Properties of thermal analgesia in a human chronic low back pain model

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PURPOSE

For years heat has been used for comfort and analgesia and is recommended as a first line therapy in many clinical guidelines. Yet, there are questions that remain about the effectiveness of heat for a condition as common as chronic low back pain, and factors such as time of onset, optimal temperature, and duration of effect. Against this background the present study was designed using a chronic low back pain model. The primary hypothesis was that higher level thermal stimulation would produce better analgesia than lower temperatures in a well design placebo controlled randomized double blinded study. In addition, this study was designed to carefully document two poorly understood outcomes of thermal analgesia: 1) the onset and 2) duration of analgesia after 30 minutes of thermal stimulation.

METHODS

A randomized double blinded controlled trial was designed to compare the analgesic response to heat delivered via pulses at 45°C (experimental group, N=49) to steady heat at 37°C (control group, N=51) in subjects with longstanding low back pain. Treatment lasted 30 minutes with follow-up out to four hours. Time of onset and duration of effect was also measured. The study devices used were manufactured by Soovu Labs Inc. and were identical in both the experimental and control groups. Only the temperature settings differed between groups.

RESULTS

Both groups were similar in average duration of pain (10.3 years). The primary outcome measure was pain reduction 30 minutes after the end of treatment, using a 10 points numeric pain scale. Reduction in pain was greater for the experimental group than the control group (difference in mean reduction = 0.72, 95% CI 0.15 - 1.29, p = 0.014). Statistically significant differences in pain levels were observed from the first measure at 5 minutes of treatment through 120 minutes after completion of treatment. Reduction with movement was greater in the active heat group than the placebo group (p = 0.04).

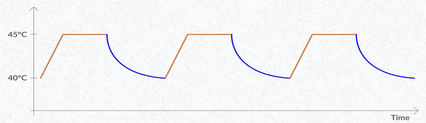

Figure 1: Schematic representation of the pulsed heat algorithm for the active device used in the study.

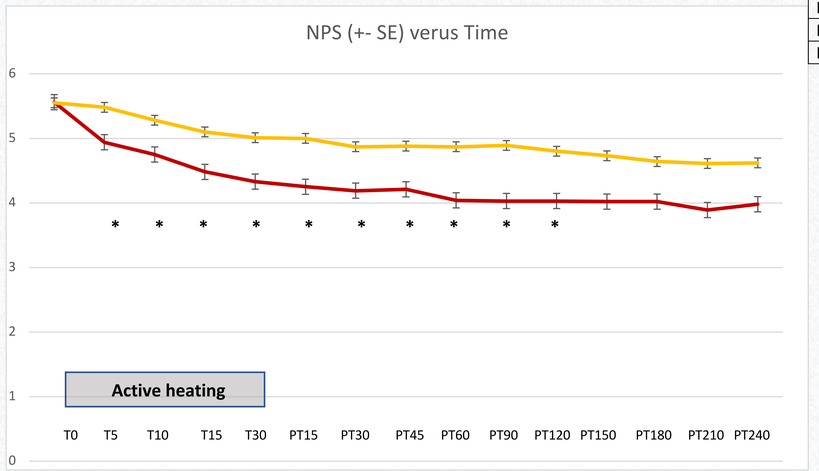

Figure 2: Graphical representation of reduction (± SE) in pain scores (0-10) over time. T = treatment time and ranged from T-0 (baseline) to 30 minutes of treatment (T30) and is indicated by the shaded area. The time after cessation of treatment rages from 15 minutes post treatment (PT15) to 210 minutes post treatment (PT 210). The experimental arm (45° C) produced a statistical reduction in reported pain as compared to the control arm (37° C) from the first pain assessment (T-5 minutes) through 120 minutes after cessation of treatment. Statistically significant ($p < 0.05$) is indicated by asterisks (*).

Time	Estimated effect	Std. Error	p-value	95% Confidence intervals
T-5	0.48	0.15	0.001	0.19 – 0.77
T-10	0.51	0.16	0.002	0.19 – 0.83
T-15	0.62	0.19	0.001	0.26 – 0.99
T-30	0.65	0.21	0.002	0.24 – 1.06
post T-15	0.77	0.23	0.001	0.32 – 1.22
Post T-30	0.74	0.26	0.005	0.23 – 1.24
Post T-45	0.71	0.29	0.016	0.13 – 1.28
Post T-60	0.79	0.29	0.008	0.21 – 1.37
Post T-90	0.91	0.30	0.003	0.31 – 1.51
Post T-120	0.87	0.30	0.005	0.27 – 1.47
Post T-150	0.62	0.33	0.058	-0.02 – 1.27
Post T 180	0.62	0.33	0.068	-0.05 – 1.28
Post T-210	0.60	0.35	0.089	-0.09 – 1.30

Figure 3: Difference in improvement of pain scores over baseline between the experimental heat group (45°C) and the control heat group (37° C). The experimental heat group shows a statistically significant improvement in reported pain over the control group at the first measurement of five minutes of treatment out to 120 minutes after the cessation of treatment.

CONCLUSIONS

High level pulsed heat (45°C) produced significantly more analgesia as compared to steady heat at 37°C at the primary end point and for an additional 2 hours after treatment. The onset of analgesia was rapid, < 5 minutes of treatment. The results of this trial provide insight into the mechanisms and properties of thermal analgesia that are not well understood in a chronic low back pain model.

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