

REVIEW

Quality of life measurements in patients with osteoporosis and fractures

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To review all specific questionnaires regarding quality of life in osteoporosis and to describe their distinctive indications, we searched Medline, the Scientific Electronic Library Online database, and the Latin-American and Caribbean Health Sciences Literature database. Nine specific questionnaires related to osteoporosis quality of life were found: 1) the Women's Health Questionnaire, 2) Osteoporosis Quality of Life Questionnaire, 3) Osteoporosis Assessment Questionnaire, 4) Osteoporosis Functional Disability Questionnaire, 5) Quality of Life Questionnaire of the European Foundation for Osteoporosis, 6) Osteoporosis-Targeted Quality of Life Questionnaire, 7) Japanese Osteoporosis Quality of Life Questionnaire, 8) the 16-item Assessment of Health-Related Quality of Life in Osteoporosis, and 9) the Quality of Life Questionnaire in Osteoporosis (QUALIOST™). The Quality of Life Questionnaire of the European Foundation for Osteoporosis is the osteoporosis-specific questionnaire most commonly used in the literature. The Quality of Life Questionnaire of the European Foundation for Osteoporosis and the Osteoporosis Quality of Life Questionnaire are targeted more toward fracture assessment, and the Osteoporosis Functional Disability Questionnaire can be used for longitudinal studies involving exercise. In the present study, the authors summarize all of the specific questionnaires for osteoporosis and demonstrate that these questionnaires should be selected based on the objectives to be evaluated. Osteoporosis-specific quality of life questionnaires should be validated in the language of the country of origin before being used.

KEYWORDS: Quality of Life; Osteoporosis; Questionnaires; QUALEFFO; OQLQ; OPAQ.

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INTRODUCTION

Defining quality of life

The World Health Organization Quality of Life (WHOQOL) project was initiated in 1991. The aim of the project was to develop an international cross-cultural quality of life assessment instrument. The WHOQOL instrument assesses individual perceptions in the context of culture, value systems, personal goals, standards, and concerns (1). This definition demonstrates that quality of life should not be measured by the frequency with which a medical service is offered to the patient but by the degree to which the results obtained serve the purposes of prolonging life, easing pain, restoring function, and preventing incapacity (2).

Two major developments in the health field are recognizing the importance of patient-based disease evaluations and the importance of assessing the quality of the therapeutic measures being employed (3).

Assessing functional status and quality of life has been considered central to evaluating disease progression and

developing new treatments, particularly in chronic diseases such as osteoporosis (4). Assessing quality of life in osteoporosis is commonly used as an outcome measure secondary to the biomechanical and radiographic evaluations following each fracture event (5,6).

Quality of life encompasses various facets of life, including health status, environment, financial aspects and human aspects. Health status is a subset of quality of life that covers physical, mental, and social well-being (5,7).

To measure quality of life is to assess subjective feelings objectively. Using quality-of-life questionnaires, we can evaluate treatment effects in clinical trials (5,8,9). Questionnaires have been used in epidemiological studies to assess quality of life and to obtain data regarding disease severity, disease morbidity, health care, and treatment (5,6).

In this review, we describe the characteristics and specific indications for osteoporosis quality of life questionnaires. The purpose of the present article was to discuss the adequacy of these questionnaires and their best indication according to osteoporosis clinical studies.

Quality of life and osteoporosis

Assessing health-related quality of life has been considered an important marker of the clinical evolution of patients with osteoporosis and fractures (9-13). In addition, this assessment is central to health science research and clinical trials. Physical, emotional, and psychological incapacity, combined

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with the pain that results from hip, spine, or wrist fractures, can alter quality of life (14).

After a hip fracture, only 25% of individuals return to their activities of daily living, such as cooking or going to the mall (15). The loss of independence that results from the inability to walk (caused by functional limitations or by the fear of falling) is the principal consequence of a hip fracture. This inactivity worsens osteoporosis and increases the risks of falling and suffering new fractures (16).

The functional alterations caused by a vertebral fracture can reduce the ability of patients to perform the activities of daily living at home and care for themselves, which increases the fear of falling and the risk of new fractures (17,18). Vertebral fractures are present in approximately one third of the elderly Brazilian population (19). Vertebral fractures are strongly associated with lumbar pain and functional limitations (20,21). In addition, such fractures reduce lung, heart, stomach, and urinary capacities, thereby significantly reducing the quality of life (22).

During the period following a wrist fracture, the individual can experience pain and movement limitations. Certain activities may be restricted, and such individuals could have chronic pain and reduced functions (23).

Fracture events can affect the physical and mental domains of quality of life to different degrees depending on the type and severity of the fracture (24). Fracture patients experience psychological sequelae, such as anxiety, fear, depression, reduced self-esteem, and social isolation (8).

By measuring quality of life, we can predict clinical evolution and functional changes, as well as understand the conditions that will lead to developing better osteoporosis treatments, thereby improving patient health, reversing bone loss and reducing the risk of fractures.

Therefore, the search for osteoporosis-targeted questionnaires is essential to monitor and therapeutically evaluate individuals who suffer from this metabolic bone disease.

MATERIALS AND METHODS

The systematic search for quality of life questionnaires was conducted in Medline, the Scientific Electronic Library Online database, and the Latin-American and Caribbean Health Sciences Literature database; data over the last 20 years (January 1991-January 2011) was searched using the following MeSH terms: osteoporosis, quality of life, questionnaires, and instruments.

Specific instruments

In recent decades, specific instruments that measure quality of life in osteoporosis patients have been developed. Nine questionnaires were initially developed, and another five were derived from those nine.

Women's Health Questionnaire

The Women's Health Questionnaire (WHQ) was developed to evaluate menopausal and postmenopausal women (25). It covers specific symptoms that are observed during this phase of life. The WHQ is reproducible and exhibits excellent correlations with estrogen levels and other quality-of-life scales (8,26). The WHQ has been tested for its ability to assess the efficacy of interventions and has exhibited high sensitivity for detecting changes in specific symptoms that

are associated with quality of life after patients undergo medical or non-medical treatments (27).

Osteoporosis Quality of Life Questionnaire

The Osteoporosis Quality of Life Questionnaire (OQLQ) is administered during an approximately 20-min interview. The questionnaire consists of 30 items that are distributed into five domains: symptoms, physical function, activities of daily living, emotional function, and leisure. All of the patients selected for the OQLQ development were diagnosed with chronic lower back pain (28) and osteoporosis and had previously suffered moderate or severe vertebral fractures (11). The OQLQ is used to evaluate pharmacological treatments and physical rehabilitation programs. Studies have reported that this questionnaire correlates well with generic measures and fractures and is able to detect health improvements or disabilities (17).

Mini-Osteoporosis Quality of Life Questionnaire

The Mini-Osteoporosis Quality of Life Questionnaire (mini-OQLQ) was developed to reduce the time needed in clinical practice to apply the OQLQ (29). The mini-OQLQ is a 10-item abbreviated form of the original 30-item OQLQ. Nevertheless, the mini-OQLQ comprises the same five domains: symptoms, physical function, activities of daily living, emotional function, and leisure. The mini-OQLQ is a self-reported questionnaire that requires approximately 3 min to complete.

Osteoporosis Assessment Questionnaire

The Osteoporosis Assessment Questionnaire (OPAQ) is a self-reported instrument that assesses quality of life in postmenopausal women with osteoporosis and fractures (30), and it was recently used by our group to analyze the quality of life after a balance training program in women with senile osteoporosis (31,32). The OPAQ comprises five questions that assess overall well-being and another 79 questions that are grouped into 18 domains. These domains are distributed into four dimensions (33): physical function, psychological status, symptoms, and social interaction. Cantarelli (34) adapted and validated this questionnaire for use in Brazil (in Brazilian Portuguese) and demonstrated that the OPAQ is a valid and reproducible instrument to evaluate osteoporosis patients. Because the OPAQ comprises a large number of questions and requires 30-40 min to complete, revised versions of the questionnaire have been developed, namely the Osteoporosis Assessment Questionnaire 2 (OPAQ2) and the Osteoporosis Assessment Questionnaire Short Version (OPAQ SV).

Osteoporosis Assessment Questionnaire 2

The OPAQ2 comprises 67 items grouped into 14 health scales (26). The OPAQ2 is a self-reported questionnaire that has been tested in elderly populations (35), and it requires 20-30 min to complete.

Osteoporosis Assessment Questionnaire Short Version

The OPAQ SV consists of 34 items organized into three dimensions: physical function, emotional status, and symptoms (36). The OPAQ SV does not collect data related to the patient's daily activities or social status (37).

Osteoporosis Functional Disability Questionnaire

The Osteoporosis Functional Disability Questionnaire (OFDQ) (38) was developed to assess functional disabilities in osteoporosis patients who experienced vertebral compression and lower back pain caused by vertebral fractures. The OFDQ has been evaluated in clinical trials involving exercise programs (38) and proved sensitive for detecting improvements in the activities of daily living among the patients in rehabilitation programs. The OFDQ is a self-reported questionnaire that requires approximately 25 min to complete. The questionnaire comprises 59 items grouped into five domains: pain, depression, functional status, social activities, and confidence in the treatment proposed. The OFDQ has proven useful in assessing clinical severity and exhibits a reliable correlation with spinal injury caused by osteoporosis (8,33,38).

Quality of Life Questionnaire of the European Foundation for Osteoporosis

The Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) originally comprised 48 questions, including six visual analogue scales (39). The QUALEFFO is specific to patients with vertebral fractures and comprises five domains: pain, physical function, social function, general health perception, and mental function (8,40). The questionnaire has been used in prevention and treatment protocols, and it has proven to be reproducible and coherent. After the QUALEFFO had been validated, two summarized versions of it were developed.

41-item Quality of Life Questionnaire of the European Foundation for Osteoporosis

The 41-item Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-41) was developed to measure the quality of life in patients with vertebral deformities (41). The QUALEFFO-41 consists of 41 questions grouped into five domains: pain, physical function, social function, general health perception, and mental function (8,39).

31-item Quality of Life Questionnaire of the European Foundation for Osteoporosis

The 31-item Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO-31) was developed as a shortened version of the QUALEFFO-41 (41). The QUALEFFO-31, which consists of three domains (pain, physical function, and mental state), excludes the most redundant questions of the QUALEFFO-41 and improves its conceptual structure.

Osteoporosis-targeted quality of life

The Osteoporosis-Targeted Quality of Life (OPTQoL) questionnaire is used in epidemiological studies assessing the quality of life of elderly women with or without clinical osteoporosis (39). The OPTQoL questionnaire is a reliable instrument that comprises 26 scored questions that are distributed in three domains (physical activity, adaptations for activities of daily living, and fears) and six additional questions regarding the clinical and diagnostic alterations of osteoporosis (5,8,42).

Japanese Osteoporosis Quality of Life Questionnaire

The Japanese Osteoporosis Quality of Life Questionnaire (JOQOL) was based on the OPAQ and QUALEFFO-41 and

adapted to the lifestyle of the Japanese people (43). The JOQOL comprises 38 items that are grouped into six domains: pain, activities of daily living, social activity and leisure, general health, postural awareness, psychological factors, and falls (44).

16-item Assessment of Health-Related Quality of Life in Osteoporosis

The 16-item Assessment of Health-Related Quality of Life in Osteoporosis (ECOS-16) is a short questionnaire that is rapidly applied and easily administered (45). The ECOS-16 comprises 16 questions, four of which are from the QOLQ, and 12 of which are from the QUALEFFO. These 16 questions are grouped into four categories: physical function, disease-related fear, psychosocial status, and pain. The ECOS-16 is a self-reported questionnaire with satisfactory preliminary psychometric properties. The questionnaire appears to be a promising tool for use in research and clinical practice when evaluating postmenopausal women with osteoporosis with or without vertebral fractures (46).

Quality of Life Questionnaire in Osteoporosis

The Quality of Life Questionnaire in Osteoporosis (QUALIOSTTM) was developed in 2001 (47). The QUALIOST is a specific instrument that is used in conjunction with the generic Medical Outcomes Study 36-item Short-Form Health Survey because the QUALIOST includes domains that are not addressed by the latter instrument (fear of the future, self-image, well-being, mobility, localized pain, and specific mental repercussions). The QUALIOST is a self-reported questionnaire comprising 23 questions that are distributed into two dimensions: physical and emotional. The questionnaire can be used in therapeutic trials to assess the impact of vertebral fractures on the quality of life of women with postmenopausal osteoporosis.

DISCUSSION

Indications of osteoporosis-targeted quality-of-life questionnaires

Perimenopause

The WHQ should be used to evaluate women in perimenopause because it addresses the specific characteristics of this population. A disadvantage of the WHQ is that it does not address the feelings that result from social interactions and is restricted to evaluating how women perceive the perimenopause-related alterations in their bodies (48).

Fractures: comparisons of specific questionnaires

The most extensively tested questionnaires regarding vertebral fractures are the OQLQ (interviewer-administered) and the QUALEFFO (self-report). The OQLQ has been tested in patients with osteoporosis and fractures associated with chronic lower back pain. The QUALEFFO has been tested in patients with osteoporosis and fractures with or without chronic lower back pain. These two questionnaires were developed as instruments to be used in evaluating the outcomes of clinical trials. The OQLQ and the QUALEFFO were compared in a study assessing the quality of life in women with osteoporosis with vertebral

fractures (49). The authors found that the performance of the OQLQ was superior to that of the QUALEFFO. This evaluation was in part attributed to the fact that the QUALEFFO is a self-reported questionnaire. The studied population took longer to complete the QUALEFFO, and a greater number of questions were left unanswered on the QUALEFFO than on the OQLQ. In addition, it was observed that the degree of difficulty in completing the QUALEFFO was inversely proportional to the patient's level of education. Furthermore, the psychometric properties of the OQLQ were found to be significantly superior to those of the QUALEFFO when evaluating women with one or more vertebral fractures, a result that was also reported by other authors (49,50).

In its original form, the OPAQ was largely unsuccessful within the scientific community for clinical practice and research purposes because it was quite extensive and time-consuming. Therefore, shorter versions of this questionnaire were developed: the OPAQ2 (26) and the OPAQ SV (36). The OPAQ2 was initially used to evaluate hip fracture cases (35).

Mode of administration: self-reported or interviewer-administered?

In clinical practice, self-reported questionnaires are an excellent option because patients can complete such questionnaires in the waiting room. However, this procedure depends on the patient's level of education.

Time required for questionnaire administration

The time required to complete a questionnaire is dependent on the behavior of the patient and the physician. Short questionnaires can be easily completed by the patient in a short period of time, thus increasing the patient's willingness to do so. The mini-OQLQ, for instance, requires 2-3 min to complete (29). The mini-OQLQ is considered a sensitive instrument for evaluating patients with osteoporosis, vertebral fractures and pain, (51) as well as postmenopausal women with osteoporosis and vertebral fractures (52). However, one study demonstrated that the mini-OQLQ score exhibits a weak correlation with the clinical severity of the disease (11). Another short questionnaire is the ECOS-16. The ECOS-16 comprises 16 questions, has adequate preliminary psychometric properties and seems promising for use in research and clinical practice when evaluating women with postmenopausal osteoporosis with or without vertebral fractures.

Focus on patient adaptations

If the assessment focuses on disability, the need for patients to make adaptations to perform daily living activities and related patient concerns, the OPTQoL questionnaire should be used.

Effects of exercise on quality of life using osteoporosis-specific questionnaires

Only three studies have used specific questionnaires to assess the effect of exercise on quality of life (35,51,52).

1) The first study assessed quality of life after patients engaged in an exercise program (37). The authors of the study developed the OFDQ to determine whether disability and back pain caused by vertebral fractures

correlated significantly with the disease. By applying the OFDQ, the authors were able to detect significant improvements in the performance of daily living activities and social interactions as well as reduced pain in patients who performed aerobic exercises. However, osteoporosis patients who were sedentary exhibited increased pain and reduced abilities to perform activities of daily living (37). It would be interesting to apply the OFDQ in studies assessing the effect of exercise on disability. However, this effect was not described by the authors who developed the OFDQ, making it impossible for the scientific community to use the questionnaire for that purpose.

- 2) The second study used the OQLQ to assess the efficacy of a six-month in-home exercise program (stretching, strength training and walking) in fragile elderly women with vertebral fractures (53). The authors observed an improvement in quality of life in terms of the symptoms, emotional aspect, leisure and social activity, as well as a reduction in fatigue and pain when walking.
- 3) The third study demonstrated the reproducibility of the QUALEFFO (54). By administering this questionnaire, the authors observed that resistance training and agility training significantly improved the quality of life, social interaction, physical ability and back pain of elderly women with osteopenia or osteoporosis.
- 4) The fourth study, conducted by our group, demonstrated that over a 12-month period, the Balance Training Program reduces falls and improves functional balance (31) and quality of life (32). The quality of life was evaluated before and at the end of the trial using the Osteoporosis Assessment Questionnaire (OPAQ) and demonstrated an improvement in the followings domains: well-being, physical function, psychological status, symptoms and social interactions (32).

Assessing quality of life is essential to health research and clinical trials involving osteoporosis. The choice of the instrument used to assess quality of life depends on the type of research and on the research question asked; each instrument has specific advantages and disadvantages (8). Furthermore, it is important that these instruments be available in the patient's native language because a specific methodology has been established to validate their use (2,55,56).

Most quality of life osteoporosis questionnaires have been developed in the English language (33,42,28). Thus, for these instruments to be used in international studies and in clinical practice, it is necessary that these instruments address the same concepts in all languages to make it possible to pool data and compare results across countries. In fact, these nine questionnaires should be validated and proven reliable before being used.

Indeed, many questionnaires have already been validated for use in other countries and/or cultures (57-61). The QUALEFFO (39) is the quality of life osteoporosis instrument most validated in other countries, including the following languages: Serbian (7), Turkish (58), Chinese (59), Spanish (60), and Italian (61). Only the OPAQ instrument has been validated in Portuguese (34).

Measuring health-related quality of life has become an important issue in health service research and in clinical

trials involving osteoporosis. Nine specific questionnaires related to osteoporosis (OP) quality of life are available in the literature. The choice of a particular questionnaire (WHQ, OQLQ, OPAQ, OFDQ, QUALEFFO, OPTQOL, JOQOL, ECOS-16, and QUALIOSTTM) will depend on the type of research and the major question being asked because each instrument may have particular advantages. It is important that all of these OP-specific questionnaires be validated in the language of the country of origin before being used in clinical research and clinical practice.

Key points:

- Nine specific questionnaires related to osteoporosis (OP) quality of life are available in the literature.
- QUALEFO is the OP-specific questionnaire most commonly used in the literature.
- QUALEFFO and OQLQ are targeted more toward fracture assessments.
- OFDQ is used in longitudinal studies involving exercise.
- Osteoporosis-specific quality of life questionnaires should be validated in the language of the country of origin before being used.

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AUTHOR CONTRIBUTIONS

Pereira RM and Madureira MM were responsible for the study concept and design. Madureira MM and Pereira RM conducted the analysis and interpretation of the data. Madureira MM, Ciconelli R, and Pereira RM prepared and revised the manuscript.

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