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Quality of life among postmenopausal women enrolled in the Minnesota Green Tea Trial☆

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ABSTRACT

Background: Postmenopausal symptomatology has not been elucidated in large, long-term human clinical trials. Our objective was to measure quality of life in postmenopausal women aged 50–70 years.

Methods: A Menopause-Specific Quality of Life-Intervention (MENQOL) questionnaire was completed by women enrolled in the Minnesota Green Tea Trial (n = 932) to assess vasomotor, physical, sexual, and psychosocial symptoms in the years following menopause. Responses were coded; mean overall and domain scores ranged from 1 to 8. A higher score indicated more severe symptoms.

Results: Mean overall MENQOL scores were highest in women aged 50–54.9 years. A pattern of reduced symptom severity with increasing age was observed overall and within each domain. Women aged 50–54.9 years had more severe night sweats and sweating than other age groups ($P \leq 0.001$) and more severe hot flashes than women aged ≥ 60 years ($P \ll 0.001$). No differences between age groups were seen on mean score in the Sexual domain. Compared with women aged 50.0–54.9 years (the reference group), study participants aged 60–64.9 and ≥ 65 years had lower MENQOL scores in the Psychosocial domain ($P = 0.029$ and $P \ll 0.001$). Women aged 50–54.9 years had more severe symptoms related to negative mood than women ≥65 years ($P \leq 0.009$). Compared with women aged 50–54.9 years, those in the age groups 60–64.9 and ≥ 65 years had lower scores for "poor memory" (2.98 ± 1.75 and 2.66 ± 1.68 vs. 3.43 ± 1.87, $P \ll 0.001$). Women ≥ 65 years reported lower scores for "feeling tired or worn out", "difficulty sleeping", and "lack of energy" than all other age groups ($P \leq 0.003$).

Conclusion: The findings of this descriptive analysis of postmenopausal women may help clinicians counsel women about expectations and treatment options to address menopause-associated symptoms and the relationship between postmenopausal symptoms and overall health.

1. Introduction

Menopause is a normal physiologic event, defined by the World Health Organization (WHO) as the permanent cessation of menstruation resulting from loss of ovarian follicular function [1]. Spontaneous or natural menopause is recognized retrospectively after 12 months of amenorrhea [1]. It occurs at an average age of 52 years, but the age of natural menopause can vary widely from 40 to 58 years. Induced menopause refers to the cessation of menstruation that occurs after either bilateral oophorectomy or iatrogenic ablation of ovarian function (e.g., by chemotherapy or pelvic radiation) [2].

By the year 2025, the number of postmenopausal women is expected to rise to 1.1 billion worldwide [2]. Understanding the physical, emotional, and sexual repercussions of this important life stage is sure to prove valuable for the care of many women in the future. And yet, detailed information on a full spectrum of menopause-related symptoms is lacking in large randomized trials. Intervention studies targeted at postmenopausal women represent an excellent opportunity to evaluate quality of life in this demographic group. The Menopause-Specific Quality of Life (MENQOL) questionnaire [3,4] is a validated and widely used research tool aimed at measuring condition-specific quality of life in postmenopausal women. Its use in both clinical and epidemiological research has been steadily increasing over the past two decades since it was first published. However, translation of its results into clinical practice has remained largely uncertain, possibly due to wide demographic variation and small sample sizes of many studies conducted to date.

In order to assess women's menopausal state in a large data set, we looked to the results of the Minnesota Green Tea Trial (MGTT) [5], a placebo-controlled, double-blinded, randomized phase II clinical trial

☆ This trial was registered at clinicaltrials.gov as NCT00917735 on June 8, 2009.

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designed to investigate the effect of green tea extract (GTE) on risk factors for postmenopausal breast cancer. The MGTT randomized over one thousand postmenopausal women at increased risk for breast cancer development due to high breast density to receive either GTE or placebo for 12 months. With its large sample of healthy postmenopausal women across a wide age range, examining quality of life issues of women enrolled in the MGTT provided an excellent chance to assess health status and needs of the aging woman. Menopause can be viewed as a sentinel event that affords a unique opportunity for a dialogue between women and their healthcare providers to evaluate and improve health-related practices. By considering women's concerns, values, and preferences, menopause practitioners have the potential to enhance womens' sense of well-being not only at menopause, but for the remainder of their lives. The purpose of this analysis was to evaluate the psychometric properties of the MENQOL questionnaire in a sample of postmenopausal women across the ages of 50–70 years.

2. Study design and methods

2.1. Participants

A detailed description of the Minnesota Green Tea Trial (MGTT) design, eligibility criteria, study conduct, and participant flow through the trial has been published separately [5]. Briefly, the study recruited postmenopausal women aged 50–70 years and classified as having high mammographic density from 2009 to 2013 in the Minneapolis-St. Paul metropolitan area. Of 1075 randomized women, 538 were assigned to receive four oral GTE capsules containing 1315 mg ± 116 total catechins per day (843 ± 44 mg as (−)-epigallocatechin-3-gallate [EGCG]) and 537 were randomized to receive placebo. Nine hundred thirty-seven women (87.2%) completed the study. Participants, investigators, laboratory staff, and those monitoring clinical outcomes and adverse events were blinded to treatment assignment. The primary objectives were to determine the effects of GTE supplementation on mammographic density, circulating reproductive hormones and circulating insulin-like growth factor axis proteins. Institutional Review Board (IRB) approval was obtained at each clinical center and all participants provided written informed consent.

No differences in any baseline or MENQOL variable were seen when comparing GTE and Placebo groups. Therefore, the following manuscript describes results obtained from analysis of the full study population, combining GTE and Placebo groups.

2.2. MENQOL-intervention questionnaire

The MENQOL-Intervention questionnaire [3,4] was developed to assess side effects of specific therapies that may impact quality of life and consists of 32 items divided into four domains: vasomotor (3 items), psychosocial (7), physical (19) and sexual (3). At baseline (Month 0), participants were asked whether they had experienced each item in the previous week. If their response was 'no', the participant would proceed to the next item. If her response was, "yes", she indicated how bothered she was by the item on a 7-point Likert scale ranging from '0': 'not at all bothered' to '6': 'extremely bothered'. Therefore, a higher score is indicative of a higher degree of menopausal symptoms. For analysis, questionnaire scores were converted to 1 for a "no" response, 2 for "yes, not bothered" through to 8 for "yes, extremely bothered". Each domain score is the mean of the item scores forming that domain and can range from 1 to 8. MENQOL scores were organized categorically as follows: No symptoms: 1.0, Mild to Moderate Symptoms: 1.01-3.67; and Moderate to High Symptoms: 3.68–8.0.

2.3. Health history questionnaire

Each participant completed a baseline health history questionnaire that included information on demographics, lifestyle factors, medical history, medication use, and reproductive history. Participants also self-rated their overall health on a scale from 1 to 4, with 1 = Poor, 2 = Good, 3 = Very Good, and 4 = Excellent health.

2.4. Statistical analysis

Although the MGTT study had three data collection points, (baseline, 6 month, and 12 months), only baseline data were analyzed as no statistically significant changes were seen between time points (data not shown). Participant age was recoded from a continuous variable to four categories by five year increments; 50.0–54.9, 55.0–59.9, 60.0–64.9 and ≥ 65.0 years to determine if there were differences in symptom rating by age. Simple crosstab comparisons of demographics by age groups verified that there were no differences in the four groups for race, education, overall health and other demographic characteristics that may account for group differences. One-way between-subjects ANOVA tests were used to compare the average effect of age on MENQOL domains and symptoms between the four age groups. If the overall F-test was significant, the ANOVA was followed by post-hoc pairwise comparisons adjusted for multiple comparisons using the Tukey method. A two-way ANOVA was conducted on MENQOL subscales to determine the effect of overall self-assessed health and age on MENQOL scores. Our study population rated themselves as generally healthy overall, with none of the women selecting "Poor" overall health in the four point scale. There was no statistically significant interaction between the two variables for any of the MENQOL domains. Therefore, we removed age and ran a one-way ANOVA of the self-assessment of health with the four MENQOL domains followed by post-hoc pairwise comparisons adjusted using the Tukey method. SPSS 23.0 was used for all analyses.

3. Results

3.1. Participants

Baseline demographics and participant information are presented in Table 1. On average, women were 59.9 years old, primarily white (96.4%), and had a mean BMI of 25.1 kg/m^2. No differences in race-ethnicity, education, or self-assessed general health status were noted between age groups. Participants in the 55–59.9 year age group were slightly older at menopause as compared to the 50–54.9 and ≥ 65 years groups (P = 0.001). Groups also varied in terms of past use of oral contraceptives (P = 0.002). Past use of systemic MHT was highest in the ≥ 65 years age group and lowest in the youngest age group; percentage of never smokers was highest in the 50–54.9 and 55–59.9 age groups as compared to the 60–64.9 and ≥ 65 years age groups, indicating a temporal effect in the known health consequences of MHT and smoking.

3.2. Overall domain scores

Baseline MENQOL-Intervention results were available for 932 participants. Information on each of the four domains by age group is shown in Fig. 1. Mean overall MENQOL scores were highest in the 50–54.9 year age group (3.04), followed by those aged 55–59.9 years (2.90), 60–64.9 (2.76), and ≥ 65.0 (2.51). The distribution of symptom severity by age group was significantly different for Vasomotor, Physical, and Psychosocial domains and generally followed a predictable pattern of reduced symptom severity with increasing age (Table 2). No significant difference in distribution of symptoms by age was seen in the Sexual domain (P = 0.11). As demonstrated in Table 2, mean domain scores ranged from 2.01 to 3.66, indicating that overall symptomology of MENQOL variables was mild to moderate for all age groups. However, wide between-subjects variability was observed (Fig. 1).