Aranha LLM[I]

Mirón Canelo JA[I]

Alonso Sardón M[I]

Del Pino Montes J[II]

Sáenz González MC[I]

Health-related quality of life in Spanish women with osteoporosis

ABSTRACT

OBJECTIVE: To analyze the health-related quality of life in patients with osteoporosis and to compare it with the overall population.

METHODS: A cross-sectional descriptive study was carried out with 60 female patients of the rheumatology service at a university hospital, in Spain, from April to October 2003. The Short Form-36 (SF-36) questionnaire was applied in order to obtain demographic data, clinical characteristics and data about lifestyles related to health. Patients were classified in age groups. The statistics tests performed were Chi-square, general linear model, Student's t-test.

RESULTS: The interviewees' average age was 65.57 years old (SD: ±9.7 years), and average time interval for diagnosis was 3.4±2.84 years. The best scores were in social functioning (89), emotional aspects (72.2), mental health (63), and vitality (53.7). The lowest scores were in general health (45.1), physical capacity (47.7), pain (52.3) and physical aspects (59.9). The patients' average scores were lower than the general Spanish population's scores in the following dimensions: functional capacity, physical aspects, pain and overall health status. The greatest differences between the average SF-36 scores for patients and for the overall Spanish population were in the age group ranging from 55 to 64 years old. Scores were lower or similar to the general Spanish population in all other dimensions of the questionnaire. No significant associations were found between the dimensions of the SF-36 contemplated in this study and the clinical, demographic and lifestyle data.

CONCLUSIONS: The patients presented bad quality of life, particularly with respect to those dimensions that are most relevant with respect to osteoporosis, when compared with the overall Spanish population. The physical dimensions were the ones most affected.

KEYWORDS: Osteoporosis. Quality of life. Sickness impact profile. Questionnaires. Spain.

[I] Departamento de Medicina Preventiva y Salud Pública Facultad de Medicina. Universidad de Salamanca. Salamanca, España

[II] Departamento de Medicina. Facultad de Medicina. Universidad de Salamanca. Salamanca, España

Correspondence:
José Antonio Mirón Canelo
Campus Miguel de Unamuno, s/n
Departamento de Medicina Preventiva y
Salud Pública, Universidad de Salamanca
37000 Salamanca, Espanha
E-mail: luciana_aranha10@yahoo.com.br

INTRODUCTION

The World Health Organization (WHO) considers osteoporosis the second major public health problem in the world, being the first cardiovascular illnesses.[12] In Spain, it has been noted that approximately two million women have osteoporosis, which is prevalent in 26.1% of the women over who are 50 years of age and older.[6]

Osteoporosis is a relevant clinical and social problem with serious clinical consequences. The most frequent is lumbar or low back pain that may have an important impact on the development of daily activities, influencing well-being and health related quality of life (HRQOL). Frequently patients present limitations with respect to the normal exercise of their professional, social and leisure activities, and present an important emotional affliction.[4]

Evaluating sanitary assistance in terms of health does not suffice. It is necessary to incorporate the HRQOL to clinical decisions and public health planning.[7]

The measurement of HRQOL in patients with osteoporosis has been investigated during the past few years. The objective of these studies has been to determine what changes are necessary in order to obtain patients' well-being.[5,11,15]

Evaluation of the HRQOL is undertaken, in the majority of cases, by means of either general or specific questionnaires.[10] The latter are multidimensional, exploring diverse components of the HRQOL being relevant as well in the evaluation of the consequences of chronic diseases.*

The short form-36 questionnaire[8,9,13] (SF-36) is a generic instrument that was developed in the United States in order to measure eight of the most conspicuous concepts related to health. It is aplicable both to the general population and to specific patients, and is also utilizad in descriptive studies.

The objective of the present study was to evaluate the quality of life related to health of patients with osteoporosis and compare it to the quality of life of the general population.

METHODS

This is a descriptive cross-sectional study conducted in consultations of an outpatient rheumatology serv-ice of a university hospital in the city of Salamanca, Spain, between April and October 2003.

The patients, all of whom are women, were selected by means of their medical records. All patients diagnosed with osteoporosis and whose bone mineral density (T) was inferior to -2.5 were included in this study.[14]

The T values considered were those of each patient's most recent bone densitometry. Information as to the clinical history, laboratory exams and bone densitometry were obtained from all of the patients' medical records. All of them were undergoing pharmacological treatment and were diagnosed at least six months before the beginning of this study.

The patients' consent to participate in this study was obtained verbally when they came in for their scheduled appointments.

Among the 79 patients initially selected for the study, six did not come to their scheduled appointments, six did not want to participate in the study and seven were attended by the doctor at a moment different then the scheduled appointment and were therefore not located for the interview. Thus, 60 patients were interviewed for this study.

A questionnaire consisting of 49 items was applied. It was subdivided in three modules: demographic data, health related life styles and HRQOL. The interview took place in the waiting room of the doctor's office, prior to the appointment so that the doctor's opinion as to the state of the patient's health would not influence the responses.

The only instrument utilized to measure HRQOL was the SF-36 generic questionnaire, since it was validated in more than 15 countries, including Spain[1] and Brazil.[3] It evaluates physical and mental health, has psychometric robustness and its relative simplicity were factors that influenced the option for this instrument. The SF-36 contains 36 items, of which 35 are grouped into eight dimensions and a last item evaluates changes in health through time. For each dimension, the SF-36 items are codified, aggregated and transformed into a scale that goes from zero (worst health status) to 100 (best health status).**

Statistical analysis of the data was conducted by means of the 11.0 version of the SPSS statistical program. Initially, a descriptive study of the frequencies of each quantitative and qualitative variable was

---

*Badía X, Salamero M, Alonso J. La Medida de la Salud. Guía de escalas de medición en español.[The measure of health. A Spanish guide to measuring scales] 3 ed. Barcelona: Fundación Lilly; 2002.
**Institut Municipal d'Investigación Mèdica (IMIM). Manual de puntuación de la versión española del Cuestionario de Salud SF-36 [Scoring Manual for the Spanish version of the SF-36 Health Questionnaire]. Barcelona; 2000.

undertaken. The SF-36 scores were calculated for each dimension of the total sample and for each age group.

General population data was obtained from a study[2] on drug use, in which a personal interview, conducted in the subject's residence, included the SF-36 questionnaire as well as demographic data and data concerning the consumption of drugs. A cross-sectional study of a multiphase stratified random sample of the population aged 15 years and older, residing in the Spanish territory. The results presented were considered as norms or populational values of reference for the Spanish version of the SF-36 health questionnaire. The measures of central tendency and dispersion of the questionnaire were calculated for each dimension according to age and sex, as well as Cronbach's alpha coefficient of reliability.

Bivariate and multivariate analysis were undertaken to test the associations between clinical and demographic variables, patients' lifestyles and the SF-36 scores, with the following statistical tests: Chi-square, general linear model, Student-t test. A 5% level of significance was established ($p < 0.05$).

RESULTS

The interviewees were aged from 32 to 88 years old, with a mean of 65.57 years and a 9.7 standard deviation (SD). The sociodemographic characteristics of the patients are presented in Table 1. Only 1.7% of the patients had university education. As to the current occupational status, the majority of the women were either retired (40%) or housewives (45%). Among the economically active patients, manual work was more frequent. Only 5% lived alone and without family support, and the rest of the patients received support or lived with other people.

As to the patients' lifestyles, 41.7% were inactive, that is, they did not practice any kind of physical activity. Almost all of them did not currently have the habit of smoking (98%) and the majority (68.3%) did not consume alcoholic beverages.

As to their clinical characteristics, the mean number

Table 1 - Sociodemographic characteristics and lifestyles associated to patients' health. Salamanca, Spain, 2003.

Variable	% (n)
Age (groups)	
≤54 years	6.7 (4)
55-64 years	43.3 (26)
65-74 years	33.3 (20)
≥75 years	16.7 (10)
Schooling	
None	30.0 (18)
Elementary and Junior High School	55.0 (33)
High School	13.3 (8)
University	1.7 (1)
Current occupational situation	
Active manual work	10.0 (6)
Active intellectual work	5.0 (3)
Housewife	40.0 (24)
Retired	45.0 (27)
Living situation	
Lives alone with the family's support	18.3 (11)
Lives with someone else	76.7 (46)
Lives alone without family support	5.0 (3)
Physical activity	
Inactive	41.7 (25)
Occasional	26.7 (16)
Regular	31.7 (19)
Cigarette smoking	
Smokes	1.7 (1)
Former smoker	10.0 (6)
Does not smoke	88.3 (53)

of years since the diagnosis of osteoporosis was 3.4±2.84 SD, the lowest value was six months since the diagnosis and the highest value being 12 years. The majority of the patients (63.3%) were polymedicated, that is, besides their treatment for osteoporosis, they took two or more other drugs. The most frequently used medications are those for articular ailments (40%), for depression or sleep disturbances (35%), for arterial hypertension (30%) and for heart conditions (23.3%). As to diagnosed comorbidities, the most frequent ailments were: other articular ailments (53.3%), arterial hypertension (21.7%), heart conditions (18.3%), depression or sleep disturbances (13.3%) and gastric ailments (13.3%).

It was observed in the descriptive data that the means and standard deviation for each of the dimensions of the SF-36 fluctuated from 45.1±26.2 SD for the general state of health, to 89±23.8 SD for the social aspects dimension. With the exception for the dimensions of the emotional and physical aspects, the percentage of individuals with a minimum score (floor effect) was less than 3.5%. As to the dimensions so-

Table 2 - Scores on the SF-36 questionnaire of the total sample studied according to age groups. Salamanca, Spain, 2003.

| Dimensions of the SF-36 questionnaire	Total study sample			55 to 64 years			65 to 74 years			75 years and over		
	Mean	SD	Md	Mean	SD	Md	Mean	SD	Md	Mean	SD	Md
Functional capacity	47.7	24.8	45.0	53.6	27.7	57.5	52.7	16.8	55.0	39.0	24.2	32.5
Physical aspects	59.9	41.7	75.0	61.5	40.1	75.0	67.5	42.2	87.5	52.5	36.2	50.0
Pain	52.3	24.6	52.0	54.3	27.4	56.5	49.8	21.4	56.5	50.3	30.5	37.0
General health	45.1	26.2	40.0	45.0	25.5	41.0	47.6	25.3	40.0	39.3	24.5	33.5
Vitality	53.7	24.5	52.5	57.5	23.7	60.0	55.2	24.1	50.0	49.5	22.4	57.5
Social aspects	89.0	23.8	100	84.6	27.4	100	96.2	12.2	100	82.5	33.4	100
Emotional aspects	72.2	40.8	100	69.2	43.1	100	70.0	40.3	100	86.7	23.3	100
Mental health	63.0	20.7	64.0	65.2	21.0	64.0	64.0	21.4	64.0	66.8	18.2	68.0

N=60; SD: Standard-deviation; Md: median
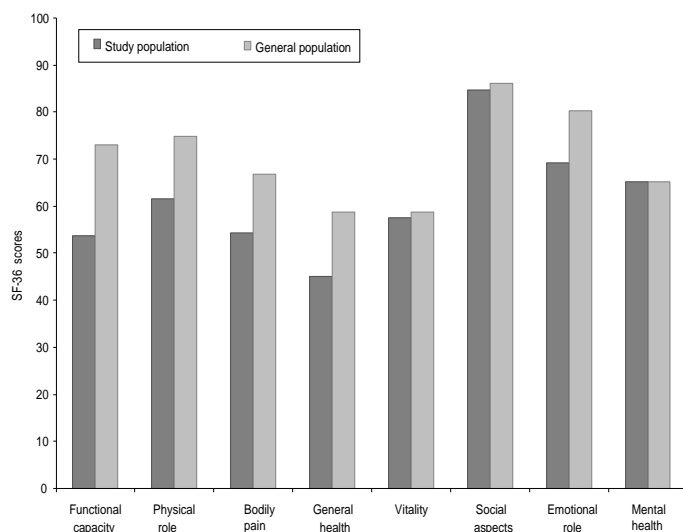
Figure 1 - Comparison between the SF-36 values in the study population and in the general population among women in the age group from 55 to 64 years old. Salamanca, Spain, 2003.

cial aspects and emotional aspects, the percentage of individuals with a maximum score (ceiling effect) was over 60%. The best scores were obtained in the dimensions social aspects (89), emotional aspects (72.2) and mental health (63). The lowest scores correspond to the dimensions that are relevant in osteoporosis: general state of health (45.1), functional capacity (47.7), pain (52.3) and physical aspects (59.9). Table 2 presents the data and results according to age group.

Figures 1, 2, and 3 present a comparison between the mean scores of the SF-36 among the population studied and populational values in Spain[2] according to age groups. In general, patients' mean scores were lower than those of the general population in the dimensions that are relevant to the pathology being investigated: functional capacity, physical aspects, pain and general health. The greatest differences correspond to the age group from 55 to 64 years of age and are observed in the dimensions functional capacity (19), physical aspects (13), pain (12) and general health (13). The mean scores obtained in the present study in the remaining dimensions of the SF-36 are also inferior, but there's a smaller difference in the scores or they are similar to the norms of the Spanish populations. The only dimensions that did not obtain scores inferior or similar to the mean for the Spanish population are the dimensions that refer to the social and emotional aspects among women within the 55 to 64 years age group.

DISCUSSION

The results of the present study revealed that patients with osteoporosis attended in the rheumatology have a bad quality of live, being that the physical areas are the most affected. These results are consistent with the clinical aspects of the disease and the natural history of the osteoporotic ailment.

The lowest scores (worse state of health) were observed in the domains of pain, functional capacity and physical aspects and were lower than those presented in another study concerning osteoporosis:[11] functional capacity (47.7-73), pain (52.3-68) and general state of health (45.1-55.3). In like manner, the highest scores, in the domains of the social and emotional aspects, were higher than those of that other previously mentioned study:[11] 89-78.6 and 72.2-65.6, respectively. In the remaining dimensions, similar scores were obtained.

Possible explanations for the differences in the results could be the due to the methods utilized and the samples selected for the studies. For example, patients with osteopenia were included in the sample of the comparative study[11] and the distinct associated comorbidities in both studies.

The bivariate and multivariate analyses found no significant statistical associations between the dimensions of the SF-36 and the clinical and sociodemographic variables included in the study. However, in some dimensions, the scores are not very far removed
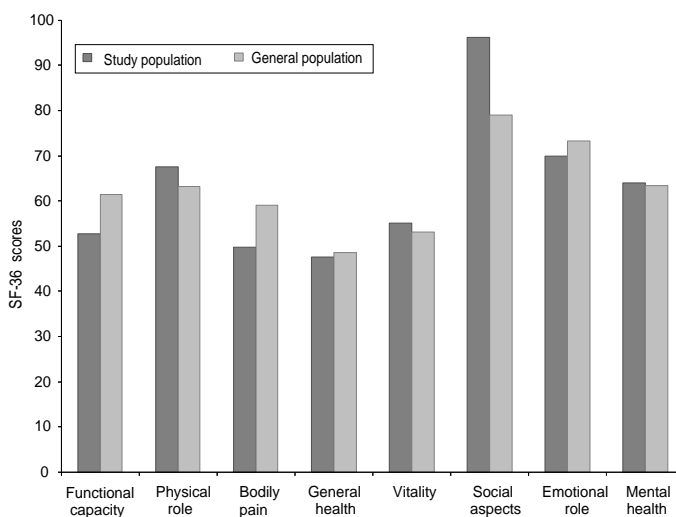

Figure 2 - Comparison between the SF-36 values in the study population and in the general population among women in the age group from 65 to 74 years old. Salamanca, Spain, 2003

from what would be considered clinically relevant, as occurs with the dimensions functional capacity and pain.

As expected, patients' median scores in the relevant dimensions of the disease (functional capacity, physical aspects, pain and general state of health) were inferior to scores of the corresponding age groups[2] in the general population. The scores in this study that were superior or similar to those SF-36 reference values for the Spanish population, could be explained by the inclusion of subjects who had autonomous ambulatory capacity or who came to the appointment accompanied by another person. However, in Naves Díaz et al's study,[11] the interviews were conducted at the interviewee's residence.

Figure 3 - Comparison between the SF-36 values in the study population and in the general population among women in the 75 years and older age group. Salamanca, Spain, 2003.

Generalizations of the results are justified in three aspects: 1) The patients studied are representative of the general population of Salamanca, and there are no epidemiological reasons for not extrapolatin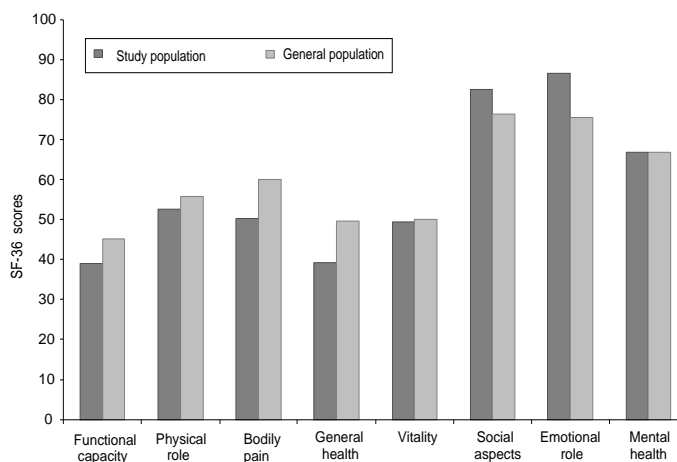g the results to the general Spanish population. 2) The Spanish public health system characterizes itself as public, free of charge and universal in its coverage, being the demand for and utilization of the hospital services generalized. 3) The rheumatology service in question is a reference in the province of Salamanca and in the region as well.

REFERENCES

1. Alonso J, Prieto L, Antó JM. La versión española del SF-36 health survey (cuestionario de salud SF-36): un instrumento para la medida de los resultados clínicos. *Med Clin (Barc)*. 1995;104(20):771-6.

2. Alonso J, Regidor E, Barrio G, Prieto L, Rodríguez C, Fuente L. Valores poblacionales de referencia de la versión española del cuestionario de salud SF-36. *Med Clin (Barc)*. 1998;111(11):410-6.

3. Ciconelli RM, Ferraz MB, Santos W, Meinão I, Quaresma MR. Tradução para a língua portuguesa e validação do questionário genérico de avaliação de qualidade de vida SF-36 (Brasil SF-36). *Rev Bras Reumatol*. 1999;39(3):143-50.

4. Cook DJ, Guyatt GH, Adachi JD, Epstein RS, Juniper EF, Austin PA, et al. Development and validation of the mini-osteoporosis quality of life questionnaire (OQLQ) in osteoporosis women with back pain due to vertebral fractures. *Osteoporos Int*. 1999;10(3):207-13.

5. Cvijetic S, Mestrovic T, Crkvenac A, Davila S, Korsic M. Quality of life in osteoporotic patients with hip fracture and without fracture. *Arh Hig Rada Toksikol*. 2002;53(4):257-62.

6. Diaz Curiel M, Garcia JJ, Carrasco JL, Honorato J, Perez Cano R, Rapado A, et al. Prevalencia de osteoporosis determinada por densitometría en la población femenina española. *Med Clin (Barc)*. 2001;116(3):86-8.

7. Fitzpatrick R, Fletcher A, Gore S, Jones D, Cox D. Medida de la calidad de vida en los servicios sanitarios I: aplicaciones y aspectos a valorar. *BMJ (Ed Esp)*. 1995; Separata Especial:1-5.

8. McHorney CA, Ware JE, Lu JFR, Sherbourne CD. The MOS 36-item short form health survey (SF-36) III: tests of data quality scaling assumptions and reliability across diverse patient groups. *Med Care*. 1994;32(1):40-66.

9. McHorney CA, Ware JE, Raczek AE. The MOS 36-item short-form health survey (SF-36) II: psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care*. 1993;31(3):247-63.

10. Minayo MCS, Hartz ZMA, Buss PM. Qualidade de vida em saúde: um debate necessário. *Ciênc Saúde Coletiva*. 2000;5(1):7-18.

11. Naves Díaz M, Díaz López JB, Rodríguez Rebollar A, Gómez Alonso C, Díaz Corte C, Cannata Andía J. Efecto de la fractura vertebral sobre la calidad de vida relacionada con la salud en población asturiana mayor de 54 años. *Med Clin (Barc)*. 2001;116(14):533-5.

12. Organización Mundial de la Salud - OMS. Informe preliminar y recomendaciones de una comisión de expertos de la Organización Mundial de la Salud sobre una estrategia global para la osteoporosis. *Rev Esp Enfer Metab Óseas*. 2000;9(2):78-83.

13. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36) I: conceptual framework and item selection. *Med Care*. 1992;30(6):473-83.

14. World Health Organization - WHO. Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Geneve; 1994. (Technical Report Series, 843).

15. Yoh K, Tanaka K, Ishikawa A, Ishibashi T, Uchino Y, Sato Y, et al. Health-related quality of life (HRQOL) in japanese osteoporotic patients and its improvement by elcatonin treatment. *J Bone Miner Metab*. 2005;23(2):167-73.