Development and testing of a new instrument to measure self-care in patients with osteoporosis: the self-care of osteoporosis scale

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ABSTRACT

Purpose: The aim of this study was to develop and test the Self-Care of Osteoporosis Scale (SCOS), a new instrument to measure self-care in postmenopausal women with osteoporosis.

Methods: A cross-sectional study was conducted. The SCOS was developed by a panel of experts and it was theory-driven. Confirmatory factor analysis (N = 544) was used to test the instrument's factorial validity; Cronbach's alpha and McDonald's omega were used to derive the measure's internal consistency reliability; an intraclass correlation coefficient was used to evaluate test-retest reliability.

Results: Confirmatory factor analysis resulted in supportive fit indices for the hypothesized three-factor structure of the SCOS (RMSEA = 0.065; CFI = 0.99). The SCOS was demonstrated to have content validity, internal consistency and test-retest reliability.

Conclusions: The SCOS demonstrated excellent psychometric characteristics in terms of validity and reliability. It may be used by healthcare providers to identify if patients show lower self-care and require educational interventions.

KEYWORDS

Osteoporosis, adherence, health promotion, self-care.

Introduction

Osteoporosis is a common chronic illness and a major public health problem in terms of mortality, morbidity and social cost [1]. Globally, 200 million people are affected by osteoporosis [2,3], 80% of whom are postmenopausal women. However, this number will increase in the coming years due to the ageing of the population [4].

Osteoporosis is known as the "silent disease" because bone loss often progresses asymptomatically [5], and often patients only start to become aware of the disease because of pain and changes in their body image [4]. However, through adequate self-care, osteoporosis patients can improve their outcomes and reduce the risk of fragility fractures by between 30% and 70% [6-10].

Self-care has been defined as activities that patients perform to maintain disease stability (self-care maintenance), monitor the signs and symptoms of their disease (self-care monitoring), and respond to signs and symptoms when they occur (self-care management) [11]. In osteoporosis, self-care monitoring and self-care management activities are hindered because the disease progresses asymptomatically. However, self-care maintenance (SCM) principles can be successfully applied to osteoporosis patients. In fact, these persons typically need to perform several activities aimed at maintaining disease stability and reducing the risk of fracture (e.g., taking medications as prescribed, eating a diet that includes calcium, and wearing non-slip shoes). Because SCM behaviors are fundamental for osteoporosis patients, it is important for researchers and clinicians to have a psychometrically-sound instrument to measure this construct.

The literature does not report any disease-specific or theory-driven instruments for measuring SCM in osteoporosis patients. In fact, the Morisky Medication Adherence Scale [12] and Hayne's single-item adherence question [13] are two widely-used and psychometrically-sound instruments in this field, but they measure only adherence to pharmacological treatments. On the other hand, the ADherence Evaluation of OSteoporosis treatment questionnaire [14] is a disease-specific instrument, but it only considers treatment with oral antiresorptive medications. None of the above instruments is theory-driven or investigates the important non-pharmacological factors that maintain osteoporosis stability and prevent fragility fractures, such as diet, physical activity and the implementation of safety

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measures (safety performance). Therefore, the aim of this study was to a) develop the Self-Care of Osteoporosis Scale (SCOS), a new theory-driven and disease-specific instrument to measure self-care in osteoporosis patients, and b) test its psychometric properties.

Methods

Design

A cross-sectional design was used; patients were enrolled from January 2014 to January 2016.

Settings and participants

The psychometric analysis of the SCOS was performed by enrolling patients from 53 different osteoporosis centers across Italy: 18 located in northern, 14 in central, and 21 in southern Italy. Only women who were not in the pilot study and met the following inclusion criteria were enrolled: a) postmenopausal, b) medical diagnosis of osteoporosis, and c) able to read and write Italian. We excluded from participation: a) women who were severely ill or mentally disabled, b) those with severe kidney failure and/or neoplastic disease, and c) persons who were unable to complete the questionnaire.

Eligible participants completed the SCOS during appointments in orthopedics and traumatology outpatient settings. After completing the SCOS, participants were asked to complete a sociodemographic and clinical questionnaire aimed at collecting the following participant variables: age, education, employment status, weight and height (to compute their body mass index, BMI), type of menopause (spontaneous or surgical), fracture history, i.e. past fractures and current fractures still in the healing process at the time of the interview. Thirty days after the first interview, the SCOS was readministered for test-retest reliability evaluation purposes.

SCOS developments

The SCOS was developed in four phases in accordance with the middle-range theory of self-care of chronic illness [11]. The first phase consisted of a literature review aimed at retrieving existing instruments used to measure self-care in osteoporosis patients. As no instruments were found, in the second phase, a second literature review was performed searching for factors that maintain osteoporosis stability, as defined in the above theory, and prevent injuries in patients with osteoporosis. In this second literature review, particular attention was paid to analyzing the existing international guidelines on osteoporosis [15]. At the end of this phase, a first draft of the SCOS items was generated. These were grouped into three domains: medication adherence, diet and physical activity, and safety performance.

In the third phase, three focus groups were convened in order to refine the SCOS items. The groups were comprised of a multidisciplinary panel of experts (five nurses and five physicians experienced in osteoporosis and, in addition, a psychometrician). In one of these groups, the preliminary SCOS items were also evaluated by two women suffering from severe osteoporosis. At the end of the third phase, the pre-final version of the SCOS was derived. It consisted of 3 domains and 15 items. The possible responses to each item consisted of ratings following a 5-point Likert scale format: 1 = never, 2 = rarely, 3 = sometimes, 4 = often, and 5 = always. For item 2 on knowledge, the Likert format was: not at all, slightly, somewhat, moderately, extremely. In the fourth phase, the SCOS underwent pilot testing with a convenience sample of 15 women affected by osteoporosis at various treatment stages. The objective was to identify potential problems in SCOS administration (e.g., concerning the phrasing and sequence of the questions, clarity and comprehensiveness) and the need to add or eliminate questions. After pilot testing, the multidisciplinary panel of experts decided to modify some items to improve their clarity and readability. Then, the final version of the SCOS was achieved where a higher score indicating better self care. Specifically, for those women who take osteoporosis drugs, the total score ranges from 15 to 75, while for those who do not take any osteoporosis drug the score is between 13 and 65. In the latter situation, the first two items should be classified as not applicable. Moreover, to obtain a user-friendly 0-100 score the following formula should be used (mean-1)*25. This final version underwent the following psychometric analysis.

Ethical considerations

The study was approved by an independent ethics committee of the hospital where it was conducted. Before data collection, potential participants were fully informed of the study aims; data collection began only after they had signed the informed consent form. Participants were also informed that they could leave the study at any time without giving a reason and that their data would be kept confidential.

Statistical analysis

Descriptive statistics (mean, standard deviation and frequencies) were used to describe the participants' sociodemographic and clinical characteristics. Descriptive statistics (mean, standard deviation, skewness and kurtosis) were also used to describe SCOS items. The SCOS validity was tested via confirmatory factor analysis (CFA) and hypothesis testing [16,17]. In consideration of the literature and the theoretical underpinning guiding the development of the SCOS, a three-factor model for CFA was identified using the following factors and items: the first factor was medication adherence, covered by items 1, 2 and 3; the second was diet and physical activity and included items 4–10; finally, the third, safety performance, included items 11–15 (Table III). Given that responses were collected by means of a five-point ordinal Likert scale, the CFA was conducted with asymptotic covariance matrices and robust maximum likelihood estimation methods. As fit indices, MLχ^2 test statistics were used in conjunction with other tests that are less dependent on sample size [18]: (a) the root mean square error of approximation index (RMSEA) [19]; (b) the comparative fit index (CFI) [20]; and (c) the non-normed fit index (NNFI) [21]. MLχ^2 test values associated with $p > .05$ were considered to indicate models with good fit; values up to .06 or lower were considered well-fitting models for the RMSEA [22]; while values > .95 indicated a good fit for the CFI [20] and the NNFI.

Hypothesis testing was conducted by comparing the SCOS scores of participants who had had a fragility fracture due to

osteoporosis with the scores of participants who had not; Student's t-test was used for this analysis. The rationale underpinning this comparison consisted of literature reports [23,24] stating that patients who have had fragility fractures report higher self-care than those who have not.

The SCOS internal consistency reliability (for the total scale and its factors) was tested with Cronbach's alpha and McDonald's omega [25,26]. Reliability was also tested using a test-retest procedure in which the SCOS total scores and dimension scores collected at baseline and after 30 days were correlated (using the intraclass correlation coefficient).

The CFA was performed with Lisrel 8.80 software [27]. All other analyses were performed with R 3.2.2 language and environment for statistical computing [28]. An alpha level of 0.05 was used for all statistical tests.

Results

The characteristics of study participants are summarized in Table I. The sample included 544 postmenopausal osteoporotic women with a mean age of 71 years (± 10, range 44–96). A significant number of participants (60.47%) did not have a high school level of education. Most of the women worked (63.42%), while the others were retired (33.82%). The majority of the women were in physiological menopause (88.24%) with a normal BMI (40.62%). A total of 189 women (34.75%) were healing from a bone fracture at the time of enrollment, 257 women (47.22%) reported a previous bone fracture, and 98 women (18.03%) had never suffered any bone fractures.

Table I Sociodemographic characteristics of the study participants (n = 544).

VARIABLE	N (%)
Age (mean ± SD; range) 71 ± 10; 44–96	
Educational level	
- None	68 (12.52)
- Below high school level	329 (60.47)
- High school level	127 (23.34)
- University level	19 (3.49)
- Missing data	1 (0.18)
Employment status	
- Worked	345 (63.42)
- Unemployed	14 (2.58)
- Retired	184 (33.82)
- Missing data	1 (0.18)
Body Mass Index	
- Underweight (15–19.9)	54 (9.92)
- Normal weight (20–24.9)	221 (40.62)
- Overweight / pre-obesity (25–29.9)	142 (26.11)
- Class I obesity (30–34.9)	41 (7.53)
- Class II obesity (35–39.9)	9 (1.65)
- Class III obesity (> 40)	6 (1.12)
- Missing data	71 (13.5)
Menopause	
- Physiological	480 (88.24)
- Induced	64 (11.76)
Fracture	
- Never	98 (18.03)
- Previous	257 (47.22)
- In the process of healing	189 (34.75)
Pharmacotherapy for osteoporosis	
-Yes	488 (89.71)
-No	56 (10.29)

Table II Descriptive analysis of items.

ITEM	MEAN	SD	SKEWNESS	KURTOSIS
1. Take osteoporosis drugs as prescribed	4.10	1.09	-0.99	-0.02
2. Know the consequences if do not take osteoporosis medications	3.98	1.16	-0.97	-0.04
3. Take daily supplements of calcium and vitamin D	3.87	1.21	-0.75	-0.64
4. Perform physical exercise (muscle strengthening, balance and coordination)	3.27	1.34	-0.19	-1.19
5. Spend at least 10–15 minutes outdoors each sunny day	3.72	1.23	-0.68	-0.58
6. Reaching and maintaining a healthy body weight	3.72	1.24	-0.76	-0.48
7. Avoid sudden or twisting movements and bending during domestic activities	3.46	1.21	-0.38	-0.92
8. Eat a balanced diet with at least two main meals per day	3.94	1.15	-1.04	0.27
9. Eat and drink calcium-rich foods daily (1,000 mg/day) and know which foods are good sources of calcium (yogurt, milk, orange juice)	3.66	1.16	-0.68	-0.44
10. Drink at least 1.5 liters of water per day	3.42	1.24	-0.36	-0.97
11. Illuminate the home environment well	3.91	1.13	-0.95	0.22
12. Turn on the night light when getting out of bed	3.73	1.23	-0.75	-0.39
13. Create a safe environment by removing home hazards (slippery floors, obstacles, carpets, insufficient lighting)	3.59	1.16	-0.54	-0.49
14. Use all necessary aids (bathtub chairs, handrails, etc.)	3.51	1.17	-0.39	-0.63
15. Wear comfortable non-slip shoes for stable balance	3.78	1.14	-0.68	-0.32
The above scores are not standardized				

A significant number of women (89.71%) took drugs for osteoporosis (e.g., teriparatide, bisphosphonate, denosumab, and strontium ranelate). Table II details the SCOS item descriptive analysis. The items with the highest scores were Items 1 ("take drugs as prescribed") and 2 ("know the consequences if do not take osteoporosis medications"); the items with the lowest scores were numbers 4 ("perform physical exercise") and 10 (drink at least 1.5 liters of water per day"). All items were normally distributed, with a skewness and kurtosis ranging from -1 to 1 (with the exception of Item 8, which exhibited a negligible negative skew of -1.04).

Validity testing of the SCOS

CFA testing of the three-factor model of the SCOS with adherence, diet and physical activity, and safety performance factors resulted in the following supportive fit indices: MLχ^2 (87) = 660.91, $p < .001$, RMSEA = 0.065, CFI = 0.99, and NNFI = 0.988 (Table III). The factor loadings were all statistically significant and ranged between 0.70 for Item 4 ("perform physical exercise, muscle strengthening, balance and coordination") and 0.93 for Item 1 ("take drugs as prescribed"). The SCOS factors were strongly and significantly correlated (r = .82, r = .86, and r = .86, respectively, for medication adherence and diet and physical activity, medication adherence and safety performance, and diet and physical activity and safety performance), suggesting the presence of a higher-order factor that can explain the significant correlations observed. This latter model was not tested, as it is an equivalent model [29].

Validity testing via hypothesis testing, comparing patients who had had a previous fragility fracture versus those who had not, showed statistically significant differences in the SCOS total and fracture scores (Table IV).

Table III Confirmatory factor analysis of the SCOS.

ITEM	FACTOR		
	1 [MA]	2 [DPA]	3 [SP]
1. Take drugs as prescribed	.93	–	–
2. Know the consequences if do not take osteoporosis medications	.87	–	–
3. Take daily supplements of calcium and vitamin D	.77	–	–
4. Perform physical exercise (muscle strengthening, balance and coordination)	–	.70	–
5. Spend at least 10–15 minutes outdoors each sunny day	–	.79	–
6. Reaching and maintaining a healthy body weight	–	.83	–
7. Avoid sudden or twisting movements and bending during domestic activities	–	.75	–
8. Eat a balanced diet with at least two main meals per day	–	.86	–
9. Eat and drink calcium rich foods daily (1,000 mg/day) and know which foods are good sources of calcium (yogurt, milk, orange juice)	–	.75	–
10. Drink at least 1.5 liters of water per day	–	.71	–
11. Illuminate the home environment well	–	–	.89
12. Turn on the night light when getting out of bed	–	–	.86
13. Create a safe environment by removing home hazards (slippery floors, obstacles, carpets, insufficient lighting)	–	–	.84
14. Use all necessary aids (bathtub chairs, handrails, etc.)	–	–	.77
15. Wear comfortable non-slip shoes for stable balance	–	–	.79

MA: medication adherence; **DPA:** diet and physical activity; **SP:** safety performance; the numbers in three factor columns are standardized loadings

Table IV Validity testing of the SCOS via hypothesis testing.

	PATIENTS WITH PREVIOUS FRACTURES	PATIENTS WITHOUT PREVIOUS FRACTURE	*P*
SCOS total score (Mean and SD)	57.19 (12.68)	53.82 (12.40)	0.003
Medication adherence factor score (Mean and SD)	12.05 (2.98)	11.17 (2.94)	0.001
Diet and physical activity factor score (Mean and SD)	26.01 (6.26)	24.58 (6.42)	0.014
Safety performance factor score (Mean and SD)	19.12 (4.79)	18.07 (4.68)	0.016
The above scores are not standardized			

Reliability testing of the SCOS

Regarding the reliability of the SCOS scale, the data showed a good level of internal consistency as expressed by a Cronbach's alpha [30] of .94 for the overall scale, .84 for the medication adherence factor, .88 for the diet and physical activity factor, and .85 for the safety performance factor; and a McDonald's omega [26] of .94 for the overall scale, .85 for the medication and adherence factor, .87 for the diet and physical activity factor, and .88 for the safety performance factor.

Test-retest reliability, correlating the SCOS total and factors' scores between the first and second administration with a 30-day interval, showed the following intraclass correlation coefficients: .86 for the SCOS total scores; .87 for the medication adherence factor scores; .80 for diet and physical activity; and .85 for safety performance.

Discussion

The purpose of this study was to develop and test the psychometric properties of the SCOS. To our knowledge, this is the first theory-driven and disease-specific instrument that measures SCM in women with osteoporosis. Our analysis showed the SCOS to be a valid and reliable instrument.

Regarding SCOS development, our study followed a rigorous process with the involvement of a multidisciplinary team including experts in osteoporosis, a psychometrician, and patients suffering from osteoporosis. During the process of item generation, we also consulted the most recent evidence and guidelines to ensure that we obtained an instrument that measures evidence-based behaviors that help to maintain the health and stability of osteoporosis patients. Interestingly, CFA testing of the three hypothesized dimensions of the SCOS (medication adherence, diet and physical activity, and safety performance) resulted in supportive fit indices. This is evidence that SCM behaviors in osteoporosis patients reflect the above dimensions; as such, the ins and contribute to the development of future theoretical works on the self-care behaviors adopted by osteoporosis patients. In fact, to our knowledge, no theory on SCM, and self-care in general, has to date been developed for this population. The three theoretical dimensions found in this study could therefore serve as a starting point.

The literature has reported some instruments that could be used in osteoporosis patients [13, 31-34], but these studies focused only on medication adherence. Medication adherence only partially reflects SCM. For example, evidence has shown that, to maintain osteoporosis stability, patients need to follow a diet containing calcium [35], take exercise [36], and also create a safe environment [37, 38]. No behaviors related to diet, physical activity and safety performance were considered in the existing instruments. Consequently, the SCOS allows a comprehensive evaluation of all the important behaviors patients should adopt when they are diagnosed with osteoporosis.

Regarding the CFA, the fit indices were excellent for both the first-order, three-factor solution, and the second-order, one factor solution. The validity of the instrument was also determined via hypothesis testing. Here, significant differences in SCOS scores were found between patients who had suffered a previous fragility fracture and patients who had not. The adoption of this external criterion is important because it strengthens the SCOS validity. With regard to reliability testing, all three first-order factors and the second-order factor resulted in supportive internal consistency reliability with both Cronbach's alpha and McDonald's omega. Supportive reliability on test-retest, with high intraclass correlation coefficients, was also found. This means that the SCOS can reliably measure the three separate SCM dimensions of medication adherence, diet and physical activity, and safety performance, as well as the total SCM. It is important to have a precise evaluation of patients' SCM abilities in order to provide them with tailored interventions.

This study has several limitations. First of all, only post-menopausal women were included. Indeed, 80% of osteoporosis patients are women [39]. However, we believe that the SCOS items can also be used for a male population since they are not sex-specific. Use of the SCOS in the male population should nonetheless be approached with caution, as we did not involve male patients in the development of the instrument. Another limitation is the selection of a convenience sample from a single country. Consequently, generalization of the results to other countries should be done with caution. We tried to balance the above limitations by conducting a multisite study, enrolling patients from 53 osteoporosis centers. Finally, we enrolled only women with osteoporosis in post-menopause. Consequently, the SCOS should be used with caution in premenopausal women.

This study has practical and scientific implications. From a practical point of view, the SCOS allows clinicians to evaluate SCM in osteoporosis patients in the three dimensions of medication adherence, diet and physical activity, and safety performance, as well as total SCM. This is important because all behaviors included in the SCOS are evidence-based and have been associated with positive outcomes in this population. As the SCOS is divided into three reliable dimensions, the score obtained from each domain could be used to devise interventions for individual osteoporosis patients. For example, in administering the SCOS, if clinicians observe a high score in the medication adherence dimension but a low score in the diet and physical activity dimension, they could educate patients more in this latter dimension of osteoporosis care. Since the SCOS is comprised of only 15 items and requires just five minutes to administer, it could also be used routinely to monitor SCM levels. From a scientific point of view, the SCOS would enable the measurement of SCM behaviors in osteoporosis patients with validity and reliability. However, further studies should be conducted to further confirm the psychometric properties of this instrument. It is important that future studies test the SCOS in other cultures, in other countries, in men, and in women before menopause. Also, it is important to test the SCOS for its predictive validity to see whether SCOS scores can predict patient outcomes. Indeed, behaviors considered in the SCOS have been already associated with patient outcomes [15, 23, 40].

Conclusions

In conclusion, the study showed that the SCOS has good psychometric properties in terms of factorial validity and re-

liability. Further studies are needed to test the SCOS in other cultures and other osteoporotic populations. Furthermore, other aspects of validity (e.g., predictive validity) should be determined. That said, as the SCOS items are evidence based, we expect SCOS scores to be predictive of patient outcomes. Considering its short administration time, we recommend that clinicians and researchers use the SCOS in practice and empirical investigations.

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