

A viable methodology for assessing the onset of treatment for low back pain

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Purpose

Low back pain (LBP) is a common and costly medical problem that causes pain, disability, and economic loss. Using a stopwatch to measure the time of the onset of the analgesic effect has not been evaluated in a LBP model. This pilot study was to evaluate the sensitivity of using the methodology for assessing LBP relief with ThermaCare low back/hip HeatWraps.

Method

In this single-center, single-dose (single wrap wear occasion), randomized, single-blind, placebo-controlled trial, subjects between 18 and 55 years old with baseline primary muscle acute LBP of at least moderate intensity were randomized to one of two primary study groups, ThermaCare HeatWraps or oral placebo. Unheated "sham" wrap or oral ibuprofen were also included for blinding purposes only, which were not included in the analyses.

At the time of wrap application/oral administration, two stopwatches were started. Subjects stopped the first stopwatch upon feeling the "first perceptible" pain relief, and stopped the second stopwatch upon feeling "meaningful" pain relief. Subjects assessed pain relief hourly (the 5-through-8 hour assessments outside the clinic via diaries).

Results

Sixty-one (61) eligible subjects were randomized to the following groups: ThermaCare HeatWraps treatment (n=26), oral placebo (n=25), sham (inactive) wrap (n=5), and oral ibuprofen (n=5).

The time weighted sum of pain relief scores from 0 through 8 hours (TOTPAR 0-8) was significantly higher for the ThermaCare HeatWraps treatment group than the oral placebo group (22.0 vs 11.5; $P < .001$). The mean pain relief scores over time for the heatwrap treatment group were significantly higher than those for the oral placebo at all time points through the end of the study (hour 1 to hour 8). The time to confirmed first perceptible relief and time to meaningful pain relief were significantly shorter for the ThermaCare HeatWraps treatment group compared to the oral placebo group (median of 96.5 minutes vs >240 minutes and 215.7 minutes vs >240 minutes, respectively; $P < .05$ for both comparisons). Among subjects who received the ThermaCare HeatWraps, 53.8% reported both first perceptible and meaningful relief, compared to 28% who received oral placebo. Three adverse events were reported as mild in severity and the investigator considered them unrelated to the study product.

Conclusions

ThermaCare HeatWraps provided significantly faster pain relief than oral placebo in subjects with muscular low back pain. The double stopwatch is a viable approach for assessing the onset of analgesia in low back pain.