Patient Satisfaction with Miniature, Ambulatory, Postmenopausal Hot Flash Recorder

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Abstract: Although much research is underway to develop new treatments for postmenopausal hot flashes, it is hindered by a lack of suitable outcome measures. Therefore, the author invented a miniature, ambulatory hot flash recorder. The purpose of this study was to ascertain patient satisfaction with this device. Subjects were 38 postmenopausal women reporting frequent hot flashes. They wore the recorder for 3 consecutive weeks. Patients reported that the recorder interfered minimally with their daily activities, was easy to use, and was acceptable in appearance. This device should be useful in evaluating treatments for postmenopausal hot flashes.

INTRODUCTION

Hot flashes (HFs) are the most common symptom of postmenopause and currently affect approximately 35 million women in the U.S. [1, 2]. They consist of profuse sweating and peripheral vasodilation accompanied by feelings of intense heat (also known as hot flushes). Until recently, hormone replacement therapy (HRT) was the gold standard treatment for postmenopausal hot flashes. However, results from the Women's Health Initiative (WHI) showed that, for many women, the risks of HRT outweighed the benefits and its use has rapidly declined [3]. Thus, there is a great need for research on new treatments for hot flashes**.** It should be noted that changes in quality of life during postmenopause are more related to emotional symptoms than to postmenopause per se [1, 2].

However, this research has been hindered by the lack of suitable outcome measures. Patient-reported outcome measures have not been standardized and suffer from lack of compliance, recall bias, and lost data, among other factors [4, 5].

Research conducted by the author and others have identified sternal skin conductance level (SCL) as the best objective indicator of hot flashes [6-10]. These studies compared a criterion SCL response (2 μmho/30 sec.) with patient self-reports using an event marker and/or diaries. However, existing recording devices are cumbersome and difficult to use. Moreover, they require the use of electrodes which must be changed every 24 hours due to accumulation of sweat and drying of the gel.

The author and collaborators have invented a miniature hot flash recorder (1.5" diameter) that attaches over the sternum and does not use electrodes [11]. It is easy to remove and reapply and will run for at least 31 days on a single watch battery.

The purpose of this paper is to report upon patient experience with this device.

MATERIALS AND METHODOLOGY

Subjects were 38 postmenopausal women reporting frequent (> 5/day) hot flashes. They were enrolled in a study to test the effectiveness of an antidepressant drug (escitalopram) upon postmenopausal hot flashes. Women taking any antidepressant drug, any hot flash treatment, or any dietary supplement, such as soy, were excluded. The study was double-blind in design and compared escitalopram with a placebo. All subjects gave written, informed consent and all procedures were approved by the Wayne State University Human Investigation Committee. Their mean age was 52.1 ± 3.2 (SD) years, and they had been postmenopausal for 6.6 ± 4.8 years. Their mean Body Mass Index (BMI) was 26.4 ± 3.8.

Subjects were instructed in the use of the recorder in the laboratory of the author. They were told not to get it wet and to remove it prior to bathing and to replace it afterwards. They were given a supply of double-sided adhesive collars for attachment of the recorder to the skin over the sternum. The recorder, which weighs 14 grams, is shown in Fig. (**1**).

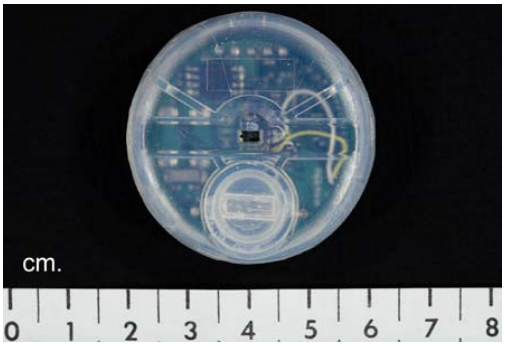

Fig. (1). Miniature hot flash recorder. The weight of the recorder is 14 g, scale in centimeters.

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Subjects were then sent home with these materials for 3 weeks. At the end of this period, they completed a brief questionnaire which inquired about their experience with the recorder.

RESULTS

In response to the question, "Did the recorder interfere with your daily activities?," 26 subjects (68.4%) replied "not at all," and 12 (31.6%) replied "a little." In response to the question, "Did you have trouble changing the sticky disk?," 32 (84.2%) replied "not at all," 5 (13.2%) replied "a little," and 1 (2.6%) replied "a lot." In response to the question, "Was the appearance of the recorder acceptable?," 34 (89.5%) replied "yes" and 4 (10.5%) replied "no." These are the only questions that were asked. The questionnaire was developed by the author and has not yet been further validated.

CONCLUSION

The above results demonstrate, for the most part, that patients found the recorder easy to use and acceptable in appearance. Methods of analysis of data from this device have been previously described [10] and are straightforward. That study demonstrated that the present device was superior to the Biolog in positive predictive value, sensitivity, and specificity. The present study is limited by the possibility of recall bias as well as possible confounding effects of the drug. For MAS these reasons, the device described herein should prove useful in the evaluation of treatments for postmenopausal hot flashes.

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Professor Robert Freedman is President and CEO of Biomedical Monitors LLC, the manufacturer of the recorder and has a pending U.S. Patent #60,741,376.

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