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Measuring hot flash phenomenology using ambulatory prospective digital diaries

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Abstract

Objective—This study provides the description, protocol, and results from a novel prospective ambulatory digital hot flash phenomenon diary.

Methods—This study included 152 midlife women with daily hot flashes who completed an ambulatory electronic hot flash diary continuously for the waking hours of 3 consecutive days. In this diary, women recorded their hot flashes and accompanying characteristics and associations as the hot flashes occurred.

Results—Self-reported hot flash severity on the digital diaries indicated that the majority of hot flashes were rated as mild (41.3%) or moderate (43.7%). Severe (13.1%) and very severe (1.8%) hot flashes were less common. Hot flash bother ratings were rated as mild (43%), or moderate (33.5%), with fewer hot flashes reported bothersome (17.5%) or very bothersome (6%). The majority of hot flashes were reported as occurring on the on the face (78.9%), neck (74.7%), and chest (61.3%). Prickly skin was reported concurrently with 32% of hot flashes, 7% with anxiety and 5% with nausea. A novel finding, 38% of hot flashes were accompanied by a premonitory aura.

Conclusion—A prospective electronic digital hot flash diary allows for a more precise quantitation of hot flashes while overcoming many of the limitations of commonly employed retrospective questionnaires and paper diaries. Unique insights into the phenomenology, loci and associated characteristics of hot flashes were obtained using this device. The digital hot flash phenomenology diary is recommended for future ambulatory studies of hot flashes as a prospective measure of the hot flash experience.

Keywords

Digital diary; hot flash measurement; hot flash phenomenology; hot flash loci; hot flash aura

Hot flashes, the most commonly reported symptom of the menopause transition, are experienced by approximately 70% of women living in the United States¹. Hot flashes (also known as hot flushes, night sweats, and vasomotor symptoms) have been described as a transient but recurrent experience of heat, flushing, palpitations, chills, clamminess, and sweating of the face, head, neck and chest^{2, 3}. Hot flashes have been reported to be preceded by a premonitory aura for some women^{2, 4, 5}. The study of hot flashes is important as this symptom has been associated with fatigue and poor sleep^{6–9}, poorer endothelial function^{10–12}, an adverse cardiovascular disease risk factor profile^{11, 13–15}, reduced sexual function¹⁶, depression^{17, 18}, anxiety^{1, 19, 20}, and decreased quality of life^{6, 21–23}. Safe and effective treatments for hot flashes are limited, and the underlying physiology of hot flashes is not well understood. To further understanding of the study of the etiology of, and treatments for hot flashes, accurate measurement of this important midlife symptom is necessary.

Historically, hot flashes have been studied predominately via hot flash diaries – a retrospective self-report of frequency and/or severity. In these diaries, respondents typically report on their hot flashes at the end of the day and/or upon waking for reporting overnight events. Other diaries ask participants recall their hot flashes experienced over the prior 24 hours. The accuracy of these retrospective summative diaries is in question. For example, similar inventories that characterize other symptoms such as pain have shown significant limitations in the participant's ability to accurately recall their symptoms²⁴ and that mood at the time of reporting can influence the recall of these symptoms^{25–27}. In research employing hot flash diaries, the recall of hot flashes was similarly biased by reconstructive recall²⁸, anxiety^{28, 29} and negative affect²⁸.

Prospective diaries overcome many of the limitations of retrospective reporting in hot flash diaries. In prospective diaries, participants report their hot flash experiences *as they occur*. A comparative study examining the differences between retrospective and prospective diaries of hot flashes found that participants underestimated the number of hot flashes during the day and overestimated the hot flashes they had while sleeping using retrospective diaries compared to prospectively-assessed hot flashes. Further, racial/ethnic differences in hot flash recall were observed²⁸.

Prospective diaries have the advantage of reducing the recall and reconstruction inherent in retrospective diaries. However, typically these diaries are in paper format. While paper diaries are low cost and easy to administer, backfilling, or the act of completing diary entries *after* the event of interest, is common³⁰. A study of pain revealed that only 11% of the diary entries were correctly filled out at prompts, despite 90% of their paper diary entries indicating an appropriate time, suggesting a significant degree of faked compliance³¹. Technology has enabled researchers to present diaries to participants via digital devices such as palm-top computers, web-based surveys, and app-enabled smartphones. Electronic diaries have several advantages over paper diaries: they eliminate the need for costly and data-prone data entry, they automatically record the date and time of completion, and they can prompt participants at fixed or random intervals for responses.³² Additionally, participant compliance to electronic diaries has been shown to be superior (e.g. 94%) to paper diaries³¹.

An additional shortfall of previously-employed hot flash diaries is that largely only the frequency and severity of hot flashes is queried. The presence of additional hot flash characteristics and associations, such as loci^{33, 34}, bother^{35, 36}, premonitory aura^{5, 37}, prickly skin³⁸, cold chills³⁹, nausea⁴⁰ and anxiety⁴¹ are rarely examined. This limit to traditional retrospective hot flash diaries may limit the understanding of hot flash etiology and treatment.

This study provides the description, protocol, and results from a novel prospective ambulatory digital hot flash phenomenon diary. In this study, 152 midlife women with daily hot flashes completed an ambulatory electronic hot flash diary continuously for the waking hours of 3 consecutive days. In this diary, women recorded their hot flashes and accompanying characteristics as the hot flashes occurred.

Methods

Study sample

This study involves a subcohort of women from a larger observational study of hot flashes and cardiovascular risk. The parent study recruited 304 late perimenopausal and postmenopausal women ages 40–60 and nonsmoking. By design, half of the women reported daily hot flashes/night sweats, and half reported no hot flashes/night sweats (past three months). The 152 women reporting daily hot flashes were studied here. Exclusion criteria included hysterectomy and/or bilateral oophorectomy; a reported history of heart disease, stroke, arrhythmia, gynecological cancer, pheochromocytoma, pancreatic tumor, kidney failure, seizures, Parkinson's disease, or Raynaud's phenomenon; current pregnancy; or having used the following medications within the past 3 months: estrogen or progesterone, selective estrogen receptor modulators, selective serotonin reuptake inhibitors, serotonin norepinephrine reuptake inhibitors, gabapentin, insulin, beta-blockers, calcium channel blockers, alpha-2 adrenergic agonists, or other antiarrhythmic agents. Women who had undergone uterine ablation, endarterectomy, or who were undergoing chemotherapy, hemodialysis, or peritoneal dialysis were excluded. Participation and refusal rates for this study were 71% and 29%, respectively.

Design and Procedures

The study protocol included anthropometric measures, questionnaires, a three-day ambulatory hot flash assessment protocol with included electronic diary reporting of hot flash phenomenology. Women also underwent an exit interview wherein they were asked to provide feedback and comments, and to report any problems they had with the hot flash diary. All participants completed all three days of monitoring. Procedures were approved by the University of Pittsburgh Institutional Review Board and all participants provided written informed consent.

Hot Flash Digital Diary

Participants were provided an electronic digital diary: the Palm Z22 (Figure 1; © 2005 Palm, Inc.). The Palm Z22 is a 3.4-ounce handheld device that operates using flash memory, the Palm OS Garnet 5.4.9 operating system, a 200 MHz Samsung S3c2410 ARM920T-based

processor and 32 MB NVRAM. The palm has a 160x160 STN screen that is capable of displaying 4,096 colors (12 bit). Input on the device is touchscreen, connectivity was via USB, and it is powered by a rechargeable lithium-ion battery that sufficiently powered the device for the duration of the study. Survey items and programming were uploaded to the device using Satellite Forms, a visual integrated software development environment (©Thacker Network Technologies Inc.).

Completed diary data was downloaded from the device in the form of Microsoft Access® files onto study PCs. Participants were trained on how to operate the device and employed the device continuously for three consecutive days during waking hours. The participants were asked to report each hot flash on the device as they experienced it, including events where they were unsure of whether they were having a hot flash or not. At every entry, participants completed items that assessed hot flash presence, loci on the body, severity, bother, aura and other sensations.

The Hot Flash Digital Diary included six items about the presence, severity, loci, bother, accompanying aura, and other sensations associated with a hot flash (Table 1). The diary when activated by alarm or button press would ask the participant if they were having a hot flash (yes, no, maybe). If the participant answered 'yes' or 'unsure,' the participant was provided questions as to the severity of their hot flash (mild-very severe), the location of the hot flash (face, neck, back, chest, and/or other), how bothersome the hot flash was (mild-very bothersome), whether the hot flash was accompanied by an aura/a sense that it was going to come on (yes/no), and whether the hot flash was accompanied by other sensations (prickly skin, cold chills, nausea, anxiety).

Statistical Analyses

Means, medians, and frequencies of participant characteristics were calculated. A daily hot flash rate (number of reported hot flashes reported during waking hours / number of waking hours) was calculated for each day of participation. Frequencies of hot flash characteristics (severity, bother, location, aura, additional sensations) as well as experiences with the diary were calculated.

Results

The women in this study were, on average, 53 years old, postmenopausal, overweight, married, and college educated (Table 2). Thirty percent of the sample was African American, 65% white, and 5% identified with another racial group. Using the digital diary, 152 participants recorded a total of 1672 hot flash events during waking hours over three consecutive days. Of the 1672 hot flash events, 95 (5%) were marked as 'unsure.' The mean hot flash rate (number of reported hot flashes reported during waking hours / waking hours) per day was: Day 1=3.82; Day 2=3.02; Day 3 =2.70.

Self-reported hot flash severity on the digital diaries indicated that the majority of hot flashes were rated as mild (41.3%) or moderate (43.7%). Severe (13.1%) and very severe (1.8%) hot flashes were less common (Figures 2, 3). Hot flash bother ratings were similar

with the majority of hot flashes as rated as mild (43%), or moderate (33.5%), with fewer hot flashes reported bothersome (17.5%) or very bothersome (6%).

Women were queried about where they experienced each hot flash on the body. The majority of hot flashes were described as occurring on the face (78.9%), neck (74.7%), and chest (61.3%; Figure 4.). Other sensations beyond heat were also frequently reported with hot flashes, with 32% of hot flashes reportedly accompanied by a sensation of prickly skin, 7% with anxiety and 5% with nausea. Particularly notable was that 38% of hot flashes were accompanied by a premonitory aura. In fact, over half of the women (55.2%, n=90) reported aura with at least one of their hot flashes. Of the women who reported aura, 21 women (12.9%) reported an aura with every hot flash.

At exit interview wherein women were asked to report any problems they had keeping the diary, the majority (96%) reported no problem with the diary. However, four participants (2%) reported battery issues, two participants (1%) reported difficulty in completing diary entries at work, one participant (<1%) reported device failure, and one participant (<1%) reported initial difficulty in operating the diary.

Discussion

Here we report on the largest study of an ambulatory, prospective digital hot flash diary in midlife, menopausal women. The prospective digital hot flash diary was effective at capturing the subjective report of hot flashes, collecting 1672 hot flashes reported by 152 postmenopausal women over three consecutive days. The digital diary was consistent with previous hot flash studies in terms of frequency and reported severity, however, this study provided novel insights into the phenomenology of the hot flash experience, including hot flash bother, loci, and associated sensations (e.g., prickly skin, cold chills, nausea and anxiety). Usable and portable, reports of technical issues or difficulties with the diary were rare.

This study is important and innovative as previous studies of hot flashes have employed primarily paper retrospective diaries or inventories. These paper diaries are commonly completed retrospectively by end of day or the next morning to capture overnight hot flashes/night sweats. These methods have several limitations, such as the issue of recall and the influence of mood on symptom reporting. For example, dysphoric mood can amplify somatic symptom reporting on self-report instruments⁴². Further, paper diaries do not allow the investigator to understand when the respondent completed the diary, a particular issue since backfilling paper diaries is well-documented³¹. Prospective digital diaries have been introduced to overcome these limitations and provide several notable advantages. Digital diaries are prospective, eliminating the need for costly and error-prone data entry, they can remind participants of scheduled times for responses, and can prompt participants at fixed or random intervals for responses³². Digital diaries can also improve compliance³¹.

Currently the only validated self-report hot flash measure to-date is the Patient-Reported Hot Flash Diary⁴³. This paper instrument allows the characterization of hot flashes solely by frequency and severity (mild, moderate, severe, and very severe), with hot flash number

multiplied by the average severity providing a hot flash score. The digital hot flash diary used in the present study differs from the Patient-Reported Hot Flash Diary not only in that our diary is in digital format, but that additional information on the phenomenology of hot flashes including bothersomeness, loci, aura, and accompanying sensations. These data are entered and time-stamped at each reported event versus at end of day or the following morning, thus reducing recall biases.

Over the three consecutive days, participants completed a total of 1672 hot flash entries during waking hours, with a mean of 11 digital diary entries per participant. Consistent with previous research on the frequency and severity of hot flashes among peri- and postmenopausal women⁴⁴, severity and bother in this study were reported as generally mild. Additionally, hot flash bother was also generally mild with only six percent of all reported hot flashes rated as very bothersome.

The diary allowed reporting on associated sensations with each hot flash. This question yielded an interesting finding involving hot flash auras, or a premonitory sensation. This sensation has been described as a queasy feeling, a feeling of unease, anxiety or a pressure in the head just prior to and distinct from the sensation of the hot flash.^{5, 45} In a laboratory study of the thermoregulatory and cardiovascular changes that accompany hot flashes, aura preceding hot flashes were noted.⁴⁵ In this study, 38% of hot flashes were preceded by aura, with 55.2% of participants experiencing this phenomenon. It is also notable that although previous definitions of hot flash aura commonly refer to it as encompassing a feeling of anxiety, only 7% of hot flashes in the present study were concurrent with a report of anxiety.

Another novel finding from this study was in the loci of the hot flash sensation. Participants in this study indicated the majority of their hot flashes occurred on the face (78.9%), neck (74.7%), and chest (61.3%). Previous studies using retrospective questionnaires used body diagrams of heat flow during hot flashes to report population variations in the loci of hot flash sensations³³. To the best of our knowledge, this study is the largest ambulatory ecological momentary assessment study to report the loci of every hot flash sensation as they occurred. This finding has potential implications in the study of regional sweating differences as well as in the concordance of subjective measures to physiologic measure of hot flashes using skin conductance.

This study was limited as it only included naturally menopausal, nonsmoking women. The sample was highly educated and primarily employed; future work should evaluate the utility of the diary among less educated participants. Additionally, participants taking commonly prescribed medications (e.g. SSRIs, beta-blockers) were also excluded. Although the diary described here is an older device, diary content can be readily employed across handheld devices. This study has notable strengths. It is the largest sample of women studied using a digital hot flash diary and the first to prospectively assess multiple aspects of the phenomenology of hot flashes in a large sample of women over three consecutive days.

Conclusion

Hot flashes are a highly prevalent symptom experienced by women in menopause, as well as by men and women who undergo some cancer-related treatments^{46–49}. In order to develop a better understanding of the etiology, phenomenology and effective treatments for hot flashes, accurate measurement is vital. A prospective electronic digital hot flash diary allows for a more precise quantitation of the experience hot flashes while overcoming many of the limitations of commonly employed retrospective questionnaires and paper diaries. In addition, digital diaries can provide unique insights into the phenomenology, loci and associated characteristics of hot flashes. The digital hot flash diary is recommended for future ambulatory studies of hot flashes as a prospective measure of the hot flash experience.

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Figure 1.
Palm Z22

Figure 2.
Hot Flash Digital Diary

Figure 3.
Hot Flash Severity

Figure 4.
Hot Flash Bother

Figure 5.
Hot Flash Loci & Associations

Table 1

Sample characteristics

N	152
Age (y), mean ($\pm$ SD)	53.35 (3.58)
Race, N (%)	
White	100 (65.8%)
Black, African-American	48 (30.3%)
Asian or Pacific Islander	4 (2.6%)
Mixed Race	1 (0.7%)
Hispanic, Latino	1 (0.7%)
Education, N (%)	
Less than College	28 (18.4%)
College	82 (53.4%)
Graduate	42 (27.6%)
Employment status, N (%)	
Full-time	97 (63.8%)
Part-time	26 (17.1%)
Other	29 (19.1%)
Menopause status, N (%)	
Perimenopausal	30 (19.7%)
Postmenopausal	122 (80.3%)
Marital status, N (%)	
Married, married-like relationship	90 (59.2%)
Divorced, separated, never married	62 (40.8%)
Waist Circumference, mean ($\pm$ SD)	35.02 (5.92)
BMI, mean ($\pm$ SD)	29.01 (6.60)
CES-D Score, ^a median ($\pm$ SD)	6.0 (7.6)
Trait anxiety, ^b median ($\pm$ SD)	33.0 (9.76)

^aCenter for Epidemiological Studies-Depression, range 0–60, 16 = Depressed

^bState Trait Anxiety Score, range 20–80, higher indicates greater anxiety