewish people aged 60 and over.

Examples of the most frequently used disease-specific HRQOL instruments for patients with osteoporosis are the Quality of Life Questionnaire, issued by the European Foundation for Osteoporosis (QUALEFFO-41), Osteoporosis Assessment Questionnaire, Osteoporosis Quality of Life Questionnaire, and Osteoporosis-Targeted Quality of Life Questionnaire (1, 15, 20, 27, 28). QUALEFFO-41 can discriminate between women with and without vertebral fractures and identify differences between groups by number and location of vertebral fractures (29).

GHQ and QUALEFFO-41

The General Health Questionnaire (GHQ) was developed to be used in primary medical care settings, in the general population, in community surveys, and among general medical outpatients. It was originally designed to measure current psychological distress or affective disorders; it covers the areas of depression, anxiety, social impairment and hypochondriasis, and is generic (30). Its focus is on a break in normal functioning rather than on lifelong traits (31), and is chiefly concerned with the inability to carry out normal, healthy functions, and the appearance of new symptoms of a distressing nature (30). Validity assessments of the GHQ have been conducted in a variety of settings and cultures, and an extensive review of these studies can be found in the User's Guide to the General Health Questionnaire (32). The Norwegian version of GHQ is also well described and validated (33). However, GHQ has not been validated in populations suffering from low BMD or osteoporosis.

QUALEFFO-41 is a disease-specific, validated questionnaire designed by the Working Party for Quality of Life of the European Foundation for Osteoporosis, and is based on common problems affecting the life of a person with vertebral osteoporosis, i.e. those with one or more vertebral fractures (20, 21) QUALEFFO-41 is self-administered and contains questions in five sections: pain, physical function (performing activities of daily living, jobs around the house, mobility), social function, perception of general health, and mental function. These five sections can be evaluated individually or represented in a total score giving the sum of all the 41 items.

Earlier studies validated QUALEFFO-41 with different generic HRQOL questionnaires, such as the Short Form 36 (34), EQ-5D (formerly known as EuroQoL) (22) and NHP (22). To our knowledge, QUALEFFO-41 has not been validated with the generic HRQOL questionnaire (GHQ) as reference measure, although many studies have shown that people with a diagnosis of osteoporosis suffer from psychological distress. Thus, the purpose of our study was to assess the correlation between the different domains of QUALEFFO-41, total score QUALEFFO-41 and the total score of GHQ-20 in a population of women living at home with well-established osteoporosis, who had suffered at least one vertebral fracture, and also to take into account internal consistency and floor and ceiling effects of the different domains, and total scores. We also wished to examine whether the mean values of the various HRQOL scores were significantly different for group consisting of the 75% of the women in the group with the best performance on mobility and balance, compared with the 25% in the group with poorest performance on mobility and balance: as far as we know this distinction has not been studied before.

Our hypotheses are that the level of correlation between the *generic* questionnaire GHQ-20 and *disease-specific* questionnaire QUALEFFO-41 can be characterized as moderate to good, since they are both measurements of HRQOL. We also hypothesized that the 25% of women with the poorest mobility and balance would have a significantly poorer mean value on the measured HRQOL than the rest of the group on the mobility and balance performance tests.

'Validity' is defined as the relationship between what a test is meant to measure and what it actually measures (35), and is estimated by correlation analyses. Concurrent validity assesses the degree to which two measures of the same concept are correlated. In summary, concurrent validity confirms that the scale is correlated with other known measures of the concept (36). Floor and ceiling effects were considered to be present if more than 15% of the respondents achieved the lowest or highest possible scores, respectively (37). Ceiling effects relate only to those instruments that have a defined maximum score.

MATERIALS AND METHODS

Subjects

This cross-sectional study used a 'convenience sample' consisting of subjects who were consecutively recruited from among 155 women referred to the out-patient clinic from the Osteoporosis Department at Ostfold Hospital. In total, 89 subjects wished to participate, and were interviewed and tested between May 2004 and December 2007. All participants in this cross-sectional study had agreed to participate in a community-based 3-month course of exercises. Criteria that excluded some patients were: recent vertebral fractures, patient's inability to complete the questionnaires, or major cognitive impairment (MMSE) (MMS≤23) (38). Patients included were women aged 60 or over with established (clinical) osteoporosis who had had at least one vertebral fracture confirmed by radiography. Bone mineral density (BMD) was measured by Dual-Energy X-Ray Bone Absorptiometry (DXA). Osteoporosis was diagnosed according to the definition of the World Health Organization classification criteria mentioned above. After assessment (n=89), none of the group were excluded due to cognitive impairment according to the Mini Mental State Examination (MMSE) (38) or other exclusion criteria.

The Regional Ethics Committee for Medical Research approved the study, but did not allow the authors to contact non-participants. The project was funded by the Norwegian "Fond for etter-ogvidereutdanningavfysioterapeuter".

Measurements

Demographic data were collected on age, whether the patient was using analgesics or not, type of any walking aids used, and whether the subject was married or living with a partner or not.

HRQOL

HRQOL was evaluated by means of two questionnaires: the generic instrument GHQ-20 and a specific instrument for osteoporosis, QUALEFFO-41. In this study we used the 20-item version called GHQ-20 to register distress and psychopathology. The answers to each item were treated as a "Likert Scale" and had weights assigned to each position (0-1-2-3), in which 0 is no distress, and 3 is severe distress. This gives a possible range for the total GHQ-20 score of 0-60, and the sumscore in this study is called 'GHQ-20: total score'.

The five sections of QUALEFFO-41 are described as: 'QUALEFFO-41: general health perception', 'QUALEFFO-41: leisure time/social function', 'QUALEFFO-41: physical function', 'QUALEFFO-41: mental function', 'QUALEFFO-41: pain', and the total score of all the 41 items as 'QUALEFFO-41: total score'. All scores on QUALEFFO-41 are expressed in values ranging from 0-100, where 0 represents the best and 100 the worst (20, 21). The questionnaire has been shown to be suitable for clinical studies of patients with postmenopausal osteoporosis (22), and to be reliable and valid (21, 22).

Mobility and balance

The mobility of participants was tested by asking them to walk at maximum speed (m/s) for 20 m indoors. No acceleration or deceleration phase was used. The type of walking aid used during testing was recorded. Participants walked as fast as possible and wore their ordinary shoes. The test was performed once. Time were measured with a stopwatch. The walking test has been shown to be a reliable measure of maximum speed (39, 40).

Balance, measured by Functional Reach (FR), is the maximum distance in cm that a person can reach forward in the standing position while maintaining a fixed base of support. Subjects were instructed to stand sideways against a wall in a natural position and to stretch one arm forward to the height of the shoulder. The position of the third metacarpophalangeal (MCP) joint was taken as the zero point. With the body tilted forward as far as possible, subjects continued to stretch the arm parallel to the ground. Three measurements were made, and the mean value was recorded (41) and found to be sensitive to change (42).

Statistics

Statistical analysis was performed with the Windows 17.0 version of SPSS Software (SPSS Inc., Chicago, IL, USA). A significance level of 0.05 for all statistical analyses was chosen. Sample size was based on the general recommendations made by Altman that a study comparing methods should include at least 50 subjects (36). The values of continuous variables are expressed as means±SD, and the values of categorical variables are measured as percentages. In all statistical analyses, a correlation coefficient of 0-0.25 was interpreted as "no or very poor", correlation 0.25-0.50 as "poor-moderate, 0.50-0.75 as "good" and 0.75-1.00 as "very good" (15). Internal consistency was checked by calculating Cronbach's alpha, considered as high if it was at least 0.70 (43). A high alpha coefficient (≥0.70) suggests that the items within a dimension measure the same construct and support the construct validity

(44). Cronbach's alpha coefficient was calculated to evaluate internal consistency. A Pearson correlation coefficient was calculated for concurrent validity. A *t*-test for independent groups was used to check for significant differences between groups.

RESULTS

We studied 89 women with osteoporosis and diagnosed vertebral fractures, mean age 71.1 (range 60-83, SD 5.8). Almost none used any walking aids (88.8%). Of those using walking aids, seven used a stick and three a frame. As regards medication, half the women (50.6%) used analgesics, three were being treated with parathyroid hormone, and all the others were being treated with bisphosphonates. The use of analgesics did not vary significantly with age. Users of analgesics had a significantly worse mean value of HRQOL on all recorded measurements compared with non-user; they also had a significantly poorer mean value on QUALEFFO-41: general health (mean 65.4), QUALEFFO-41: physical function (35.4), QUALEFFO-41: pain (27.3), QUALEFFO-41: total score (37.5) and GHQ-20: total score (21.9) compared with non-users of analgesics, for whom the mean values were 43.4, 15.7, 32.7, 25.5 and 16.7, respectively.

Table 1 lists summary statistics regarding minimum, maximum, 25-75 percentiles, medians, means and standard deviations of participants completing the questionnaire on the two quality of life measurements, as well as their scores on the tests of balance and mobility.

The values of the group consisting of those with results among the poorest 25% were, on QUALEFFO-41: general health perception, 37.5; QUALEFFO-41: leisure time/social function, 8.8; QUALEFFO-41: physical function, 11.8; QUALEFFO-41: mental function, 26.4; QUALEFFO-41: pain, 30.0; QUALEFFO-41: total score 21.5. Their GHQ-20: total score was 14.0, Walking speed 1.2 m/s and FR 23.7 cm. The corresponding figures for the 75% group were 70.8, 50.2, 28.0, 44.5, 65.0, 40.1, 22.5, 1.7 and 31.4.

The best score of zero (ceiling) in QUALEFFO-41 was recorded on pain, leisure time/social function and general health perception by 6.7%, 9% and 1.1%, respectively, of the sample. The worst score, 100 (floor) was recorded in only one domain, general health perception, by 7.9 of the participants.

There was no significant association between age and the reported total sum score of 'GHQ-20: total score' or 'QUALEFFO-41: total score', nor in five of the various domain scores of QUALEFFO-41 ($p>0.05$). However, those who were married or had a partner were significantly younger, mean age 69.3 years ($p=0.003$) than those who were not married (72.9 yrs). Regarding measurement of QUALEFFO-41, there was a significant difference ($p=0.03$) between those who were married or had a partner and those who were single on the domain concerning 'social function/ leisure time'. The mean value of those who were married or had a partner was 24.8 and of those living alone 36.5. However, regarding the other four domains, 'QUALEFFO-41: total score' and 'GHQ-20 total score', no significant differences were discovered between those living with a partner and those living alone.

The oldest women had significantly poorer scores on maximum walking speed ($r=0.31$, $p=0.003$) and FR ($r=-0.30$, $p=0.004$). Those who were married or had a partner had significantly higher maximum walking speeds ($p=0.002$) and this difference remained significant after controlling for age. The mean maximum walking speed of the former group was 1.6 m/s compared with 1.3 m/s for those who were single.

HRQOL instruments: level of internal consistency and correlations

The internal consistency calculated with Cronbach's alpha coefficient for 'QUALEFFO-41: general health per-

Table 1 - *Characteristics of sample population (n=89).*

Variables#	Minimum	Maximum	Percentile 25-75	Median	Mean	SD
QUALEFFO-41: general health perception	0.0	100	37.5-70.8	50.0	54.5	25.0
QUALEFFO-41: leisure time/social function	0.0	95.0	8.8-50.2	24.5	30.7	24.6
QUALEFFO-41: physical function	1.5	58.8	11.8-28.0	20.6	21.6	13.3
QUALEFFO-41: mental function	8.3	77.8	26.4-44.5	33.3	35.3	12.7
QUALEFFO-41: pain	0.0	90.0	30.0-65.0	50.0	46.5	24.9
QUALEFFO-41 total score	5.5	66.8	21.5-40.1	31.5	31.6	13.6
GHQ-20: total score	2.0	56.0	14.0-22.5	19.0	19.3	7.9
Walking speed over 20 m, m/s	0.6	3.3	1.2-1.7	1.4	1.5	0.4
Functional reach, cm	7.3	39.6	23.7-31.4	26.8	26.7	6.5

#Higher values indicate poorer results except for 'Functional reach' and 'Walking speed' where higher values indicate better performance. QUALEFFO-scores range between 0 and 100; GHQ-20: total scores range between 0 and 60. SD: standard deviation.

Table 2 - *Correlation matrix for measurements of health-related quality of life (n=89).*

Test and questionnaires	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
1: QUALEFFO-41: general health perception	1								
2: QUALEFFO-41: leisure time/social function	0.592**	1							
3: QUALEFFO-41: physical function	0.648**	0.627**	1						
4: QUALEFFO-41 : mental function	0.513**	0.380**	0.385**	1					
5: QUALEFFO-41: pain	0.543**	0.358**	0.601**	0.330**	1				
6: QUALEFFO-41: total score	0.803**	0.797**	0.896**	0.619**	0.716**	1			
7: GHQ-20: total score	0.529**	0.277**	0.314**	0.628**	0.341**	0.487**	1		

*Correlation is significant at 0.05 level (2-tailed); **Correlation is significant at 0.01 level (2-tailed).

ception', 'QUALEFFO-41: leisure time', 'QUALEFFO-41: physical function', 'QUALEFFO-41: mental function', 'QUALEFFO-41: pain', 'QUALEFFO-41: total score' and GHQ-20: total score, was 0.80, 0.82, 0.86, 0.61, 0.83, 0.92 and 0.92 respectively.

The correlation between 'QUALEFFO-41: total score' and 'GHQ-20: total score' was 0.49.

Regarding the 'GHQ-20: total score', the correlation coefficients of the domain scores of 'QUALEFFO-41' ranged from 0.28 to 0.63. Significant correlations between the five domains of the 'QUALEFFO-41' ranged from 0.25 to 0.65. Correlation coefficients between the domains of 'QUALEFFO-41' and 'QUALEFFO-41: total score', ranged from 0.62 to 0.90 (Table 2).

HRQOL, balance and mobility

Table 3 shows the mean HRQOL scores for those among the 25% group with the slowest maximum walking speed and shortest FR compared with the rest of the group with the highest maximum walking speed and the longest FR. Those in the 75% group with the highest maximum walking speed had better disease-specific quality of life measurements in the 'QUALEFFO-41: physical function', 'QUALEFFO-41: leisure time 'and 'QUALEFFO-41: total score' than those in the 25% group with a slower maximum walking speed (Table 3). However, there was no significant difference in the generic HRQOL. Regarding FR, those in the 75% group with the best performance had a better HRQOL in the 'QUALEFFO-41: leisure time' (Table 3) than those in the 25% group with worse performance.

DISCUSSION

The main purpose of this study was to assess the correlation between the disease-specific QUALEFFO-41 and the generic HRQOL GHQ-20 focusing on mental distress. The significant correlation coefficients between the variables representing the two ranging from 0.28 to 0.63, show evidence of 'poor-moderate' to 'good' according to the criteria of Kocygit et al. (15) mentioned earlier. This is an advantage rather than a defect. If the correlations between the two instruments had been very close, it would have meant that one of the instruments was redundant, according to Altman (36). What counts as a

Table 3 - *Mean values of groups consisting of 25% with poorest performance and 75% with best performance on maximum walking speed and functional reach (n=89).*

Health-related quality of life measurements#	**Maximal walking speed (mean value)**			**Functional reach (mean value)**		
	Group of 25% with slowest speed	**Group of 75% with fastest speed**	***p*-value***	**Group of 25% with shortest distance**	**Group of 75% with longest distance**	***p*-value***
QUALEFFO-41: general health perception	62.1	52.0	0.10	54.6	54.5	0.99
QUALEFFO-41: leisure time/social function	48.1	24.9	0.000	39.6	27.8	0.04
QUALEFFO-41: physical function	30.4	18.7	0.000	24.5	20.6	0.24
QUALEFFO-41: mental function	38.4	34.5	0.20	38.0	34.5	0.26
QUALEFFO-41: pain	49.3	45.5	0.54	46.6	46.4	0.98
QUALEFFO-41: total score	39.8	20.3	0.001	34.9	30.5	0.19
GHQ**-20: total score	20.3	19.0	0.51	20.2	19.1	0.55

#Higher values indicate poorer results. QUALEFFO-scores range between 0 and 100; GHQ-20: total scores range between 0 and 60. Quality of Life Questionnaire issued by European Foundation for Osteoporosis ('QUALEFFO-41'). *Level of significance based on independent t-test **Sum of the 20 items of the General Health Questionnaire (GHQ-20).

"satisfactory" level of correlation is a matter of interpretation. Correlation coefficients between measures of the same attribute should fall in the midrange of 0.40-0.80 (45), which proved to be the case with 'GHQ-20: total score' and 'QUALEFFO-41: mental functioning' and 'QUALEFFO-41: general health perception' and 'QUALEFFO-41: total score'. According to de Oliveira Ferreira et al. (46), the correlation coefficients between 'SF-36 mental composite score' and 'SF-36 physical composite score' are 0.46 and 0.60 respectively, which correspond well with our results regarding the size of the correlation coefficients of 'GHQ-20: total score' and 'QUALEFFO-41: total score', 'QUALEFFO-41: general health', 'QUALEFFO-41: mental functioning' and 'QUALEFFO-41: total score'. Our correlation coefficients also match those of Cockerill et al. (5) who compared a disease-specific and generic quality of life instrument, reporting correlation coefficients between 'QUALEFFO-41' and SF-12 ranging from 0.42 to 0.82.

We found no floor or ceiling effects regarding the sumscore of the various domains and the total scores of the two HRQOL measurements, indicating that subjects with the lowest or highest possible scores were less than 15% of all participants (37). The mean values in our results regarding the scores on the QUALEFFO-41 questionnaires are similar to those from other reports on women with osteoporosis and fractures (14-16, 47-49) as well as studies of postmenopausal women with osteoporosis (46, 50), which may indicate that our sample is representative of subjects with osteoporosis with and without fractures.

Internal reliability is generally acceptable for factors with a Cronbach's α coefficient of 0.7 or above (43). A high α coefficient (≥0.70) suggests that the items within a dimension measure the same construct and support construct validity (44). In our study, internal consistency, as measured by Cronbach's α for each section, ranged from 0.61 to 0.92. In a Malaysian version, the internal consistency of QUALEFFO-41 was generally good, Cronbach's α ranging between 0.67 and 0.93 for each domain (20, 51). Similar results were achieved in other studies in Europe (0.70-0.92) (21), UK (0.65-0.90) (52) and Turkey (0.70-0.97) (15). In the study by Murrell et al. (52), the internal consistency of QUALEFFO-41 was assessed and Cronbach's α values of the domains ranged from 0.70 to 0.91. In our study, the coefficient of internal consistency was 0.61 for mental function, lower than the value calculated for other domains. Koçyigit et al. (15) reported similarly for domains ranging from 0.70 to 0.91, mental function having the lowest value. Cronbach's α for the entire QUALEFFO-41 in the study by Koçyigit et al. (15) was 0.97, which matches our results.

Functional status is reported to be by far the most important factor affecting the quality of life in old age (53), and the quality of life depended among other things on mobility and performance of activities of daily living (20). Our results showed that QUALEFFO-41 can discriminate between the 25% of patients with lowest maximum walking speed and shortest distance on FR compared with the rest of the women with better performance. This corresponds well with the results of Lips and van Schoor (20), who stated that the quality of life of patients with osteoporosis depends on mobility. O'Brien et al. (54) and Chow and Moffat (55) reported a significant negative correlation between thoracic kyphosis and the FR test – a score which may explain the relationship between FR and HRQOL. We found that those with poor performance on FR had a worse disease-related HRQOL for leisure time. This fits with the fact that disease-targeted measures can include items that are more closely related to the disease process and therefore more sensitive to that process when they are well designed (1). The disease process is also related to balance and mobility and this may explain why the disease-specific quality of life questionnaires showed that 25% of the women with the poorest performance on FR and maximum walking speed reported the poorest quality of life on the disease-specific HRQOL questionnaire, but not on the generic questionnaire.

There were some limitations of this study. The two HRQOL questionnaires have limited evaluation of psychometric properties, and the results obtained in this study may therefore be due to limited reliability (e.g. test-retest), rather than specifically the concurrent validity of the instruments. We have little information about the severity of osteoporosis, the number and severity of vertebral fractures or the presence of other fragility fractures which may have had a significant influence on the results. Most of the participants seemed to be in good fit, only 11.2% used walking aids and their mean scores on FR and walking speed were quite high compared with those scored in other studies of women with osteoporosis. This group of older women with osteoporosis may have less back pain and functional limitations than those who did not participate. All participants were women aged 60-83 living at home, and were not recruited from the community at large, but selected from patients who had undergone bone density determination. Thus, general conclusions must be drawn with caution, and no conclusions should be drawn outside these age groups and the reported characteristics of the sample.

In conclusion, our study showed that disease-specific and generic HRQOL questionnaires are not redundant when applied together: on the contrary complement each other. The size of the correlation indicates that the disease-specific 'QUALEFFO-41' and the generic GHQ-20 measure different aspects of HRQOL. There are 'poor-moderate' to 'good' and 'high to moderate' correlations between the five domains of 'QUALEFFO-41' and 'QUALEFFO-41: total score' and the sumscore of

'GHQ-20: total score', which establishes the concurrent validity of the QUALEFFO-41 and GHQ-20 in women with osteoporosis who have suffered a fracture. The QUALEFFO-41 appears to be a more sensitive assessment tool in identifying people with balance and mobility problems. One implication of our study is that when checking scores in the poorest 25% on QUALEFFO-41: leisure time, QUALEFFO-41: physical function and QUALEFFO-41: total score, further evaluation of walking speed and FR may be important in offering relevant interventions. Another implication is that both QUALEFFO-41 and GHQ-20 provide valuable complementary information to clinicians about patients' HRQOL.

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