ORIGINAL STUDY

Improving the identification of genitourinary syndrome of menopause through the utilization of the Day-to-Day Impact of Vaginal Aging questionnaire

Jennie Mastroianni, DNP,1 Julie A. Thompson, PhD,2 Jan L. Shifren, MD,3 Andrea L. Zuckerman, MD,1 and Katherine Pereira, DNP2

Abstract

Objective: Genitourinary syndrome of menopause (GSM) affects nearly 50% of postmenopausal women. Yet women fail to recognize GSM as a chronic condition and are reluctant to discuss their vaginal or sexual complaints with a health care provider. This quality improvement project implemented the Day-to-Day Impact of Vaginal Aging (DIVA) questionnaire to improve the identification and diagnosis of GSM in women ≥ 45 years of age presenting for an annual wellness examination or a vulvovaginal/genitourinary complaint.

Methods: From October 2019 to February 2020, the DIVA questionnaire was distributed in a large women’s health practice setting to women ≥ 45 years of age, for completion before their annual wellness visit or for evaluation of a GSM-related complaint. GSM diagnosis rates during the implementation period were compared with diagnosis rates during a 4-month period immediately preceding the implementation. Data collected during the implementation period were examined to evaluate if GSM diagnosis was more likely in patients who completed the DIVA questionnaire when compared to those women who did not complete the questionnaire.

Results: Of the 175 women who met the inclusion criteria, 113 completed the DIVA questionnaire. Completion of the DIVA questionnaire demonstrated a relative percentage increase in GSM diagnosis by 30.7% when compared to the 4-month preimplementation period (10.1% to 13.2%, P = 0.231). This change was not statistically significant. During the implementation period, a statistically significant difference in GSM diagnosis was observed for patients who completed the DIVA questionnaire when compared to those patients who did not complete the questionnaire (37.2% vs 9.7%, P < 0.001). When results were stratified by visit type, women presenting for an annual wellness visit who completed the DIVA questionnaire had a higher GSM diagnosis rate than those who did not complete the questionnaire (37.2% vs 10%, P < 0.001). When results were stratified by menopausal status, GSM diagnosis rates were also more likely for postmenopausal women who completed the DIVA questionnaire when compared to those who did not complete the questionnaire (44.2% vs 8.5%, P < 0.001).

Conclusions: The DIVA questionnaire is a brief, but comprehensive screening tool that can increase GSM identification and treatment, particularly for postmenopausal, and midlife women presenting for an annual wellness visit in a busy women’s health practice setting.

Key Words: Atrophic vaginitis – DIVA questionnaire – Genitourinary syndrome of menopause – Menopausal symptoms – Sexual health – Vulvovaginal atrophy.

Video Summary: http://links.lww.com/MENO/A655.

Genitourinary syndrome of menopause (GSM) is defined as a constellation of signs and symptoms associated with menopause and other conditions caused by estrogen deficiency.1 GSM affects approximately 50% of women during their postmenopausal years causing symptoms of vaginal dryness, irritation, decreased vaginal
If untreated, GSM is progressive and can negatively impact sexual function and overall quality of life. A recent survey demonstrated that women not only fail to recognize GSM as a chronic condition but are reluctant to discuss their vaginal or sexual complaints with a health care provider due to embarrassment or concern regarding treatment side effects. Additionally, health care providers often fail to discuss GSM with their patients. Barriers to GSM identification and treatment include limited time during patient visits, lack of provider education regarding the diagnosis and treatment of this condition, and a misconception that GSM only affects women who are sexually active.

The purpose of this quality improvement (QI) project was to implement The Day-to-Day Impact of Vaginal Aging (DIVA) questionnaire, a validated patient reported outcome measure, to improve the identification of GSM for perimenopausal and postmenopausal women seen at Tufts Women’s Care Boston. The DIVA questionnaire was used to facilitate a provider-initiated conversation to increase patient awareness of GSM and to improve GSM identification, diagnosis, and treatment.

LITERATURE REVIEW

Symptoms of GSM negatively impact sexual function and quality of life. However, multiple barriers within the healthcare setting impede the identification, clinical diagnosis, and treatment of GSM. Despite the prevalence of GSM in the postmenopausal population, many women have limited knowledge and lack a general understanding that their symptoms constitute a medical condition. In the Vaginal Health: Insights, Views and Attitudes survey, 45% of women experienced vaginal symptoms, whereas only 4% attributed these symptoms to menopause-induced vaginal atrophy. In addition, patients are unaware that GSM can be safely and effectively treated. In the Clarifying Vaginal Atrophy’s Impact on Sex and Relationships online survey, less than half of US respondents used any form of hormone therapy to treat their vaginal symptoms. The majority of women learned about local estrogen therapy through their health care providers.

Postmenopausal women experience embarrassment and a general reluctance to broach this topic with their health care providers due to negative societal attitudes associated with midlife and older age sexuality. Likewise, many clinicians feel uncomfortable initiating patient conversations and addressing sexual intimacy issues. Evidence suggests that less than 50% of health care providers initiate GSM discussions, whereas patients initiate these conversations less frequently. However, women are more inclined to be receptive to a GSM discussion if their provider begins the conversation. In a multicenter cross-sectional study, a 35.9% increase in GSM symptom reporting occurred when providers initiated the conversation.

Results of a cross-sectional survey of breast and gynecological cancer survivors also revealed that 70% of patients preferred a provider-initiated discussion regarding sexual health. The use of ubiquity-style inquiries has been suggested to assist providers in eliciting more open and honest patient responses concerning sexual health problems.

Limited provider training in sexual health and midlife women’s care has also been identified as a barrier to care. In one web-based study, approximately 85% of oncologists reported inadequate training in discussing sexual health concerns with their patients. They also verbalized a lack of adequate clinical knowledge to initiate safe, effective treatment for their patients. There are a growing number of nonhormone and hormone therapies currently available to treat GSM. Although low-dose vaginal estrogen remains a safe and highly effective hormone treatment option for GSM, many women and clinicians have concerns about estrogen therapy, particularly in the setting of a woman’s personal or high risk history of breast or hormone receptor-positive gynecological cancer. The many options available pose an additional challenge to providers as they attempt to keep abreast of available GSM treatments. A systematic review demonstrated that no one single treatment was completely effective in alleviating GSM related dyspareunia in women with female sexual dysfunction. The implementation of a personalized multimodal approach to GSM management is recommended to address each woman’s specific symptom complex. The North American Menopause Society (NAMS), The International Society for the Study of Women’s Sexual Health, and The American Society for Clinical Oncology have developed clinical practice guidelines to facilitate this multifaceted decision making process.

Many reliable and validated instruments have been used in prior research to measure menopause-related genitourinary and sexual symptoms and treatment response in midlife women. These include the Female Sexual Function Index, the Menopause Visual Analogue Scale, and the Urogenital Distress Inventory. The Female Sexual Function Index is a measure of the multidimensional nature of female sexual function across a broad age range, including postmenopausal women. The Menopause Visual Analogue Scale was designed to assess the severity of physical and psychological symptoms in women undergoing the menopausal transition. Although the Urogenital Distress Inventory includes one item that assesses pain or discomfort in the genital area, this tool primarily addresses symptoms associated with lower urinary tract disorders. The DIVA questionnaire was developed as a patient reported outcome measure to assess the impact of vaginal symptoms on patient functioning and well-being. It was validated in a large population of racially and ethnically diverse postmenopausal women in the United States. Due to its comprehensive focus on the impact of menopausal vaginal symptoms, the DIVA questionnaire was selected for this QI project. The DIVA questionnaire is a validated, structured, self-administered patient reported outcome measure of the impact of postmenopausal vaginal symptoms on four dimensions of functioning and well-being: activities of daily living, emotional well-being, self-concept and body image, and
sexual functioning. The DIVA is a brief, 22-item questionnaire that can be completed in approximately 5 minutes. The preliminary psychomotor properties of the tool were evaluated across a broad age range of multiethnic postmenopausal women. Methods for developing the DIVA instrument included an extensive literature review, development of self-report items based on cognitive pretesting interviews and evaluation of face validity, field testing, exploratory and factor analyses, and evaluation of construct validity and internal consistency. For the four dimensions of function and well-being, Cronbach’s alpha ranged from 0.82 to 0.93. Intraclass coefficients ranged from 0.47 to 0.72. The tool is in the public domain and has been successfully used in prior research to measure impact of vaginal symptoms on sexual functioning and overall quality of life.

**PROJECT AIMS**

The ultimate goal of this QI project was to facilitate evidence-based GSM care for perimenopausal and postmenopausal patients seen at Tufts Women’s Care Boston. The DIVA questionnaire was used to provide a systematic method for identifying patient symptoms and facilitating a provider-initiated discussion regarding GSM. As such, more women could be diagnosed resulting in improved treatment, counseling, and greater patient satisfaction with care. These benefits were expected to increase sustainability of this innovation on both departmental and institutional levels.

Primary aims of the project were to:

- Implement the DIVA questionnaire as a screening tool for identifying GSM in women 45 years of age or older presenting for an annual visit or for evaluation of a vulvovaginal or genitourinary complaint
- Improve GSM diagnosis by 20% during the 4 month utilization of the DIVA questionnaire when compared to 4 months immediately preceding the implementation period
- Evaluate if GSM diagnosis was more likely during the implementation period in patients who completed the DIVA questionnaire when compared to those women who did not complete the questionnaire

**METHODS**

This QI project was a pre/post project design. The project included a convenience sample of women 45 years or older, scheduled for an annual gynecological visit or for evaluation of a specific vulvovaginal or genitourinary complaint at Tufts Women’s Care Boston. Patients unable to read the English language were excluded from the sample as the project’s clinical content and patient management were presented in English.

This innovation was implemented in a multiphase process. The project lead, a NAMS Certified Menopause Practitioner, presented the QI project to the Tufts Women’s Care providers at a monthly Division meeting. The DIVA questionnaire and scoring instructions were reviewed. A PowerPoint presentation on the assessment and treatment of GSM, including strategies to facilitate a provider-initiated conversation, was stored on the shared computer drive and reviewed by the nine attending physicians and three nurse practitioners. All questions regarding clinical content and patient management were forwarded to the project lead and were addressed in person or through email correspondence. A face-to-face GSM educational lecture was also given to ten resident staff physicians during one of their weekly didactic education sessions.

Provider schedules were reviewed each week to identify women who met the inclusion criteria. Eligible patients were flagged in the electronic health record (EHR) to facilitate daily distribution of the DIVA questionnaire by the front desk staff. At check-in, the selected patients were given the DIVA questionnaire for completion in the waiting room. Providers independently reviewed the DIVA scores in the examination room during the initial patient encounter. Total scores for each domain scale were measured by computing the average score for all items within each domain. Scores ranged from 0 to 4, with higher scores indicating greater impact of vaginal symptoms. Additional clinical information was elicited during a focused history with the patient. Each participant underwent a pelvic examination that included visual inspection of the vulvar anatomy and a vaginal speculum examination. Patients were evaluated for objective signs of GSM, including mucosal pallor, fissuring, epithelial thinning, evidence of petechiae, and decreased vaginal elasticity. They were also evaluated for other possible etiologies of midlife vaginal symptoms including vaginitis, dermatologic disorders, genital herpes, lichen sclerosis, and vulvar lesions. Vaginal cultures were obtained if clinically indicated. A diagnosis of GSM was confirmed upon evaluation of the physical examination and laboratory findings. The DIVA results and objective clinical findings were discussed with the patient. The NAMS Vaginal Dryness MenoNote, a consumer information sheet developed by The Education Committee of NAMS, was also given to facilitate a thoughtful provider-initiated GSM discussion.

The MenoNote provided women with evidence-based information regarding GSM and all available treatment options. After the patient encounter, the provider documented the review of the DIVA results, clinical examination findings, and treatment plan in the patient’s EHR using a standardized template designed by the project lead. The completed DIVA questionnaire was also scanned into the patient’s EHR by the provider’s assigned medical assistant.

**DATA COLLECTION AND DATA ANALYSIS**

The data collection plan included a retrospective medical record review of patients who received the DIVA questionnaire. Data collection included the following information: age, race, body mass index (BMI), comorbidities, cancer history, and date of last menstrual period (LMP). Descriptive statistics (n, %) were used to calculate the number of patients screened with the DIVA questionnaire compared to the total number of patients eligible for screening in the daily review of the schedule. Additionally, descriptive statistics were used to evaluate adherence to the project protocol and DIVA implementation. Charts were reviewed to assess the following
were further examined to evaluate if GSM diagnosis was more likely for women who completed the DIVA questionnaire compared to those who did not complete the questionnaire. A Fisher’s exact test was used to conduct this statistical analysis.

RESULTS

The project was implemented from October 2019 through February 2020. Eleven providers participated in the implementation. There were 175 patients who met the inclusion criteria. Participant demographic data are presented in Table 1. The majority of patients were white with a mean age of 56 years. Age demographics ranged from 45 to 80 years of age. A large percentage of patients (85.1%) had associated medical comorbidities although only a small percentage (12%) had a documented history of cancer. The majority of patients were postmenopausal (n = 124) with a large percentage (78%) reporting a LMP occurring 4 years or more.

To assess adherence (fidelity) to the project protocol, the full sample was examined. The sample then was stratified according to visit type and menopausal status for further analyses. Visit type was categorized as annual or problem-based. Annual examinations that included a vulvovaginal or genitourinary chief complaint were categorized as problem visits. Menopausal status was divided into two categories: perimenopausal (LMP within 1 year of participation date) and postmenopausal (LMP > 1 year before participation).

Table 2 depicts the results of the fidelity outcomes during patient visits. Descriptive statistics (n, %) are presented for the full sample. Almost 65% of patients completed the DIVA questionnaire (n = 113) with 76 of those 113 (67.3%) engaging in discussion with their provider about their DIVA responses. For each stratification variable (Visit type and Menopausal Status), comparison of percentages is presented based on Fisher’s exact tests. As shown, visit type was not related to fidelity outcomes (all P > 0.05). Menopausal status was not related to DIVA completion rates (P = 0.085) but significantly impacted DIVA review and discussion rates. Relative to postmenopausal patients, a significantly higher percentage of perimenopausal patients had their DIVA questionnaire reviewed by the provider (84.2% vs 60%, P = 0.010), and engaged in a discussion with their provider about their DIVA responses (81.6% vs 60%, P = 0.033).

A Fisher’s exact test was used to compare GSM identification rates 4 months before DIVA implementation and 4 months during the implementation of the questionnaire.

TABLE 2. Fidelity outcomes stratified by visit type and menstrual status

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Full sample</th>
<th>Visit type</th>
<th>Menstrual status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N = 175</td>
<td>(n = 136)</td>
<td>(n = 39)</td>
</tr>
<tr>
<td>DIVA completed</td>
<td>113 (64.6)</td>
<td>86 (63.2)</td>
<td>27 (92.2)</td>
</tr>
<tr>
<td>DIVA reviewed</td>
<td>76 (67.3)</td>
<td>60 (69.8)</td>
<td>17 (63)</td>
</tr>
<tr>
<td>DIVA discussed</td>
<td>48 (27.4)</td>
<td>37 (27.2)</td>
<td>11 (28.2)</td>
</tr>
<tr>
<td>GSM diagnosed</td>
<td>50 (28.6)</td>
<td>38 (27.9)</td>
<td>12 (30.8)</td>
</tr>
<tr>
<td>GSM treatment plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meno note given</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DIVA, Day-to-Day Impact of Vaginal Aging questionnaire; GSM, genitourinary syndrome of menopause.
DISCUSSION

This QI project evaluated the effect of implementing the DIVA questionnaire as a tool to facilitate GSM identification at Tufts Women’s Care Boston. Although several reliable and validated questionnaires assess midlife urogenital and sexual symptoms, these self-report measures do not specifically focus on postmenopausal vulvovaginal symptoms. As such, the DIVA questionnaire was selected as the most appropriate tool to achieve our project’s aims.

A large proportion of women presenting for a well woman visit or evaluation of vulvovaginal or urinary complaints received and completed the DIVA questionnaire. This provided busy clinicians with a readily available patient history concerning impact of vaginal symptoms on daily functioning and well-being. Although the completion rate for the questionnaire was slightly higher for problem-based visits (69%) compared to annual visits (63%), patients scheduled for an annual wellness examination were receptive to completing the DIVA questionnaire even though they did not present with a problem. This provided the stimulus for a large number of provider-initiated patient conversations regarding GSM. Results also illustrated that a significantly higher percentage of DIVA questionnaires were reviewed by providers and discussed with perimenopausal as compared with postmenopausal patients. These findings suggest that perimenopausal patients were more comfortable discussing their GSM symptoms and sexual problems with a health care provider. These results are consistent with prior research supporting that sexual problems are more distressing in midlife women who are younger and more sexually active.24,35 Implementation of the DIVA questionnaire in this patient population was successful in increasing the GSM diagnosis rate by 30.7% when compared to the four month preimplementation period. However, this increase did not reach statistical significance. During the implementation period, a GSM diagnosis was more likely for those patients who completed the questionnaire compared to those who did not (P < 0.001). Among women presenting for an annual wellness visit, a GSM diagnosis was also more likely when the DIVA questionnaire was completed. Similarly, a GSM diagnosis was more likely for postmenopausal patients who completed the DIVA questionnaire compared to those who did not. This finding is consistent with prior studies demonstrating that postmenopausal women are more likely to feel embarrassed raising this topic with their health care provider due to negative societal attitudes associated with midlife and older age sexuality.1,11,12 This supports the use of the DIVA questionnaire as an effective screening tool in increasing the identification of GSM, particularly for postmenopausal women or midlife patients presenting for a wellness visit when GSM cases would otherwise be missed.

<table>
<thead>
<tr>
<th>TABLE 3. GSM diagnosis rates and DIVA questionnaire completion (N = 175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSM diagnosed</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

DIVA, Day-to-Day Impact of Vaginal Aging questionnaire; GSM, genitourinary syndrome of menopause.

Of the 308 eligible patients identified in the preimplementation phase, 31 patients were diagnosed with GSM. After the DIVA implementation, 48 of 365 eligible patients were diagnosed. The relative percentage increase in GSM diagnosis was 30.7% (10.1% to 13.2%). Although the target increase of 20% in GSM diagnosis was met, the difference between proportions was not statistically significant (P = 0.231).

A Fisher’s exact test was used to determine if study patients who completed the DIVA questionnaire were more likely to be diagnosed with GSM. Results in Table 3 indicate a statistically significant difference in GSM diagnosis rates for patients who completed the DIVA when compared to those patients who did not (37.2% vs 9.7%, P < 0.001).

To explore the data further, DIVA completion and GSM diagnosis rates were compared according to visit type (annual vs problem-based) using two separate Fisher’s exact tests. As shown in Table 4, a significantly higher GSM diagnosis rate was observed for patients in the annual group who completed the DIVA questionnaire when compared to those patients who did not complete the questionnaire (37.2% vs 10%, P < 0.001). In the problem visit group, DIVA completion was not associated with GSM diagnosis.

DIVA completion and GSM diagnosis were also compared according to menopausal status. There was no association between DIVA completion and GSM diagnosis for women who were perimenopausal (P = 0.703). For postmenopausal women, a significantly higher GSM diagnosis rate was observed for patients who completed the DIVA questionnaire when compared to those who did not (44.2% vs 8.5%, P < 0.001). For perimenopausal women, DIVA completion was not associated with GSM diagnosis rates (see Table 5).

<table>
<thead>
<tr>
<th>TABLE 4. GSM diagnosis rates and DIVA questionnaire completion according to visit type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit type</td>
</tr>
<tr>
<td>GSM diagnosed</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

DIVA, Day-to-Day Impact of Vaginal Aging questionnaire; GSM, genitourinary syndrome of menopause.
For all patients diagnosed with GSM, an individualized GSM treatment plan was devised, regardless if the DIVA questionnaire was completed. This underscores the importance of educating providers so that they are comfortable prescribing GSM therapies based on the current evidence. The NAMS Vaginal Dryness MenoNote was given to only 29% of the total patient group. It is anticipated that over time, busy providers will incorporate this valuable patient education tool as a standard practice for all midlife women seeking care at Tufts.

The strengths of this project included raising provider awareness about the prevalence and impact of GSM. The DIVA questionnaire served as an efficient, readily available tool for providers to identify and assess the impact of postmenopausal vaginal symptoms on patient functioning and well-being. A significant number of provider-initiated discussions resulted from completion of this survey. As such, GSM identification, diagnosis, and treatment were improved. All patients diagnosed with GSM were provided an individualized vaginal health treatment plan. The integration of a standardized EMR template was also beneficial in facilitating provider documentation in the medical record. The project included a sample size that was adequately powered to address the statistical questions presented in the project aims. This implementation was readily accepted by patients and practice providers with limited experience in midlife and postmenopausal care. Although patient satisfaction scores were not measured, women appeared happy with their care. The project generated a greater number of midlife patient referrals to the project lead, a NAMS Certified Menopause Practitioner. Increased provider collaboration regarding GSM care and menopausal management was also observed.

There were several limitations to this project. The project was relatively short (4 mo) in duration. Teaching methods and duration of provider training were limited due to multiple scheduling conflicts within the timetable of this QI project. The DIVA questionnaire is validated only in English, so exclusion of non-English speaking women was another limitation of this study. Although many women completed the DIVA questionnaire, providers had limited time to review and discuss the DIVA results with their patients during standard 20 minutes visit intervals. A few providers were unable to fully participate in the project implementation since their practices focused on other gynecology subspecialty areas, such as minimally invasive gynecologic surgery. Although their time was spent on other significant gynecological conditions, these providers recognized the need to refer patients with GSM and midlife issues for further care. Provider feedback was not solicited regarding the utility and value of this implementation. A cost-savings analysis was not conducted to determine if improved GSM identification resulted in more cost-effective care. Further assessment of the sustainability of this intervention would be informative.

**CONCLUSION**

The findings of this QI project support the use of the DIVA questionnaire in a busy women’s health practice setting to facilitate GSM identification and treatment during both annual and problem-based visits. Supplemented by provider training and education, implementation of the DIVA questionnaire raised provider awareness concerning the prevalence and potential impact of GSM related symptoms on patient functioning and overall well-being. Thoughtful provider-initiated patient conversations were facilitated. As a result, more patients were diagnosed and received individualized treatment and counseling. The DIVA questionnaire is a brief, but comprehensive tool that can be easily implemented in women’s health, primary care, and oncology practice settings. With increased identification and treatment, midlife women will receive improved GSM care.

**Acknowledgments:** The authors would like to thank the staff of Tufts Women’s Care Boston who contributed to this QI project.

**REFERENCES**


IDENTIFYING GSM WITH THE DIVA QUESTIONNAIRE