RESEARCH NOTE

Vasomotor symptoms monitoring with a commercial activity tracking watch [version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract

Personal fitness/health tracking devices that include electrodermal activity sensors enable tracking of vasomotor symptoms (hot flashes). Multiple conditions are associated with vasomotor symptoms. This article describes nighttime tracking of vasomotor symptoms for an individual over a two-year period. This volunteer was a participant in a longitudinal study on volunteers wearing physiological monitors. Personal tracking of vasomotor symptoms will provide new insights on the differences between conditions and impacts on individual's health.

Keywords

Vasomotor symptoms, hot flashes, menopause, galvanic skin response, GSR, electrodermal activity, EDA, physiological monitoring, health tracking

Open Peer Review

Approval Status ? ✓

	1	2
version 1	?	✓
20 Dec 2017	view	view

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2. **JoAnn E Manson**, Harvard Medical School, Boston, USA
Deirdre Tobias, Harvard Medical School, Boston, USA

Any reports and responses or comments on the article can be found at the end of the article.

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Author roles: Ricke DO: Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Software, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Introduction

Continuous tracking of electrodermal activity (EDA), also known as galvanic skin response (GSR), values with commercial fitness devices for individuals with vasomotor symptoms (hot flashes) provides a path forward for future studies with fine resolution monitoring. This can improve upon the current reliance on the use of personal diaries (Regestein *et al.*, 2015). There are multiple conditions associated with vasomotor symptoms including menopause/early menopausal transition (Hale *et al.*, 2014), medications (Quinestrol, tramadol, etc.), chemotherapy and Tamoxifen, hyperthyroidism, infections (Inflammatory Bowel Disease – IBD, etc.), and more. Multiple studies have characterized hot flashes in premenopausal and menopausal women using self reported methods, laboratory polysomnographic recording, and some specially designed devices (Freedman, 2014). However, it is difficult for an individual to track and accurately report nighttime vasomotor symptoms without the aid of a physiological monitoring device (Freedman, 2014). Emerging commercial and custom devices with EDA meters will greatly facilitate the nighttime monitoring of hot flashes for individuals for more informative longitudinal studies of conditions with associated vasomotor symptoms. This report illustrates the potential fine-resolution monitoring of nighttime vasomotor symptoms using commercially available activity-tracking devices with an EDA sensor.

Methods

MIT Lincoln Laboratory conducted a longitudinal study on volunteers wearing physiological monitors (June 15 2014 to October 2 2016). The study protocol and written consent form were reviewed and approved by the MIT Committee on the Use of Humans as Experimental Subjects (COUHES). The commercial devices in the study include the Basis B1 watch and Basis Peak watch monitors for tracking heart rate, sleep with predicted sleep phases (light, deep, and REM – rapid eye movement), activity, skin temperature, and perspiration (EDA/GSR) without the use of electrodes or gel. The Basis B1 and Peak watches are no longer commercially available, but similar devices with EDA/GSR sensors are available.

Vasomotor symptoms started disrupting the sleep of a female volunteer on November 23, 2015, calling attention to their occurrence. After November 23, 2015, the volunteer started personally logging the occurrence of vasomotor symptoms, noting that the recorded EDA signals reflected the logged hot flash intensities and durations.

Results

Figure 1 shows data from eight days around this time period. Freedman (Freedman, 1989) identified a good agreement between an increase of 2 $\mu\text{S}/\text{cm}$ in 30 s time period with volunteer

Figure 1. Eight nights illustrating nighttime hot flashes tracked with Basis Peak watch. Vertical axis shows EDA values in $\mu\text{S}/\text{cm}$.

self-reports for vasomotor symptoms. For November 15th, the EDA median value was $6.8 \times 10^{-4} \mu\text{S/cm}$ and average value of $4.9 \times 10^{-4} \mu\text{S/cm}$. For November 16th, the EDA median value was $6.8 \times 10^{-4} \mu\text{S/cm}$ and average value of $1.9 \times 10^{-4} \mu\text{S/cm}$. Across all nights tracked, the EDA median value was $3.7 \times 10^{-4} \mu\text{S/cm}$ illustrating baseline EDA values for this volunteer. The longitudinal data collected indicates that the volunteer's vasomotor symptoms may have been occurring as early as June 2014, but went unnoted until higher intensity vasomotor symptoms caused sleep disruptions. A review of all sleep time data indicates an increase in sleep interruption minutes as reported by Basis ($52/1957=2.9\%$ for EDA range 10-15 $\mu\text{S/cm}$ and $15/311=4.8\%$ for EDA range 15-25 $\mu\text{S/cm}$ compared to $3823/258119=1.5\%$ for EDA < 1 $\mu\text{S/cm}$). This is consistent with

volunteer observations. Nights like November 23 and 24, 2015 cause sleep disruptions. **Figure 2** illustrates over two years of nighttime EDA values while this volunteer was sleeping. Starting in December 2015, the volunteer started self-tracking EDA values and vasomotor symptoms. Daytime peaks were associated with both exercise and vasomotor symptoms. The volunteer reports that daytime vasomotor symptoms and sleep-disrupting vasomotor symptoms were consistent with recorded EDA peaks but they did not record these observations. Nighttime EDA peaks well above baseline values were observed in clusters from June 2014 until November 2016. Note that nights with low EDA values still occur frequently for this volunteer, indicating nights free of vasomotor symptoms. The volunteer did not take hormone or

Figure 2. Volunteer's nightly Basis watch EDA values for 1.5 years. Heatmap of each minute of volunteer's nighttime Basis EDA values tracked with Basis B1 or Basis Peak watch and line plot of nightly maximum EDA values in $\mu\text{S/cm}$.

nonhormonal formulations for the treatment of vasomotor symptoms. Note that the volunteer's Basis B1 watch was replaced with a Basis Peak watch in August 2015.

Discussion

Longitudinal studies of large numbers of volunteers will provide new foundations for tracking vasomotor symptoms associated with menopause and other conditions. Continuous tracking of EDA values with readily available commercial tracking devices will provide a path forward for future fine-resolution longitudinal studies of conditions associated with vasomotor symptoms. Insights into understanding and treating vasomotor symptoms will be greatly advanced by these longitudinal studies, as the different causes of vasomotor symptoms may vary in intensities and durations. EDA is also reported as a sensitive index of sympathetic nervous system activity (Poh *et al.*, 2010). In addition, commercial devices with EDA meters will be valuable personal monitoring tools to premenopausal and menopausal women and individuals experiencing vasomotor symptoms.

Data availability

The nighttime EDA values tracked are available in Ricke, Darrell, 2017, "GSR nights", doi: [10.7910/DVN/ONAUUZ](https://doi.org/10.7910/DVN/ONAUUZ), Harvard Dataverse.

Consent

Written informed consent was obtained from the volunteer for the publication of her details.

Competing interests

No competing interests were disclosed.

Grant information

This material is based upon work supported by the Assistant Secretary of Defense for Research and Engineering under Air Force Contract No. FA8721-05-C-0002 and/or FA8702-15-D-0001. Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Assistant Secretary of Defense for Research and Engineering. Assistant Secretary of Defense for Research and Engineering has no involvement in this report.

The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Acknowledgments

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[PubMed Abstract](#) | [Publisher Full Text](#)

Open Peer Review

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The article by D.O. Ricke provides details of the experience of an individual research participant in a longitudinal study that involved wearing physiological monitors, allowing a comparison of personal tracking of nighttime vasomotor symptoms (VMS) with the parallel capture of VMS data via the monitor's recording of electrodermal activity. This is essentially a case report of a single individual's experience/data and serves as a "proof of principle". The report achieves its goal for this limited purpose; however, additional information about the background study leading to this report, the participant's daily (daytime and nighttime) frequency and severity/"bother" of VMS if available (the report focuses on night-time tracking), and any use of medications for VMS by the patient would be helpful for the reader. Also, the literature review is limited, especially in terms of reviewing other investigators' experience with objective monitors for VMS (results have not always been concordant with subjective reports). Readers would benefit from an expanded reference list addressing prior relevant research on this topic and from the author's recommendations regarding integrating and/or reconciling data that may conflict from patient-reported and objective monitor sources.

Nonetheless, the Research Note does provide a compelling illustration of the potential utility of commercial fitness devices, which have the potential to advance our understanding of the correlates, lifestyle/behavioral "triggers" of VMS, and the response to interventions/treatments. The present study does make a contribution in showing that high resolution data captured from these devices may add to patient-reported methods such as diaries, particularly for nighttime events. Additional research is clearly needed to follow up on this N=1 study; such research will fill important gaps and will ultimately support (or refute) the value and utility of the approach.

Is the work clearly and accurately presented and does it cite the current literature?

Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?

No

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

No

Are the conclusions drawn adequately supported by the results?

Yes

Competing Interests: No competing interests were disclosed.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 06 February 2018

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The author provides information on a single research study participant who incidentally experienced vasomotor symptoms while testing a physiological monitor in what is presumably a separate study. Changes in electrodermal activity appeared to correlate with self reported night time vasomotor symptoms.

This case report describes the experience of a single volunteer. There are several details missing that would make it easier to understand how the original study was conducted. The scholarship of the manuscript is also incomplete.

1. The parent study in which the participant with vasomotor symptoms was recruited is inadequately described. If already published, a reference to the study would be helpful. If it not published or is proprietary, basic information about inclusion and exclusion criteria for the parent study is important to provide (age and sex of participants, BMI inclusion/exclusion, if any, comorbidity or medications, for a start).

2. It is curious why the author recorded only night time EDA. Why not perform a subjective, daytime hot flash assessment concurrent with the wearing of the monitor to assess the relationship better?
3. The presentation would benefit greatly from a more quantitative assessment of the agreement between night time hot flashes that disrupted the participant's sleep and objectively determined hot flashes using the monitor.
4. The Figures do not convey information with sufficient clarity. It appears that two days of EDA data are overlaid, yet we do not know whether these were nights with vasomotor symptoms or not. It appears to be assumed that a rise in EDA means the same thing as a hot flash. How can the author be sure of this? The presentation of two years' data in Figure 2 is also unclear.
5. In terms of scholarship, the author does not include past literature on skin conductance monitors that have been tried (Newton KM, *et al.* Methods for the Design of Vasomotor Symptom Trials: The MsFLASH Network¹ and the Bahr DE, *et al.* Miniature ambulatory skin conductance monitor and algorithm for investigating hot flash events² are two examples the come immediately to mind).
6. There is debate within the field as to the helpfulness of objective hot flash measurements using skin conductance. Many clinicians and patients believe that, since subjective symptoms drive treatment-seeking, objective assessments are relatively moot. The author should at least attempt to address this limitation in the manuscript.

References

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2. Bahr DE, Webster JG, Grady D, Kronenberg F, et al.: Miniature ambulatory skin conductance monitor and algorithm for investigating hot flash events. *Physiol Meas*. 2014; **35** (2): 95-110 [PubMed Abstract](#) | [Publisher Full Text](#)

Is the work clearly and accurately presented and does it cite the current literature?

Partly

Is the study design appropriate and is the work technically sound?

Partly

Are sufficient details of methods and analysis provided to allow replication by others?

No

If applicable, is the statistical analysis and its interpretation appropriate?

Not applicable

Are all the source data underlying the results available to ensure full reproducibility?

No

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: I am not involved with any research or companies specifically exploring the use of objective hot flash monitoring. However I work with 2 companies who are developing treatments for hot flashes: 1. Menogenix: Scientific Advisory Board and stock options 2. Ogeda/Astellix: Scientific Advisory Board

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 19 Feb 2018

Darrell Ricke, MIT Lincoln Laboratory, 244 Wood Street, Lexington, USA

The article on the parent study has now been released: Ricke DO, Harper J, Shcherbina A *et al.* Integrated Biomedical System [version 1; referees: awaiting peer review]. *F1000Research* 2018, **7**:162 (doi: [10.12688/f1000research.13601.1](https://doi.org/10.12688/f1000research.13601.1)). Details on age, sex of participants, BMI inclusion/exclusion, comorbidity, medications, etc. are not included as the parent study was not focused on vasomotor symptoms. As noted in the text "The volunteer did not take hormone or nonhormonal formulations for the treatment of vasomotor symptoms." This volunteer is female as noted in the text.

Accurate detection and recording of night time vasomotor symptoms while sleeping is difficult to quantify outside of laboratory polysomnographic studies.

The article includes quantitative assessment of sleep impact derived from the Basis watch sleep monitoring: "A review of all sleep time data indicates an increase in sleep interruption minutes as reported by Basis (52/1957=2.9% for EDA range 10-15 $\mu\text{S}/\text{cm}$ and 15/311=4.8% for EDA range 15-25 $\mu\text{S}/\text{cm}$ compared to 3823/258119=1.5% for EDA < 1 $\mu\text{S}/\text{cm}$)." Inclusion of self-reported sleep quality like Pittsburgh Sleep Quality Index (PSQI) was not included in the original study design, but would have been a nice addition for interested volunteers.

Figure 1 illustrates eight nights flanking immediately before and during the first nights that the volunteer became self-aware of vasomotor symptoms occurring. Figure 2 illustrates fluctuations in night time vasomotor symptoms spanning a two-year format in both a heat map and a summary graph with peak EDA measurements. Data are available for download for closer examinations.

The article by Newton *et al.* evaluates and rejects three monitors as being unsuitable. The article by Bahr *et al.* describes another device that attaches over the sternum with adhesive hydrogels; removal of this device after a week can cause skin irritations. These articles would be good additional articles to cite.

The reviewer raises the question of subjective symptoms and the drive for treatment-seeking. This article includes only quantified measurements. This volunteer did not seek treatments. In contrast the volunteer felt empowered being able to confirm symptoms with EDA measurements via Basis provided phone and web interfaces to personal measurements.

Competing Interests: No competing interests were disclosed.

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