

# Validation of a Sternal Skin Conductance Criterion for Measuring Hot Flashes in Breast Cancer Patients

Marie-Hélène Savard, Ph.D.<sup>1-2</sup> • Josée Savard, Ph.D.<sup>1-3</sup> • Hans Ivers, Ph.D.<sup>1-3</sup>

1. Centre de recherche du CHU de Québec  
3. School of Psychology, Université Laval

2. Centre de recherche sur le cancer, Université Laval  
Québec (Québec), Canada

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## INTRODUCTION

- Although hot flashes are most frequently assessed using subjective reports (e.g., questionnaires, diaries), sternal skin conductance level (SCL) is currently considered the “gold-standard” for objectively assessing them.
- The typically used criterion (an increase of 2 microsiemens [ $\mu\text{mho}$ ] within a 30-second period) to identify a hot flash by SCL may not be appropriate for some clinical populations, such as breast cancer patients (e.g., radiotherapy damage to the sweat glands).
- Discordance between self-reported hot flashes and an ambulatory recording of SCL of up to 47% have been found when using the 2  $\mu\text{mho}$  criterion to detect hot flashes among breast cancer patients (Carpenter, 2004, 2005).
- An SCL increase of 1.78  $\mu\text{mho}$  was found to constitute a better threshold for identifying hot flashes among prostate cancer patients (Hanisch, 2007).

## STUDY GOALS

This study aimed to establish the SCL increase that would optimally detect hot flashes among breast cancer patients.

## METHODS

### Participants (N = 56)

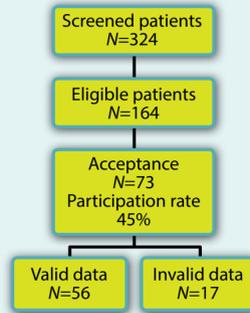
Patients were recruited from a larger longitudinal study or solicited at the radio-oncology department of L’Hôtel-Dieu de Québec (CHU de Québec).

### Inclusion criteria

- Between 30 and 70 years of age
- Having received a first diagnosis of non-metastatic breast cancer
- Having completed in the past four months a treatment protocol combining surgery, chemotherapy, and radiotherapy
- Have been receiving hormone therapy for a minimum of five weeks

### Exclusion criteria

- A diagnosis of sleep apnea or PLMS
- Having received neoadjuvant chemotherapy for breast cancer
- Having a score <24 on the Mini-Mental State Examination (Folstein, 1975)
- Having any medical, neurological or psychological disorder that is known to significantly alter sleep (e.g., multiple sclerosis, major depression)
- Occasionally or regularly using any medication (other than psychotropic medication) known to significantly affect sleep (e.g., corticosteroids, opioids)



## Participants’ Characteristics by Group

Variable	M	(SD)
Age	51.8	(7.6)
BMI	25.7	(4.8)
	%	
<b>Marital status</b>		
Married/Cohabiting	58.9	
<b>Education</b>		
College or University degree	62.5	
<b>Annual family income (CAD)</b>		
\$60 000 and higher	46.5	
<b>Occupation</b>		
Sick leave	60.7	
<b>Menopausal status at diagnosis</b>		
Pre	57.8	
Peri	6.3	
Post	35.9	
<b>Past hormone replacement therapy use</b>	26.6	
<b>Use of a medication to manage hot flashes (venlafaxine, paroxetine, gabapentin)</b>	23.2	
<b>Use of another psychotropic medication</b>	42.9	
<b>Cancer stage</b>		
I	23.2	
II	48.2	
III	28.6	

## Procedure and Measures

Participants completed a home-based recording of hot flashes using sternal skin conductance level (SCL) measurement, starting at approximately 09:00 AM until bedtime (lights out).

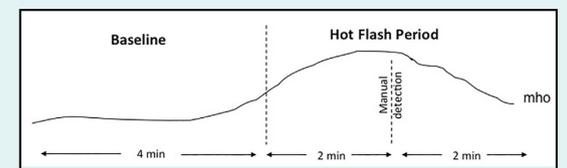
- Conductance levels were recorded at a 200-Hz sampling frequency rate by the Notta® device (Stellate Systems, Montréal, QC, Canada), via an amplifier.
- Participants were instructed to use an event marker located on the device each time they felt a hot flash was beginning.
- All traces were visually scanned to detect artifacts. SCL raw data were analyzed with an in-house hot flash detection software (Ivers et al., 2007).

## Statistical Analyses

- A Receiver Operating Characteristic (ROC) analysis: provides sensitivity and specificity rates for the entire range of SCL values (i.e. minimal to maximal increase in SCL during a 30-second period) corresponding to a manual hot flash detection.

Event marker (participant)	yes	SCL (device)	
		yes	no
yes	yes	true positive	false negative
no	no	false positive	true negative (10-minute periods preceding each hot flash period)

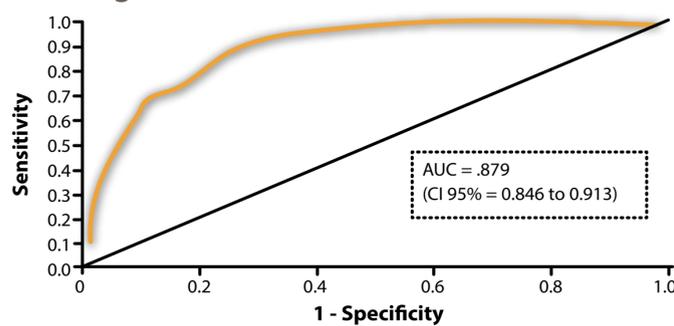
- Differences in SCL values between the baseline (i.e. the 4-minute period before) and each of the 240 seconds of the hot flash period (i.e. from 2 minutes before to 2 minutes after each manually-detected hot flash) were calculated. Then, mean, median, and 10, 25, 75, and 90<sup>th</sup> percentiles of the distribution of delta conductance values were computed.



## RESULTS

### 1) ROC Curve Analysis

Figure 1. ROC curve obtained for the entire range of sternal skin conductance values.



**From a clinical standpoint, the selected criterion should be able to detect the greatest possible number of hot flashes and thus to limit the number of false-negatives (i.e. a self-perceived hot flash that is not detected objectively).**

Note. Sensitivity represents the probability of detecting an hot flash with SCL when one was self-reported (the criterion standard), whereas specificity represents the probability of detecting no hot flash with SCL when none was self-reported.

Table 2. Comparison of standard and proposed SCL criteria for self-reported hot flash detection.

	Standard SCL criterion (2 $\mu\text{mho}$ increase within 30-sec)	Proposed criterion (1.2 $\mu\text{mho}$ increase within 30-sec)
nb of objective hot flashes detected by the participants	84	134
Sensitivity	32.7%	60.8%
Specificity	97.0%	90.4%
positive predictive value (PPV; proportion of objectively-detected hot flashes that are true positives)	92%	86%
negative predictive value (NPV; proportion of SCL periods correctly identified as true negatives)	59%	70%
false-negative rate (a self-reported hot flash that does not correspond to a sufficient SCL increase)	41%	30%

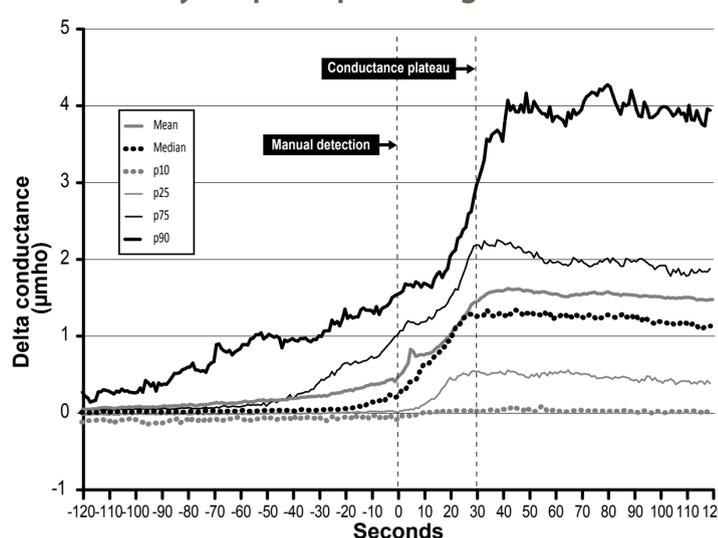
Table 1. Sensitivity, specificity, positive predictive values, and negative predictive values for detecting a hot flash as a function of various SCL values (maximum change observed in SCL within a 30-second period).

Delta ( $\mu\text{mho}$ )	Sensitivity	Specificity	PPV	NPV
0.2	.970	.548	.684	.947
0.4	.889	.731	.770	.867
0.6	.794	.797	.798	.793
0.8	.734	.838	.820	.757
1.0	.668	.888	.858	.726
1.2	.608	.904	.864	.695
1.4	.523	.934	.889	.659
1.6	.442	.949	.898	.628
1.8	.362	.964	.911	.599
2.0	.327	.970	.915	.588
2.2	.286	.975	.919	.575
2.4	.246	.980	.925	.563
2.6	.201	.985	.930	.550
2.8	.181	.985	.923	.543
3.0	.156	.985	.912	.536
3.2	.141	.985	.903	.532
3.4	.121	.985	.889	.526
3.6	.116	.985	.885	.524
3.8	.111	.985	.880	.523
4.0	.101	.985	.870	.520

Note. PPV = positive predictive value; NPV = negative predictive value.  
= proposed threshold; = standard threshold

### 2) SCL Percentiles

Figure 2. Increase in sternal skin conductance during the 4-minute period surrounding a manual hot flash detection by the participant using the event marker.



## CONCLUSION

- This study suggests that the optimal threshold for detecting hot flashes among breast cancer patients is below the standard criterion of a 2  $\mu\text{mho}$  increase in SCL. Indeed, the probability of detecting self-reported hot flashes was only 32%.
- The more liberal criterion that was retained was an increase in SCL of 1.2  $\mu\text{mho}$  or more within a 30-sec period, which was associated with a probability of detecting 61% of the self-reported hot flashes.
- However, the use of self-reported hot flashes as a “gold standard” to validate an objective measure represents an important limitation inherent to this research field.
- Larger and prospective studies are warranted to document the changes in SCL levels that occur during the cancer care trajectory (e.g., following irradiation of the axillary nodes).