



## Differences in symptom clusters before and twelve months after breast cancer surgery



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### ABSTRACT

**Purpose:** Given the inter-relatedness among symptoms, research efforts are focused on an evaluation of symptom clusters. The purposes of this study were to evaluate for differences in the number and types of menopausal-related symptom clusters assessed prior to and at 12-months after surgery using ratings of occurrence and severity and to evaluate for changes in these symptom clusters over time.

**Methods:** Prior to and at 12 months after surgery, 392 women with breast cancer completed the Menopausal Symptoms Scale. Exploratory factor analyses were used to identify the symptom clusters.

**Results:** Of the 392 women evaluated, the mean number of symptoms (out of 46) was 13.2 ( $\pm$  8.5) at enrollment and 10.9 ( $\pm$  8.2) at 12 months after surgery. Using occurrence and severity, three symptom clusters were identified prior to surgery. Five symptom clusters were identified at 12 months following surgery. Two symptom clusters (i.e., pain/discomfort and hormonal) were relatively stable across both dimensions and time points. Two symptom clusters were relatively stable across both dimensions either prior to surgery (i.e., sleep/psychological/cognitive) or at 12 months after surgery (i.e., sleep). The other four clusters (i.e., irritability, psychological/cognitive, cognitive, psychological) were identified at one time point using a single dimension.

**Conclusions:** While some menopausal-related symptom clusters were consistent across time and dimensions, the majority of symptoms clustered together differently depending on whether they were evaluated prior to or at 12 months after breast cancer surgery. An increased understanding of how symptom clusters change over time may assist clinicians to focus their symptom assessments and management strategies.

### 1. Introduction

Prior to and following breast cancer treatment women experience multiple co-occurring menopausal-related symptoms (Barton and Ganz, 2015; Howard-Anderson et al., 2012). Most of this research has focused on descriptions of single menopausal-related symptoms (e.g., hot flashes) during or after chemotherapy (CTX) and/or endocrine therapy (ET) in breast cancer survivors. Given the inter-relatedness among symptoms, current research efforts are focused on an evaluation of symptom clusters (Glaus et al., 2006; Marshall et al., 2016; Seib et al., 2017).

A symptom cluster is defined as a group of two (Kim et al., 2005) or more (Dodd et al., 2001) concurrent symptoms that are related to one another through a common etiology, mechanism, variance, or outcome

(Barsevick, 2016; Miaskowski et al., 2007, 2017). The identification of differences in the number and types of menopausal-related symptom clusters before and after breast cancer treatment may assist clinicians to focus both their assessments and management strategies. For example, rather than treating a single symptom, clinicians may be able to target several symptoms within a cluster (Kwekkeboom et al., 2012) and minimize the need for women to take multiple medications. For example, in a recent study (Lengacher et al., 2017), a mindfulness-based stress reduction intervention improved the severity of several symptoms within a psychological/cognitive symptom cluster. Given that relative to single symptoms, symptom clusters are associated with poorer functional status and quality of life (QOL) (Kim et al., 2012), management of several symptoms within a cluster may improve patient outcomes. Moreover, the identification of menopausal-related symptom

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clusters may suggest a common etiology for symptoms within a cluster.

In women with breast cancer, the majority of the research on symptom clusters has evaluated common symptoms associated with cancer treatment using instruments like the Memorial Symptom Assessment Scale (MSAS) (Portenoy et al., 1994) or the MD Anderson Symptom Inventory (MDASI) (Cleeland et al., 2000) (for review see (Nguyen et al., 2011)). While both the MSAS and MDASI include some symptoms that would be found on a menopausal symptom inventory like the Menopausal Symptom Scale (MSS) (Radtko et al., 2011), neither instrument assess for hot flashes, the most commonly reported menopausal-related symptom in women with (Gupta et al., 2006) and without (Woods and Mitchell, 2005) breast cancer.

In studies of individual symptoms, breast cancer patients reported bothersome symptoms prior to and following surgery and that these symptoms had a negative impact on their QOL (Denieffe et al., 2014). Yet, with the major focus on the identification of symptom clusters during treatment, no studies were identified that evaluated for menopausal-related symptom clusters prior to breast cancer surgery. Only three cross-sectional studies (Glaus et al., 2006; Marshall et al., 2016; Seib et al., 2017) evaluated for menopausal-related symptom clusters following breast cancer treatment (Supplementary Table 1). In the first study that evaluated breast cancer patients on ET, a single symptom cluster was found using symptom occurrence rates from the Clinical Checklist for Patients with Endocrine Therapy (C-PET) (Glaus et al., 2006). This single ‘menopausal’ cluster included: hot flashes, weight-gain, tiredness, reduced sexual interest, and vaginal dryness.

In the second study that evaluated breast cancer survivors 8 months after their cancer diagnosis (Marshall et al., 2016), menopausal-related symptom clusters were derived from the Women's Health Initiative Checklist. Five clusters were identified using dichotomous ratings of severity. These five clusters varied slightly depending on whether moderate and severe (i.e., menopausal, pain, fatigue/sleep/gastrointestinal (GI), psychological, increased weight/appetite) or severe (i.e., menopausal, pain, fatigue/psychological/GI, GI, increased weight/appetite) symptoms were evaluated. In addition, menopausal-related symptom clusters were evaluated using symptom data derived from messages on a breast cancer forum. The four clusters identified from the social media data were: pain/fatigue, menopausal/psychological, GI, and miscellaneous.

The third study compared menopausal-related symptom clusters in women with and without breast cancer (Seib et al., 2017). The symptom clusters were using the severity scores from the Greene Climacteric Scale. In the women with breast cancer, the following symptom clusters were identified: psychological, vasoactive, sensory somatic, peripheral somatic, nervous tension, and general somatic. With the exception of the general somatic symptom cluster, the same clusters were identified in women without breast cancer. However, the specific symptoms within each of the five clusters varied between these two groups of women. Across these three studies of breast cancer survivors (Glaus et al., 2006; Marshall et al., 2016; Seib et al., 2017), the menopausal-related cluster was the only consistent symptom cluster identified in patients with breast cancer. Within this cluster, hot flashes was the only consistent symptom.

While these three studies provide preliminary evidence of menopausal-related symptom clusters in breast cancer survivors (Glaus et al., 2006; Marshall et al., 2016; Seib et al., 2017), several limitations warrant consideration. The instruments and dimensions used to evaluate for symptom clusters were not consistent. In addition, all three studies evaluated for symptom clusters using only a single dimension of the symptom experience (i.e., occurrence (Glaus et al., 2006) or severity (Marshall et al., 2016; Seib et al., 2017)). Finally, time since cancer diagnosis (Glaus et al., 2006; Marshall et al., 2016; Seib et al., 2017), demographic and clinical characteristics (Marshall et al., 2016), and specific cancer treatments (Seib et al., 2017) were not reported. These limitations make it difficult to compare findings across these three studies.

Given these limitations and the paucity of research on menopausal-related symptom clusters in women prior to and following breast cancer surgery, the purposes of this study, in a sample of breast cancer patients, were to: evaluate for differences in the number and types of menopausal-related symptom clusters assessed prior to and at 12-months after surgery using ratings of occurrence and severity and to evaluate for changes in these symptom clusters over time. Given that the occurrence and severity of menopausal-related symptoms vary over the course of treatment (Ganz et al., 2011), we hypothesized that the number and types of symptom clusters would differ over time but not by dimension.

## 2. Methods

This study is part of a larger descriptive, longitudinal study that evaluated neuropathic pain and lymphedema in women who underwent breast cancer surgery. The methods for this study are described in detail elsewhere (Doong et al., 2015; Kyranou et al., 2013; Langford et al., 2014; McCann et al., 2012; Van Onselen et al., 2013). In brief, patients were recruited from Breast Cancer Centers located in a Comprehensive Cancer Center, two public hospitals, and four community practices. Eligibility criteria included: adult women ( $\geq 18$  years) who were scheduled for unilateral breast cancer surgery; were able to read, write, and understand English; agreed to participate; and provided written informed consent. Patients were excluded if they had bilateral breast surgery and/or had distant metastases at the time of diagnosis.

### 2.1. Instruments

The demographic questionnaire obtained information on age, education, ethnicity, marital status, employment status, living situation, and financial status. Menopausal status was determined by the patient's response (yes/no) at the time of enrollment to the question “Have you gone through menopause yet (stopped having your menstrual cycle)?”. Patients were asked to indicate if they exercised on a regular basis (yes/no). The Karnofsky Performance Status (KPS) scale was used to evaluate functional status. Patients rated their functional status using the KPS scale that ranged from 30 (I feel severely disabled and need to be hospitalized) to 100 (I feel normal; I have no complaints or symptoms). The KPS scale has well established validity and reliability (Karnofsky et al., 1948).

The Self-Administered Comorbidity Questionnaire (SCQ) is a short and easily understood instrument that was developed to measure comorbidity in clinical and health service research settings (Sangha et al., 2003). The questionnaire consists of 13 common medical conditions that were simplified into language that could be understood without any prior medical knowledge. Patients indicated if they had the condition; if they received treatment for it (proxy for disease severity); and if it limited their activities (indication of functional limitations). SCQ scores can range from 0 to 39. The SCQ has well established validity and reliability and has been used in studies of patients with a variety of chronic conditions (Brunner et al., 2008; Cieza et al., 2006).

The Menopausal Symptoms Scale (MSS) was modified from the Seattle Women's Health Study questionnaire (Woods et al., 1999). The MSS evaluated the occurrence, severity, and distress of 46 menopausal-related symptoms. Patients were asked to indicate whether they experienced each symptom during the past week (i.e., symptom occurrence). If they experienced the symptom, they were asked to rate its severity and distress. Symptom severity was rated using a 0 (none) to 10 (intolerable) numeric rating scale (NRS). The MSS has well established validity and reliability (Woods et al., 2014).

### 2.2. Study procedures

The study was approved by the Committee on Human Research at the University of California, San Francisco and by the Institutional

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