Low level steady heat compared to high level pulsed heat for the treatment of premenstrual pain

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Introduction

Dysmenorrhea affects a large percentage of menstruating women. Primary menstrual syndrome (PMS) affects more than 50 percent of all women who have a menstrual period. Approximately 5 to 15 percent of these women have severe pain that interferes with daily activities (1). About 20% to 40% of women who have PMS experience symptoms that make life difficult and 2.5% to 5% experience PMS that is debilitating (2). Heat is a well recognized self treatment technique used to help relieve the cramps and the pains (back, abdominal, and pelvic) associated with PMS. Recent studies demonstrate that low level heat can significantly reduce PMS pain and even reduce the amount of adjunctive pain medications used to treat PMS (3).

In spite of both empiric evidence and formal studies little is known about basic mechanisms surrounding heat and PMS relief. For instance, what temperature do subjects prefer, does the temperature response display dose curve characteristics, and how large of an area needs heated to produce an analgesic response? Based on earlier studies it was hypothesized that there was a dose dependent response curve associated with thermal analgesia (6). Furthermore the characteristics of the heating wave could also affect analgesic outcomes.

In a previous study we showed that subjects strongly preferred temperatures that were significantly hotter (mean 44.6 º C, range 42-48 º C) than those provided by chemical hot packs (39-40° C) and that heating a relatively small area of skin at high temperatures could produce analgesia comparable to that produced by heating large areas of skin at lower temperatures (4). In the present study we created an experimental device that allowed subjects to preselect levels of pulsed heat that were significantly higher than temperatures used in common commercial heating products. The hypothesis of this study was that the high-level pulsed heat delivered via the experimental device would be more effective than low-level continuous heat from a commercial hot pack in relieving PMS pain.

Procedures

This study compared the pain relieving effects of an experimental electronic heating device termed, *Series-3* with ThermaCare® wraps. The name Series-3 was used to designate the third laboratory iteration of the experimental device. Series-3 consisted of two electronic heating pads set to a temperature selected by the individual subject (figure 1 and 2). The temperature of the experimental device can be set by the user in a range from 42 to 47 °C via a wireless control. The Series-3 experimental device is shown in figures 1 and 2.The control device, ThermaCare®, is a commercially available, over the counter chemical hot pack. ThermaCare® is attached to the skin using its own elastic wrap and heats at a steady 40 ° C.

All subjects met with a research assistant (RA) prior to the start of the study. The RA explained and demonstrated both devices, their purpose and the methods of the study. Subjects were randomly assigned to one of two groups, Series-3 or ThermaCare group. All subjects completed a questionnaire about their pain.

Once randomization occurred subjects rated their pain level using both a numeric pain scale and the Iowa pain thermometer. Those subjects initially assigned to the control group had the device placed over their area of greatest pain. All ThermaCare wraps were allowed at least 30 minutes to warm up before being placed on the subject and a temperature of at least 40°was confirmed. Subject rated their pain levels at baseline and after 10 minutes, 20 minutes, and 30 minutes. After the first treatment session there was a 30-minute washout period after which subjects crossed over to the other treatment arm.

Subjects randomized to the experimental treatment group were shown the study device. The RA facilitated a run in period in which the subject was able to gradually increase the temperature of the Series-3 device starting at 108 degrees Fahrenheit (41 °C) up to a maximum of 116.6 degrees Fahrenheit (47 °C). Once the study temperature was selected subjects wore the device and provided pain assessments at baseline and after 10 minutes, 20 minutes, and 30 minutes.

After completing the study subjects filled out an exit interview questionnaire and were paid $100 for study participation. Results were analyzed using paired t-tests.

Results

Pain Reduction: Series-3 versus ThermaCare©

Results of a paired-sample t-test indicated significantly greater decrease in Iowa Pain Thermometer scores from baseline to 30 minutes when participants used the Series 3 device ($t(43)$, $p<.001$). Similar differences were found from baseline to 10 minutes (t (43), $p=.005$), and from the 20 to 30 minute assessment (t (43), $p=.009$). No significant differences were found on reduction of scores on the IPT from 10 to 20 minutes (Table 1).

Reduction of pain rating on the Numeric Rating Scale from baseline to 30 minutes was also greater with use of Series 3 ($t(43)$, $p<.001$). Those using the Series 3 also reported greater reduction of pain on the Numeric Rating Scale from baseline to 10 minutes ($t(43)$, $p=.003$), and from 20 to 30 minutes ($t(43)$, $p=.003$). No significant differences were found from 10 to 20 minutes (Table 2).

Paired sample t-tests were also used to compare reduction in reported pain in participants with PMS. Participants with menstrual/premenstrual pain reported greater pain reduction from baseline to 30 minutes on the both measures (t (16), $p=.001$) and $t(16)$, $p>.001$), when they used Series 3. From baseline to 10 minutes, use of Series 3 was associated with significant reduction in NRS scores (t (16), $p=.04$), but differences were not significant for IPT scores. From 10 to 20 minutes, no significant difference was found in pain reduction for either measure. From 20 to 30 minutes, participants reported greater reduction in pain on both the IPT and NRS (t (16), $p=.002$ and t (16), $p<.001$) when using Series 3 (Tables 3, 4 and figure 3).

Conclusions

In spite of both empiric evidence and formal studies little is known about mechanisms or dose response data surrounding heat and PMS relief. Based on earlier studies (see Characteristics of Thermal Analgesia in Human Subjects), it was hypothesized that there was a dose dependent response curve associated with thermal analgesia (4). In that study the mean temperature preferred by subjects was 44.6 º C (range 42-48 º), temperatures much hotter than those produced by chemical hot packs (40 º C).

Both treatments produced significant reduction in pain in subjects who suffered from chronic low back pain. When compared to ThermaCare, Series -3 produced faster onset and significantly better pain relief. In addition subjects were able to place the thermal pods directly over the region of the body (front or back) that produced the most effective relief. Based on the rapid onset and heat profile it is likely that the analgesic response noted from the high-level pulsed heat may be related to stimulation of a-delta thermal receptors. The findings of this study may help identify unique properties and characteristics of a well-established treatment (heat) that can improve the speed of onset and quality of pain relief. Coupled with advances in wireless connectivity, lithium battery technology and low cost embedded chip sets these finding may offer novel mobile and more effective drug free options for patients who suffer from PMS.

References

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Timepoint	Series-3		ThermaCare	
	mean	median	mean	median
0-10 min	1.24	1.0	0.71	0.0
10-20 min	0.59	0.0	0.47	0.0
20-30 min	.82	1.00	-0.47*	0.0
0-30 min	2.65	3.00	0.71	1.0

Table 1: Mean and median change in participant PMS pain rating on a Iowa Pain Thermometer at 10, 20, and 30 (N=17).
* negative change indicates an increase in pain.

Timepoint	Series-3		ThermaCare	
	mean	median	mean	median
0-10 min	0.94	1.0	0.24	0.0
10-20 min	0.53	0.0	0.65	0.0
20-30 min	0.82	1.00	-0.35*	0.0
0-30 min	2.30	3.00	0.71	1.0

Table 2: Mean and median change in participant PMS pain rating on a Numeric Rating Scale at 10, 20, and 30 (N=17).
* negative change indicates an increase in pain.

Timepoint	PMS (N=17)				
	Mean diff.	Std. Dev.	t	df	p
0-10 min	0.53	1.740	1.26	16	.23
10-20 min	0.12	0.93	0.52	16	.61
20-30 min	1.30	1.40	3.80	16	.002
0-30 min	1.94	1.85	4.32	16	0.001

Table 3. Mean differences: change in participant PMS pain rating on Iowa Pain Thermometer at 10, 20, and 30 minutes.

Timepoint	PMS (N=17)				
	Mean diff.	Std. Dev.	t	df	p
0-10 min	0.71	1.26	2.30	16	0.04
10-20 min	-0.12	0.78	-0.62	16	0.54
20-30 min	1.18	1.01	4.78	16	0.00
0-30 min	1.76	1.39	5.22	16	0.00

Table 4: Mean differences: change in participant PMS pain rating on Numeric Rating Scale at 10, 20, and 30 minutes.

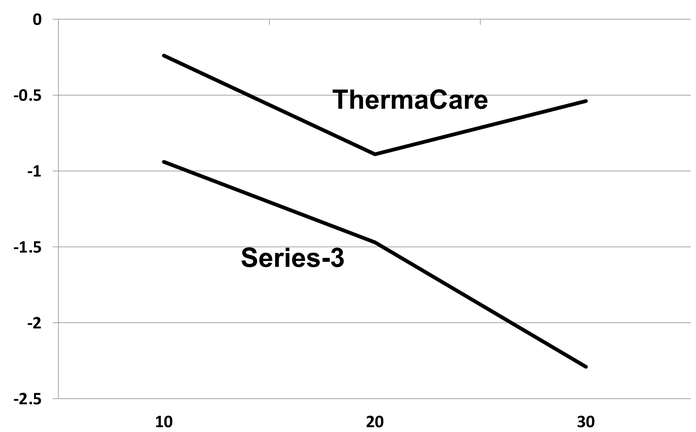

Figure 3: Reduction in PMS pain in subjects 0-10 scale after 10, 20, and 30 minutes of treatment.