

Quality of Life and the Prevalence of Vasomotor Symptoms in a Population-Based Sample of Peri- and Post-Menopausal Women

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ABSTRACT

Aims: The current study estimates the prevalence of vasomotor symptoms (VMS) and quality of life (QOL) among peri- and post-menopausal women.

Methods: Participants were recruited from a Knowledge Networks panel, the only online panel based on a random digit dial sample of the full US population. Over 4,000 pre-, peri- and post-menopausal women (n= 4,402) completed portions of the web-based survey. Analyses are limited to the 3,135 peri- and post-menopausal participants meeting study criteria.

In addition to reporting VMS frequency, severity, and related healthcare, respondents completed the Menopause-Specific Quality of Life Questionnaire (MENQOL), a 29-item self-report measure assessing the presence and bothersomeness of menopausal symptoms.

Subjects were classified into 3 groups based on VMS in the past month: 1) met FDA draft guidance (7 or more moderate-to-severe daily hot flashes/night sweats); 2) hot flashes/night sweats but less than FDA draft guidance; or 3) no hot flashes/night sweats.

Results: Mean age of the sample was 55.1 years. Over two-thirds of the sample (67%) reported any VMS within the past month (59% reported daytime hot flashes, 55% reported night sweats). Only 7% of the sample met FDA draft guidance.

MENQOL scores between the peri- and post-menopausal groups did not dramatically differ. However, significant differences in MENQOL total and subscale (Vasomotor, Psychosocial, Physical, Sexual) scores were observed among the 3 VMS groups, with both VMS groups reporting significantly diminished QOL (p<0.05).

Conclusions: The current study provides much-needed prevalence estimates of VMS and their impact on QOL among menopausal women. US regulatory draft guidance focuses on women with 7 or more moderate-to-severe menopausal symptoms per day. However, VMS significantly impact QOL for a much larger portion of the peri- and post-menopausal population.

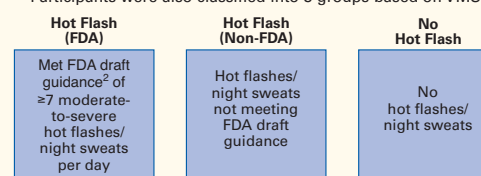
INTRODUCTION

- Menopausal symptoms have been shown to substantially reduce quality of life (QOL).¹
- Vasomotor symptoms (VMS; e.g., hot flashes, night sweats) are among the most common symptoms of menopause.
- Little information is available on:
 - Population-based estimates of menopausal symptoms
 - The impact of VMS on QOL.

METHODS [1]

Participants

- Participants were selected from a population-based sample of peri- and post-menopausal (natural or surgical) women between 40 and 65 years
- Participants were also classified into 3 groups based on VMS



* Demographics are presented in Table 1.

METHODS [2]

Survey

- Eligible participants completed the web-based survey:
 - Menopause-Specific Quality of Life Questionnaire (MENQOL)³
 - 29-item self-report measure
 - Assesses the presence (Yes/No) and bothersomeness (rating 0-6) of menopausal symptoms
 - Higher scores on any symptom indicate greater levels of bothersomeness.
 - Additional survey items addressed VMS frequency, severity, and related healthcare.

RESULTS

Table 2. Prevalence of VMS (and 95% Confidence Intervals)

Characteristic	Peri-menopausal (n=432)	Post-menopausal (n=2,703)	Overall (n=3,135)
Hot flashes and/or night sweats	79% (76%-83%)	65% (63%-67%)	67% (65%-68%)
Hot flash (FDA definition)	9% (6%-12%)	7% (6%-8%)	7% (6%-8%)
Daytime hot flashes*	72%	57%	59%
Night sweats*	65%	53%	55%

*95% confidence intervals not calculated.

Table 3. MENQOL by Menopausal Status

MENQOL Score	Statistic	Peri-menopausal (n=432)	Post-menopausal (n=2,703)	Overall (n=3,135)
Overall score*	N	431	2,689	3,120
	Mean (SD)	3.4 (1.4)	3.2 (1.5)	3.2 (1.4)
Vasomotor subscale*	N	431	2,701	3,132
	Mean (SD)	3.7 (2.1)	3.2 (2.2)	3.3 (2.2)
Psychosocial subscale*	N	431	2,702	3,133
	Mean (SD)	3.5 (1.7)	3.3 (1.8)	3.3 (1.8)
Physical subscale	N	431	2,702	3,133
	Mean (SD)	3.6 (1.4)	3.5 (1.5)	3.5 (1.5)
Sexual subscale	N	431	2,690	3,121
	Mean (SD)	2.8 (2.1)	2.9 (2.1)	2.9 (2.1)

*Significant differences between groups were detected (p<0.01 from t-test); however, the clinical significance of these differences is unclear.

Table 1. Study Population

Characteristic	Peri-menopausal (n=432)	Post-menopausal (n=2,703)	Overall (n=3,135)
Age in years (mean ± SD)	49.9 ± 4.0	55.9 ± 6.1	55.1 ± 6.2
White, non-Hispanic	73%	80%	79%
Some college or higher	56%	52%	52%
Work as a paid employee	59%	47%	49%

SD = standard deviation

Table 4. MENQOL by VMS Severity

MENQOL Score	Statistic	Hot Flash (FDA) (n=227)	Hot Flash (non-FDA) (n=1,865)	No Hot Flash (n=1,043)
Overall score*	N	227	1,854	1,039
	Mean (SD)	4.8 (1.4)	3.6 (1.3)	2.3 (1.0)
Vasomotor subscale*	N	227	1,862	1,043
	Mean (SD)	6.6 (1.5)	4.0 (1.8)	1.1 (0.4)
Psychosocial subscale*	N	227	1,863	1,043
	Mean (SD)	4.2 (2.1)	3.6 (1.8)	2.7 (1.5)
Physical subscale*	N	227	1,863	1,043
	Mean (SD)	4.7 (1.7)	3.8 (1.5)	2.9 (1.4)
Sexual subscale*	N	227	1,855	1,039
	Mean (SD)	3.7 (2.5)	3.1 (2.1)	2.3 (1.8)

*Significant differences among all 3 VMS groups (p<0.001 from one-way ANOVA and/or t-test).

CONCLUSIONS

- This study is the first large-scale web-based survey of a representative sample of menopausal women.
- The majority (67%) of menopausal women report current VMS.
- FDA draft guidance suggests that clinical trials enroll women with 7 or more moderate-to-severe VMS per day (7% of the respondents in this survey).
- The clinical trial guidance focuses on populations with severe VMS, yet VMS affect the majority of menopausal women, indicating high burden of disease.

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