Validation of the MENQOL for use with women who have been treated for gynecologic or breast cancer

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ABSTRACT

Purpose: To conduct a psychometric evaluation of the MENQOL, a condition-specific, self-report instrument to assess menopausal symptoms in women with gynecologic and breast cancers.

Methods: Identify face and content validity of the MENQOL with experts, and reliability and construct validity with a group of women diagnosed with cancer who are suffering from treatment-induced menopause.

Results: Eighty-two women with treatment-induced menopause completed the MENQOL, EORTC-C30, and the SVQ. The MENQOL was shown to have good face and content validity, and acceptable reliability (homogeneity and test-retest) and validity (concurrent and construct). Additionally, 85.5% of the women reported experiencing hot flashes. However, the most bothersome symptoms were weight gain and fatigue (feeling worn out).

Implications: The MENQOL can be used to assess treatment-induced menopausal symptoms in women diagnosed with breast or gynecologic cancer.

INTRODUCTION

Cancer and its treatment have more than a physical impact. There are social, emotional, psychological and spiritual consequences, as well (Fitch, 2000). For women diagnosed with gynecologic or breast cancer, treatment-induced menopause may be a side effect they experience that has varying degrees of influence on quality of life (Davis, Zinkand & Fitch, 2000). It is important from a clinical perspective to be able to measure the impact of treatment-induced menopause with a standardized instrument that is reliable and valid for the population of concern. Standardized measurement allows for easy monitoring and documentation over time, as well as identification of individuals experiencing side effects and quality-of-life issues. In this study, we completed a psychometric evaluation of the Menopause-Specific Quality of Life Questionnaire (MENQOL) in women experiencing cancer treatment-induced menopause.

BACKGROUND

With natural menopause, the ovaries can continue to produce testosterone and androstenedione, which are converted to estrogen peripherally, for many years after menopause (Society of Obstetricians and Gynecologists of Cancer, 2006). Treatment-induced menopause, whether from surgery, radiation, or chemotherapy, is unlike natural menopause in that ovarian sources of androgen and estrogen are removed prematurely and simultaneously. Hormone levels fall dramatically, typically resulting in more sudden and severe symptoms (North American Menopause Society [NAMS], 2007). Each of these changes could have an influence on dimensions of quality of life including relationships, sexual satisfaction, self-esteem, emotional well-being, and capacity to return to work (Davis et al., 2000; Howell, Fitch & Deane, 2003; Cebeci, Yangin, & Tekeli, 2010; Abbott-Anderson & Kweekeboom, 2012).

It is important in clinical practice to be able to easily identify the women who are feeling a significant impact on their quality of life because of treatment-induced menopause. Having a reliable, valid measurement tool is imperative for consistent and correct assessment, as well as monitoring over time. The tool must also be easily administered and scored if it is to be used in a busy ambulatory setting, with relatively little response burden for the women.
The Menopause-Specific Quality of Life (MENQOL) was developed as a tool to measure the impact of menopause in a population of women who had undergone menopause as a natural life event (Hilditch et al., 1996). Women with a diagnosis of gynecologic or breast cancer may undergo treatment that will, in all likelihood, render them menopausal. It has been suggested that side effects and symptoms are more intense when menopausal change happens as a treatment-induced alteration. Additionally, cancer treatment may have other side effects and can have an impact on quality of life. This could result in elevated scores on a measurement tool that had originally been developed and validated for a general population. In particular, somatic items could contribute to the elevation of scores. Thus, it is important to validate the tool in a cancer population prior to its use in routine clinical practice.

**PURPOSE**

This study was undertaken to validate the psychometric properties of the condition specific MENQOL for use in a population of women treated for gynecologic or breast cancer who had experienced treatment-induced menopause. Once validated for this population, the instrument can be used as a foundation for providing person-centred care and tailoring the care for women suffering from this potentially debilitating side effect.

**METHODS**

A psychometric evaluation of the MENQOL was designed to assess its reliability (test-retest and internal consistency) and validity (face, content and construct) in women treated for gynecologic or breast cancer who had experienced treatment-induced menopause. Eligibility criteria included the following: a confirmed diagnosis of gynecologic or breast cancer, minimum of two months post-cancer treatment, experienced menopause as a result of the cancer treatment, 18 years of age or older, and able to read and understand English. If women had had hormone replacement therapy within the three months prior to accrual they were excluded from participation. Ethics approval for this study was granted by the Sunnybrook Health Sciences Centre Research Ethics Committee.

As a first step, face and content validity were evaluated. Face validity was assessed by purposefully selecting 10 women who met the eligibility criteria and asking them to review the MENQOL instrument and answer the following question: “How well do you think this tool measures a woman’s quality of life after she has experienced treatment-induced menopause because of her cancer treatment?” Their response was recorded on a five-point response Likert item. The response options ranged from “0” (not at all) to “4” (very well). Any additional comments the women wanted to offer about the tool and the instruments were captured in an open comment item.

Content validity was assessed by purposefully selecting a cross-section of 10 experts in cancer care, quality of life, gynecologic or breast cancer treatment, or treatment-induced menopause and asking them to review the MENQOL. Specifically, they were asked to indicate if there were important omissions or inappropriate items when considering the gynecologic or breast cancer populations and treatment-induced menopause. If a particular item was recommended for addition or deletion, participants were asked to record the reasons for their suggestions.

Reliability and construct validity were assessed in a sample of 82 women attending a large ambulatory comprehensive cancer clinic. A cross-sectional, convenience sample of women who met the eligibility criteria was accrued and asked to complete measurement instruments on two occasions. At Time 1, women completed the following instruments: Demographic Items (age, time since diagnosis, education, marital status, treatment), MENQOL (menopause quality of life), EORTC-C30 (quality of life), JENSEN – SVQ (sexual function – vaginal changes questionnaire), and visual analogue scale for hot flushes. Two weeks later, at Time 2, the women completed the MENQOL and the visual analogue scale for hot flushes. The sample size was determined on the basis of requiring at least five participants per questionnaire or scale item (Nunnally, 2006).

Women were accrued in an outpatient cancer clinic. Initially, a nurse approached the women and determined if they met the criteria for the study and were interested in speaking with the research co-ordinator. The co-ordinator followed up with any women who expressed interest in the study, described what participation involved, and sought their informed consent. Women completed the questionnaires in the clinic during the appointment time. Those who were not scheduled to return to the clinic in the two-week time interval were given an envelope to take home containing the MENQOL, visual analogue scale, and a prepaid return envelope in which to mail back their completed second survey.

**Instruments**

The Menopause-specific Quality of life Questionnaire (MENQOL) was designed as a condition-specific quality-of-life measure (Hilditch, Lewis, Peter, van Maris, Ross, Franssen et al., 1996). It is a self-administered instrument designed from the experiences of women with menopause. It was developed with women two to seven years post-menopause with a uterus and not currently on hormone replacement therapy. It has 30 items covering four domains (i.e., subscales of vasomotor, physical, psychosocial, sexual) and a global quality-of-life question. Each item asked the women whether or not they are experiencing a specific issue (e.g., hot flushes, difficulty sleeping, vaginal dryness) and, if so, how bothered are they by it (rated on a Likert-type scale of 0–6). Face content and construct validity have been reported in addition to reliability and responsiveness. Test-retest coefficients for subscales ranged from 0.55 to 0.81 and the scale discriminates between women according to their quality of life.

The EORTC QOL-C30 is an instrument designed to measure quality of life in cancer populations. The content areas covered by this questionnaire reflect the multi-dimensionality of the quality-of-life construct. This questionnaire...
The analysis for the content validity assessment consisted of collating and summarizing the responses regarding each item and any written responses.

The internal consistency of the MENQOL was determined by calculating Cronbach’s alpha for the respective subscales using the data from Time 1. Test-retest reliability was calculated by applying Pearson Product Moment Correlation Formula to the MENQOL subscale data from Time 1 and Time 2. The linear analogue data were used to determine if significant changes occurred in the intensity of hot flushes between Time 1 and Time 2 (paired t-test).

Construct validity was assessed using data from Time 1. The results from the MENQOL subscales were compared to the respective results from the subscales of the EORTC-C30 and the SVQ using the Pearson Product Moment Correlation Formula. It was anticipated that the performance on the subscales for the MENQOL would be similar to the performance on the same subscales for the other two instruments and the calculated correlation coefficients would be significant (p<0.05).

RESULTS
Sample
A total of 82 women participated in this study. The mean age was 47 years with a range of 29 to 58. Seventy-three percent were married and 73% had completed college or university education. On average, the women were 33 months post diagnosis. Three-quarters (75.6%) had been diagnosed with breast cancer and the remainder with gynecologic cancer. Sixty percent had received chemotherapy, 37% had received radiation therapy, and 17% had undergone surgery. All had experienced menopause, as a result of their cancer treatment. The mean rating on the hot flushes linear analog was 2.09 (standard deviation = 0.95) at Time 1 and 1.98 (standard deviation = 0.87) at Time 2. No statistical difference was observed.

Face Validity
The ten women who reviewed the MENQOL indicated all items were appropriate in light of their experiences with treatment-induced menopause. None of the women suggested making any changes in the instrument. They rated all items as highly relevant to their experiences with treatment-induced menopause.

Content Validity
The 10 healthcare professionals who reviewed the MENQOL included the disciplines of gynecology, gynecologic oncology, general practice (family medicine), and oncology nursing. Each individual indicated the items on the instrument were appropriate and relevant to the situation based on their clinical experience. No one suggested removing or adding specific items.

Reliability
Cronbach’s alphas (internal consistency) for the four MENQOL subscales ranged from 0.88 (sexual) to 0.94 (vasomotor). The test-retest coefficients for the four subscales were calculated using Pearson Product Moment Correlation Formula. The coefficients range from 0.79 (sexual) to 0.89 (vasomotor) and all were significant at p<0.0001 (See Table 1). The visual analogue item measuring hot flushes at Time 1 and Time 2 showed no significant differences (t=1.35, p=0.182) for the two-week time interval.

| Table 1: Mean scores and reliability results for MENQOL subscales |
|-----------------|-----------------|-----------------|-----------------|
| MENQOL Subscale  | Mean (Standard Deviation) | Cronbach’s alpha | Test-retest coefficient* |
| Vasomotor       | 4.76 (2.2)       | 0.94            | 0.89            |
| Sexual          | 4.20 (2.5)       | 0.88            | 0.79            |
| Physical        | 3.84 (1.5)       | 0.91            | 0.84            |
| Psychosocial    | 3.82 (1.8)       | 0.89            | 0.81            |

*p<0.0001
Mean Subscale Scores
The mean bother scores on the MENQOL subscales ranged from 3.82 to 4.76 (highest score is 6). The highest mean bother scores were reported for the vasomotor (4.8) and sexual (4.2) subscales (see Table 1). The mean functioning scores for the EORTC-C30 subscales ranged from 62.1 (emotional) to 86.3 (physical) (see Table 2) (highest scores equal 100). High scores on the EORTC instrument reflect a better level of functioning. The mean scores for the SVQ subscales ranged from 40.1 (sexual satisfaction) to 67.7 (sexual interest) (See Table 2). Higher scores on these subscales reflect fewer difficulties.

Construct Validity
Moderate to high correlations between the physical and psychosocial subscales of the MENQOL and each of the EORTC-Q30 subscales and global health scores were statistically significant and showed negative relationships, as predicted (see Table 3). Correlations were also significant between the EORTC-Q30 emotional and social subscales and the vasomotor and sexual MENQOL subscales. The cognitive EORTC-Q30 subscale and the MENQOL sexual subscale were also correlated.

Moderate positive correlations were observed between the physical and psychosocial MENQOL subscales and the Intimacy SVQ subscale (see Table 4). The MENQOL sexual subscale was positively correlated with the sexual interest subscale and global sexual satisfaction, but was negatively correlated with vaginal changes scores on the SVQ. The physical subscale score on the MENQOL was also positively correlated with global sexual satisfaction and negatively with vaginal changes.

Frequently Identified Issues for Women
The most frequently identified issues experienced by women and endorsed on the MENQOL are listed in Table 5. Experiencing hot flashes (85.5%) and feeling tired or worn out (82.1%) were endorsed most frequently. However, issues listed as most bothersome were slightly different. Table 6 lists the top five issues rated as most bothersome for the women in this study. Physical issues (weight gain, fatigue, difficulty sleeping)
and sexual changes (interest in sex and intimacy) were the issues that resulted in the highest bothersome ratings.

**DISCUSSION**

This work was undertaken to validate the psychometric properties of the condition-specific MENQOL for use in a population of women treated for gynecologic or breast cancer who had experienced treatment-induced menopause. The MENQOL had been designed for use in a general population of women experiencing menopause and needed to be tested in a population of women experiencing menopause as a result of their cancer treatment.

The face and content validity testing did not result in any changes to the tool prior to its application with women in the cancer population. The women who participated had all experienced treatment-induced menopause. Their clinical picture had not changed between the Time 1 and Time 2 completions of the instruments.

The reliability of the MENQOL was acceptable in this cancer population and reflects what has been reported in other psychometric evaluations of this instrument (Hilditch et al., 1996; Radtke, Terhorst & Cohen, 2011). Both homogeneity and test-retest coefficients reached high levels. Additionally, the construct validity reflected anticipated results. There were acceptable correlations between the subscales on the EORTC-30 and MENQOL physical and psychosocial subscales, but not the sexual and vasomotor. This makes sense in light of the identified need to develop the SVQ as a scale to augment the EORTC-30 for use in relation to sexuality issues. Comparison of the SVQ and the MENQOL showed good agreement only between SVQ Intimacy and the MENQOL Physical and Psychosocial subscales. Other subscales are not overlapping. In particular, the MENQOL is unique in measuring the vasomotor items.

Clearly this group of women who had treatment-induced menopause were experiencing a range of symptoms and changes in their sexual lives, which is similar to reports by other investigators (Davis et al., 2000; Cebeci, Yangin, & Tekeli, 2010; Abbott-Anderson & Kwekkeboom, 2012). More than three-quarters reported experiencing hot flashes and fatigue. It is of interest, however, that the most frequently experienced issues were not the same as the issues that were most bothersome. Exactly what makes an issue bothersome bears further investigation. One could imagine that certain clusters of symptoms could be especially bothersome, as well. For example, the combination of night sweats, difficulty sleeping, and feeling tired could be seen as a cluster of symptoms that might have an increased effect over experiencing a single one.

**IMPLICATIONS**

The primary implication from these study results is that the MENQOL can be considered reliable and valid for use in the cancer population of women experiencing treatment-induced menopause. The instrument can be used in daily practice, as a way of providing a baseline assessment when a women experiences treatment induced menopause. It could also provide a way of monitoring changes over time.

The other implication from this work is the need for women diagnosed with cancer and their care providers to be aware of the myriad of symptoms that could be experienced with treatment-induced menopause. Oncology nurses are in an ideal position to help women be prepared for what they might expect and to manage with the subsequent issues. Ongoing communication with patients will about the topic will help to identify any issues early.

Future research ought to focus on finding effective interventions for the symptom clusters for women experience with treatment-induced menopause. Ideally it would be preferable to find ways to prevent the issues; but if that is not possible, then early identification and intervention would improve the patient experience.

**REFERENCES**


Abbott-Anderson, K., & Kwekkeboom, K.L. (2012). A systematic review of sexual and sexual changes (interest in sex and intimacy) were the issues that resulted in the highest bothersome ratings.

**Table 6: Items identified as most bothersome for women (endorsed on MENQOL)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean*</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain</td>
<td>4.44</td>
<td>1.937</td>
</tr>
<tr>
<td>Change in your sexual desire</td>
<td>4.32</td>
<td>1.942</td>
</tr>
<tr>
<td>Avoiding intimacy</td>
<td>4.11</td>
<td>2.162</td>
</tr>
<tr>
<td>Feeling tired or worn out</td>
<td>4.04</td>
<td>1.527</td>
</tr>
<tr>
<td>Difficulty sleeping</td>
<td>4.02</td>
<td>1.944</td>
</tr>
</tbody>
</table>

*rating out of a scale of 0-6


