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Missing documentation in breast cancer survivors: genitourinary syndrome of menopause

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Abstract

Objective—Breast cancer survivors often take hormonal treatments to prevent the recurrence of breast cancer, particularly aromatase inhibitors that can worsen the symptoms of genitourinary syndrome of menopause (GSM) such as dyspareunia, dysuria, and urinary incontinence, all of which may adversely affect survivors' quality of life. Few breast cancer survivors experiencing GSM receive adequate assessment or treatment.

Methods—In this descriptive study, we reviewed medical records for documented GSM and any treatments administered or referrals for treatment in 800 female patients who visited the Breast Cancer Survivorship Clinic at a comprehensive cancer center between July 1, 2010, and June 30, 2011, either 5 years after completion of treatment for invasive breast cancer or 6 months after completion of treatment for ductal carcinoma in situ.

Results—Of the 279 patients with documented symptoms of vaginal atrophy, only 111 (39.8%) had documentation of having received any form of treatment or referral. Of the 71 patients with documented symptoms of urinary tract atrophy, only 33.8% had documentation of having received treatment or referral for treatment.

Conclusion—Breast cancer survivors often experience GSM due to lack of estrogen. The worrisome lack of documentation of assessment or treatment for GSM in a large breast cancer survivorship practice reveals missed opportunities to improve quality of life. Dissemination of recent progress in the development of GSM assessment tools, patient handouts, and new treatments to providers who care for breast cancer survivors is needed to improve this process.

Keywords

Breast cancer survivors; Genitourinary symptoms; Menopausal symptoms; Genitourinary syndrome of menopause; GSM; Breast cancer

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Introduction

Breast cancer survivors, particularly those who are postmenopausal, often experience genitourinary syndrome of menopause (GSM), which adversely affects their quality of life [1–4]. Broeckel et al. [5] found that breast cancer survivors treated with adjuvant chemotherapy had decreased sexual function compared with age-matched women with no history of cancer. The study also revealed that vaginal dryness was one of the most important predictors of decreased sexual function in breast cancer survivors. Breast cancer survivors receiving adjuvant aromatase inhibitor therapy also reported distressing GSM and sexual dysfunction [6,7]. In addition, women reporting vaginal dryness often had pain with gynecologic examinations [8].

Breast cancer survivors who experience atrophic vaginitis are usually given nonhormone therapies, although such therapies often offer inadequate symptom relief [9–10]. Although vaginally administered estrogen has been shown to be an effective treatment for atrophic vaginitis [2–4, 11–12], there has been concern that vaginal estrogen may be systemically absorbed, stimulate breast tissue, possibly leading to recurrence [10, 13–14]. However, Le Ray and Dell’Aniello [15] showed no increase in breast cancer recurrence among patients using vaginal estrogen who were treated with tamoxifen. The American College of Obstetricians and Gynecologists [16] recommends that vaginal estrogen be offered to those patients who are unresponsive to nonhormone remedies after an informed decision-making and consent process about the potential risks and benefits of using vaginal estrogen in collaboration with their oncologist.

Recently, several new therapies became available including thermo-ablative fractional CO₂ laser therapy and newly FDA-approved intravaginal dehydroepiandrosterone (DHEA). Thermo-ablative fractional CO₂ laser is a new, well-tolerated, and effective option currently used for treatment of vulvovaginal atrophy [17–18]. The long-term effectiveness of laser therapy is still being studied. Pieralli et al. [19] evaluated 50 breast cancer survivors after a course of vaginal fractional CO₂ laser treatment found that 52% were satisfied after intermediate term follow-up (mean time 11 months). The recommended course of therapy costs thousands of U.S. dollars, involves three treatments spaced 6 weeks apart, and has a recommended follow-up maintenance of about a year after completion of therapy. This procedure is neither approved nor cleared by the FDA for the specific indication of treating vulvovaginal atrophy [20].

Intravaginal DHEA, another new treatment, was approved by the FDA on November 17, 2016, to treat moderate to severe dyspareunia [21–23]. Although studies have shown that the steroid concentrations used in this treatment remain within normal postmenopausal values in women receiving daily 0.5% intravaginal DHEA for 12 weeks, it is contraindicated in breast cancer survivors because there was a small increase in serum levels of estrogen [24]. Since intravaginal DHEA only recently received FDA approval, it is currently in the production phase and not yet available for patient use.

Ospemifene is an estrogen agonist/antagonist with an FDA indication for the treatment of moderate to severe dyspareunia. It has not been adequately studied in breast cancer survivors and should not be used in this population.

Since the prevalence of distressing sexual dysfunction in breast cancer survivors is very high, we sought to determine how often clinicians documented GSM and the percentages of patients with symptoms who received treatment in a very large breast survivorship clinic at a comprehensive cancer center.

Materials and Methods

We conducted a descriptive study of female patients who were treated at the Breast Cancer Survivorship Clinic, housed in the Cancer Prevention Center at The University of Texas MD Anderson Cancer Center. In addition to breast oncologists, the health care providers in this clinic include two family doctors, one internist, and eight nurse practitioners, all specially trained in cancer prevention, screening, diagnosis, and survivorship care.

After Institutional Review Board approval, we reviewed the medical records of patients who completed treatment for invasive breast cancer at least 5 years before their visit to the survivorship clinic or who completed treatment for ductal carcinoma in situ at least 6 months before their visit. Medical records were designated ineligible if the patient did not have a pathological diagnosis of breast cancer or was not examined in the Breast Cancer Survivorship Clinic, or if the records were duplicate (only 1 record per patient was included).

Patient data were stored in databases designed and maintained by Patient-Reported Outcomes, Survey and Population Research (PROSPR), a shared resource of the Cancer Center Support Grant at MD Anderson. The PROSPR group also helped prepare the datasets and conduct the analyses.

Data were extracted from the patients', clinic notes, medication lists, and review of systems sections of the medical records. The review of systems "Genitourinary" section of the clinic note only listed urinary symptoms as listed in Table 1. We collected and recorded demographic information, the status of ovarian function, the presence of pelvic pain, current vaginal infections or vaginal discharge, and symptoms suggestive of vaginal atrophy including vaginal dryness, pruritus, and/or vaginal bleeding. Symptoms related to atrophy of the lower urinary tract, including urinary burning, frequency, hematuria, dribbling, and incontinence, were also recorded. If available, the date of the patient's last menstrual period, sexual activity status (sexually active or not), and the results of the most recent Papanicolaou test and pelvic examination were also noted, including whether the test revealed vaginal atrophy. Use of hormonal and anti-hormonal therapy (estrogen, progesterone, testosterone, raloxifene, tamoxifen, anastrozole, letrozole, and/or exemestane) was also recorded.

Attempts were made to sample all age groups for a total of 800 patient medical records. This sample size was based on the resources available, including one medical student for chart review and data collection. The sample size for each of 10 separate age range groups (>21, 21–40, 41–45, 46–50, 51–55, 56–59, 60–65, 66–70, 71–75, >75) was determined by the

number of available MD Anderson medical records in each age group. We sorted the medical record in ascending order for each age group. Sampling began with the lowest medical record number in each age group and ended either when we reached the group sample size or when no more records were available. All eligible medical records for women younger than 45 years were included because of the small number of available records in these age groups. Ineligible and duplicate patient records were not included in the analyses.

Descriptive statistics were used to summarize the data. The Pearson chi-square test was used to assess the relationship between sexual activity (sexually active vs. sexually inactive) and the prevalence of symptoms of urogenital atrophy. The Fisher exact test was used when any of the cells had values <5. By convention, a P value of <0.05 indicated statistical significance. P values were calculated based on the chi square and fisher exact tests. Odds ratios are reported for significant findings and were calculated using the 2×2 tables, no logistic regression models were run. All statistical analyses were carried out SAS (SAS Institute Inc., Cary, NC).

Results

Approximately 4,000 total electronic medical records were available for the study period, with the majority for patients older than 60 years. We evaluated 800 unique patient records in this study including all of the 10 separate age range groups. Patient demographic information is summarized in Table 2.

There were 624 (78.00%) postmenopausal patients and 153 (19.13%) premenopausal patients, leaving 23 (2.88%) patients with unknown status of ovarian function.

Treatment with vaginal estrogen and vaginal lubricants/moisturizers included none versus two of the 24 patients using tamoxifen, one versus one of the 11 patients on raloxifene, and two versus four of the 18 patients on aromatase inhibitors, respectively.

Of the 800 patients studied, 279 (34.9%) had documented symptoms suggestive of atrophic vaginitis (Table 3). The most common symptom reported was vaginal dryness (n = 181; 22.6%), followed by vaginal bleeding (n = 37; 4.6%). Sexual activity status was documented for only 152 patients (19%).

The number of patients with documented symptoms suggestive of lower urinary tract atrophy was much smaller (n = 71; 8.88%; Table 4). The most common urinary symptom documented was increased frequency (n = 23; 2.9%), followed by dribbling (n = 22; 2.8%).

Of the 403 patients with documented results from a recent Papanicolaou test and pelvic examination, 214 (53.1%) had documented vaginal atrophy according to one or both of these tests. The documented symptom of vaginal dryness occurred significantly more often among patients with documented vaginal atrophy than among patients without documented vaginal atrophy on the recent Papanicolaou test or pelvic examination (64/214 [29.9%] vs. 35/189 [18.5%]; OR = 1.615 (1.023, 2.548); P = 0.0023). No statistically significant differences in urinary symptoms were observed between women with vaginal atrophy and those without vaginal atrophy on a recent Papanicolaou test or pelvic examination.

Of the 279 patients with documented symptoms of vaginal atrophy, only 111 (39.8%) had documentation that they received some form of treatment or referral to a health care specialist. Of the 71 patients with documented symptoms of lower urinary tract atrophy, only 24 (33.8%) had documentation that they received some form of treatment or referral.

Discussion

Our results revealed a troubling lack of documentation of ascertainment of GSM in this population of breast cancer survivors. Also, for the small minority with documented symptoms, there is a woeful lack of treatment plans. These results demonstrate a need to improve the current practice of evaluation and management of GSM in breast cancer survivors. Even if GSM were elicited and treated but not documented, this results in an incomplete medical record and also negatively affects follow-up care. These results are consistent with many surveys that reveal that patients want to have discussions about GSM during their oncology visits but such discussions rarely occur [25–27].

This study focused on how often clinicians documented GSM and the percentages of patients with symptoms who received treatment in a very large breast survivorship clinic at a comprehensive cancer center, and the lack of documentation was worrisome. Bradford et al. [28] studied the effect of a brief intervention to increase routine screening for sexual problems in this same breast survivorship clinic by giving a seminar for clinic nurses and adding several screening items on sexuality in the review of systems form. Sexual problems were documented in 5.2% of 233 records before implementation and in 7.6% of 236 records after implementation ($p = 0.278$). There was much less documentation of interventions for sexual problems, with 2.6% of records before implementation and 3.0% of records after implementation ($p = 0.803$). Although 88.1% of survivors completed the screening items and 22.6% of the respondents listed one or more sexual problems, only 23.4% of those listing sexual problems had a documented intervention. This study showed that screening by self-report alone is insufficient to change clinical practice to improve care for breast cancer survivors with sexual problems.

Substantial progress has been made by members of the Scientific Network on Female Sexual Health and Cancer who developed a Sexual Symptom Checklist for Women after Cancer for use in the clinic to assess female oncology patients. They also developed patient handouts, including Vulvovaginal Dryness, Vulvovaginal Health, and Loss of Desire after Cancer Treatment. Finally, this Network provides information on how to expand a referral network of specialized providers to address GSM [29]. Zhou et al. [30] provided tips and strategies for primary care physicians to improve the management of sexual health problems in men and women; Boswell and Dizon [31] provided additional strategies for the management of sexual health problems for breast cancer survivors.

There is a need to provide continued medical education to disseminate these strategies that address the genitourinary health of postmenopausal cancer survivors. Health care professionals should be educated about current nonhormone treatments for GSM and when and how to initiate vaginal estrogens if needed. Studies should be conducted for intravaginal DHEA, ospemifene, and other upcoming therapies for vaginal atrophy suitable for breast

cancer survivors. Advances in these areas with more treatment options may increase the likelihood that genitourinary concerns will be adequately addressed.

The volume of breast cancer survivorship clinic visit records that were eligible for evaluation is a major strength of the study. Unfortunately, evaluation of these records revealed sparse documentation of GSM and treatment plans. Our results also showed that even when these symptoms were documented, health care professionals addressed them in fewer than 40% of patients. These findings are consistent with previous findings of Chin et al. [32], which revealed that less than one-third of postmenopausal breast cancer survivors receiving endocrine therapy who reported GSM received some form of treatment for these symptoms. Ganz et al. [33] showed that treating GSM can greatly reduce pain, improve sexual desire or pleasure, and ultimately improve quality of life for breast cancer survivors.

Since these results are from a single clinic, albeit a very large clinic, generalizability of the results is limited. However, these results are consistent with other studies detailing the need for more assessments and treatments for genitourinary problems in breast cancer patients [7, 34]. Another possible limitation to our study is that some women with documented vaginal atrophy on examination were not troubled by the atrophy and did not report symptoms. It is very probable that some women with documented vaginal atrophy on examination were not sexually active. More than 50% of American women older than age 50 years do not have a functional male sexual partner and tend to be less distressed about GSM [7]. Another limitation in this study is the lack of correlation between the status of ovarian function and the symptoms documented in the medical record. Determination of sexual activity was listed for only 19% of patients, very little additional information can be reliably learned from this variable.

Conclusion

Significant progress has been made with the development of GSM assessment tools, patient handouts, and new treatments. Since most breast cancer survivors today live long, cancer-free lives, it is imperative to disseminate the progress made in these areas for integration into the practices of providers who care for breast cancer survivors. We must all screen for GSM, perform a proper evaluation with a treatment plan and document this process for every patient.

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Table 1

“Review of Systems” Genitourinary section in the clinic note

<i>Check all the following problems that you are HAVING NOW</i>	
GENITOURINARY:	
<input type="radio"/> Burning	<input type="radio"/> NONE
<input type="radio"/> Frequency	
<input type="radio"/> Blood in urine	
<input type="radio"/> Dribbling	
<input type="radio"/> Unable to control	
<input type="radio"/> Bladder	
<input type="radio"/> OTHER	

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Table 2

Patient demographic information (n = 800)

Characteristic	No. of patients (%)
Marital status	
Single	82 (10.25)
Married	601 (75.12)
Divorced	82 (10.25)
Separated	9 (1.13)
Widowed	26 (3.25)
Ethnicity	
White	586 (73.25)
Hispanic	83 (10.38)
African American	81 (10.13)
Asian	42 (5.25)
American Indian/Alaska Native	3 (0.37)
Native Hawaiian/Pacific Islander	2 (0.25)
Other	3 (0.37)
Age*	
Younger than 60 years	504 (63)
60 years or older	296 (37)

* Mean age: 56.1 years (standard deviation, 9.6 years).

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Table 3

Genital symptoms reported (n = 800)

Symptom	No. of patients (%)	No. of treatments offered	No.-Type of treatment
Pelvic pain	35 (4.38)	12	1-testosterone 1-top progesterone 3-lubricants/moisturizers 6-referral 6-other
Vaginal discharge	32 (4.00)	13	2-lubricants/moisturizers 10-referral 4-other
Vaginal bleeding	37 (4.63)	19	2-vaginal estrogen 1-topical testosterone ** 1-topical progesterone ** 6-lubricants/moisturizers 10-referral 6-other
Vaginal dryness	181 (22.63)	71	18 vaginal estrogen 44 lubricants/moisturizers 14-referral 14-other
Vaginal pruritus	23 (2.88)	13	5-vaginal estrogen 5-lubricants/moisturizers 3-referral 4-other
Dyspareunia	25 (3.13)	16	3-vaginal estrogen 9-lubricants/moisturizers 7-referral 4-other
Other	59 (7.38)	26	2-vaginal estrogen 1-topical testosterone ** 1-topical progesterone ** 8-lubricants/moisturizers 12-referral 10-other
Total reporting genital symptoms *	279 (34.88)	170	

* Some patients reported multiple symptoms and some received multiple treatment options.

** Treatment through outside physician.

Table 4

Urinary symptoms reported (n = 800)

Symptom	No. of patients (%)	No. of treatments offered	No.-Type of Treatment
Dysuria	7 (0.88)	3	2-Referral 1-Other Rx
Increased frequency	23 (2.88)	5	2-Lubricants Moisturizers 1-Referral 2-Other Rx
Incontinence	4 (0.50)	2	1-Lubricants Moisturizers 1-Referral 1-Other Rx
Hematuria	8 (1.00)	3	1-Vag/estrogen 1-Referral 1-Lubricants Moisturizers
Dribbling	22 (2.75)	8	1-Vag/estrogen 4-Referral 2-Lubricants Moisturizers 1-Other Rx
Other	24 (3.00)	8	1-Vag/estrogen 3-Other Rx 1-Top testosterone ** 1-Top progesterone ** 3-Lubricants Moisturizers 5-Referral
Total *	71 (8.88)	29	

* Some patients reported multiple symptoms and some received multiple treatment options.

** Treatment through outside physician.