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How well do different measurement modalities estimate the number of vasomotor symptoms? Findings from the Study of Women's Health Across the Nation FLASHES Study

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Abstract

Objective—Studies of vasomotor symptoms (VMS) typically measure VMS via daily diaries completed at the end of the day. VMS can also be measured via diaries completed throughout the day or via physiologic monitors, modalities with lower recall demands. We examined the degree of correspondence between three VMS measurement modalities: retrospective end-of-day/ morning diaries, prospective reporting, and physiologic monitoring. We determined whether discrepancies between measurement modalities varied by subject characeristics.

Methods—25 African-American and 27 white women from the Pittsburgh site of Study of Women's Health Across the Nation with VMS, a uterus and both ovaries, and free of medications affecting VMS underwent four days of ambulatory VMS and actiwatch monitoring. VMS were recalled in end-of-day and morning diaries, were reported prospectively during the day, and were measured physiologically via a hot flash monitor. Associations between anxiety, sleep, or race/ ethnicity and VMS measurement modality difference scores were examined using generalized estimating equations.

Results—Women underestimated the number of daytime VMS at the end of the day as compared to VMS that were prospectively-reported or physiologically-measured throughout the day. This pattern was particularly pronounced among African-American women (beta (b) (standard error (SE))=−3.01(0.93), p=0.001) and women with higher anxiety (b(SE)=−3.13(1.53), p=0.04). For nighttime VMS, women overestimated the number of VMS in the morning upon waking as compared to prospective measures, particularly if they had poorer sleep (higher wakening after sleep onset; b(SE)=0.03(0.008), p=0.001).

Conclusion—Different measurement modalities yield different VMS estimates. Negative affect, sleep, and race/ethnicity may affect the recall of VMS.

Keywords

Hot flashes; Vasomotor symptoms; Recall; Anxiety; Negative affect; Race/ethnicity

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INTRODUCTION

Vasomotor symptoms (VMS), such as hot flashes and night sweats, affect approximately 70% of naturally menopausal American women[1] and are a leading concern for women during their menopausal transition. For example, women cite VMS as the most commonly discussed menopausal symptom with their health care professionals,[2] and women with VMS consult doctors more often than women without these symptoms.[3] Therefore, VMS are an important midlife women's health issue.

The reluctance of many women to take postmenopausal hormone therapy since the publication of the Women's Health Initiative findings[4, 5] has led to a recent search for new nonhormonal treatments for VMS and associated clinical trials. In these trials, daily diaries are considered the gold standard measure of VMS.[6] In many of these diaries, women are asked to recall at the end of the day their VMS experienced over the previous day, and upon waking, their VMS experienced during the night.[7–10] Other methodologies ask women to recall their VMS over the prior 24 hours, summing those experienced during the day and night. In contrast to a prospective report in which women record a VMS event as she is experiencing it, these diaries are retrospective in that they are asking women to recall their VMS over a given period of time. It is not known how well these retrospective reports correspond with prospective VMS reports or physiologically-assessed VMS.[11]

One key factor affecting VMS reporting is negative affect, which influences the memory for other physical symptoms.[12] In fact, anxiety is the strongest, most consistent factor associated with the reporting of VMS.[1, 13–16] Although the relationship between anxiety and VMS may be multifactorial,[17] in the Study of Women's Health Across the Nation (SWAN), higher baseline anxiety was significantly and independently associated with more VMS reporting.[1] Moreover, SWAN women with elevated negative affect reported being more bothered by their VMS even after controlling for the frequency at which VMS were reported to occur.[18] One study found that reported VMS lacking physiologic evidence were most common among women with elevated negative affect.[19]

The primary aim of the current study is to compare the VMS estimates from daily diaries to prospectively-reported or physiologically-recorded VMS during waking and sleeping hours across 4 days and nights. Next, we examine the role of negative affect in relation to the degree of similarity or difference between these measurement modalities. Given anxiety's established association with VMS reporting,[1, 15] we hypothesize that compared to women with low levels of anxiety, women with higher anxiety symptoms would 1) recall more daytime VMS at the end of day than were prospectively reported or physiologically detected during the day and 2) recall more overnight VMS upon waking the next morning than were reported or physiologically detected over the prior night. In an exploratory fashion, we investigate whether discrepancies between VMS estimates by these measurement modalities vary by race/ethnicity and sleep continuity, given the importance of these factors to VMS and their reporting.[1, 15, 18, 20, 21]

METHODS

Study population

SWAN is a multi-site, multi-ethnic, longitudinal study looking to characterize biological and psychosocial changes during the menopausal transition.[22] At their 10th annual visit for SWAN, a subset of women (25 African Americans, 27 whites) from the Pittsburgh site were invited to participate in SWAN FLASHES, an ancillary study including physiological measurement of VMS, methods for which have been described previously.[20, 23] Briefly,

inclusion criteria for SWAN FLASHES included having a uterus and both ovaries, currently experiencing VMS (in the past two weeks), and not being pregnant. Use of oral contraceptives, hormone therapy, selective serotonin reuptake inhibitor/serotonin-noradrenaline reuptake inhibitor antidepressants, or undergoing chemotherapy for breast cancer were exclusionary. Participants were recruited such that an approximately equal number of African American and white women were represented in each obesity category (lean: <25 kg/m2, overweight: 25–29 kg/m2, obese: ≥30.0 kg/m2).

Design and procedures

Women were assessed for height and weight, given questionnaires (i.e. demographics, medical history, and psychological measures), and equipped with a daily diary to be completed before bed and upon waking the next morning, an electronic diary to be completed throughout the day, a physiological hot flash monitor, and a wrist actigraph for four 24-hour ambulatory assessment periods. Procedures were approved by the University of Pittsburgh institutional review board, and all participants provided written informed consent.

End-of-day-recalled and morning-recalled VMS

Prior to falling asleep each night, participants were asked to report the number of VMS they experienced during that day in their end-of-day diary. In addition, upon waking each morning, participants were asked to report the number of VMS they experienced during the prior night in their morning diary.

Prospectively-reported VMS

Throughout the day, participants were asked to report their VMS at the time of occurrence. They reported these VMS events in three ways: 1) completed an entry in the portable electronic diary (Palm Z22: Palm, Inc., Sunnyvale, CA); 2) pressed event mark buttons on the physiological hot flash monitor (3991/2-SCL Single-Channel Hot Flash Monitor BioLog: UFI; Morro Bay, CA), and 3) pressed a button on the wrist actigraph (Minimitter Actiwatch-64: Respironics Inc.; Murrysville, PA). A report of a VMS on any of these three devices was considered a prospective report of a VMS.

Physiologically-detected VMS

VMS were measured physiologically via sternal skin conductance using the Biolog hot flash monitor,[11, 24] a portable device worn around the waist, which measures sternal skin conductance continuously in the ambulatory setting. Skin conductance was sampled at 1 Hz from the sternum via a 0.5-V constant voltage circuit passed between two silver/silver chloride electrodes (UFI) filled with 0.05 M KCl Velvachol/glycol paste.[25] Using the UFI software (DPS v3.6), any skin conductance rise of 2 μmho in 30 seconds[11] with a characteristic VMS pattern was coded as a physiological VMS. Events showing the characteristic VMS pattern yet having less than 2 μmho per 30-second rise were also coded as VMS.[26, 27] A 20-minute lockout period was implemented after the start of each VMS event during which no further events were coded.

Psychological questionnaires

Anxiety symptoms were evaluated with the Spielberger State Trait Anxiety Inventory (STAI), a well-validated scale that measures state and trait anxiety;[28] depressive symptoms with the widely-used and well-validated Center for Epidemiologic Studies Depression Mood Scale (CES-D);[29] perceived stress with the widely-used Cohen Perceived Stress Scale (PSS), which queries about one's general appraisal of stress.[30]

Sleep characteristics

Sleep characteristics were measured by both diary report and via actigraphy. In their morning diary completed upon waking each morning, participants reported the number of awakenings and total minutes of awakening during the prior night, as well as how that night of sleep compared with a usual night for them (5-point scale ranging from “much worse” [0] to “much better” [4]). Self-reported bedtime and rise time were entered for calculation of sleep-wake variables. Actigraphic sleep was measured via wrist actigraph, Actiwatch-64, worn throughout the ambulatory monitoring period. Actigraphy data were collected in 1-minute epochs and were analyzed using the Actiware Version 5.04 software program.[20] Each awakening was defined as a total activity count greater than a sensitivity threshold of 40. Wakefulness after sleep onset (WASO; total minutes of wakefulness between sleep onset and final wake time) was determined via actigraphy and considered as the main sleep characteristic here given the previously-documented associations between reported VMS and wakening during the night.[20, 21]

Covariates

Demographics, medical history, medication use, menstrual history and health behaviors were assessed by questionnaires administered during SWAN FLASHES visit. Race/ethnicity was determined in response to the question “How would you describe your primary racial or ethnic group?” Education status was determined from self-reported highest grade completed and separated into 3 categories: high school, some college or vocational school, and college or higher. Menopausal status was determined from reported bleeding patterns (perimenopausal status was defined as bleeding in previous 3 months with a decrease in cycle predictability in past year or more than 3 but less than 12 months of amenorrhea; postmenopausal status was defined as more than 12 months of amenorrhea). Alcohol and tobacco use were determined by the current reported number of drinks per day/week/month and cigarettes/day, respectively. BMI was calculated from height that was measured with a fixed stadiometer (Seca, Hanover, MD) and weight that was obtained from a calibrated balance beam scale (Healthometer, Alsip, IL).

Statistical analysis

We calculated the number of VMS that were retrospectively reported in daily diaries, prospectively reported, and physiologically measured during daytime and overnight. For each subject, the number of recalled daytime VMS from the end-of-day diary was compared to the number of prospectively reported or physiologically measured VMS that occurred throughout that same day. Similarly, the number of recalled overnight VMS from the morning diary was compared to the number of prospectively reported or physiologically measured VMS that occurred overnight. Difference scores (number of VMS) between these measurement modalities were calculated: 1) end-of-day/morning-recalled – prospectively-reported VMS and 2) end-of-day/morning-recalled – physiologically-measured VMS.

Since VMS data were collected over multiple days/nights per woman (usually four), generalized estimating equations (GEE) were used to examine associations between outcomes, covariates, and predictors. State and trait anxiety, depressive symptoms, perceived stress, and WASO were considered in relation to each difference score in separate models. State anxiety, trait anxiety, and depressive symptoms were natural log transformed for analysis. Covariates were selected based upon their association with the outcome at $p<0.15$, with age, race/ethnicity, postmenopausal status, and BMI included in final models. We tested interactions between race/ethnicity and psychosocial or sleep characteristics with cross-product terms, and where interactions were significant, stratified models were presented. All tests were two-tailed with alpha=0.05. Analyses were performed with SAS (v 9.3; SAS Institute: Cary, NC)

RESULTS

Participants were on average 58 years old and postmenopausal (Table 1). Compared to white women, African-American women had a higher BMI, reported more VMS prospectively, and experienced more physiological VMS.

At the end of the day, women underestimated the number of daytime VMS as compared to those that were prospectively reported or were physiologically recorded throughout the day (Table 2). This tendency varied by race/ethnicity, with African-American women more likely to recall fewer VMS than were prospectively reported or physiologically detected relative to white women. For nighttime VMS, on average women slightly overestimated the number of VMS upon waking than were prospective reported or detected on physiologic monitoring.

Daytime VMS reporting differences

In multivariable models adjusted for age, race/ethnicity, menopausal status, and BMI, higher trait anxiety was associated with greater underestimation of VMS at the end of the day than those that were prospectively reported or physiologically measured throughout the day (Table 3). A similar but slightly weaker pattern was apparent for depressive symptoms and perceived stress (perceived stress, b(SE) = −0.11(0.07), P=0.08). Considering the covariates in these models, neither BMI nor age were associated with these VMS reporting differences (P's>0.10); although postmenopausal status was associated with greater underestimation of daytime VMS (for end of day recalled-prospectively reported VMS, b(SE): −2.09 (0.62), P<0.05; for end of day recalled-physiologically measured VMS, b(SE): −5.82 (1.43), P<0.05).

We observed some indication of differences by race/ethnicity in relations between negative affect and the discrepancies between the number of VMS recalled at the end of the day and the number prospectively reported throughout the day (interactions with race: for state anxiety, P=0.07; trait anxiety, P=0.09; depressive symptoms, P=0.03) as well as the difference between the number of VMS recalled at the end of the day and those that were physiologically measured throughout the day (interaction for race and depressive symptoms: P=0.08) in multivariable models adjusted for age, race/ethnicity, menopausal status, and BMI. For example, the greater underestimation of VMS at the end of the day versus those prospectively reported with elevated negative affect was apparent only among African-American women (state anxiety, b(SE) = −4.60(2.01), P=0.02; trait anxiety, b(SE) = −3.66(1.61), P=0.02; depressive symptoms, b(SE) = −1.20(0.59), P=0.04) but not white women (P's>0.10).

Nighttime VMS reporting differences during sleeping hours

With respect to nighttime VMS, higher WASO was associated with greater overestimation of overnight VMS in the morning diary as compared to VMS physiologically detected during the night (Table 4). Notably, no affective factors were associated with nighttime VMS reporting differences (P's>0.10), nor were any of the covariates (BMI, age, menopausal status) associated with nighttime VMS reporting differences (P's>0.10).

Suggestion of effect modification by race/ethnicity (P=0.09) was noted for the relation between WASO and the difference between morning-recalled and overnight-reported VMS in multivariable models adjusted for age, race/ethnicity, menopausal status, and BMI. For example, the tendency with worse sleep to overestimate VMS in the morning as compared to the number of VMS prospectively reported or physiologically measured was apparent only among white women (versus prospective report: b(SE) = 0.02(0.01), P=0.02; versus

physiologic monitor: b(SE) = 0.04(0.01), P=0.002) but not African-American women (P's>0.05).

DISCUSSION

The primary aim of this study was to examine the accuracy of end-of-day and morning VMS recall by comparing them to prospective report and physiological detection of VMS. We found that the women in this study had a tendency to *underestimate* the number of VMS at the end of the day compared to those prospectively reported or physiologically measured throughout the day. The tendency to underestimate daytime VMS was especially pronounced among African American women and, contrary to our expectations, more anxious women. For overnight VMS, women *overestimated* the number of overnight VMS upon waking as compared to those prospectively reported or physiologically detected during the night. This pattern was particularly pronounced among women with poorer sleep (more wakefulness during the night). Racial/ethnic differences pointed to a pattern of African American women being most likely to underestimate VMS and white women to overestimate VMS, particularly in the context of negative affect or poor sleep.

This study is one of few to investigate the degree of correspondence between VMS assessed through retrospective recall, prospective report, and physiological detection. This study is important given that findings in studies using VMS diaries completed prospectively or retrospectively are often treated interchangeably. However, daytime VMS may be systematically underestimated, and overnight VMS systematically overestimated. Moreover, recalled VMS are subject to the additional influence of affect. These findings underscore the potential importance of using prospective VMS reports.

Other symptom literatures, such as those related to pain, have previously described the difficulty individuals have in recalling these types of chronic repeated symptoms accurately. Notably, research from the pain literature shows greater accuracy of recall for novel, acute pain than for chronic or repeated episodic pain,[12, 31] such as the VMS experienced here. Memory of pain is also influenced by the mood at recall[12, 32] and, negative affect, particularly anxiety, impact both symptom reporting and memory of pain for a range of physical conditions.[33–35] For VMS, anxiety plays an important role in VMS reporting.[14–16] However, negative affect is typically associated with over-estimation of symptoms.[36] Why anxiety was related to underestimation of VMS in our study is not entirely clear. A possible theory is that anxiety plays differential roles in prospective and retrospective symptom reporting, as some research shows that anxiety is associated with elevated prospective symptom reports but not symptom recall.[37] It is also notable that the greater underestimation associated with higher negative affect was most apparent among African American women. Prior work has not considered that the relation between affect and VMS reporting may vary by race; our findings suggest the potential importance of considering racial/ethnic differences.

Overestimation of nighttime VMS upon waking compared to those prospectively reported or physiologically measured during the night is in accordance with our previous work showing moderate to no correlation between prospectively reported or physiological VMS with morning-diary-recalled VMS, respectively.[20] Consistent with links between poor sleep and VMS,[18, 20] women overestimated VMS upon waking if they had poorer sleep, i.e. more sleep disruptions. Measuing nighttime VMS via self-report is a challenge, given that women are typically sleeping, and thereby physiologic monitoring can be useful to obtained overnight VMS estimates. However, physiologic monitoring is often not feasible for large studies, and thus the accuracy of morning reports become paramount. Consistent with our

prior work,[20] the present findings indicate that these morning reports may be somewhat inflated if a woman has had a poor night of sleep.

Consistent with previous reports,[1, 15, 16, 38–40] African-American women prospectively reported more VMS and experienced more physiological VMS than white women. Greater underestimation of daytime VMS at the end of the day versus prospective measures was also more apparent among African-American women. The reason for this racial/ethnic difference is not entirely clear, and should be interpreted with caution given the small numbers of women in these stratified models. We considered whether the racial/ethnic differences in BMI might have been accounted for by BMI, but BMI was adjusted for in all models and was generally not associated with the reporting difference scores. Other demographic factors (e.g., age, employment status, marital status, living arrangements) were also considered but were not related to VMS reporting outcomes nor did they account for these racial/ethnic differences (data not shown). Other works show variations by race/ethnicity in both VMS[19] and pain reporting.[25, 41–44] The present findings highlight the importance of considering racial/ethnic differences in patterns of VMS reporting, as well in replicating the present work.

Several limitations of this study should be mentioned. The small size of our sample may have limited the power to detect associations, especially for interactions and stratified models. Interpretation of racial/ethnic differences in particular requires caution. Moreover, given the inclusion of only African American and white women, we cannot draw conclusions about other racial/ethnic groups.

This study has numerous strengths. This is the first study to examine the concordance/discordance of three different VMS measurement modalities: retrospective daily diary, prospective report, and physiological detection. We compared both subjective versus objective and retrospective versus prospective assessments of VMS. This study also evaluated daily diaries similar to those used in recent studies on treatments of VMS[6–10]. In addition, as mentioned above, we provided three different ways to prospectively report VMS events and monitored women in the home setting. Finally, this study included a well-characterized sample of African American and white women in approximately equal numbers.

CONCLUSIONS

In summary, this work highlighted that different measurement modalities yield different VMS estimates. In particular, women underestimated the number of VMS at the end of the day compared to those prospectively- eported or physiologically detected throughout the day. Women overestimated the number of VMS they experienced during the night upon waking, particularly if they had poorer sleep. These findings have implications for understanding the results of VMS treatment studies, which largely rely upon retrospectively recalled VMS that may capture not only VMS, but aspects of sleep and mood. These findings underscore the potential importance of prospective VMS measures for research requiring precise VMS estimates.

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TABLE 1

Sample characteristics for the total sample and by race/ethnicity

	Total sample (n=52)	White (n=27)	African-American (n=25)
		M (SD)	
Age (yr)	58.2 (2.3)	58.6 (2.5)	58.1 (2.1)
Body mass index (BMI)[b]	29.9 (5.0)	28.8 (4.7)	31.1 (5.3)
State anxiety	31.6 (9.4)	31.7 (10.9)	31.5 (7.6)
Trait anxiety	33.6 (9.0)	32.4 (8.4)	34.9 (9.6)
Depressive symptoms	7.4 (6.5)	6.5 (6.1)	8.4 (6.9)
Perceived stress	11.5 (6.2)	11.2 (6.6)	11.8 (5.9)
Wakefulness after sleep onset (WASO)	53.1 (27.8)	53.7 (23.7)	52.4 (32.2)
		N (%)	
Education			
High School	10 (19.2)	8 (29.6)	2 (8.0)
Some college/vocational	37 (71.2)	20 (74.1)	17 (68.0)
College or higher	15 (28.9)	7 (25.9)	8 (32.0)
Menopausal status			
Perimenopausal	5 (9.62)	3 (11.1)	2 (8.0)
Postmenopausal	47 (90.4)	24 (88.9)	23 (92.0)
Daytime VMS (#)		M (SD)	
End of day recalled VMS	4.29 (3.88)	4.35 (4.48)	4.22 (3.07)
Prospectively reported VMS	5.42 (4.25)	5.10 (4.30)	5.81 (4.20)
Physiologically measured VMS[a]	7.90 (5.29)	6.75 (4.64)	9.26 (5.71)
Overnight VMS (#)		M (SD)	
Morning recalled VMS	4.32 (3.90)	4.35 (4.48)	4.29 (3.08)
Prospectively reported VMS	1.84 (1.77)	1.77 (1.78)	1.92 (1.78)
Physiologically measured VMS[a]	3.05 (2.45)	2.75 (2.28)	3.41 (2.60)

Note: Anxiety measured via the Spielberger State Trait Anxiety Inventory, depression via the Center for Epidemiologic Studies Depression Scale, perceived stress via the Cohen Perceived Stress Scale

Differences by race/ethnicity:

[a] P<0.05

[b] P<0.10

TABLE 2

Differences in the number of VMS reported/measured via various modalities, for total sample and by race/ethnicity

	Total sample	White	African-American
	M(SD)	M(SD)	M(SD)
Daytime VMS (#)			
End of day recalled – prospectively reported VMS [b]	−0.75 (2.88)	−0.24 (1.96)	−1.34 (3.61)
End of day recalled – physiologically measured VMS[a]	−3.22 (5.00)	−1.89 (4.37)	−4.79 (5.29)
Overnight VMS (#)			
Morning recalled – prospectively reported VMS	0.16 (3.56)	0.20 (3.01)	0.10 (4.13)
Morning recalled – physiologically measured VMS	1.37 (2.72)	1.18 (2.21)	1.60 (3.22)

Differences by race/ethnicity:

[a] P<0.05

[b] P<0.10

Note: More negative indices represent fewer VMS (#) recalled than prospectively reported or physiologically measured; more positive represents more VMS (#) recalled than prospectively reported or physiologically-measured.

TABLE 3

Negative affect associated with greater underestimation of VMS recalled at the end of the day as compared to VMS prospectively reported or physiologically measured throughout the day

	Daytime VMS	
	End of day recalled - prospectively reported VMS	**End of day recalled – physiologically measured VMS**
	B(SE)	**B(SE)**
Trait anxiety	−1.96(1.06)[b]	−3.13(1.53)[a]
Depressive symptoms	−0.42(0.28)	−0.61(0.36)[b]

Covariates: Age, race/ethnicity, postmenopausal status, and BMI. Note that each psychological variable is considered in a separate model. State anxiety, trait anxiety, and depressive symptoms were natural log transformed.

[a] P<0.05

[b] P<0.10

Note: Negative coefficient represents greater underestimation of VMS when recalled than prospectively reported or physiologically measured with higher negative affect.

TABLE 4

More wakening after sleep onset associated with greater overestimation of VMS recalled upon waking as compared to VMS physiologically measured overnight

	Overnight VMS	
	Morning recalled – prospectively reported VMS	**Morning recalled – physiologically measured VMS**
	B(SE)	**B(SE)**
Sleep (Wakefulness after sleep onset)	0.01(0.01)	0.03(0.01)[a]

Covariates: age, race/ethnicity, postmenopausal status, and BMI.

[a] P<0.05

Note: Positive coefficient represents greater overestimation of VMS recalled than prospectively reported or physiologically measured with worse sleep (higher awakening after sleep onset).