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The Day-to-Day Impact of Vaginal Aging Questionnaire: A Multidimensional Measure of the Impact of Vaginal Symptoms on Functioning and Well-being in Postmenopausal Women

Alison J. Huang, MD, MAS[1], **Steven E. Gregorich, PhD**[1], **Miriam Kuppermann, PhD, MPH**[2], **Sanae Nakagawa, MA**[2], **Stephen K. Van Den Eeden, PhD**[3], **Jeanette S. Brown, MD**[2], **Holly E. Richter, MD, PhD**[4], **Louise C. Walter, MD**[1], **David Thom, MD, PhD**[5], and **Anita L. Stewart, PhD**[6]

[1]Department of Medicine, University of California San Francisco

[2]Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco

[3]Kaiser Permanente Division of Research, Oakland, California

[4]Department of Obstetrics and Gynecology, University of Alabama at Birmingham

[5]Department of Family and Community Medicine, University of California San Francisco

[6]Institute of Health and Aging, University of California San Francisco

Abstract

Objective—To develop a self-report questionnaire assessing the impact of vaginal dryness, soreness, itching, irritation, and pain on functioning and well-being in postmenopausal women.

Methods—Structured self-report items were developed to address the impact of vaginal symptoms on functioning and wellbeing based on findings from focus groups with racially/ethnically diverse, symptomatic postmenopausal women. Items were refined after cognitive interview pre-testing and then field-tested among symptomatic postmenopausal women enrolled in a multiethnic cohort study in California. Exploratory (SAS PROC VARCLUS) and confirmatory factor analyses evaluated factor structure and eliminate poorly fitting items. Additional evidence of construct validity was obtained via examination of correlations with other measures of related constructs. Internal consistency and test-re-test reliability were assessed using Cronbach's alpha and correlation coefficients, respectively.

Results—Of the 745 postmenopausal women completing the draft questionnaire, mean (SD) age was 56.2 (8.5) years, and 66% were racial/ethnic minorities. The refined questionnaire included four multi-item scales addressing symptom impact on: 1) activities of daily living, 2) emotional well-being, 3) sexual functioning, and 4) self-concept and body image. The four factor model provided good approximate fit (comparative fit index = 0.987, standardized root-mean-square residual = 0.038). Correlations with other measures of symptom bothersomeness, sexual function,

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depression, and anxiety conformed to hypotheses. Cronbach's alpha ranged from 0.82 to 0.93. Intra-class coefficients ranged from 0.47 to 0.72.

Conclusions—The Day-to-Day Impact of Vaginal Aging (DIVA) questionnaire is a new multidimensional self-report measure designed to facilitate evaluation of the impact of vaginal symptoms in postmenopausal women of diverse backgrounds.

Keywords

vaginal dryness; vaginal itching; dyspareunia, vulvovaginal atrophy; female sexual dysfunction

Introduction

Vaginal symptoms are a common complaint of women during and after menopause, with up to a third of postmenopausal women reporting problems with vaginal dryness, soreness, itching, irritation, or pain that can affect their day-to-day activities, feelings, and relationships.[1,2] Unlike other menopausal symptoms such as hot flashes that tend to cluster in the immediate perimenopausal period, vaginal symptoms such as dryness frequently persist for decades after women cease to menstruate, causing ongoing discomfort and distress to women in older age.[3,4]

To date, clinical studies of conditions such as vaginal atrophy that give rise to vaginal symptoms in postmenopausal women have either relied on physical or laboratory measures to assess severity and evaluate treatment effects, or have emphasized single-item ratings of change in women's "most bothersome symptom" that do not adequately reflect the scope of impact of these symptoms on women's day-to-day lives.[1,5,6] At the 2006 New Interventions for Menopausal Symptoms conference, an expert panel expressed concern about the lack of validated measures to assess vaginal symptomatology across diverse populations of menopausal women and called for better methods for measuring improvement in quality of life with treatments for these symptoms.[7]

To address this need, we developed the Day-to-Day Impact of Vaginal Aging (DIVA) questionnaire, a structured self-administered questionnaire assessing the impact of vaginal symptoms such as dryness, irritation, itching, soreness and pain on multiple dimensions of functioning and well-being and evaluated its preliminary psychometric properties in a multiethnic population of postmenopausal women. Our goal was to develop a sensitive and reliable instrument for administration in observational and therapeutic studies that has good face validity among clinicians and researchers and is relevant to symptomatic postmenopausal women across a range of ages and racial/ethnic backgrounds.

Methods

Summary of measurement development process

Our methods to develop and examine the psychometric properties of DIVA included: 1) review of the literature and qualitative research to develop and refine our conceptual model; 2) development of a pool of structured self-report items and refinement based on one-on-one cognitive pre-testing interviews and assessment of face validity; 3) field-testing of draft

items in a community-based cohort to examine response variability and generalizability; 4) exploratory analyses to empirically identify the factor structure of the instrument, followed by confirmatory factor analysis to assess the fit of the empirically derived factor structure; 5) further exploration of construct validity by examination of hypothesized associations with measures of related constructs; and 6) evaluation of internal consistency and test-retest reliability of our refined scales.

Development of a conceptual model through qualitative research

To develop a preliminary conceptual model of the impact of postmenopausal vaginal symptoms on women's functioning and well-being, we conducted focus groups with postmenopausal women aged 40 years and older who reported moderate-to-severe vaginal symptoms such as dryness, soreness, irritation, itching, or pain with sexual intercourse (dyspareunia). As described elsewhere, forty-four symptomatic women aged 48 to 75 years from three racial/ethnic groups (Black, Latina, and White) were recruited from the general San Francisco Bay area to participate in focus groups to discuss the impact of their vaginal symptoms on their activities, feelings, and relationships.[8] Focus groups consisted of 6 to 10 women and were led by trained moderators who were matched by race/ethnicity, language, and general age with participants. Findings were used to assess the relevance of potential functional and quality-of-life domains suggested by the existing literature on postmenopausal vaginal symptoms, identify additional domains affected by these symptoms, and assess variation in themes across age and racial/ethnic groups. Transcripts were independently analyzed by members of a multidisciplinary team using grounded theory, and the constant comparative method was used to resolve differences between team members. As a result of this formative work, five preliminary dimensions of functioning and well-being with the potential to be affected by postmenopausal vaginal symptoms were identified: 1) activities of daily living, 2) sexual function, 3) emotional well-being, 4) self-concept and body image, and 5) interpersonal relations.[8]

Development of an item pool, assessment of face validity, and cognitive pre-testing

Based upon the above concepts, we developed a preliminary pool of 100 structured self-report items to assess the impact of symptoms on the hypothesized domains. Items used 5-point ordered response options to assess the degree to which vaginal symptoms interfered with specific aspects of women's day-to-day activities, sexual function, emotional well-being, self-concept and body image, or interpersonal relationships (e.g., 0 = not at all, 1 = a little bit, 2 = moderately, 3 = quite a bit, 4 = extremely). All of the items addressing impact on day-to-day activities, emotional well-being, self-concept and body image, and interpersonal relationships were designed to be applicable to all symptomatic women; however, a subset of items addressing the impact on sexual function were appropriate only for sexually active women (i.e., women with a history of vaginal sexual intercourse, other partnered sexual activity, or un-partnered sexual activity such as self-stimulation or masturbation in the past four weeks); these items included at "not applicable" response option for women reporting no recent sexual activity.

To assess face validity among clinicians, a sample of 10 clinicians experienced in evaluating and treating women's health conditions (including gynecologists and general internists)

were asked to review and rank preliminary items in terms of their perceived relevance to postmenopausal women's lives. Items that received consistently poor rankings were eliminated on the basis of poor face validity.

We then conducted one-on-one cognitive interview pre-testing with 12 racially/ethnically diverse, symptomatic postmenopausal women to probe for appropriateness and ambiguity of the remaining items. Participants were asked to comment on the clarity and appropriateness of the questionnaire instructions, item stems, and response options. Scripted and unscripted probes were used to explore the meaning of specific words or phrases, assess whether similar items were perceived as redundant, identify cognitive processes involved in answering questions, and determine if any items were viewed as offensive. After every three interviews, problematic items were revised or eliminated, and remaining items were re-formatted for distribution to additional women. This resulting draft questionnaire consisted of 35 items; six of these items were applicable only to women with a history of sexual activity (either vaginal sexual intercourse or other types sexual activity) in the prior four weeks.

Field-testing in a community-based cohort

The draft questionnaire was then administered within a multiethnic, observational cohort study of community-dwelling middle-aged and older women in northern California, the Reproductive Risks of Incontinence Study at Kaiser (RRISK). Details about the construction of the RRISK cohort have been reported elsewhere.[9] Briefly, participants were women aged 40 years and older who were long-time enrollees in the Kaiser Permanente Northern California integrated health care delivery system, and were randomly sampled from within age and race/ethnicity strata to achieve an overall composition of approximately 20% Asian, 20% Black, 20% Latina, and 40% White women. Although the goal of the parent RRISK study was to identify risk factors for urinary tract dysfunction, no urinary tract symptoms were required for participation, and prior studies have indicated that RRISK participants are generally similar in clinical characteristics to female Kaiser Permanente Northern California enrollees at large.[9]

During the third wave of RRISK study visits conducted between November, 2008 and April, 2012, women who reported at least 6 months of spontaneous amenorrhea or having undergone bilateral oophorectomy were asked if they had experienced any symptoms of vaginal dryness, soreness, itching, irritation, or pain with sexual intercourse in the past month. Those reporting at least one vaginal symptom were asked to complete the draft DIVA questionnaire and to provide further information about the bothersomeness of their symptoms. A subset of women drawn from all four racial/ethnic groups in RRISK repeated self-administration of the questionnaire at home approximately one to two weeks after their study visits and return it to study staff by mail. All participants provided informed consent before completing the draft questionnaire, and all data collection procedures were approved by the institutional review boards of the University of California San Francisco and the Kaiser Foundation Research Institute.

Item review and consolidation

Following field-testing, item response distributions were examined in the overall respondent sample as well as stratified by sexual activity status. Draft items that demonstrated poor response variability (e.g., for which ~85% to 90% of respondents reported minimal impact on the activity, feeling, or concept addressed by the question) or raised other concerns about generalizability or relevance to postmenopausal women in the general population were re-examined by the research team. Eight draft items were eliminated on the basis of poor response variability and/or concerns about conceptual relevance or generalizability, including items originally hypothesized to assess impact on activities of daily living (two items), emotional wellbeing (one item), self-concept and body image (one item), and interpersonal relations (four items). The preliminary interpersonal relations domain was subsequently eliminated due to insufficient number of items.

Additionally, responses to two draft items addressing 'desire or interest' in 1) vaginal sexual intercourse and 2) other types of sexual activity, respectively, were replaced by a single combined response variable. The score for this combined item variable was assigned based on the type of sexual activity that was *most* affected by each woman's symptoms. Similarly, responses to two items examining frequency of 2) vaginal sexual intercourse and 2) other sexual activity, respectively, were replaced by a second combined response variable. The above items consolidations reduced the total number of questionnaire items to 25, of which four items were relevant only to women with a history of sexual activity in the prior four weeks (either vaginal sexual intercourse or other sexual activity).

Factor analysis models

Using the consolidated set of items, we fit oblique principal components cluster analysis models (SAS PROC VARCLUS; SAS 9.3; SAS Institute Inc, Cary, NC.) to provisionally identify a first-order factor questionnaire structure.[10] Solutions with 1 to 20 clusters were generated and evaluated to guide selection of the solution that best balanced parsimony and conceptual unidimensionality of item clusters. We then fit confirmatory factor analysis (CFA) models via LISREL (version 9.10)[11] to evaluate the fit of the measurement models suggested by the chosen PROC VARCLUS cluster solutions. Goodness of CFA model fit was assessed by examining the maximum likelihood (ML) and Satorra-Bentler Scaled chi-squares (SB),[12] the comparative fit index (CFI),[13] and the standardized root-mean-square residual (SRMR). Consistent with past research, CFI values above 0.95 and SRMR values below 0.05 were considered to reflect approximate model fit.[14,15]

Because some DIVA items were applicable only to women with a history of recent sexual activity, all factor analysis models were fit twice: one set of models was fit to the full respondent sample but used only the subset of 21 items that were relevant to all women regardless of sexual activity status; another set was fit to the subset of women who reported being sexually active in the prior four weeks, but used all 25 items. Although fewer than 1% of all DIVA item responses were missing, we accommodated missing values via various methods: (i) for PROC VARCLUS, we used the expectation-maximization (EM) item covariance matrix; (ii) for the CFA model parameter and standard error estimates, and ML

chi-square, we used full information maximum likelihood (FIML); and (iii) to estimate the CFI and SRMR indices, we used multiple imputation.

Evaluation of multi-item scale distributions and item-scale correlations

Following confirmatory factor analyses, we created domain scale scores representing each first-order factor as the mean of corresponding item responses for each participant. We then examined the distribution of multi-item scale scores and calculated item-scale and inter-scale correlations for these domain scales using Pearson coefficients. For the sexual function scale, two separate scale versions were examined-- a short version appropriate for all women regardless of sexual activity status, and a longer version appropriate only for sexually active women.

Additional assessment of construct validity

To further evaluate the construct validity of the refined DIVA scales, we examined correlations between these scales and three other self-report measures administered in the parent cohort. For these analyses, Pearson correlation coefficients of <0.20, 0.20–0.29, 0.30–0.39, and ≥0.40 were considered to indicate minimal, weak, moderate, and strong correlations between the DIVA domain scales and these validity measures. Because some validity measures were applicable to sexually active women only, all construct validity analyses were confined to sexually active respondents. Appendix B summarizes each of the validity measures and our hypotheses regarding associations with various DIVA domain scales:

A. A) Vaginal symptom bothersomeness scale: Participants completed a 5-item vaginal symptom bothersomeness measure, in which they rated the overall subjective bother associated with symptoms of vaginal dryness, soreness, itching, irritation, and pain with sexual intercourse using a 5-level ordered response scale (“not at all,” “a little bit,” “moderately,” “quite a bit,” and “extremely”). Total scale scores, calculated by averaging the scores of individual items, range from 0 to 5, with higher scores indicating greater bother associated with symptoms. We hypothesized that women reporting greater impact of vaginal symptoms on their activities of daily living, emotional well-being, sexual function, and self-concept and body image on the respective DIVA scales would also report greater overall bother associated with their vaginal symptoms (Appendix B).

B. B) Female sexual problems measure: The second validity measure was a 4-item female sexual problems measure derived from the Female Sexual Function Index[16] and administered in other women’s health outcome studies.[17,18] Designed for women with a history of recent sexual activity, this measure assesses difficulty with sexual arousal, lubrication, orgasm, and pain in the past three months. Total scores, calculated by averaging the scores of the individual items, range from 0 to 4, with higher scores indicating more sexual activity-specific problems. We hypothesized that women reporting greater impact of their vaginal symptoms on sexual functioning as measured by the DIVA sexual function scale would also report worse overall sexual function as measured by this generic sexual problems measure. We also anticipated that scores on the DIVA self-concept and body image

scale would be weakly correlated with scores on this generic sexual problems measure.

C. C) Hospital Anxiety and Depression Scale (HADS): The HADS is an established 14-item instrument which assesses respondents' feelings of anxiety and depression in the past four weeks.[19] It consists of a 7-item subscale assessing depression and a 7-item subscale assessing cognitive anxiety; subscale scores are scaled from 0 to 21, with higher scores indicating greater depression or anxiety.[19] We hypothesized that women reporting greater impact of vaginal symptoms on their emotional well-being as measured by DIVA would also report greater depression and anxiety on both of these HADS subscales (Appendix B). Given that poor self and body image can contribute to feelings of depression and anxiety,[20] we also hypothesized that scores on the DIVA self-concept and body image scale would be weakly correlated with HADS anxiety and depression subscale scores.

Examination of reliability

Internal consistency reliability of the refined DIVA domain scales was assessed using standardized Cronbach's alphas, with thresholds of ≤0.60, 0.61–0.70, 0.71–0.80, and >0.80 indicating poor, moderate, good, and excellent reliability, respectively. Test-retest reliability was assessed by intraclass correlation coefficients (ICCs) using data from a subset of 175 women drawn from all racial/ethnic groups who repeated administration of a mail-in version of the DIVA questionnaire 1 to 2 weeks after their initial visit; ICCs of ≤0.40, 0.41–0.60, 0.61–0.80, and ≥0.80 were interpreted as indicating poor, moderate, good, and excellent correlation, respectively.

Results

Study population

Of the 757 symptomatic postmenopausal women in the parent RRISK3 cohort, 745 (98.4%) field-tested the draft DIVA questionnaire. The mean (±SD) age of respondents was 56.2 (±8.5), with a range of 41 to 81 years (Table 1). Over two thirds were racial/ethnic minorities, including 20.5% Asian, 20.8% Black, and 25.1% Latina women. Over three quarters were married or reported being in a significant relationship. Over 40% of participants described their overall health as being "excellent" or "very good," as opposed to "good," "fair," or "poor" (Table 1). Scores on the physical and mental subscales of the SF-12 Medical Outcomes Study short-form questionnaire[21,22] were generally high, indicating good overall physical and mental health-related functioning (mean [±SD] score of 45.3 [±6.8] and 44.4 [±5.9], respectively, out of a total possible range of 0 to 50). Less than 30% of respondents overall were normal or underweight, with the majority being overweight or obese. The most commonly reported vaginal symptom among all respondents was dryness (76.4%), followed by itching (42.6%), pain with sexual intercourse (29.5%), irritation (28.7%), and soreness (14.2%) (Table 2).

Factor analysis results

Based on the PROC VARCLUS analyses, we ultimately selected four-factor solutions that corresponded to four of the original hypothesized domains, for both the full respondent sample as well as the sexually active subsample: 1) activities of daily living, 2) sexual function, 3) emotional well-being, and 4) self-concept/body image. During preliminary confirmatory factor analyses, we found that overall model fit was adequate for both the shorter version of the instrument completed by all women regardless of sexual activity status and for the longer version completed by sexually active women only: CFIs equaled 0.978 and 0.975, and SRMRs equaled 0.038 and 0.045, respectively. However, two items hypothesized to represent the emotional well-being domain each had low-valued cross-loadings on two factors; these items subsequently were dropped and the models refit. For the refined models including 19 items for the full sample and 23 items for sub-sample of sexually active women (Table 3), model fit indices again suggested approximate fit: $\chi^2(146)=470.15$, $p<.0001$, and $\chi^2(224)=716.81$, $p<.0001$; CFIs equal to 0.987 and 0.979; SRMRs equal to 0.038 and 0.048, respectively.

Scale distributions, correlations, and reliability

The final DIVA questionnaire consisted of four multi-item domain scales addressing the impact of women's vaginal symptoms on activities of daily living (5 items), emotional well-being (4 items), sexual functioning (5 items for short version, 9 items for the longer version), and self-concept and body image (5 items) (Appendix A). Mean scores on each of the domain scales, which were calculated by taking the average of scores from the individual contributing items and were scaled so that higher scores indicated greater symptom impact, tended to be low, ranging from 0.29 to 0.85 on the possible 0 to 4 scale (Table 4)—suggesting relatively low overall impact in this population-based sample of women. Item-scale correlations corrected for overlap were well above the 0.30 minimum threshold for all scales. Pearson inter-scale correlation coefficients ranged from 0.14 to 0.58. Internal consistency Cronbach alphas ranged from 0.82 to 0.93. Test-retest correlations ranged from 0.47 to 0.72.

Additional examination of construct validity

Consistent with our hypotheses, we detected moderate-to-strong correlations between participants' scores on each of the DIVA domain scales and their ratings of the overall bothersomeness of their vaginal symptoms (Table 5). Also as hypothesized, scores on the DIVA sexual functioniong scale were strongly correlated with scores on a more generic female sexual problems measure. We also observed moderate correlations between scores on the DIVA self-concept and body image scale and scores on this generic sexual problems measure. As hypothesized, there were also moderate correlations between the DIVA emotional well-being scale scores and the HADS depression scale and anxiety scale scores; we also observed weak-to-minimal correlations between DIVA self-concept/body image scale and the HADS depression and anxiety subscales (Table 5).

Discussion

The DIVA questionnaire was developed to assess the impact of vaginal symptoms such as dryness, soreness, itching, irritation, and pain on functioning and wellbeing in postmenopausal women of diverse backgrounds. In addition to advancing overall scientific understanding of the impact of these vaginal symptoms, our goal was to promote more effective evaluation of new treatments for postmenopausal vaginal symptoms, by providing an instrument that could potentially be used to assess treatment-related changes on women's lived experience of these symptoms.

Our measure development process, which included qualitative research in racially and ethnically diverse women, one-on-one cognitive interview pretesting of preliminary items, assessment of face validity, and exploratory and confirmatory factor analyses, resulted in creation of four multi-item scales addressing major domains of functioning and well-being. These scales were found to have excellent internal consistency reliability among the symptomatic postmenopausal women who completed the DIVA questionnaire. Correlation between scores from the baseline and repeat administrations of DIVA was good for the emotional well-being and self-concept/body image scales and moderate for the activities of daily living and sexual function scales.

While our analyses provide preliminary evidence of construct validity, the factor analyses models reported here were exploratory in nature, and confirmatory testing of this four-factor model in other respondent samples are needed. Also, further assessment of correlations between the DIVA domain scales and other measures assessing similar constructs would be helpful to confirm that the DIVA scales appropriately address the concepts they were designed to measure.

Although research on the impact of postmenopausal vaginal symptoms is scarce, a few other questionnaires addressing related or overlapping symptoms or conditions have previously been developed. The Urogenital Atrophy Quality of Life Questionnaire, a 20-item measure developed and tested in a sample of 96 postmenopausal women in the United Kingdom and Sweden,[23] includes items addressing vaginal soreness and itching; however, this measure also addresses urinary tract symptoms such as incontinence and urgency that are not necessarily associated with menopause.[24,25] The Vulvovaginal Symptoms Questionnaire, a 21-item measure adapted from an existing measure of the impact of skin disease symptoms, was developed in a sample of primarily white 120 postmenopausal women presenting to a gynecology practice.[26] Because most items in that questionnaire assess the presence or impact of vulvar symptoms (i.e., vulvar itching, burning, hurting, irritation, and dryness), that instrument may be more appropriate for women who have primarily vulvar rather than vaginal symptoms.

Although women who completed the DIVA questionnaire as part of the parent cohort study provided information about a wide variety of other demographic and clinical variables, they did not undergo pelvic examination or laboratory testing to evaluate the etiology of their symptoms. In addition to vaginal atrophy, other potential causes of vaginal symptoms in postmenopausal women include vaginal infections, contact allergy or irritation, and

malignant or pre-malignant lesions. Future research should assess for differences in the psychometric properties of DIVA among postmenopausal women with physical or laboratory signs of vaginal atrophy as opposed to other clinicopathologic processes. Additionally, the cross-sectional design of the parent RRISK study did not allow us to assess whether women experienced vaginal symptoms earlier in life, such as prior to the cessation of menses. The severity, quality, and impact of women's vaginal symptoms may differ depending on the amount of time since symptom onset or the context in which they first developed. Vaginal symptoms developing before the cessation of women' menses are less likely to be caused directly or exclusively by hormonal changes associated with menopause.

Several other limitations of this research should be noted. Although our analyses were conducted in a racially and ethnically diverse sample of women, all participants were from northern California and were long-time enrollees in Kaiser Permanente. Future research should evaluate the generalizability of these findings by assessing the properties of this instrument in women of more diverse backgrounds. Additionally, overall symptom burden in our study sample was low, given that RRISK3 was a community-based cohort study that was not specifically designed to assess vaginal symptoms. The psychometric properties of DIVA may differ in clinical or referral populations, such as women presenting specifically for treatment for vaginal symptoms. Furthermore, as already noted, our empirical DIVA measurement model was based upon exploratory analyses. Findings should therefore be considered provisional and require confirmation in subsequent samples.

Conclusions

In summary, the DIVA questionnaire is a new, structured, self-administered measure of the impact of postmenopausal vaginal symptoms on women's activities of daily living, emotional well-being, sexual function, and self-concept and body image. When used in conjunction with a screening measure of the presence and bothersomeness of vaginal symptoms, this questionnaire may be helpful in facilitating evaluation of the impact of vaginal symptoms in postmenopausal women across a range of ages and backgrounds.

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Appendix A: The Day-to-Day Impact of Vaginal Aging Questionnaire

We are interested in understanding the impact of vaginal symptoms such as vaginal dryness, soreness, irritation, and itching on your day-to-day life. For each question below, please check the answer that best describes how your activities, relationships, and feelings have been affected by any of these symptoms during the past four weeks.

PART A. During the past four weeks, how much have vaginal symptoms such as dryness, soreness, irritation, or itching made it uncomfortable or interfered with your ability to:

1. Walk at your usual speed?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

2. Wear the clothing or underwear you want?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

3. Use the toilet or wipe yourself after using the toilet?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

4. Sit for more than an hour?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

5. Get a good night’s sleep?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

PART B. During the past four weeks, how often have vaginal symptoms such as dryness, soreness, irritation, or itching caused you to feel:

6. Depressed or down?

☐0	☐1	☐2	☐3	☐4
Never	Rarely	Sometimes	Fairly often	Very often

7. Embarrassed?

☐0	☐1	☐2	☐3	☐4
Never	Rarely	Sometimes	Fairly often	Very often

8. Frustrated or resentful?

☐0	☐1	☐2	☐3	☐4
Never	Rarely	Sometimes	Fairly often	Very often

9. Bad about yourself?

☐0	☐1	☐2	☐3	☐4
Never	Rarely	Sometimes	Fairly often	Very often

PART C. The following questions ask about the impact of your symptoms on vaginal sexual intercourse as well as other types of sexual activity such as self-stimulation or masturbation. During the past four weeks, have vaginal symptoms such as dryness, soreness, irritation, or itching affected:

10. Your desire or interest in having sexual intercourse or other types of sexual activity (including self-stimulation or masturbation)?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

11. How frequently you had sexual intercourse or other types of sexual activity (including self-stimulation or masturbation)?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

12. Your ability to become aroused during sexual activity (including self-stimulation or masturbation)?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

☐

Not applicable – I have not had sexual activity of any kind recently

13. Your ability to be spontaneous about sexual activity (including self-stimulation and masturbation)?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

☐

Not applicable – I have not had sexual activity of any kind recently

15. The amount of pleasure you experienced during sexual activity (including self-stimulation or masturbation)?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

☐

Not applicable – I have not had sexual activity of any kind recently

16. Your desire or interest in being in a sexual relationship?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

17. Your confidence that you could sexually satisfy a partner?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

18. Your overall satisfaction with your sex life?

☐0	☐1	☐2	☐3	☐4
Not at all	A little bit	Moderately	Quite a bit	Extremely

PART D. The following statements describe ways in which your vaginal symptoms may have affected your feelings about yourself and your body. Please indicate how true each of the following statements has been for you during the past four weeks.

19. My vaginal symptoms make me feel like I'm getting old.

☐0	☐1	☐2	☐3	☐4

Not at all true	A little true	Somewhat true	Mostly true	Definitely true

20. I feel undesirable because of my vaginal symptoms.

☐0	☐1	☐2	☐3	☐4
Not at all true	A little true	Somewhat true	Mostly true	Definitely true

21. When I think about my vaginal symptoms, I feel like I have lost something.

☐0	☐1	☐2	☐3	☐4
Not at all true	A little true	Somewhat true	Mostly true	Definitely true

22. My vaginal symptoms make me feel like my body is deteriorating.

☐0	☐1	☐2	☐3	☐4
Not at all true	A little true	Somewhat true	Mostly true	Definitely true

22. I feel less sexy because of my vaginal symptoms.

☐0	☐1	☐2	☐3	☐4
Not at all true	A little true	Somewhat true	Mostly true	Definitely true

Thank you!

Recommended scoring

Total scores for each domain scale are computed by calculating the average of scores for the corresponding individual items. The possible score range for all domain scales is 0 to 4, with higher scores denoting greater impact of vaginal symptoms.

Two versions of the sexual functioning scale are available: 1) a short, 5-item version that can be administered to all postmenopausal women, regardless of sexual activity status; and 2) a longer, 9-item version that includes 4 additional items (12, 13, 14, and 15) that are only appropriate for women with a history of recent sexual activity.

Activities of daily living domain: items 1, 2, 3, 4, 5

Emotional well-being domain: items 6, 7, 8, 9

Sexual functioning domain (short version): items 10, 11, 12, 16, 17, 18

Sexual functioning domain (longer version): items 10, 11, 12, 13, 14, 15, 16, 17, 18,

Self-concept and body image domain: items 19, 20, 21, 22, 23

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- Please refer to the questionnaire using its complete name – the Day-to-Day Impact of Vaginal Aging questionnaire - and provide the appropriate citation.
- Modifications may be made without written permission. However, please clearly identify any modifications in any publications as having been made by the users. Please let the corresponding author know of any changes for our records.

- If you translate the questionnaire into another language, please send the corresponding author a copy for our records.
- If other investigators are interested in obtaining the survey, please refer them to the source document to assure they obtain the most recent version and scoring instructions.

Appendix B: Hypothesized correlations between Day-to-Day Impact of Vaginal Aging domain scales and other measures of convergent-divergent constructs

Additional measures	Day-to-Day Impact of Vaginal Aging domain scales			
	Activities of daily living	Emotional wellbeing	Sexual functioning	Self-concept and body image
Vaginal symptom bothersomeness scale[a]	++	++	++	++
Female sexual problems measure[b]	.	.	++	+
Hospital Anxiety and Depression Scale[c]				
Depression subscale	.	++	.	+
Anxiety subscale	.	++	.	+

++ = moderate-to-strong correlation, + = weak correlation,. = no specific hypothesis

[a]. This 5-item measure assesses the presence and bothersomeness of vaginal dryness, itching, irritation, soreness, and pain during sexual intercourse in the past month; higher scores indicate greater overall bother associated with symptoms.

[b]. This 4-item measure assesses difficulty with sexual arousal, lubrication, orgasm, and pain with sexual activity in the past three months; higher scores indicate more severe sexual activity-specific problems.

[c]. This measure consists of a 7-item subscale assessing depression and a 7-item subscale assessing cognitive anxiety in the past four weeks; higher scores indicate greater depression or anxiety, respectively.

Table 1

Demographic and clinical characteristics of symptomatic postmenopausal women completing the Day-to-Day Impact of Vaginal Aging questionnaire

	Total women (N=745)	Sexually active women (N=462)
Age in years		
Mean (±SD)	56.2 (±8.5)	54.7 (7.9)
Range	41 to 81	41 to 79
Race/ethnicity		
White	250 (33.6%)	167 (36.1%)
Black	155 (20.8%)	80 (17.3%)
Latina	187 (25.1%)	115 (24.9%)
Asian	153 (20.5%)	100 (21.6%)
Relationship status		
Currently married	483 (64.8%)	357 (77.3%)
Other significant relationship	64 (8.6%)	34 (7.4%)
Gynecologic surgical history		
Hysterectomy (total or subtotal)	77 (10.3%)	49 (10.6%)
Bilateral oophorectomy	42 (5.6%)	24 (5.2%)
General self-reported health		
Excellent	78 (10.5%)	57 (12.3%)
Very good	248 (33.3%)	170 (36.8%)
Good	271 (36.4%)	166 (35.9%)
Fair	124 (16.6%)	60 (13.0%)
Poor	24 (3.2%)	9 (1.9%)
Health-related habits		
Current cigarette smoker	38 (5.1%)	21 (4.5%)
5 or more alcoholic drinks/week	72 (9.7%)	51 (11.1%)
Physical and mental functional status		
SF-12 Medical Outcomes Study physical subscale score[a]	45.3 (±6.8)	45.9 (±6.5)
SF-12 Medical Outcomes Study mental subscale score[a]	44.4 (±5.9)	44.5 (±5.5
Medications used in the past year[b]		
Estrogen therapy (systemic or topical)	183 (25.0%)	122 (27.0%)
Estrogen inhibitors or receptor modulators	26 (3.6%)	14 (3.1%)
Body mass index (kg/m^2)		
Mean (±SD)	29.9 (±7.3)	29.4 (±7.0)
Less than 25 (normal or underweight)	206 (27.8%)	140 (30.5%)
25 to 29 (overweight)	225 (30.3%)	142 (30.9%)
30 or higher (obese)	311 (41.9%)	177 (38.6%)
Vaginal symptoms reported		

	Total women (N=745)	Sexually active women (N=462)
Vaginal dryness	567 (76.4%)	375 (81.5%)
Vaginal itching	317 (42.6%)	165 (35.7%)
Pain with vaginal sexual intercourse[c]	220 (29.5%)	184 (39.8%)
Vaginal irritation	214 (28.7%)	127 (27.5%)
Vaginal soreness	106 (14.2%)	66 (14.3%)
Construct validity measures -- mean (±SD) score		
Vaginal symptom bothersomeness scale[d]	1.1 (±0.8)	1.1 (±0.8)
Female sexual problems measure[e]	1.4 (±0.9)	1.4 (±0.9)
Hospital Anxiety and Depression Scale[f]		
Depression subscale	3.4 (±3.1)	2.9 (±2.8)
Anxiety subscale	(±3.5)	4.9 (±3.3)

[a]. Scores on the physical and mental function subscales of the SF-12 Medical Outcomes Study short-form questionnaire are scaled from 0 to 50, with higher scores indicated better overall physical and mental health-related functioning.[21,22]

[b]. Medications were assessed by abstraction of records from pharmacy databases for women reporting filling at least 80% of medications at a Kaiser Permanente pharmacy, and by self-report questionnaires for all other women

[c]. For this question, respondents could indicate that the question was not applicable to them because they had not had sexual intercourse recently; however, the prevalence of this symptom was calculated as a percentage of all respondents regardless of history of sexual intercourse.

[d]. This 5-item measure assesses the subjective bother associated with symptoms of vaginal dryness, itching, irritation, soreness, and pain during sexual intercourse in the past month, and was administered total scores range from 0 to 5, with higher scores indicating greater symptom bother. If a respondent indicated that she was not eligible to answer the question about pain during sexual intercourse (due to lack of recent sexual intercourse), then total measures score was calculated based on the remaining questions.

[e]. This 4-item measure assesses difficulty with sexual arousal, lubrication, orgasm, and pain during sexual activity, and was administered only to women reporting sexual activity in the past three months. Total scores range from 0 to 4, with higher scores indicating more sexual activity-specific problems.

[f]. This 14-item measure consists of a 7-item subscale assessing depression and a 7-item subscale assessing cognitive anxiety in the past week; subscale scores are scaled from 0 to 21, with higher scores indicating greater depression or anxiety, respectively.

Table 2

Self-reported bother associated with vaginal symptoms in postmenopausal women completing the Day-to-Day Impact of Vaginal Aging questionnaire

Reported symptom	Self-reported bother associated with symptoms[a]		
	Not at all	A little bit or moderately	Quite a bit or extremely
Vaginal dryness (N=567)	82 (14.5%)	361 (63.7%)	124 (21.9%)
Vaginal itching (N=317)	11 (3.5%)	255 (80.4%)	51 (16.1%)
Pain with sexual intercourse[a] (N=220)	6 (2.7%)	157 (71.4%)	57 (25.9%)
Vaginal irritation (N=214)	13 (6.1%)	156 (72.9%)	45 (21.0%)
Vaginal soreness (N=106)	6 (5.6%)	86 (81.1%)	15 (14.2%)

All percentages presented in this table are row percentages.

[a]. Participants were asked, “How much has this symptom bothered you in the past month?” Response options were “not at all,” “a little bit,” “moderately,” “quite a bit,” and “extremely.” Percentages are row percentages, with the denominator being the total number of women reporting each type of vaginal symptom.

[b]. For this item assessing pain with vaginal sexual intercourse, respondents could indicate that the question was not applicable to them because they had not had intercourse recently.

Table 3

Final factors, associated items, and factor loadings

Factor **Item**	**All women**	**Sexually active women**
Activities of daily living "During the past four weeks, how much have vaginal symptoms such as dryness, soreness, irritation, or itching made it uncomfortable or interfered with your ability to…"		
…walk at your usual speed?	0.71	0.69
…wear the clothing or underwear you want?	0.68	0.64
…use the toilet or wipe yourself after using the toilet?	0.63	0.58
…sit for more than an hour?	0.76	0.75
…get a good nights' sleep?	0.59	0.61
Emotional well-being "During the past four weeks, how often have vaginal symptoms such as dryness, soreness, irritation, or itching caused you to feel…"		
…depressed or down?	0.81	0.79
…embarrassed?	0.76	0.78
…frustrated or resentful?	0.76	0.73
…bad about yourself?	0.75	0.75
Sexual functioning "The following questions ask about the impact of your vaginal symptoms on vaginal sexual intercourse as well as other types of sexual activity such as self-stimulation or masturbation. During the past four weeks, have vaginal symptoms such as dryness, soreness, irritation, or itching affected…"		
…your desire or interest in having vaginal sexual intercourse or other types of sexual activity(including self-stimulation or masturbation)?	0.73	0.77
…how frequently you had sexual intercourse or other types of sexual activity (including self-stimulation or masturbation)?	0.52	0.57
…your desire or interest in being in a sexual relationship?	0.88	0.83
…your confidence that you could sexually satisfy a partner?	0.82	0.73
…your overall satisfaction with your sex life?	0.82	0.82
…your ability to become aroused during sexual activity (including self-stimulation or masturbation)?	n/a	0.71
…your ability to be spontaneous about sexual activity (including self-stimulation or masturbation)?	n/a	0.85
…your ability to relax and enjoy sexual activity (including self-stimulation or masturbation)?	n/a	0.90
…the amount of pleasure you experienced during sexual activity (including self-stimulation or masturbation)?	n/a	0.88
Self-concept and body image "The following statements describe ways in which your vaginal symptoms may have affected your feelings about yourself and your body. Please indicate how true each of the following statements has been for you during the past four weeks."		
My vaginal symptoms make me feel like I'm getting old	0.74	0.72
I feel undesirable because of my vaginal symptoms	0.79	0.79
When I think about my vaginal symptoms, I feel like I have lost something	0.85	0.83
My vaginal symptoms make me feel like my body is deteriorating	0.81	0.78
I feel less sexy because of my vaginal symptoms	0.86	0.85

Table 4

Descriptive statistics, item-scale correlations, and internal consistency and test-retest reliability for the Day-to-Day Impact of Vaginal Aging scales

Domain scale	Number of items	Participant sample	Mean (±SD) score	Observed score range[a]	Item-scale correlations	Cronbach's alpha	Test-retest intraclass coefficients[b]
Activities of daily living	5	745	0.3 (±0.5)	0 to 4	0.52 to 0.67	0.82	0.47
Emotional well-being	4	745	0.3 (±0.6)	0 to 4	0.68 to 0.74	0.86	0.67
Sexual functioning (short form) [c]	5	734	0.8 (±0.9)	0 to 4	0.52 to 0.81	0.87	0.58
Sexual functioning (longer form)[d]	9	462	0.9 (±0.90)	0 to 4	0.57 to 0.86	0.94	0.57
Self-concept and body image	5	742	0.9 (±1.0)	0 to 4	0.71 to 0.82	0.91	0.72

[a]. Possible range was 0 to 4 for all domain scales, with higher scores indicating greater impact. Domain scale scores were obtained by averaging the scores of all individual contributing items.

[b]. Test-retest intraclass coefficients were obtained from repeat administration of measures after 1 to 2 weeks in a subset of 175 women drawn from all racial/ethnic groups represented in the parent cohort.

[c]. The short, 5-item version of the sexual functioning domain scale was completed by all postmenopausal women who reported any vaginal symptoms, regardless of sexual activity status.

[d]. The longer, 9-item version of the sexual functioning domain scale was completed only by symptomatic postmenopausal women who reported sexual activity in the past four weeks.

Table 5

Observed correlations between the Day-to-Day Impact of Vaginal Aging domain scales and other measures assessing related constructs among sexually-active respondents

Additional measures	Day-to-Day Impact of Vaginal Aging (DIVA) domain scales							
	Activities of daily living		Emotional wellbeing		Sexual Functioning (longer form)		Self-concept and body image	
	Pearson coefficient	P	Pearson coefficient	P	Pearson coefficient	P	Pearson coefficient	P
Vaginal symptom bothersomeness scale[a]	0.37	< 0.01	0.42	< 0.01	0.30	< 0.01	0.32	< 0.01
Female sexual problems measure[b]	0.04	0.47	0.18	< 0.01	0.52	< 0.01	0.45	< 0.01
Hospital Anxiety and Depression Scale[c]								
Depression subscale	0.24	< 0.01	0.30	< 0.01	0.11	< 0.01	0.21	< 0.01
Anxiety subscale	0.24	< 0.01	0.32	< 0.01	0.11	< 0.01	0.18	< 0.01

Correlations were assessed only in the 462 women who reported sexual activity in the past four weeks, since some measures used to assess construct validity were relevant only to sexually active women (i.e., the female sexual problems measure).

[a]. This 5-item measure assesses the presence and bothersomeness of symptoms of vaginal dryness, itching, irritation, soreness, and pain during sexual intercourse in the past month; higher scores indicating greater bother associated with symptoms.

[b]. This 4-item measure assesses difficulty with sexual arousal, lubrication, orgasm, and pain with sexual activity in the past month; higher scores indicate more sexual activity-specific problems.

[c]. This measure consists of a 7-item subscale assessing depression and a 7-item subscale assessing cognitive anxiety over the past four weeks; higher scores indicate greater depression or anxiety, respectively.