Comprehensive Menopausal Assessment: An Approach to Managing Vasomotor and Urogenital Symptoms in Breast Cancer Survivors

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Purpose/Objectives: To describe the development and implementation of a comprehensive menopausal assessment (CMA) and intervention program for women with a history of breast cancer.

Data Sources: Published articles selected from computerized databases, conference proceedings, bibliographies of pertinent articles and books, and lay publications.

Data Synthesis: The CMA program consisted of a structured, comprehensive assessment of three symptoms (hot flashes, vaginal dryness, and stress urinary incontinence) and an individualized plan of education, counseling, nonestrogen treatments, psychosocial support, referrals, and follow-up.

Conclusions: A structured approach to evaluating and managing vasomotor and urogenital symptoms with, for example, the CMA, may help breast cancer survivors with severe symptoms more effectively manage these symptoms than "usual care."

Implications for Nursing: Nurses providing care for women with a history of breast cancer can incorporate the key elements of the CMA program into their practice to facilitate more effective management of three common menopausal symptoms that often are undertreated in this patient population.

Key Points . . .

- ➤ Vasomotor and urogenital symptoms are common and often severe in postmenopausal women treated for breast cancer.
- ➤ Several nonestrogen treatments are available to manage these symptoms; however, they have varying efficacy and side effects, which may concern breast cancer survivors.
- ➤ Comprehensive assessment of symptoms and tailored interventions, including nonestrogen treatments, patient education, shared decision making, and psychosocial support, may be used to manage vasomotor and urogenital symptoms in breast cancer survivors.

Goal for CE Enrollees:

To further enhance nurses' knowledge regarding managing vasomotor and urogenital symptoms in breast cancer survivors.

Objectives for CE Enrollees:

On completion of this CE, the participant will be able to

1. Describe the comprehensive menopausal assessment and intervention program.
2. Describe three vasomotor and urogenital symptoms.
3. Discuss the management of three vasomotor and urogenital symptoms.

Vasomotor and urogenital symptoms are common among the general population of postmenopausal women (Dennerstein, Dudley, Hopper, Guthrie, & Burger, 2000). However, increasing evidence indicates that these symptoms may be more prevalent or severe in postmenopausal women treated for breast cancer (Carpenter & Andrykowski, 1999; Carpenter, Johnson, Wagner, & Andrykowski, 2002; Ganz, Rowland, Desmond, Meyerowitz, & Wyatt, 1998). Although not life threatening, severe vasomotor and urogenital symptoms have the potential to disrupt women's physical, psychological, social, and sexual functioning (Bachmann, 1994; Greendale, Petersen, Zibecchi, & Ganz, 2001; Kronenberg, 1994b).

No definitive approaches exist to managing vasomotor and urogenital symptoms in breast cancer survivors. In women who have not been treated for breast cancer, treatment for these symptoms commonly is some form of estrogen therapy (Greendale, Lee, & Arriola, 1999). However, the use of estrogen in women treated for breast cancer currently is not advised because of its potential for promoting tumor growth (Colditz, 1998). Instead, a consensus panel of breast cancer experts and patient advocates has recommended a variety of

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"estrogen surrogates" to manage these symptoms in breast cancer survivors (Santen, 1998). These surrogates have been found to have varying efficacy, risks, and side effects (Barton et al., 1998; Quella et al., 1998). Some authors have questioned whether the use of some of these estrogen surrogates would be feasible, effective, and acceptable to symptomatic breast cancer survivors in clinical practice (Barton et al.; McPhail, 1999).

The authors developed a program, referred to as the comprehensive menopausal assessment (CMA). The randomized trial that evaluated the CMA program is described elsewhere (Ganz et al., 2000). The trial included 76 postmenopausal women with a history of breast cancer and at least one of three target symptoms—hot flashes, vaginal dryness, or urinary incontinence—that, by patient self-report, were severe. These women were assigned randomly to an intervention group or usual care group. Women in the intervention group received the CMA program, which consisted of a structured, comprehensive assessment of the three target symptoms and an individualized plan of education, counseling, nonestrogen treatments, psychosocial support, and referrals delivered by a nurse practitioner during a four-month period. Women in the control group received a follow-up telephone call from a research assistant at specified intervals during a similar period of time. Women receiving the CMA intervention were found to have reduced menopausal symptom scale scores and improved sexual functioning scale scores compared to women in the usual care group (Ganz et al., 2000). This article will describe (a) the conceptual and theoretical basis for the CMA program, (b) a review of the evidence base of the program, and (c) the CMA program components. This information may be applicable in other settings where advanced practice nurses care for women with a history of breast cancer.

Conceptual Framework

The revised version of the symptom management model developed by the University of California, San Francisco School of Nursing Symptom Management Faculty Group (1994) (Dodd, 1998) was used as the organizing framework for the CMA program. According to this model, the three dimensions of symptom experience, symptom management strategies, and symptom outcomes are interrelated and essential for effective symptom management. The process of symptom management begins with an assessment of the symptom experience from patients' perspectives, followed by identification of the focus for intervention, implementation of interventions, and evaluation of outcomes (see Figure 1).

The first dimension of the model, symptom experience, involves the interaction of patients' perceptions of a symptom, their evaluation of the symptom, and the physiologic, psychological, and behavioral responses associated with the symptom. In the CMA program, symptom experience was defined as patients' description and evaluation of the target symptoms that they perceived as problems. Specifically, the description included the physiologic, psychological, and behavioral components associated with each target symptom (e.g., for hot flashes, this might have included patients' self-reports of feeling hot, sweaty, flushed, embarrassed, or annoyed, or a description of activities that were disrupted), whereas the evaluation included the judgments made by patients about the severity, frequency, duration, and degree of bother or disruption associated with each target symptom. The symptom management model also

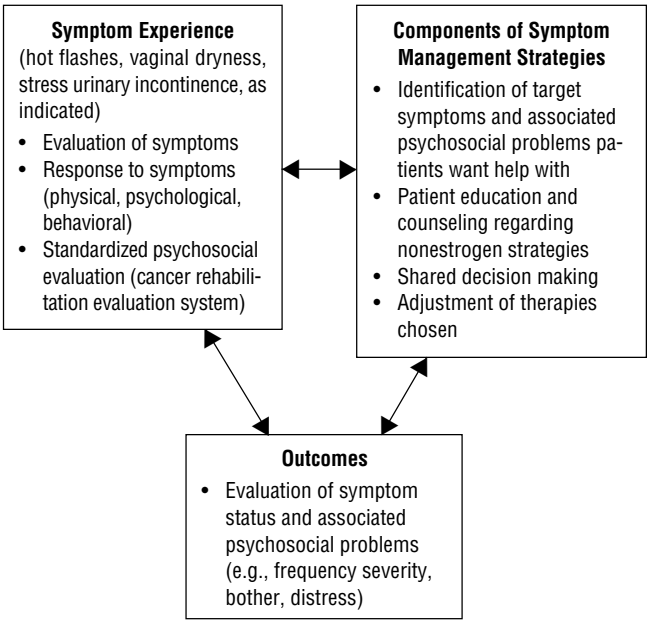


Figure 1. Dimensions of Symptom Management Model as Applied to the Comprehensive Menopausal Assessment Program

Note. Based on information from Dodd, 1998.

holds that the symptom experience is influenced by several variables related to the person, environment, and health or illness. Such factors, which may be relevant to the management of vasomotor and urogenital symptoms in breast cancer survivors, are summarized in Figure 2.

The second dimension of the symptom management model, symptom management strategies, outlines the components of intervention delivery. Specifically, these components included who delivers the intervention(s), and when, where, how, to

Person	Environment	Health and Illness
• **Demographic:** age, ethnicity, marital status, and education • **Psychological:** personality traits, cognitive capacity, and motivation • **Sociologic:** family, unit, culture, and religion • **Physiologic:** rest or activity patterns and physical capacity • **Development:** individual and family (e.g., loss or freedom from childbearing, dating issues)	• **Physical:** home, work, and play • **Social:** social support or network • **Cultural:** beliefs, values, practices related to menopause, breast cancer, health, and illness	• **Risk factors:** for breast cancer (e.g., family history) and for specific vasomotor and urogenital symptoms • **Health status** • **Disease and injury:** past medical and surgical history, including breast cancer diagnosis and treatment (e.g., type, stage, nodal involvement, treatments received, surgery, radiation, chemotherapy, tamoxifen)

Figure 2. Potential Variables Influencing Perception of Menopausal Symptoms in Breast Cancer Survivors

Note. Based on information from Dodd, 1998; University of California, San Francisco School of Nursing Symptom Management Faculty Group, 1994.

whom, how much, and why. In the CMA program, a nurse practitioner delivered the intervention to patients, tailoring treatment strategies to each patient's individual needs and preferences. Patients were encouraged to participate in all aspects of the decision-making process related to symptom management strategies.

The third and final dimension of the symptom management model focuses on the outcomes of the symptom management process. According to the model, nine outcomes may be considered: symptom status, functional status, self-care, costs, quality of life, morbidity, comorbidity, mortality, and emotional status. Although each of the target symptoms has the potential to affect a woman's daily functioning, self-care, and emotional status, outcomes in the CMA program were limited to a simple assessment of symptom status (e.g., how frequent, how severe, or how bothersome each of the target symptoms were according to each woman's self report). However, for the randomized trial that evaluated the CMA intervention, symptom outcomes included a menopausal symptom scale, a measure of symptom status, and two measures of quality of life—a vitality scale and a sexual-functioning scale (Ganz et al., 2000).

Literature Review

Most studies of vasomotor and urogenital symptoms in breast cancer survivors have examined nonestrogen management strategies, usually one at a time; none have offered patients a choice of treatment options or combination of strategies. In addition, few studies have described the symptom experience of postmenopausal breast cancer survivors with vasomotor and urogenital symptoms. Thus, the following review includes studies that focus on the symptom experience or nonestrogen management of hot flashes, vaginal dryness, and stress urinary incontinence in breast cancer survivors. However, when data are not available for breast cancer survivors, the experiences of women without breast cancer are described.

Hot Flashes

Symptom experience: Hot flashes are sudden, transient sensations of warmth to intense heat (Kronenberg, 1994a, 1994b) that may be accompanied by a wide range of physiologic, psychological, and behavioral responses such as flushing, perspiration, palpitations, anxiety, embarrassment, irritation, and disrupted activities, especially sleep (Knobf, 1998). Although the etiology of menopausal hot flashes remains unclear, a study by Freedman and Krell (1999) suggested that hot flashes may be triggered by small elevations in core body temperature occurring in a reduced thermoregulatory zone. According to Freedman (2002), a "thermoneutral" zone exists in which core body temperatures can rise and fall without triggering sweating or shivering. However, in symptomatic postmenopausal women, this zone is reduced, and even a small rise in core body temperature will trigger a hot flash (Freedman). The prevalence of hot flashes in samples of postmenopausal women ranges from 50%–85% (Greendale & Sowers, 1997), compared to 65% in studies of postmenopausal breast cancer survivors (Carpenter et al., 1998; Couzi, Helzlsouer, & Fetting, 1995; Harris, Remington, Trentham-Dietz, Allen, & Newcomb, 2002). The rate of hot flashes may be as high as 78% in breast cancer survivors treated with tamoxifen or chemotherapy (Carpenter et al., 1998). Among women who have not been treated for breast cancer, hot flashes occur most frequently in the two years prior to and after the final menstrual period and decrease as the time from last menses increases (Greendale & Sowers). However, among women with a history of breast cancer, rates of hot flashes were found to be fairly stable across time after menopause, ranging from 70%–75% in women 1–10 years postmenopause (Carpenter et al., 1998). Based on this data, Carpenter et al. (1998) concluded that hot flashes might not decrease over time in postmenopausal breast cancer survivors, possibly related to their use of tamoxifen.

Characteristics associated with frequent or more severe hot flashes in women without breast cancer include surgically or pharmacologically induced menopause, cigarette smoking, and lower body fat (Carpenter et al., 1998; Greendale & Sowers, 1997). Among postmenopausal breast cancer survivors, adjuvant therapies such as chemotherapy and tamoxifen have been associated with more frequent or more severe hot flashes. Ganz, Rowland, Meyerowitz, and Desmond (1998) found that the prevalence of hot flashes was significantly greater in women who had received adjuvant therapy compared to those who had not received adjuvant treatment. Carpenter et al. (1998) found that hot flashes were most common in breast cancer survivors with a high school education or less and those who were younger at diagnosis. Lower levels of education also were associated with a lower likelihood of using hot flash management strategies.

Although some women perceive hot flashes as a minor nuisance, other women find this symptom disruptive to their work, daily activities, and relationships (Kronenberg, 1994b). However, little is known about the factors that may influence women's perceptions of hot flashes. Finck, Barton, Loprinzi, Quella, and Sloan (1998) proposed that frequency and duration of the hot flash event might be relatively unimportant. Rather, the severity of the physiologic experience of the hot flash may be related to its psychological impact, and the distress caused by hot flashes may be related more to the context in which they occur.

In general, the construct of hot flash severity is poorly defined. Many studies ask patients to rate the severity of their hot flashes using a numerical scale that ranges from 0 (not at all severe) to 5 (extremely severe). However, these scales do not define explicitly what characterizes a mild, moderate, severe, or very severe hot flash. Finck et al. (1998) explored self-definitions of hot flash severity in breast cancer survivors. They found that women's descriptions of mild hot flashes included a physiologic component, moderate hot flashes included physiologic and behavioral components, and severe and very severe hot flashes included physiologic, behavioral, and emotional components. These authors suggested that the evaluation of hot flashes should include hot flash frequency as well as patients' subjective experiences associated with hot flashes.

Management and outcomes: Available treatments do not "cure" hot flashes; they provide relief by decreasing their frequency or severity, usually for the duration of treatment (Kronenberg, 1994a). Estrogen reduces the frequency of hot flashes by 50%–90% and is the most effective hot flash treatment (Kronenberg, 1994a). A number of nonestrogen strategies also have been proposed in the scientific and lay literature, including lifestyle and behavioral changes, medications, and alternative therapies (Kronenberg, 1994b; Love, 1997); however, few of these strategies have been tested in randomized, placebo-controlled trials. Observational studies suggested that

exercise, not smoking, and cooler ambient temperatures are associated with fewer hot flashes (Kronenberg, 1994b). The type, duration, and frequency of exercise needed to prevent or reduce hot flashes are unknown. Uncontrolled studies also suggest that dietary interventions such as limiting or avoiding caffeine, alcohol, spicy foods, and hot liquids reduce hot flashes (Kronenberg, 1994a). One randomized trial found that slow abdominal breathing decreased objectively measured hot flashes up to 50% compared to a placebo behavioral intervention (Freedman & Woodward, 1992). Since the development of the CMA program, a great interest exists in alternative and complementary therapies such as herbal remedies, dietary supplements (including phytoestrogens), and acupuncture for treatment of hot flashes; still, few of these approaches have been studied systematically and information about their safety, effectiveness, and use in breast cancer survivors remains incomplete. However, as more information becomes available, these strategies could be added to the list of treatment options.

Several nonestrogen medications (including clonidine; a combination of ergotamine, belladonna, and phenobarbitol; and megestrol acetate) have been used to treat hot flashes and, like estrogen, are associated with potential benefits, risks, and side effects. In a randomized trial of 110 breast cancer survivors taking tamoxifen, transdermal clonidine (Catapress-TTS®, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT) diminished the frequency and severity of self-reported hot flashes by 20% and 10% from baseline, respectively (Goldberg et al., 1994). Side effects included dry mouth, constipation, itchiness under the patch, and drowsiness, but precise frequencies of these side effects were not reported (Goldberg et al.).

Megestrol acetate, a synthetic progestin that is used to treat metastatic breast cancer, also is used off-label to treat hot flashes. In a study that included 97 women with breast cancer and 66 men with prostate cancer, 20 mg twice a day reduced self-reported hot flashes on average by 70% in a randomized, placebo-controlled, crossover design (Loprinzi et al., 1994). Short-term side effects included increased severity of hot flashes during the first few days of treatment in women who were concomitantly taking tamoxifen and vaginal withdrawal bleeding after the drug was discontinued. Researchers do not know whether low-dose megestrol inhibits or promotes the growth of tumor cells or interferes with the actions of tamoxifen (Quella et al., 1998). Cushing's syndrome, diabetes, and adrenal insufficiency have been reported rarely with doses of megesterol as a low as 80 mg per day (Mann et al., 1997). Although this agent has a wide range of potential metabolic and thrombotic complications, its efficacy in reduction of hot flashes is superior to all of the other nonestrogen treatments, so including this as one of the CMA treatment strategies was important.

The combination of ergotamine, belladonna, and phenobarbitol is approved for the treatment of menopausal hot flashes and associated insomnia (Kronenberg, 1994a). Although this medication showed a significant reduction in the mean number of subjectively reported hot flashes among a group of 66 women with hot flashes during the first four weeks of treatment, after eight weeks, the combination product was not superior to placebo (Bergmans, Merkus, Corbey, Schellekens, & Ubachs, 1987). These authors concluded that this medication works quickly to reduce menopausal symptoms and that a placebo may need more time to achieve the same effect. Because the combination product contains phenobarbitol, this medication is sedating and potentially addictive.

Since the development of the CMA program, some studies have evaluated additional prescription and over-the-counter pharmacologic treatments for hot flashes, including vitamin E, in randomized, placebo-controlled trials involving breast cancer survivors (Barton et al., 1998); venlafaxine, a centrally acting selective serotonin and norepinephrine reuptake inhibitor (Loprinzi et al., 2000); soy isoflavones (Quella et al., 2000); and black cohosh (Jacobson et al., 2001). Of these interventions, only the venlafaxine significantly reduced self-reported hot flashes compared to a placebo (Loprinzi et al., 2000). Although venlafaxine was not used in the CMA intervention program reported here, it could be added to the list of potential hot flash treatment strategies.

Vaginal Dryness and Atrophy

Symptom experience: Vaginal symptoms, such as dryness, itching, irritation, pain during intercourse, or decreased lubrication at the time of sexual activity, are common among postmenopausal women (Bachmann, 1994). The symptoms of vaginal dryness may or may not be associated with physical examination findings of epithelial pallor, petechiae, tissue friability, or absence of rugae (Greendale, Zibecchi, et al., 1999). The prevalence of vaginal symptoms ranges from 25%–47% in samples of postmenopausal women (Dennerstein et al., 2000) compared to 36%–48% in postmenopausal women treated for breast cancer (Carpenter & Andrykowski, 1999; Couzi et al., 1995).

Vaginal dryness is associated with painful intercourse and decreased sexual desire (Bachmann, 1994). In a series of studies involving two large, independent cohorts of breast cancer survivors, researchers examined the frequency of vaginal dryness in survivors and the relation between this symptom and sexual health and functioning (Ganz, Desmond, Belin, Meyerowitz, & Rowland, 1999; Ganz, Rowland, Desmond, et al., 1998; Meyerowitz, Desmond, Rowland, Wyatt, & Ganz, 1999). To summarize, vaginal dryness occurs with higher frequency in breast cancer survivors than in healthy comparison samples (Ganz, Rowland, Desmond, et al.; Meyerowitz et al.); increases in reported frequency when chemotherapy treatment has been given (Ganz et al., 1999; Ganz, Rowland, Meyerowitz, et al., 1998); is associated with decreased sexual interest and satisfaction and increased sexual dysfunction (Ganz et al., 1999); and was a significant predictor of sexual dysfunction in two independent samples of breast cancer survivors that controlled for multiple variables (Ganz et al., 1999). Thus, although vaginal dryness may be a troubling symptom to postmenopausal breast cancer survivors, independent of whether they are engaging in sexual intercourse, the presence of this symptom is related strongly to sexual dysfunction in those who are sexually active. The predictors of sexual dysfunction in breast cancer survivors are similar to those described in healthy postmenopausal women (Greendale, Hogan, & Shumaker, 1996).

Factors that might be associated with or aggravate the symptoms of vaginal dryness have received little attention. Anecdotally, symptoms of vaginal dryness may be aggravated by antihistamines, perfumes, powder, soaps, deodorants, panty liners, spermicides, lubricants, tight clothing, and undergarments made of synthetic fabrics (Beard, 1992). Tamoxifen, a selective estrogen-receptor modulator, causes vaginal discharge, not dryness (Day et al., 1999). Although tamoxifen has antiestrogen effects on the breast, it has been shown to have

estrogen-like effects on the vagina and endometrium (Lahti et al., 1994). To assess the estrogenic effects of tamoxifen on vaginal epithelium, Lahti et al. compared the degree of squamous cell maturation in Pap tests of 46 postmenopausal women with breast cancer on tamoxifen and 45 women with breast cancer not on tamoxifen. These researchers found fewer parabasal cells and more intermediate and superficial cells (indicating greater estrogen effect) in the tamoxifen group compared to the control group.

Management and outcomes: Systemic and topical estrogens are effective treatments for symptoms of vaginal atrophy (Bachmann, 1994; Greendale, Lee, et al., 1999; Pandit & Ouslander, 1997). Replens™ (LDS Consumer Products, Cedar Rapids, IA) reduces the symptoms of vaginal dryness in breast cancer survivors (Loprinzi et al., 1997). In a randomized, controlled trial of 45 women with a history of breast cancer and vaginal dryness or itching, Loprinzi et al. (1997) compared the effects of Replens and a placebo lubricating product and found that the intravaginal use of Replens and the placebo lubricating product decreased subjectively reported vaginal dryness by 64% and 62%, respectively, and improved dyspareunia scores by 60% and 41%, respectively. Side effects were reported frequently in this study, including local burning, irritation, itching, or discharge.

The estradiol vaginal ring (Estring™, Pharmacia Inc., Kalamazoo, MI), a slow-release preparation of estradiol that is embedded in a silicone ring, was approved for the treatment of vaginal atrophy after the CMA program was developed. The estradiol vaginal ring is inserted into the vagina (similar to a diaphragm) and remains in place for three months (Henriksson, Stjernquist, Boquist, Cedergren, & Selinus, 1996; Smith, Heimer, Lindskog, & Ulmsten, 1993). Serum estradiol is elevated in the first few days, but levels drop and are in the extremely low or undetectable range subsequently (Henriksson et al.; Smith et al.).

Stress Urinary Incontinence

Symptom experience: Urinary incontinence is defined as the involuntary loss of urine in sufficient amounts or frequency to be a social or health problem (Fantl et al., 1996). Although the relationship between menopause and urinary incontinence is uncertain (Greendale, Lee, et al., 1999), the prevalence of urinary incontinence in samples of postmenopausal women ranges from 14%–56% (Brown et al., 1999; Dennerstein et al., 2000). A number of changes occur in the lower urinary tract around the time of menopause, including atrophy of the bladder trigone, decreased sensitivity of alpha-adrenergic receptors of the bladder neck and urethral sphincter, and thinning of the urethral mucosa, and these may contribute to development of incontinence (Greendale & Sowers, 1997).

Several types of incontinence exist; however, three types account for the majority of incontinence in community-dwelling older adults: stress, urge, or mixed (Burgio & Goode, 1997). Stress incontinence is the involuntary loss of urine during coughing, sneezing, laughing, or other physical activities that increase intra-abdominal pressure (Fantl et al., 1996). This type of incontinence commonly occurs in women whose pelvic floor muscles are weakened or who have impairments of the urinary sphincter muscle (Fantl et al.). Factors associated with stress incontinence include white race, higher body mass index, and higher waist-to-hip ratio (Brown et al., 1999). Urge incontinence is the involuntary loss of urine associated with the strong desire to void (Fantl et al.). Women with urge incontinence more often report urinary frequency and nocturia than women with stress incontinence (Brown et al.). Factors associated with urge incontinence include increasing age, diabetes, and urinary tract infections (Brown et al.). When women present with symptoms of both stress and urge incontinence, the incontinence is called mixed and treatment is based on the one symptom (urge or stress) that is the most bothersome to the woman (Fantl et al.).

Urinary incontinence may exert a substantial negative impact on women's quality of life. Urinary leakage on a regular basis can cause fear of odor and embarrassment as well as require the use of an absorbent pad and modification of daily activities and physical exercise (Naughton & Wyman, 1997). In addition, urinary leakage is a predictor of sexual dysfunction in breast cancer survivors (Greendale et al., 2001).

Management and outcomes: Strategies to manage stress incontinence have included estrogens, alpha agonists, and pelvic muscle exercises (Fantl et al., 1996). Estrogens improve urethral anatomy and tone; however, studies of estrogen used only for stress and urge incontinence have mixed results (Fantl et al.). Alpha agonists increase urethral sphincter tone and, according to a review of seven prospective randomized

Visit 1

Screening History and Physical Examination (duration 45 minutes)

- History (with attention to precautions and contraindications to nonestrogen treatments and other variables or conditions that may influence management of target symptoms)
- Targeted physical examination (including measurement of height, weight, blood pressure, and pulse, as well as evaluation of neck, heart, lungs, breasts, abdomen, and pelvic area)
- Laboratory studies (including Pap test and measurement of vaginal pH for women with vaginal symptoms and a dipstick urinalysis for women with urinary symptoms)
- Instruction in completing symptom diary cards

Visit 2

Comprehensive Menopausal Assessment (duration 45–90 minutes, depending on number of target symptoms and psychosocial problems with which patients wanted help)

- Review of symptom diary cards
- Detailed assessment of each target symptom experience perceived as a problem
- Review of CARES[a] survey
- Individualized education and counseling (about target symptoms and associated responses, lifestyle changes, and nonestrogen treatments, including discussion of potential benefits and side effects of recommended management strategies)
- Decision support therapy, as appropriate
- Psychosocial support and referrals, as appropriate

Visits 3 and 4

Follow-Up (duration 15–30 minutes)

- Monitor side effects, adherence, and response to treatment(s).
- Review of CARES survey
- Adjust, discontinue, or add treatments as appropriate.
- Pelvic examination, as appropriate

Figure 3. Procedures Involved in Implementing the Comprehensive Menopausal Assessment Program

[a] Cancer Rehabilitation Evaluation System, a standardized, self-administered psychosocial questionnaire that was completed by participants at visits two, three, and four, prior to seeing the nurse practitioner

controlled studies of middle-aged, normotensive women, may cause subjective improvement in 20%–60% of patients compared to placebo response (Fantl et al.). Combining estrogen and alpha agonists may be more effective than using alpha agonists alone (Fantl et al.). Although an alpha agonist (phenylpropanolamine) was included among CMA treatment options for stress incontinence, it was not used because the patients who were eligible to use it had hypertension or other medical conditions that contraindicated its use. More recently, phenylpropanolamine was taken off the market because it was associated with an increased risk of hemorrhagic stroke. Pelvic floor (Kegel) exercises reduce urinary incontinence by 56%–95% (Bø, Talseth, & Holme, 1999; Fantl et al.). Protocols providing more intense education and ongoing supervision of pelvic floor exercises have been associated with higher rates of improvement (Fantl et al.). No studies have examined the role of Replens in improving stress incontinence; however, it may decrease stress incontinent episodes by increasing urethral turgor.

The Comprehensive Menopausal Assessment Program

The CMA program consisted of six components: (a) a screening history and physical examination, (b) a structured, comprehensive assessment of three target symptoms (hot flashes, vaginal dryness, and stress urinary incontinence), (c) "tailored" nonestrogen treatments for these symptoms, (d) education and counseling, (e) psychosocial support and referrals, and (f) follow-up. Implementation procedures are described in Figure 3. The program was intended to reduce the frequency and severity of the three target symptoms and the physiologic, psychological, and behavioral responses associated with these symptoms.

Screening History and Physical Examination

The screening history and physical examination were performed to identify the presence of conditions that might require treatments other than specific nonestrogen therapies

Table 1. Contraindications or Precautions and Common Side Effects Associated With Therapies Used in the Comprehensive Menopausal Assessment Program

Symptom	Treatment[a]	Dosage	Contraindications and Precautions	Potential Side Effects
Hot flashes	Transdermal clonidine (Catapress-TTS®, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT)	0.1 mg per day, one patch per week	Blood pressure ≤ 110/70, syncope, symptomatic hypotension, significant heart, peripheral, or cerebral vascular disease, widespread skin disease, concomitant use of central nervous system depressants	Local skin reactions, dry mouth, drowsiness, and others (e.g., constipation, headaches, dizziness)
	Megestrol acetate	20 mg orally twice daily	Thromboembolic event, liver dysfunction or disease, undiagnosed vaginal bleeding	Vaginal bleeding, weight gain, appetite stimulation, chills, mood changes, blood clots, and numbness or tingling in the hands or wrists; may increase severity or frequency of hot flashes for a few days, sometimes longer, in women who are concomitantly taking tamoxifen
	Ergotamine, belladonna, and phenobarbitol	One tablet orally HS	Heart disease such as coronary artery disease or angina, peripheral vascular disease, hypertension, impaired hepatic or renal function, glaucoma, concomitant use of central nervous system depressants	Dry mouth, blurred vision, constipation, dizziness, numbness or tingling in the hands or feet, rapid heartbeat, and mental confusion; may be habit forming
Urinary incontinence	Pelvic muscle exercises, also known as Kegel exercises	15 times per day; increase to 50–100 times per day.	May not be effective in women with a grade III cystocele or in women who have had prior surgery or irradiation to the lower genitourinary tract; require high level of patient motivation and commitment.	None
Vaginal dryness	Lubricants such as Astroglide® (Biofilm, Inc., Vista, CA) and K-Y® Jelly (Pfizer, Inc., New York, NY)	As needed at time of intercourse or one applicator intravaginally HS two times per week	Needs to be applied before or during sexual activity	Vaginal discharge, irritation, and wetness sensation
	Replens™ (LDS Consumer Products, Cedar Rapids, IA)	One applicator intravaginally HS two times per week	None	Vaginal discharge or residue, irritation, and wetness sensation

[a] The specific therapies included in this table reflect evidence-based treatments that were available from 1995–1996, when the comprehensive menopausal assessment was developed. As new, more effective treatments become available, they should be substituted as appropriate.

Note. Based on information from Goldberg et al., 1994; Loprinzi et al., 1997; Quella et al., 1998; and U.S. Pharmacopeial Convention, 1995.

(e.g., a urinary tract or vaginal infection necessitating antibiotics). The history and examination also were performed to identify serious conditions unrelated to menopause. In addition, this procedure focused on specific contraindications or precautions for CMA medications the authors intended to use (see Table 1).

A self-administered medical history questionnaire was completed prior to the initial visit and reviewed by the nurse practitioner at the time of the in-person screening visit. The questionnaire included a self-administered screening survey for depressive symptoms (Burnam, Wells, Leake, & Landsverk, 1988). After the history review was completed, a physical examination and laboratory studies were performed to rule out signs of an underlying condition that would warrant treatment other than the CMA program or contraindicate the CMA medications. Women with uncontrolled depressive symptoms or abnormal findings on physical examination or baseline laboratory studies that were outside the realm of the CMA were referred to their regular healthcare providers for further evaluation and treatment prior to entering the CMA program.

Eligible participants were instructed in the completion of a set of 28-day symptom diary cards, modeled after those used by the North Central Oncology Treatment Group (Goldberg et al., 1994). The diary cards included a definition of the target symptom and a rating scale appropriate to the symptom. For each symptom, the time and duration, severity (from 1 [mild] to 4 [severe]), and degree of interference with daily activities (from 0 [not at all] to 4 [very much]) were recorded. Comments about what participants were doing or feeling when the symptoms occurred could be recorded in an open-ended field. A checklist of physiologic responses (e.g., sweating, redness) associated with hot flashes was completed once on the 28th day of the diary card.

Comprehensive Assessment

The CMA intervention was initiated at the second study visit and consisted of (a) a review of the completed symptom diary cards, (b) a detailed assessment of each target symptom experience(s), and (c) administration and review of a self-administered survey instrument, the Cancer Rehabilitation Evaluation System (CARES) (Schag & Heinrich, 1990).

Review of the diary cards provided a focus for the education and counseling. Initial information about key symptom characteristics (i.e., frequency, duration, timing, perceived intensity, and perceived degree of disruption or distraction) and potential symptom triggers was obtained through this process. Thereafter, a semistructured interview was used to collect expanded information about physiologic, psychological, and behavioral responses associated with target symptoms, their most bothersome aspects, and the extent to which the target symptom(s) and associated responses bothered or disrupted daily functioning. Attention was focused on the onset of target symptom(s), the setting in which symptoms first occurred (e.g., in conjunction with the last menstrual period or during the time of breast cancer diagnosis or treatment), and how symptoms were affected by breast cancer treatments. Potential precipitating and ameliorating factors, including previously attempted symptom management strategies, also were explored.

Finally, to complete the comprehensive assessment, findings from the history, physical examination, and symptom review were integrated with data from CARES. CARES is a self-administered, 139-item survey instrument developed to assess health-related quality of life and rehabilitation needs of people with cancer (Schag & Heinrich, 1990). The system evaluates five major areas of functioning: physical, psychosocial, marital, sexual, and medical interaction. Respondents are asked to rate statements reflecting common problems encountered by people with cancer, such as "I am having difficulty sleeping" on a numerical scale from 0 (not at all) to 4 (applies very much). Problems rated with a three or greater were explored in the interview, with emphasis on any relationship to target symptoms. For example, CARES items related to sexual functioning could be influenced directly by the target symptom of vaginal dryness. Other problems identified on CARES that could be related to target symptoms are listed in Table 2. In the case of problems that were not a target of the CMA program (e.g., joint pain), women were encouraged to address these issues with their primary physician.

Table 2. Items on Cancer Rehabilitation Evaluation System Potentially Related to Vasomotor or Urogenital Symptoms

Target Symptom	Subscale	Item
Hot flashes	Physical activity	Reduction in energy
	Psychological distress	Anxious, depressed, angry, upset, overwhelmed by cancer, and difficulty sleeping
	Cognitive problems	Difficulty concentrating, remembering, and thinking clearly
Vaginal dryness	Sex interest	Does not feel sexually attractive, thinks not sexually attractive to partner, not interested in having sex, and does not think partner interested in sex
	Sexual dysfunction	Frequency of sex decreased, has difficulty becoming sexually aroused or reaching orgasm, and difficulty with lubrication
	Communication with partner	Difficulty talking about feelings
	Affection with partner	Any item
	Body image	Any item
	Miscellaneous	Weight gain or poor bladder control
	Psychological distress	Any item
	Dating	Any item
Stress urinary incontinence	Recreational activities	Not engaged in recreational activities
	Sexual dysfunction	Any item
	Physical activity	Difficulty doing physical activities, such as running

"Tailored" Nonestrogen Treatments

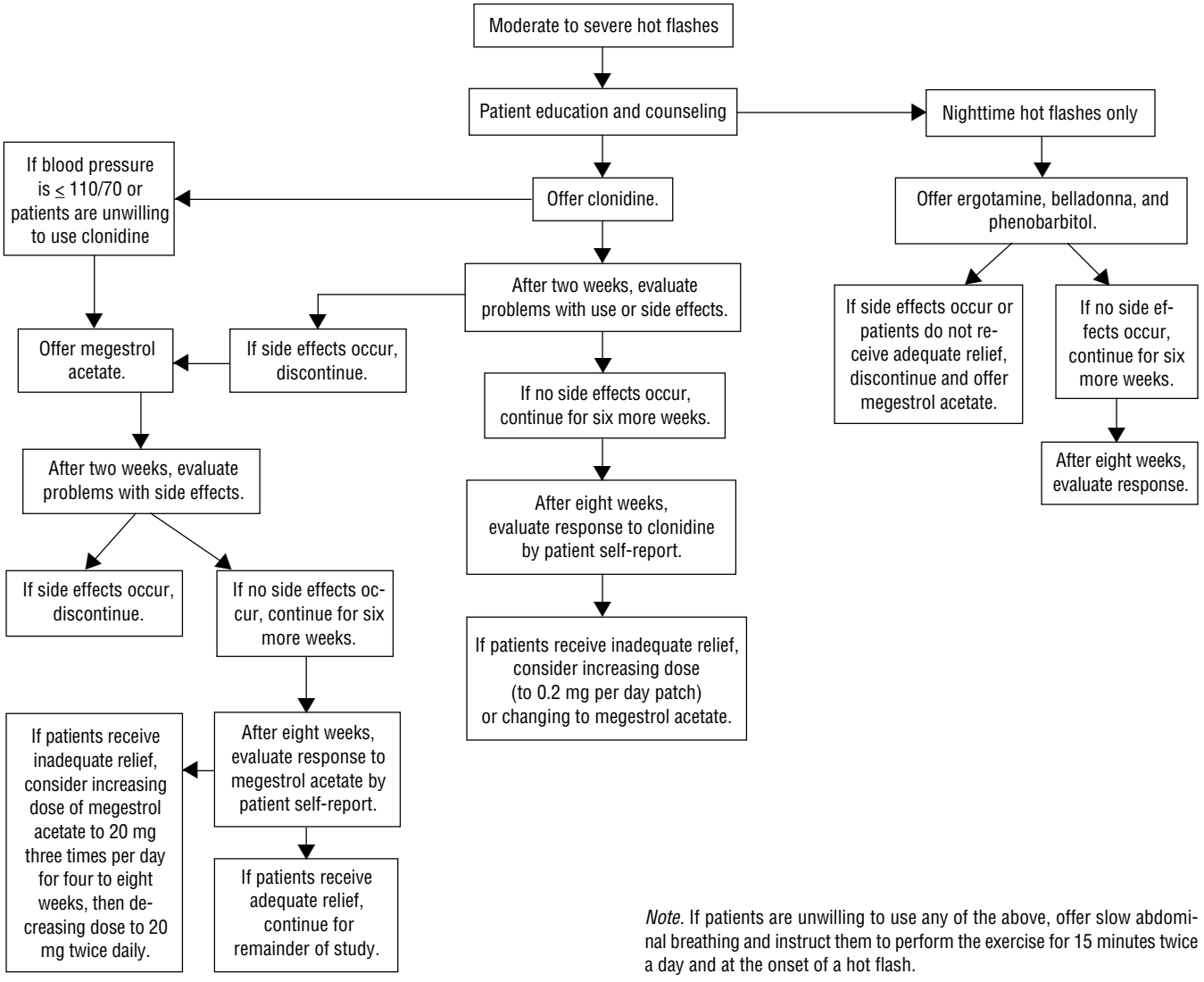
For the randomized trial, a set of treatment protocols was developed for each target symptom. These protocols included specific recommendations regarding the use of nonestrogen over-the-counter products, prescription medications, and behavioral interventions appropriate for each target symptom. The specific treatment algorithms used for hot flashes, vaginal dryness, and stress urinary incontinence are listed in Figures 4, 5, and 6.

Education and Counseling

After the assessment component of the CMA program, women received specific education and counseling designed to provide the information or skills needed to manage symptoms more effectively. The content of the education and counseling was semistructured and adjusted according to each woman's specific symptoms, psychosocial concerns, informational needs (desire for information), and preference for participation in the decision-making process (Ganz, 1995). All women received basic information about the physiology of target symptoms and the specific factors that might influence them, counseling about lifestyle changes that might help reduce target symptoms as well as promote general health, and a folder containing print materials, including several available pamphlets about target symptoms and sexuality after breast cancer, a list of self-help books about psychological and sexual health after breast cancer, and a brochure about a resource center for women with cancer (Ganz et al., 2000).

After lifestyle counseling, women were offered specific pharmacologic or behavioral interventions for each of the target symptoms for which they desired intervention. To help women make informed decisions about the recommended symptom management strategies, written materials[a]

[a] *Available from the authors on request.*



Note. If patients are unwilling to use any of the above, offer slow abdominal breathing and instruct them to perform the exercise for 15 minutes twice a day and at the onset of a hot flash.

Figure 4. Comprehensive Menopausal Assessment Protocol for Managing Hot Flashes

Note. The specific therapies included in this figure reflect evidence-based treatments that were available from 1995–1996, when the comprehensive menopausal assessment was developed. This algorithm reflects a strategy for approaching this symptom. As new, more effective treatments become available, they should be substituted as appropriate.

were developed describing their potential benefits, side effects, and use (except slow abdominal breathing, for which only verbal instructions and demonstration were given) as suggested by Rothert et al. (1997). Each woman was given an opportunity to ask questions or express concerns about the specific symptom management strategy or strategies that had been offered.

Based on the framework of O'Connor (1997), several interventions were used to assist informed decision making about

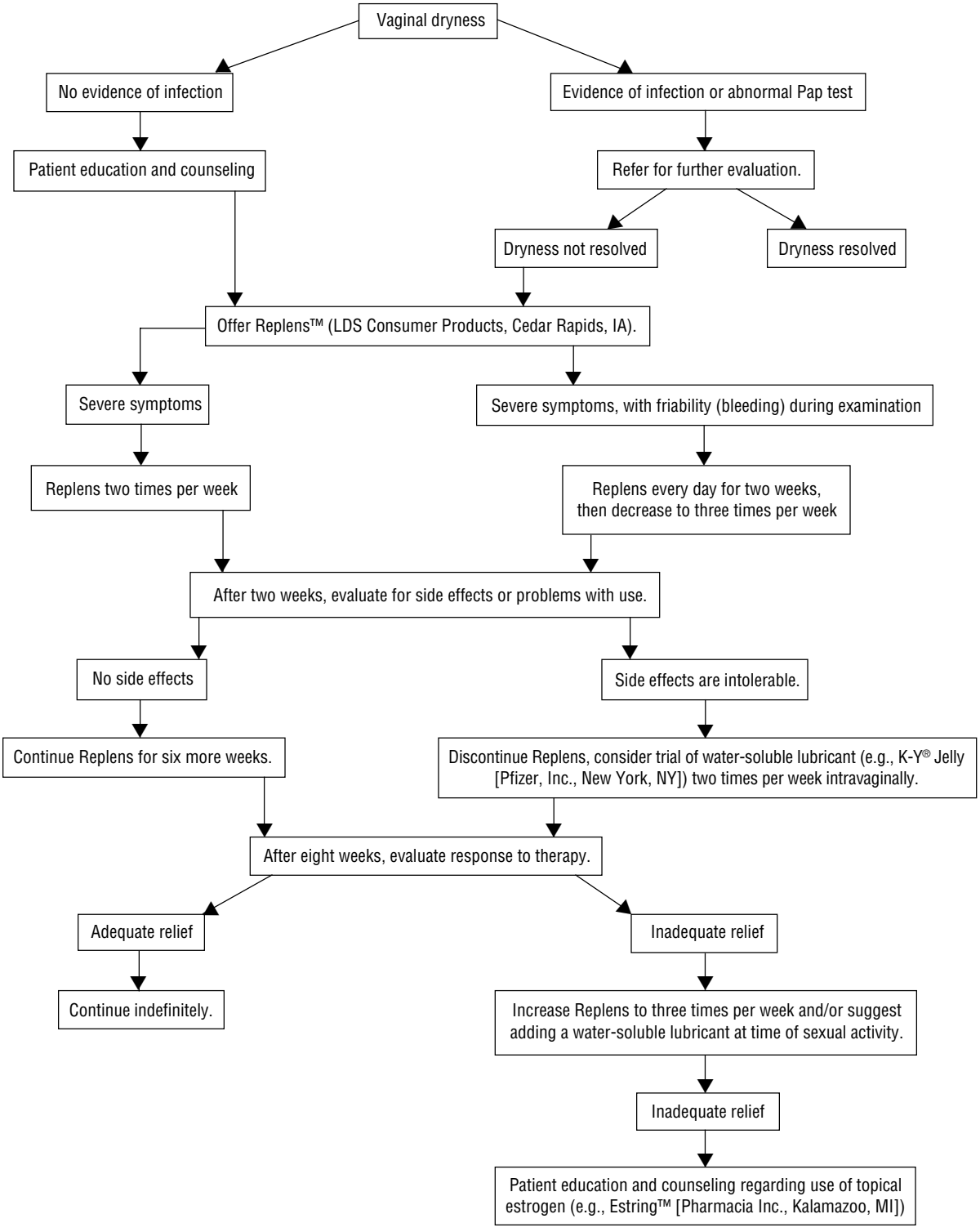


Figure 5. Comprehensive Menopausal Assessment Protocol for Managing Vaginal Dryness

Note. The specific therapies included in this figure reflect evidence-based treatments that were available from 1995–1996, when the comprehensive menopausal assessment was developed. This algorithm reflects a strategy for approaching this symptom. As new, more effective treatments become available, they should be substituted as appropriate.

recommended symptom management strategies, including (a) helping patients weigh the personal benefits (e.g., reduction in frequency and severity of hot flashes and associated physiologic, psychological, and behavioral responses) and personal costs (e.g., likelihood of developing side effects) associated with each specific strategy and addressing any misconceptions, especially about the likelihood of side effects, (b) delaying decision making to allow others to be involved (e.g., primary care physicians, oncologists, partners, friends) (O'Connor, Tugwell, Elmslie, & Jolly, 1996), and (c) using low starting doses that could diminish medication side effects. Women who decided to use a pharmacologic strategy were given a 10-week supply of medication.

Psychosocial Support and Referrals

The psychosocial component of the CMA intervention involved education and lifestyle counseling. The component consisted of identifying psychosocial problems using the CMA assessment and the CARES instrument, determining whether

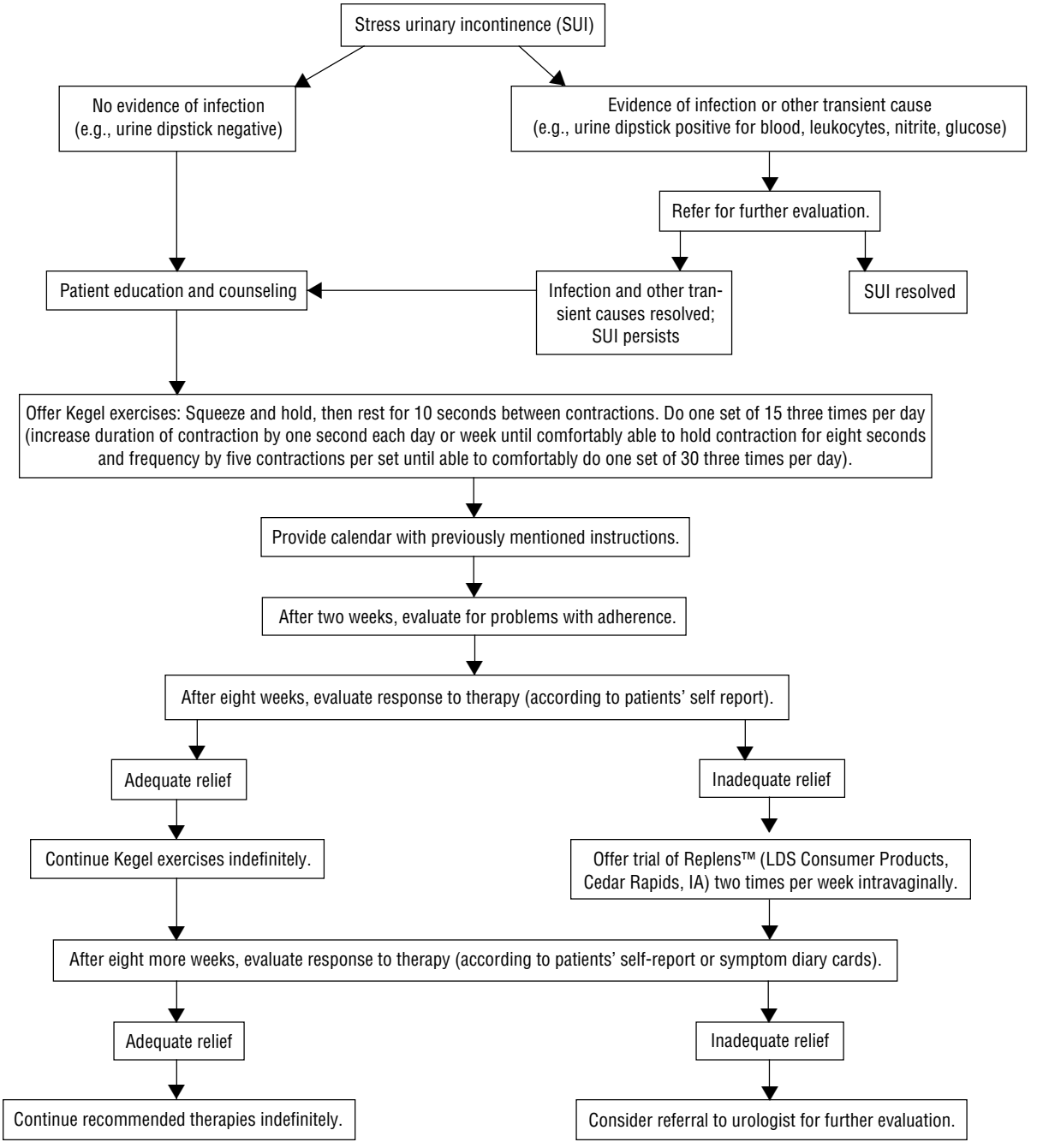


Figure 6. Comprehensive Menopausal Assessment Protocol for Managing Stress Urinary Incontinence

Note. The specific therapies included in this figure reflect evidence-based treatments that were available from 1995–1996, when the comprehensive menopausal assessment was developed. This algorithm reflects a strategy for approaching this symptom. As new, more effective treatments become available, they should be substituted as appropriate.

the women wanted help with psychosocial problems, listening to what the women said about the problems, exploring any potential relationship or effect on target symptoms (e.g., psychological distress with hot flashes, vaginal dryness with sexual dysfunction), and providing information, reassurance, or referral to self-help or professional resources, as appropriate.

Follow-Up and Monitoring of Symptoms and Side Effects

The purpose of follow-up was to monitor for side effects and evaluate response to treatment. Two weeks after the intervention, the authors telephoned participants to assess potential side effects, problems with the recommendations, and adherence. Because some of the treatments could take up to eight weeks to maximally control symptoms, response to treatment was evaluated at an interim visit at two months and a final visit at four months. The authors determined whether the target symptoms had decreased in frequency, severity, or bother based on participants' self-reports. An important aspect of the CMA intervention, unlike some research designs that test the efficacy of single medication dose or behavioral strategy, was the ability to increase or decrease the dose of medication or switch to an alternate intervention during the follow-up period, thus allowing tailoring to individuals' responses and experiences.

Discussion

A systematic, comprehensive approach to evaluating and managing three vasomotor and urogenital symptoms such as the one described in this article may help symptomatic breast cancer survivors more effectively manage these symptoms than they could with usual care. The CMA program offered women an array of nonpharmacologic and pharmacologic symptom management strategies, as well as individualized education, counseling, and psychosocial support. Several of the women in the CMA program previously tried one or more symptom management strategies but still were symptomatic enough to desire additional information and treatment (Ganz et al., 2000). Thus, this program demonstrated that nurses can play a key role in identifying, educating, treating, and counseling breast cancer survivors with vasomotor and urogenital symptoms. Nurses could implement all or parts of the CMA program, offering it to individuals or groups in a variety of settings, including comprehensive breast centers, women's health centers, and oncology, gynecology, or primary care settings.

The CMA program was time intensive in part because the design of the research protocol did not permit education and counseling to occur at the time of the first visit. The authors believe that a streamlined CMA program could be implemented during two 40-minute visits. A two-visit model is recommended for clinical practice so that the first assessment can initiate a period of self-monitoring prior to the second visit. This component of interim self-assessment is central to the development of an individualized treatment plan and may be therapeutic in itself. In the office setting, the initial CMA visit for a new patient could include a screening history, physical examination, and psychosocial evaluation. For a known patient, the initial CMA visit could consist of a briefer, more targeted history and physical examination, an in-depth assessment of symptoms, and a psychosocial evaluation. Depending on their symptoms, patients then could be offered some basic education, general lifestyle counseling, and instruction in the completion of symptom diary cards, as appropriate. The second visit could include a review of the symptom diary cards, more specific lifestyle counseling, a discussion of available treatment options, and decision support therapy. Patients seen by nurses with or without limited prescriptive privileges could be referred to their primary care providers or oncologists for further follow-up with a summary of possible treatment recommendations based on the CMA. When feasible, nurses should initiate the pharmacologic treatments. Nurses also could follow-up with patients via telephone.

A major focus of the CMA program was the assessment of key symptom characteristics such as frequency and severity; other components of the symptom experience such as associated physiologic, psychological, and behavioral responses; and the degree of bother or disruption caused by the symptom. Experiences related to vasomotor and urogenital symptoms, as well as the individual judgments made about these experiences, vary enormously among women in general. In the current study's sample of 76 patients, several women minimized the severity and degree of bother associated with one symptom in particular—hot flashes. These women reported that their hot flashes were not severe, even if they were associated with physical discomfort or disrupted activities, or that they did not let their hot flashes bother them and "they just kept going." Many had tried a number of symptom management strategies on their own but still desired information about a trial of CMA symptom management strategies. Thus, a comprehensive assessment that takes into account patients' description and evaluation of their symptom experiences and associated responses, as well as personal, environmental, menopause, and breast cancer-related variables, may assist clinicians in tailoring available symptom management strategies to the individual needs and preferences of breast cancer survivors with symptoms of menopause.

Furthermore, tailoring educational and counseling interventions to each patient's need for information and desired degree of participation in the decision-making process may be important. Available evidence-based strategies that do not involve estrogen to manage vasomotor and urogenital symptoms have varying benefits, side effects, and risks. Many breast cancer survivors are averse to using hormones or any medications after a cancer diagnosis, especially when the symptom or problem is not life threatening and the treatment has potential side effects. Others may not share these concerns. Providing individualized education about symptoms and symptom management strategies, both verbally and in writing, and offering women choices among strategies may assist women in making informed decisions about treatment options and ultimately contribute to more effective management of their menopausal vasomotor and urogenital symptoms.

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