

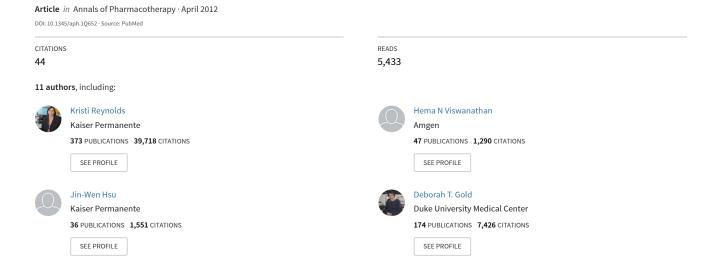
Osteoporosis MMAS (O-MMAS-8)

Preface

You indicated that you are taking medication for your osteoporosis. Individuals have identified several issues regarding their medication taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience. Please answer each question below by checking the box that best describes your response.

1. Do you sometimes forget to take your prescription osteoporosis medication (i.e. other than calcium and vitamin D)? ☐ Yes ☐ No
2. People sometimes miss taking their medication for reasons other than forgetting. Thinking over the past 2 weeks, were there any times when you did not take your osteoporosis medication?
□ Yes □ No
3. Have you ever cut back or stopped taking your osteoporosis medication without telling your doctor, because you felt worse when you took it?
□ Yes □ No
4. When you travel or leave home, do you sometimes forget to bring along your osteoporosis medication? ☐ Yes ☐ No
5. Did you take your osteoporosis medication the last time you were supposed to? ☐ Yes ☐ No
6. If you feel that your osteoporosis medication is not working, do you sometimes stop taking your medication?
□ Yes □ No
7. Taking medication exactly as prescribed is a real inconvenience for some people. Do you ever feel hassled about sticking to your osteoporosis treatment plan?
□ Yes □ No
8. How often do you have difficulty remembering to take all your medications? □ Never □ Rarely □ Sometimes □ Often □ Always

Psychometric Properties of the Osteoporosis-Specific Morisky Medication Adherence Scale in Postmenopausal Women with Osteoporosis Newly Treated with Bisphosphonates



RESEARCH REPORTS

Adherence

Psychometric Properties of the Osteoporosis-Specific Morisky Medication Adherence Scale in Postmenopausal Women with Osteoporosis Newly Treated with Bisphosphonates

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steoporosis, a skeletal disease characterized by low bone mass and structural deterioration of bone tissue leading to bone fragility and susceptibility to fractures, presents an important public health challenge. In the US, an estimated 10 million adults have osteoporosis.2 The burden is highest in postmenopausal women due to the accelerated bone loss associated with decreased estrogen concentrations.³ Furthermore, osteoporosis has become a substantial financial burden for society as a whole. In 2005, there were more than 2 million osteoporosis-related fractures among US adults, with an associated direct cost of \$17 billion.4

Clinical trials have demonstrated the efficacy of oral bisphosphonates, currently the most commonly prescribed therapy approved for treatment of postmenopausal osteoporosis, for preventing fractures.⁵⁻⁷ However, low adherence to oral bisphosphonate therapy is both common and associated with poor outcomes and increased treatment costs.⁸⁻¹³ A meta-analysis of 24 studies demonstrated that one third of patients were nonadherent to their osteoporosis drug therapy within the first year of treatment.¹⁰ In a study of more than 38,000 women with osteoporosis followed for an average of

BACKGROUND: Poor adherence to oral osteoporosis medications is common. Strategies for improving adherence begin with identification of the problem. The 8-item Morisky Medication Adherence Scale for self-reported adherence to antihypertensive medications was modified for assessing adherence to oral osteoporosis medications. An evaluation of the measurement properties of the Osteoporosis-Specific Morisky Medication Adherence Scale (OS-MMAS) was needed.

OBJECTIVE: To examine the psychometric properties of the OS-MMAS in women with postmenopausal osteoporosis.

METHODS: Five hundred women aged 55 years and older with osteoporosis who were newly prescribed daily or weekly oral bisphosphonates between May 15, 2010, and August 15, 2010, were randomly selected from Kaiser Permanente Southern California, a large integrated health care delivery system, and mailed a self-administered survey that included the 8-item OS-MMAS, Self-Efficacy for Appropriate Medication Use Scale (SEAMS), Beliefs about Medicines Questionnaire (BMQ), Treatment Satisfaction Questionnaire for Medication (TSQM), Gastro-intestinal Symptom Rating Scale (GSRS), and 12-item Short-Form Health Survey (SF-12v2). OS-MMAS scores can range from 0 to 8, with higher scores indicating better medication adherence. Internal consistency reliability was evaluated using Cronbach α coefficient. Test-retest reliability was assessed using intraclass correlation coefficients (ICCs) in a subset of 102 participants. Construct validity was assessed using confirmatory factor analysis and correlations between OS-MMAS and related measures.

RESULTS: Of 197 participants, 150 reported that they were still taking their bisphosphonate at the time of the survey and completed the OS-MMAS. Overall, 30.7%, 32.7%, and 36.7% had low, medium, and high OS-MMAS scores (<6, 6 to <8, and 8, respectively). Cronbach α was 0.82 and the ICC was 0.77. Convergent validity was supported by significant correlations with SEAMS, BMQ necessity, and TSQM scores. In confirmatory factor analysis, a single-factor scale was supported.

CONCLUSIONS: The OS-MMAS showed strong psychometric properties with good reliability and construct validity and may provide a valuable assessment of self-reported medication adherence in women newly prescribed oral osteoporosis medications.

KEY WORDS: adherence, bisphosphonates, Morisky scale, postmenopausal osteoporosis, reliability, validity.

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1.7 years, low adherence to osteoporosis medication was associated with a 16.7% increased risk of fracture and a 37.2% increased risk of all-cause hospitalization.¹¹

While poor adherence to osteoporosis therapy is well documented, there is less consensus on the definition of adherence. 10,14,15 Adherence is often used interchangeably with persistence (how long a patient continues therapy after treatment initiation) while omitting the component of compliance (taking the correct dose and frequency). An expert panel recommended that adherence definitions include both persistence and compliance.14 Measuring adherence is also challenging. Randomized clinical trials monitor adherence directly with electronic pill counts and biomarkers, but these are not practical in the clinical setting. Observational studies often measure adherence with pharmacy claims patterns, but these data are not routinely available to health care providers. Given the high burden of poor adherence to osteoporosis medications, it is crucial for health care providers to identify nonadherent patients and improve their medication behaviors to ensure they receive the full therapeutic benefits of their osteoporosis medications. However, without accurate means to measure adherence, achieving improvements is challenging. To address the need to measure adherence, the 8-item Morisky Medication Adherence Scale (MMAS-8), originally developed as a self-report measure of antihypertensive medication adherence,16,17 was modified for assessing adherence to oral osteoporosis medications.

The objective of this study was to evaluate the psychometric properties of the Osteoporosis-Specific Morisky Medication Adherence Scale (OS-MMAS) in a population of postmenopausal women newly prescribed daily or weekly bisphosphonate therapy.

Methods

POPULATION

This study was conducted with members of Kaiser Permanente Southern California, a large, integrated health care delivery system that provides comprehensive care for approximately 3.4 million members. Data on the medical care that patients receive are captured through structured administrative and clinical databases and an electronic medical record.

A total of 2372 postmenopausal women aged 55 years and older with osteoporosis, based on one or more outpatient International Classification of Diseases, Ninth Revision, Clinical Modification, diagnosis codes of 733.0x between January 1, 2009, and September 15, 2010, who were newly prescribed daily or weekly oral bisphosphonate therapy between May 15, 2010, and August 15, 2010, were identified. New prescriptions of oral bisphosphonate therapy were defined by a pharmacy fill with no fills dispensed

in the prior 365 days. Women without 12 months of continuous membership or a drug benefit prior to the initial bisphosphonate dispense date and until November 15, 2010, the date women were selected for recruitment, were excluded (n = 493). We further excluded non-English speakers (n =326), women with diagnoses of alcohol or substance abuse (n = 22), those with cognitive impairment or severe dementia (n = 36), those with incomplete address information (n = 10), and women who had died (n = 19); 1466 individuals remained available for recruitment. This study was limited to women prescribed daily or weekly bisphosphonate regimens, as other dosing schedules are uncommon in Kaiser Permanente Southern California and the medication adherence of those who have different dosing schedules may be different from weekly or daily users. The study protocol was reviewed and approved by the Institutional Review Board of Kaiser Permanente Southern California.

RECRUITMENT

Recruitment was conducted between December 1, 2010, and March 12, 2011. Of the 1466 women who met inclusion criteria for the study, a computer-generated random sample of 500 potential participants was selected with the a priori goal of recruiting 200 individuals. Potential participants were mailed an initial personalized cover letter describing the study along with a survey, a postage-paid return envelope, and a postage-paid reply opt-out postcard. Up to 2 reminder postcards were mailed to nonrespondents at 7- to 10-day intervals after the initial mailing. Participants were compensated \$40 for their time spent completing the survey. A subset of individuals was resurveyed within 1-3 weeks for test-retest reliability assessment of the OS-MMAS. The a priori goal was to have 100 individuals complete a second survey. Participants were invited to complete the retest in the order the original responses were received. Participants were compensated \$20 for completing the retest survey.

DATA COLLECTION

All surveys were self-administered. The questionnaire solicited information on demographic characteristics, including race/ethnicity, household income, education, and marital status; medical history, including parental and personal history of fractures; lifestyle factors, including alcohol consumption and smoking status; participation in other medical studies; and whether they had discontinued bisphosphonate therapy. Medication adherence was assessed using the OS-MMAS. Additional self-reported measures included the Beliefs about Medicines Questionnaire (BMQ), Self-Efficacy for Appropriate Medication Use Scale (SEAMS), Gastrointestinal Symptom Rating Scale (GSRS), Treatment Satisfaction Questionnaire for Medica-

tion (TSQM; www.quintiles.com/TSQM), and 12-item Short-Form Health Survey (SF-12v2). These measures were selected based on published evidence of the theoretical correlation between the constructs they measure and medication adherence. Scoring, including imputations for missing data if necessary, for the self-reported measures was performed according to each scale developer's guidelines.

Individuals reporting that they had discontinued use of their bisphosphonate therapy were instructed to complete the survey but to skip the OS-MMAS, SEAMS, and BMQ, as these surveys require the individual to reflect on recent medication use. Survey questionnaire data were linked with electronic health plan databases using the member's health record number, a unique identifier. The health plan data provided information about the individuals' membership history, date of birth, healthcare utilization, comorbidities and number of other medication subclasses filled in the prior year.

Osteoporosis-Specific Morisky Medication Adherence Scale

The OS-MMAS is a modified version of the MMAS-8, which has demonstrated reliability (Cronbach α coefficient = 0.83) and validity for assessing adherence to antihypertensive medication. ^{16,17} Each of the 8 items of the disease-specific OS-MMAS captures a specific medication-taking behavior. Response categories are yes/no for items 1-7 and

a 5-item Likert response for the last item (Table 1). The OS-MMAS scores can range from 0 to 8 and have been categorized into the following 3 levels of adherence: high adherence (score = 8), medium adherence (6 to <8), and low adherence (<6). These categories are the same categories used in the MMAS-8.

Osteoporosis-Specific Beliefs About Medicines Questionnaire

The Osteoporosis-Specific BMQ is an 11-item self-reported questionnaire that assesses the patients' beliefs about the necessity of prescribed medication for controlling their illness and concerns about potential adverse consequences of taking the medication.²⁰ BMO scores can range from 5 to 25 on the necessity domain and 6 to 30 on the concerns domain. Higher scores indicate stronger beliefs about the corresponding concepts in the necessity or concerns domains. Data from the BMQ can also be used to calculate a necessity-concerns differential by subtracting the concerns subscale score from the necessity subscale score. Scores on the differential can range from -4 to 4. Negative scores on the necessity-concerns differential indicate that individuals rate their concerns about medication higher than their beliefs about the necessity of the medication. If the score is positive, then the opposite applies.

Table 1. Osteoporosis-Specific Morisky Medication Adherence Scale (©OS-MMAS)			
You indicated that you are taking medication for your osteoporosis. Individuals have identified several issues regarding the havior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based ence with your prescription osteoporosis medication (ie, other than calcium and vitamin D). Please answer each question below by checking the box that best describes your response.		0	
Do you sometimes forget to take your prescription osteoporosis medication (ie, other than calcium and vitamin D)?	□ o Yes	□ ₁ No	
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past 4 weeks, were there any times when you did not take your osteoporosis medication?	□ ₀ Yes	□ ₁ No	
3. Have you ever cut back or stopped taking your osteoporosis medication without telling your doctor, because you felt worse when you took it?	□ ₀ Yes	□ ₁ No	
4. When you travel or leave home, do you sometimes forget to bring along your osteoporosis medication?	□ o Yes	□ ₁ No	
5. Did you take your osteoporosis medication the last time you were supposed to take it?	□ o Yes	□ ₁ No	
6. If you feel that your osteoporosis medication is not working, do you sometimes stop taking your medication?	□ o Yes	□ ₁ No	
7. Taking medication exactly as prescribed is a real inconvenience for some people. Do you ever feel hassled about sticking to your osteoporosis treatment plan?	□ o Yes	□ ₁ No	
8. How often do you have difficulty remembering to take all your medications?			
□ ₄ Never/Rarely			
☐ 3 Once in a while			
□ ₂ Sometimes			
□ ₁ Usually			
\square $_0$ All the time			
Use of the ©OS-MMAS is protected by US copyright laws. Permission for use is required. Licensure agreement is available ScD ScM MSPH, Professor, Department of Community Health Sciences, UCLA School of Public Health, 650 Charles E. Yogeles, CA 90095-1772. ©Morisky 2009 OS-MMAS, US English Version 1.0			

Self-Efficacy for Appropriate Medication Use Scale

The SEAMS is a 13-item questionnaire developed to measure self-efficacy for appropriate medication use.²² Scoring for SEAMS involves the addition of the response scale, with the potential score ranging from 13 to 39. Higher scores indicate higher levels of self-efficacy for medication adherence.

Gastrointestinal Symptom Rating Scale

The GSRS is a disease-specific questionnaire developed to measure common gastrointestinal symptoms. It consists of 15 questions measuring 5 domains: abdominal pain, reflux syndrome, diarrhea syndrome, indigestion syndrome, and constipation syndrome. The possible range of GSRS domain scores is 1 to 7, with higher scores indicating greater severity of gastrointestinal symptoms.^{19,21}

Treatment Satisfaction Questionnaire for Medication

The TSQM consists of 14 questions that measure an individual's perception of 4 domains of treatment satisfaction: effectiveness, convenience, side effects, and satisfaction. The possible range of TSQM scores is 0 to 10, with higher scores indicating greater satisfaction.¹⁸

12-Item Short-Form Health Survey

The SF-12v2 has been shown to be a reliable and valid measure of overall physical and mental health status.²³ SF-12v2 domain scores range from 0 to 100, with 0 indicating the lowest level of health and 100 indicating the highest level of health. Individuals were also asked a single question to rate their general health on a 5-point rating scale ranging from "excellent" to "poor."

SAMPLE SIZE

A priori analyses demonstrated that 200 participants would provide 80% statistical power to detect a Cronbach α coefficient of 0.60 or more, assuming a true Cronbach α coefficient of 0.70, and that 194 participants would be necessary to detect correlations as low as 0.2 between the OS-MMAS and the other patient-reported outcomes (BMQ, SEAMS, GSRS, TSQM, and SF-12v2). Additionally, for factor analysis, 5-10 participants for each item in the scale are recommended.^{24,25} Thus, 150 participants provided adequate statistical power to assess internal consistency reliability and factor analysis. The statistical power for measures of test-retest reliability (intraclass correlation coefficient [ICC] and κ statistic) was calculated via simulation. Assuming a true ICC of 0.90, a sample size of 100 participants provided 80% statistical power to detect an ICC >0.80. Also, with 100 participants, 80% statistical power was available to detect a κ statistic of >0.65, assuming the true κ statistic was 0.80.

STATISTICAL ANALYSIS

Mean (SD) or frequencies were used to describe participant demographics (age, race, income, education, marital status) and personal and family history of fractures, alcohol use, cigarette smoking, number of concomitant medications and comorbidities, and health care utilization. Participant characteristics were compared using analysis of variance for continuous variables and χ^2 tests for categorical variables. Fisher exact test was used for variables with expected counts <5. The distribution of OS-MMAS adherence levels was calculated. The scores for the domains on each scale (BMQ, SEAMS, GSRS, TSQM, and SF-12v2) were calculated overall and by OS-MMAS adherence level.

Internal consistency of the OS-MMAS was estimated using Cronbach α coefficient; an α of 0.70 or more is generally considered acceptable for internal reliability.26,27 The change in Cronbach α associated with deleting each item, one at a time, was examined to evaluate item performance for the OS-MMAS. Using responses from individuals who completed the second survey, test-retest reliability, or reproducibility of the OS-MMAS, was quantified by the ICC. ICCs above 0.60 over a 2-week interval are generally considered acceptable.^{27,28} Additionally, we assessed overall agreement and agreement above what would be expected by chance between low, medium, and high adherence on the first and second surveys using a weighted K statistic; values between 0.40 and 0.60 indicate moderate agreement.29 We conducted the ICC analysis in 102 participants who completed the retest survey. In addition, a sensitivity analysis on the reproducibility of the OS-MMAS restricted to those who completed the second survey within 7-21 days after the initial survey was also conducted.

Convergent validity was examined by calculating the Spearman correlation between OS-MMAS scores and the domains of the other scales with Bonferroni correction for multiple comparisons. Factor analysis was used to uncover the latent structure of the OS-MMAS and confirmatory factor analysis was evaluated to verify the factor structure. The fit of the models to the data was assessed using absolute and relative fit indices. The model tested was defined by the relationships among the items and latent constructs and tested by examining the fit between the specified model and the correlation covariance patterns observed in the data. The fit of the model was evaluated by global fit measures including χ^2 , standardized root mean square residual (SRMSR), goodness-of-fit index (GFI), adjusted GFI (AGFI), the Bentler's comparative fix index (CFI), and the Bentler-Bonett normalized fit index (NFI). For good model fit, the χ^2 test should be nonsignificant and the GFI, AGFI, CFI, and NFI should be near or above 0.90.30-32 Data analysis was conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC).

Results

PARTICIPANTS

A total of 197 (39.4%) of the 500 eligible individuals returned the survey. Participants were younger (70.9 vs 72.9 years; p = 0.021) and more likely to be married (48.5% vs 39.3%; p = 0.045) than nonparticipants. No other significant differences in participant characteristics were identified. Among the participants, 154 (78.2%) reported that they were still taking bisphosphonate therapy; 145 completed all 8 items of the OS-MMAS, 5 individuals completed 7 items, and 4 individuals completed less than 75% of the OS-MMAS questions and were excluded from the analysis based on the guidelines of the OS-MMAS developer (DEM). The final study population included 150 participants (Figure 1).

Overall, 30.6%, 32.7%, and 36.7% of study participants had low (<6), medium (6 to <8), and high (8) OS-MMAS scores, respectively. The mean (SD) OS-MMAS score among the study participants was 6.4 (1.9). Demographic and clinical characteristics of the participants are provided according to levels of adherence by the OS-MMAS in

Table 2. All of the responders were prescribed weekly bisphosphonates.

Those who discontinued bisphosphonate therapy (n = 42) were less likely to be married and had higher Charlson comorbidity index scores compared with women still taking their bisphosphonates (Appendix I; available at hwbooks. com/pdf/appendices/Q652.pdf). No other significant differences were identified.

INTERNAL CONSISTENCY RELIABILITY OF THE OS-MMAS

Cronbach α for the OS-MMAS was 0.82. The deletion of any item did not reduce the Cronbach α substantially; all Cronbach α values exceeded 0.70 (Table 3). The itemtotal correlation coefficient for the 8 items ranged from 0.40 to 0.68.

TEST-RETEST RELIABILITY AND CONCORDANCE OF INDIVIDUAL ITEMS ON THE OS-MMAS

For the 102 participants who completed the second OS-MMAS administration, the median time between the initial

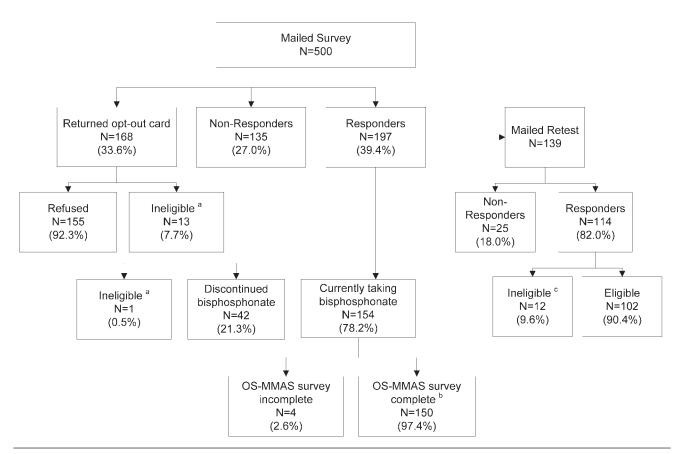


Figure 1. Recruitment flowchart.

^aReasons for ineligibility were as follows: reported no diagnosis of osteoporosis (n = 1), not currently prescribed daily or weekly bisphosphonate (n = 1), physically/mentally unable to participate (n = 2), bad address (n = 2), language barrier (n = 3), deceased (n = 5).

^bParticipants who completed 6 or more items of the Osteoporosis-Specific Morisky Medication Adherence Scale (OS-MMAS).

^eReasons for ineligibility were as follows: not currently prescribed daily or weekly bisphosphonate (n = 1), returned the survey after the end of the study period (n = 2), discontinued bisphosphonate therapy (n = 8), completed fewer than 6 items of the OS-MMAS (n = 1).

Table 2. Characteristics of Participants by OS-MMAS Score^a

Characteristic	Total (N = 150)	Low Adherence (n = 46)	Medium Adherence (n = 49)	High Adherence (n = 55)	p Value ^b
Age (y), mean (SD)	70.6 (9.1)	70.1 (8.2)	69.9 (8.7)	71.7 (10.1)	0.534
Age (y), %					0.877
55-64	31.3	30.4	32.7	30.9	
65-74	38.7	43.5	38.8	34.6	
≥75	30.0	26.1	28.6	34.6	
Race/ethnicity, %					0.824
Asian	10.7	13.0	10.2	9.1	
Black	8.7	4.4	8.2	12.7	
Hispanic	14.0	13.0	12.2	16.4	
White	62.7	63.0	67.4	58.2	
Other	4.0	6.5	2.0	3.6	
Highest education level, %					0.176
<high school<="" td=""><td>6.7</td><td>8.7</td><td>6.1</td><td>5.5</td><td>21112</td></high>	6.7	8.7	6.1	5.5	21112
High school graduate	24.7	32.6	12.2	29.1	
Some college	38.0	37.0	42.9	34.6	
College graduate	28.0	17.4	38.8	27.3	
Missing	2.7	4.3	0	3.6	
Income, %	2.7	4.0	· ·	0.0	0.216
≤\$25,000	20.7	17.4	12.2	30.9	0.210
\$25,000 \$25,001-50,000	23.3	28.3	20.4	21.8	
\$50,001-100,000	27.3	21.7	32.7	27.3	
· · · · · · · · · · · · · · · · · · ·	10.7	15.2	14.3	3.6	
>\$100,000	18.0	17.4			
Missing	64.7		20.4	16.4	0.256
Married, %		63.0	73.5	58.2	
Current smoking, %	7.3	8.7	8.2	5.5	0.794
Alcohol consumption, %	00.7	50.7	05.0	74.0	0.265
None	66.7	58.7	65.3	74.6	
<1 drink/day	21.3	30.4	20.4	14.6	
1 to <2 drinks/day	6.7	4.4	8.2	7.3	
≥2 drinks/day	4.0	2.2	6.1	3.6	
Missing	1.3	4.4	0	0	
Fracture history, %					
Personal	29.3	23.9	34.7	29.1	0.514
Mother	12.0	13.0	20.4	3.6	0.031
Father	3.3	4.4	4.1	1.8	0.737
Depression, ^c %	7.3	6.5	6.1	9.1	0.857
Weekly bisphosphonate users, %	100.0	100.0	100.0	100.0	
Concomitant medications, ^d %					0.231
0	2.0	2.2	4.1	0	
1	5.3	0	6.1	9.1	
2	3.3	4.4	4.1	1.8	
≥3	89.3	93.5	85.7	89.1	
Charlson Comorbidity Index Score, e %					0.458
0	46.7	45.7	44.9	49.1	
1	17.3	10.9	24.5	16.4	
2	12.7	10.9	14.3	12.7	
≥3	23.3	32.6	16.3	21.8	
Healthcare utilization/no. visitsf					
Ambulatory	15.3 (15.0)	18.2 (20.9)	13.1 (11.0)	14.7 (11.8)	0.244
Hospitalization	0.2 (0.5)	0.2 (0.4)	0.1 (0.4)	0.3 (0.7)	0.410
Emergency department	0.6 (1.3)	0.6 (1.3)	0.5 (1.1)	0.7 (1.5)	0.709

OS-MMAS = Osteoporosis-Specific Morisky Medication Adherence Scale.

^aScore: low adherence <6, medium adherence 6 to <8, high adherence 8.

 $^{^{}b}$ Participant characteristics were compared using analysis of variance for continuous variables and χ^{2} tests for categorical variables. Fisher exact test was used for variables with expected counts <5.

Based on International Classification of Diseases, Ninth Revision, Clinical Modification, codes within 365 days prior to study selection.

 $^{^{\}rm d}$ Includes all medications other than bisphosphonates within 365 days prior to study selection.

eBased on International Classification of Diseases, Ninth Revision, Clinical Modification, codes within 3 years prior to study selection.

^fBased on visits within 365 days prior to study selection.

and the second survey was 11 days. Participants completed the second OS-MMAS survey within 3-31 days of the first assessment. The mean (SD) OS-MMAS score in the second administration was 6.5 (1.9). The ICC value was 0.77 (95% CI 0.68 to 0.84). The overall agreement was 67.5%, with a concordance on high, medium, and low OS-MMAS adherence categories of 24.5%, 20.6%, and 20.6%, respectively (weighted κ statistic = 0.56; 95% CI 0.42 to 0.69; Table 4). Only 4.0% of participants had high adherence on one survey administration and low adherence for the other administration; 20.6% of participants had high adherence at one administration and medium adherence at the other survey administration and 9.8% had medium adherence at one survey administration and low adherence on the other. In sensitivity analyses limited to those who completed the second OS-MMAS survey within 7-21 days (n = 84) after the initial survey, the ICC value was 0.87 (95% CI 0.81 to 0.91), and 3.6% of participants had high adherence on one survey administration and low adherence for the other administration; 20.2% of participants had high adherence at one administration and medium adherence at the other survey administration; and 8.4% had medium adherence at one survey administration and low adherence at the other (weighted κ statistic = 0.59; 95% CI 0.45 to 0.73).

SUMMARY SCORES OF SELF-REPORTED MEASURES

The mean summary scores of the self-reported measures by OS-MMAS score are presented in Table 5. The mean score on SEAMS and the TSQM domain scores increased with increasing OS-MMAS score. The mean score on the BMQ necessity domain was lowest among those who had low adherence on OS-MMAS, while the mean score on the concerns domain was lowest among those who had high adherence on OS-MMAS. The necessity-concerns differential increased from low to high adherence

Table 3. Internal Consistency Reliability of the 8-Item OS-MMAS Scale				
Item	Total Correlation Coefficient	Cronbach α if Item is Deleted		
Do you sometimes forget to take your prescription osteoporosis medication (ie, other than calcium and vitamin D)?	0.52	0.80		
People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past 4 weeks, were there any times when you did not take your osteoporosis medication?	0.68	0.77		
3. Have you ever cut back or stopped taking your osteoporosis medication without telling your doctor, because you felt worse when you took it?	0.43	0.81		
4. When you travel or leave home, do you sometimes forget to bring along your osteoporosis medication?	0.58	0.79		
5. Did you take your osteoporosis medication the last time you were supposed to take it?	0.55	0.79		
6. If you feel that your osteoporosis medication is not working, do you sometimes stop taking your medication?	0.56	0.79		
7. Taking medication exactly as prescribed is a real inconvenience for some people. Do you ever feel hassled about sticking to your osteoporosis treatment plan?	0.40	0.81		
8. How often do you have difficulty remembering to take all your medications?	0.55	0.70		

OS-MMAS = Osteoporosis-Specific Morisky Medication Adherence Scale.

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OS-MMAS, US English Version 1.0

Table 4. Concordance of Adherence Categories for the OS-MMAS Administered 2 Times Over 3-31 Days ^a					Days ^a
	Level of				
	Adherence ^b	Low	Medium	High	Total
First Administration	Low	21 (20.59%)	5 (4.90%)	2 (1.96%)	28 (27.45%)
	Medium	5 (4.90%)	21 (20.59%)	11 (10.78%)	37 (36.27%)
	High	2 (1.96%)	10 (9.80%)	25 (24.51%)	37 (36.27%)
	Total	28 (27.45%)	36 (35.29%)	38 (37.25%)	102 (100%)

OS-MMAS = Osteoporosis-Specific Morisky Medication Adherence Scale.

 $^{\text{a}}\text{Weighted}\ \kappa = 0.56;\ 95\%\ \text{Cl}\ 0.42\ \text{to}\ 0.69$

bOS-MMAS score: low adherence <6, medium adherence 6 to <8, high adherence 8.

on the OS-MMAS. Mean scores on the GSRS abdominal pain, reflux syndrome, and indigestion syndrome domains were highest among those with low adherence and lowest among those with high adherence, while mean scores on the diarrhea syndrome and constipation syndrome domain were highest among those with medium adherence and lowest among those with high adherence. Those who had high adherence on the OS-MMAS had a slightly lower mean global health status score and a higher mental health component summary score on the SF-12v2.

CONVERGENT VALIDITY OF THE OS-MMAS

The correlations between OS-MMAS and the other self-reported measures are presented in Table 6. Convergent validity was supported by significant correlations between OS-MMAS and the SEAMS, BMQ necessity, BMQ necessity-concerns differential, and TSQM scores. Among the TSQM domains, convenience had the largest correlation with OS-MMAS medication adherence score, at 0.41. No significant correlations were found be-

Table 5. Summary Scores of the Patient-Reported Outcomes by OS-MMAS Score^a

	OS-MMAS Score			
Scale and Domain	Low Adherence	Medium Adherence	High Adherence	
BMQ				
Necessity	13.65 (3.77)	14.22 (3.49)	16.43 (3.83)	
Concerns	15.88 (4.63)	14.82 (4.03)	13.40 (3.72)	
Necessity-concerns differential	0.08 (1.00)	0.37 (0.72)	1.05 (0.99)	
SEAMS	30.81 (6.94)	32.42 (5.69)	36.28 (3.83)	
GSRS				
Abdominal pain	1.80 (1.15)	1.54 (0.63)	1.48 (0.80)	
Reflux syndrome	1.99 (1.42)	1.59 (0.93)	1.55 (0.97)	
Diarrhea syndrome	1.45 (0.70)	1.52 (1.08)	1.39 (0.72)	
Indigestion syndrome	2.04 (1.23)	1.85 (0.88)	1.75 (0.80)	
Constipation syndrome	1.96 (1.25)	2.20 (1.14)	1.74 (0.86)	
TSQM				
Effectiveness	49.75 (24.98)	59.85 (14.75)	67.09 (13.60)	
Convenience	57.16 (23.23)	67.86 (17.55)	77.47 (15.80)	
Adverse effects	84.80 (26.29)	94.79 (15.44)	97.50 (10.66)	
Satisfaction	48.21 (26.96)	55.61 (18.50)	67.40 (17.86)	
SF-12v2				
Global health status	45.70 (9.92)	45.75 (12.08)	44.01 (11.34)	
Physical component	40.55 (12.13)	42.67 (11.64)	40.98 (12.61)	
Mental health component	50.73 (11.77)	50.18 (8.92)	52.41 (10.05)	

BMQ = Beliefs About Medicines Questionnaire; GSRS = Gastrointestinal Symptom Rating Scale; OS-MMAS = Osteoporosis-Specific Morisky Medication Adherence Scale; SEAMS = Self-Efficacy for Appropriate Medication Use Scale; SF-12v2 = 12-item Short-Form Health Survey; TSQM = Treatment Satisfaction Questionnaire for Medication.

^aOS-MMAS score: low adherence <6, medium adherence 6 to <8, high adherence 8.

tween OS-MMAS and BMQ concerns, GSRS, and SF-12v2.

FACTOR ANALYSIS

Confirmatory factor analysis indicated that the 8 items of OS-MMAS loaded on a single factor. The item loadings ranged from 0.36 to 0.72 (Table 7). The χ^2 test was not significant (p = 0.1653), the SRMSR value was 0.0455, the GFI was 0.9653, the CFI was 0.9845, and the NFI value was 0.9427.

Discussion

In the current study, the OS-MMAS was found to be reliable, and its construct validity was well supported among women newly prescribed bisphosphonate treatment.

Adherence in osteoporosis is known to be poor. Self-report has been used in several studies of chronic conditions, including hypertension, as a reliable and valid method to assess adherence to oral medications. Unlike other methods (eg, pill counts, electronic monitoring, pharmacy

databases), self-report is simple, economically feasible, and has the added advantage of soliciting information regarding situational factors that interfere with medication adherence (eg, forgetfulness, side effects).33 Chronic disease surveys such as the 4-item MMAS have been used previously to measure osteoporosis medication adherence. 34,35 To our knowledge, there is only one other disease-specific tool, the Adherence Evaluation of Osteoporosis treatment (ADEOS), that is designed to measure treatment adherence in women with postmenopausal osteoporosis treated with oral antiresorptive medication.³⁶ The 12-item ADEOS questionnaire was recently developed in a French population and validated in women treated chronically for osteoporosis. The ADEOS-12 questionnaire was found to be moderately correlated with the 4-item MMAS $(r^2 = 0.58)$. Unfortunately, the reliability of the ADEOS-12 questionnaire was not reported.

The results of the current study provide evidence of the strong psychometric properties of OS-MMAS among women initiating oral bisphosphonates. The MMAS-8 was originally developed as a self-report measure of antihypertensive medication adherence and has demonstrated good psychometric characteristics. ¹⁷ In our study, internal consistency reliability of the OS-MMAS was high (Cronbach $\alpha = 0.82$) and test-retest reliability was also well supported, with a weight-

ed κ statistic of 0.56 and an ICC of 0.77. Furthermore, confirmatory factor analysis demonstrated the measurement of a single underlying factor. It is important to note that test-retest reliability may be best understood as temporal stability or the degree to which scores remain constant between 2 administrations of the scale.³⁸ Although ideally evaluated in a subset of individuals in whom the outcome (eg, bisphosphonate adherence) is expected to have remained stable, this is not always feasible. The time window of at least 7-21 days chosen for test-retest sensitivity analyses was used to ensure that the retest was not too close to the original survey and also not too far apart from the original survey. A window that is too short may result in individuals being able to recall their original responses, while gaps that are too long may result in a true change in the level of the construct being measured, in this case, medication adherence. In an analysis using the subset of participants who completed the retest within the 7- to 21-day window, the ICC was 0.87. In this study, the OS-MMAS showed good internal consistency reliability and test-retest reliability as a self-reported measure of medication adherence.

Table 6. Correlation Between the OS-MMAS Scores and
Other Patient-Reported Outcomes

Correlation Coefficient	p Value ^a			
0.40	<0.0001			
0.32	0.0001			
-0.23	0.006			
0.41	< 0.0001			
0.38	< 0.0001			
0.41	< 0.0001			
0.28	0.001			
0.33	< 0.0001			
-0.15	0.075			
-0.14	0.096			
-0.03	0.736			
-0.09	0.280			
-0.04	0.669			
-0.06	0.459			
0.04	0.628			
0.004	0.962			
	0.40 0.32 -0.23 0.41 0.38 0.41 0.28 0.33 -0.15 -0.14 -0.03 -0.09 -0.04 -0.06 0.04			

BMQ = Beliefs About Medicines Questionnaire; GSRS = Gastrointestinal Symptom Rating Scale; OS-MMAS = Osteoporosis-Specific Morisky Medication Adherence Scale; SEAMS = Self-Efficacy for Appropriate Medication Use Scale; SF-12v2 = 12-item Short-Form Health Survey; TSQM = Treatment Satisfaction Questionnaire for Medication.

^ap < 0.0031 is considered statistically significant when adjusted for multiple comparisons.

Convergent validity was supported by significant correlations between OS-MMAS scores and the SEAMS, BMQ necessity, BMQ necessity-concerns differential, and TSQM scores. No significant correlations were found between OS-MMAS and BMQ concerns, GSRS, and SF-12v2. As hypothesized, the OS-MMAS was positively associated with the individuals' self-efficacy for appropriate use of the bisphosphonate, treatment satisfaction, and the necessity of the bisphosphonate for managing their osteoporosis, while concerns were not significantly associated with adherence. This may be expected, as a patient may demonstrate good adherence if the belief in the need for the medication is strong enough to outweigh any concerns regarding the medication, thus resulting in adherence not being impacted by a perception of medication-related concerns. This was supported by the relationship between the BMQ necessity-concerns differential, which was significantly associated with OS-MMAS scores. The necessity-concerns differential is a more informative variable, as it takes into account the perception of needs in addition to medication-related concerns. Although the correlations between the OS-MMAS and the GSRS and BMQ concerns were not statistically significant perhaps due to the small sample size, the directionality of correlations was consistent with expectations. Specifically, women who were less adherent reported more gastrointestinal symptoms and concerns about consequences of taking the medication. These results are consistent with findings that negative beliefs about medication are associated with self-reported nonadherence. 20,39,40 The GSRS is a measure of chronic gastrointestinal symptoms and has been developed for use in individuals with gastrointestinal reflux disease. The gastrointestinal problems reported by individuals on oral bisphosphonates may differ in that such individuals may experience more temporary issues related to adverse effects and specific instructions related to taking oral bisphosphonates. Oral bisphosphonates are known to have gastrointestinal adverse effects. However, the GSRS may not be an appropriate measure to assess the specific gastrointestinal problems experienced by individuals on oral bisphosphonates, which may be more specific and temporary in nature.

As with all studies, ours has several limitations. This study was limited to women newly prescribed daily or weekly oral bisphosphonate regimens for osteoporosis from a single health plan. As such, results should not be generalized to users of monthly or parenteral osteoporosis medications. While medication costs may influence adherence, those data were not available for this study. However, members have very similar health service benefits. Over 90% of members have a pharmacy benefit that covers all or a portion of medication costs. Lastly, the OS-MMAS successfully measured several domains of adherence but the tool does not address whether the subject is taking the

medication correctly with proper technique. This study has several strengths: most notably, a broad distribution in adherence levels required to perform prespecified statistical analyses and minimal missing data, which suggest that the tool is easy to use. The OS-MMAS performed well in a study population that was heterogeneous in terms of race/ethnicity and income. By restricting to an integrated health plan, the confounding effects on adherence of access to care are minimized. The OS-MMAS has been translated into several languages and validation is ongoing in France, which should contribute further to its value.

In conclusion, this study demonstrated the strong psychometric properties of the OS-MMAS among women newly prescribed bisphosphonates for treatment of osteoporosis. The importance of adherence to therapy in women with postmenopausal osteoporosis is essential in preventing adverse outcomes. Measuring adherence to osteoporosis medications is the first step in identifying and improving adherence. These findings suggest that the OS-MMAS is a reliable and valid measure of self-reported medication adherence.

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Table 7. Factor Loadings of the 8-Item OS-MMAS Scale			
Item	One-Factor Loadings ^a		
1. Do you sometimes forget to take your prescription osteoporosis medication (ie, other than calcium and vitamin D)?	0.56		
People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past 4 weeks, were there any times when you did not take your osteoporosis medication?	0.71		
3. Have you ever cut back or stopped taking your osteoporosis medication without telling your doctor, because you felt worse when you took it?	0.37		
4. When you travel or leave home, do you sometimes forget to bring along your osteoporosis medication?	0.72		
5. Did you take your osteoporosis medication the last time you were supposed to take it?	0.58		
6. If you feel that your osteoporosis medication is not working, do you sometimes stop taking your medication?	0.53		
7. Taking medication exactly as prescribed is a real inconvenience for some people. Do you ever feel hassled about sticking to your osteoporosis treatment plan?	0.36		
8. How often do you have difficulty remembering to take all your medications?	0.66		

OS-MMAS = Osteoporosis-Specific Morisky Medication Adherence Scale.

 $^{a}\chi^{2}$ >0.05, standardized root mean square residual <0.05, goodness-of-fit index >0.90, Bentler's Comparative Fit Index >0.90, and Bentler-Bonett Normalized Fit Index >0.90.

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EXTRACTO

Propiedades Sicométricas de la Escala Morisky de Adherencia a Medicamentos Específica para Osteoporosis (OS-MMAS) en Mujeres Posmenopáusicas con Osteoporosis Nunca Antes Tratado con Bisfosfonatos

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TRASFONDO: La pobre adherencia a medicamentos orales para osteoporosis es común. Las estrategias para mejorar adherencia empiezan con la identificación del problema. La escala Morisky de adherencia a medicamentos de 8-ítems para auto reportar adherencia a medicamentos antihipertensivos fue modificada para evaluar la adherencia a medicamentos orales para osteoporosis. Una evaluación de las propiedades de la escala Morisky de adherencia a medicamentos específica para osteoporosis (OS-MMAS) fue necesaria.

K Reynolds et al.

OBJETIVO: Examinamos las propiedades sicométricas de OS-MMAS en mujeres con osteoporosis posmenopáusica.

MÉTODOS: Un total de 500 mujeres de ≥55 años con osteoporosis con nuevas prescripciones de bisfosfonatos orales diarios o semanales entre 5/15/10-8/15/10 fueron seleccionadas aleatoriamente de Kaiser Permanente Southern California, un sistema de cuidado de salud integrado, y se les envió una encuesta por correo que incluía los 8 ítems del OS-MMAS, la escala de auto eficacia para el uso apropiado de medicamentos (SEAMS), el cuestionario de creencias sobre medicinas (BMQ), el cuestionario de satisfacción con el tratamiento de medicinas (TSQM), la escala para valorar síntomas gastrointestinales (GSRS), y la encuesta de salud forma corta de 12 ítems (SF-12v2). Las puntuaciones para OS-MMAS van de 0 a 8 con los valores altos indicando mejor adherencia a la medicación. La fiabilidad en la consistencia interna fue evaluada usando el coeficiente alfa Cronbach. La fiabilidad de prueba y reprueba fue evaluada usando coeficientes de correlación intraclase (ICCs) en un subgrupo de 102 participantes. La validez construida fue evaluada usando el análisis de factor confirmatorio (CFA) y las correlaciones entre OS-MMAS y medidas relacionadas.

RESULTADOS: De 197 participantes, 150 reportaron estar tomando el bisfosfonato al momento de completar la encuesta y el OS-MMAS. En general, 30.7%, 32.7% y 36.7% obtuvieron puntuaciones bajas, medias y altas en OS-MMAS scores (<6, 6 a <8 y 8, respectivamente). El α de Cronbach fue 0.82 y el ICC fue 0.77. Validez convergente fue apoyada por las correlaciones significantes de las puntuaciones SEAMS, BMQ y TSQM. En CFA, una escala de factor sencilla fue apoyada.

conclusiones: OS-MMAS demostró propiedades sicométricas fuertes con buena fiabilidad y validez construida y puede proveer un avalúo valioso para adherencia a medicación auto-reportada en mujeres con prescripciones nuevas para medicamentos orales para osteoporosis.

Traducido por Sonia I Lugo

RÉSUMÉ

Propriétés Psychométriques d'une Variation de l'Échelle Morisky Spécifique à la Fidélité au Traitement Contre l'Ostéoporose chez les Femmes Ménopausées Débutant un Traitement de Bisphosphonate

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INTRODUCTION: La fidélité au traitement contre l'ostéoporose est souvent problématique. Toute stratégie visant à améliorer la situation commence par une identification de la source du problème. L'échelle Morisky, un questionnaire comportant 8 items servant à évaluer la fidélité au traitement à la médication anti-hypertensive, a été modifiée pour évaluer la fidélité au traitement contre l'ostéoporose. Cependant, avant de pouvoir utiliser cette échelle modifiée, une évaluation de ses propriétés psychométriques est nécessaire.

OBJECTIF: Évaluer les propriétés psychométriques de l'échelle Morisky modifiée pour l'évaluation de la fidélité au traitement contre l'ostéoporose (Osteoporosis-Specific Morisky Medication Scale - OS-MMAS) chez les femmes ménopausées.

DEVIS EXPERIMENTAL: Cinq cent femmes âgées de 55 ans et plus, membres de l'organisme de gestion intégrée des soins de la santé Kaiser Permanente Southern California, atteintes d'ostéoporose et chez qui un traitement de bisphosphonate (une ou deux fois par jour) a été initié au cours de la période allant du 15 mai au 15 août 2010 ont été invitées par la poste à participer à l'étude. Les questionnaires suivants ont été postés : l'OS-MMAS, l'échelle d'auto-évaluation de l'utilisation adéquate de médicaments (Self-Efficacy for Appropriate Medication Use Scale -SEAMS), le questionnaire sur les croyances reliées aux médicaments (Beliefs about Medicines Questionnaire - BMQ), le questionnaire sur la satisfaction au traitement (Treatment Satisfaction Questionnaire for Medicines - TSQM), l'échelle d'évaluation des symptômes gastrointestinaux (Gastrointestinal Symptom Rating Scale - GSRS), et la version à 12 questions du Short Form Health Survey (SF-12v2). Le score de l'OS-MMAS peut varier entre 0 et 8 et des scores élevés indiquent une meilleure fidélité au traitement. Le coefficient alpha de Cronbach a été utilisé pour évaluer la cohérence interne alors que les coefficients de corrélation intraclasse (CCI) ont servi à estimer la fiabilité test-retest chez un sous-groupe de 102 participantes ayant complété les questionnaires une deuxième fois. La validité de construit, quant à elle, a été évaluée à l'aide de l'analyse factorielle confirmatoire (AFC) et les corrélations entre l'OS-MMAS et les autres questionnaires.

RÉSULTATS: Cent quatre vingt dix sept femmes ont accepté de participer à l'étude. Cependant 47 d'entre elles ont été exclues de l'analyse parce qu'elles ne prenaient plus de bisphosphonate au moment de l'étude ou qu'elles n'avaient pas complété au moins 75% des questions de l'OS-MMAS, laissant ainsi les données de 150 participantes dans l'analyse. Un score OS-MMAS faible (<6) a été observé chez 30.7% des participantes alors qu'un score modéré (6 à <8) ou élevé (8) a été rapporté par 32.7% et 36.7% des participantes respectivement. Le coefficient α de Cronbach était de 0.82 alors que le CCI était de 0.77. La validité concourante a été démontrée par une corrélation significative avec le SEAMS, le domaine « nécessité » du BMQ et le TSQM. L'AFC favorisa une échelle à facteur unique.

CONCLUSION: L'OS-MMAS démontra des très bonnes propriétés psychométriques. La validité et fiabilité sont bonnes et l'OS-MMAS pourrait représenter un outil utile pour évaluer la fidélité au traitement contre l'ostéoporose.

Traduit par Suzanne Laplante

Appendix I. Characteristics of Bisphosphonate Discontinuers

Characteristic	Current Users (N = 150)	Discontinuers (N = 42)	p Value ^a
Age (y), mean (SD)	70.6 (9.1)	71.9 (7.6)	0.387
Age (y), %			0.405
55-64	31.3	21.4	
65-74	38.7	40.5	
≥75	30.0	38.1	
Race/ethnicity, %			0.175
Asian	10.7	4.8	
Black	8.7	11.9	
Hispanic	14.0	23.8	
White	62.7	50.0	
Other	4.0	9.5	
Highest education level, %			0.115
<high school<="" td=""><td>6.7</td><td>2.4</td><td></td></high>	6.7	2.4	
High school graduate	24.7	21.4	
Some college	38.0	40.5	
College graduate	28.0	23.8	
Missing	2.7	11.9	
Income, %			0.625
≤\$25,000	20.7	28.6	
\$25,001-50,000	23.3	19.1	
\$50,001-100,000	27.3	21.4	
>\$100,000	10.7	7.1	
Missing	18.0	23.8	
Married, %	64.7	40.5	0.005
Current smoking, %	7.3	7.1	0.967
Alcohol consumption, %			0.387
None	66.7	61.9	
<1 drink/day	21.3	14.3	
1 to <2 drinks/day	6.7	14.3	
≥2 drinks/day	4.0	7.2	
Missing	1.3	2.4	
Fracture history, %			0.311
Personal	29.3	21.4	
Mother	12.0	16.7	
Father	3.3	0	
Depression, ^b %	7.3	4.8	0.058
Weekly bisphosphonate users, %	100.0	100.0	
Concomitant medications, ^c %			0.374
0	2.0	7.1	
1	5.3	4.8	
2	3.3	4.8	
≥3	89.3	83.3	
Charlson Comorbidity Index Score,d	%		0.038
0	46.7	23.8	
1	17.3	31.0	
2	12.7	11.9	
≥3	23.3	33.3	
Healthcare utilization/no. visitse			
Ambulatory	15.3 (15.0)	12.9 (12.1)	0.355
Hospitalization	0.2 (0.5)	0.3 (0.9)	0.422
Emergency department	0.6 (1.3)	0.5 (0.9)	0.615

^aParticipant characteristics were compared using analysis of variance for continuous variables and χ^2 tests for categorical variables. Fisher exact test was used for variables with expected counts <5.

^bBased on International Classification of Diseases, Ninth Revision, Clinical Modification, codes within 365 days prior to study selection.

^cIncludes all medications other than bisphosphonates within 365 days prior to study

^dBased on International Classification of Diseases, Ninth Revision, Clinical Modification, codes within 3 years prior to study selection.

eBased on visits within 365 days prior to study selection.