Overnight Use of Continuous Low-Level Heatwrap Therapy for Relief of Low Back Pain

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ABSTRACT. Nadler SF, Steiner DJ, Petty SR, Erasala GN, Hengehold DA, Weingand KW. Overnight use of continuous low-level heatwrap therapy for relief of low back pain. Arch Phys Med Rehabil 2003;84:335-42.

Objective: To evaluate of the efficacy and safety of 8 hours of continuous, low-level heatwrap therapy administered during sleep.

Design: Prospective, randomized, parallel, single-blind (investigator), placebo-controlled, multicenter clinical trial.

Setting: Two community-based research facilities.

Participants: Seventy-six patients, aged 18 to 55 years, with acute, nonspecific low back pain.

Intervention: Subjects were stratified by baseline pain intensity and gender and randomized to one of the following treatments: evaluation of efficacy (heatwrap, n=33; oral placebo, n=34) or blinding (unheated wrap, n=5; oral ibuprofen, n=4). All treatments were administered for 3 consecutive nights with 2 days of follow-up.

Main Outcome Measures: Primary: morning pain relief (hour 0) on days 2 through 4 (0–5-point verbal response scale). Secondary: mean daytime pain relief score (days 2–4, hours 0–8), mean extended pain relief score (day 4, hour 0; day 5, hour 0), muscle stiffness, lateral trunk flexibility, and disability (Roland-Morris Disability Questionnaire).

Results: Heatwrap therapy was significantly better than placebo at hour 0 on days 2 through 4 for mean pain relief ($P=.00005$); at hours 0 through 8 on days 2 through 4 for pain relief ($P<.001$); at hour 0 on day 4 and at hour 0 on day 5 for mean pain relief ($P<.001$); on day 4 in reduction of morning muscle stiffness ($P<.001$); for increased lateral trunk flexibility on day 4 ($P<.002$); and for decreased low back disability on day 4 ($P=.005$). Adverse events were mild and infrequent.

Conclusion: Overnight use of heatwrap therapy provided effective pain relief throughout the next day, reduced muscle stiffness and disability, and improved trunk flexibility. Positive effects were sustained more than 48 hours after treatments were completed.

Key Words: Analgesia; Low back pain; Rehabilitation; Sleep; Thermotherapy.

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ACUTE NONSPECIFIC LOW BACK pain (LBP) is a self-limiting condition that affects most adults during their lifetime, with a lifetime incidence of 60% to 80% and a point prevalence of 15% to 30%.[1-3] LBP is the leading cause of disability in adults younger than 45 years,[4,5] the second most common painful condition after headache,[2] and the fifth most common reason for primary care office visits.[6] Signs and symptoms of LBP typically resolve within 2 to 3 months in 90% of cases, although recent research[7,8] supports multiple recurrences and pain exacerbations in the following year. Treatments commonly recommended for acute LBP include nonprescription oral analgesics, heat and cold modalities, early mobilization, and exercise.[4,9] Clinical guidelines have not addressed the role of nighttime treatment in the management of LBP or the effect of LBP on sleep. A new treatment, in the form of a heatwrap that safely provides continuous low-level heat, has been developed specifically for the treatment of LBP. Superior therapeutic benefits (increased pain relief, reduced muscle stiffness, reduced disability, increased flexibility) were obtained by using heatwrap therapy during daytime hours when compared with nonprescription oral analgesics.[10] The objective of this study was to evaluate the efficacy and safety of continuous, low-level heatwrap therapy during sleep for the treatment of acute nonspecific LBP.

METHODS

The study was a prospective, randomized, placebo-controlled, single-blind (investigator), parallel study conducted at 2 community-based research centers and approved by an institutional review board. All subjects provided informed consent, and all clinical assessments were standardized between sites.

Participants

Subjects with acute nonspecific LBP were recruited for participation. For patients to qualify, pain intensity was assessed with a categorical rating scale (0=none, 1=mild, 2=moderate, 3=moderately severe, 4=severe, 5=extreme), with a pain intensity of moderate or higher required for inclusion. Additional inclusion criteria included age 18 to 55 years, ambulatory status, muscular LBP of atraumatic origin (eg, no major traumatic injury within 48h of enrollment), and an answer of "yes" to the question "Do the muscles in your low back hurt?" Negative urine pregnancy tests and agreement to use an acceptable method of birth control were required of women of childbearing potential. Subjects were required to abstain from using therapeutic interventions that would confound the evaluation of efficacy or safety.

Exclusion criteria included regular insomnia for more than 1 week or inability to remain sleeping for at least 6 hours at a time, evidence or history of radiculopathy or other neurologic deficits of the lower extremities (eg, abnormal straight-leg raising test, patellar reflexes, bowel or bladder function), his-

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tory of back surgery, fibromyalgia, diabetes mellitus, poor circulation, peripheral vascular disease, osteoporosis, gastrointestinal ulcers, gastrointestinal bleeding or perforation, renal disease, pulmonary edema, cardiomyopathy, liver disease, intrinsic coagulation defects, bleeding diseases or anticoagulant therapy, skin lesions (eg, rash, bruising, swelling, irritation, laceration, excoriation, ulceration) on the lumbar region, history of alcohol and/or drug abuse within the past year, involvement in active litigation or a worker's compensation claim involving low back disability, daily back pain for more than 3 consecutive months, and hypersensitivity to nonsteroidal anti-inflammatory drugs (NSAIDs) or heat.

Procedures

Qualified subjects were stratified according to baseline categorical pain intensity and gender and then randomized in a 6:6:1:1 ratio to 1 of 4 groups—for evaluation of efficacy: a wearable heatwrap (ThermaCare® HeatWrap[a]), which heats to 104°F (40°C) within 30 minutes of exposure to air and maintains this temperature continuously for an 8-hour period of wear, or oral placebo (2 tablets); and for blinding: oral ibuprofen (2 tablets; total dose, 400mg) or unheated wrap. The back wraps were applied approximately 15 to 20 minutes before patients retired to bed for the night and were worn during sleep for approximately 8 hours each night for 3 consecutive nights. Oral treatments were administered approximately 15 to 20 minutes before patients retired to bed each night for 3 consecutive nights.

Measures

Pretreatment baseline measures for efficacy evaluation included muscle stiffness, lateral trunk flexibility, and disability assessment; skin quality was also assessed at baseline. Treatment efficacy variables included pain relief, muscle stiffness, pain affect, disability, lateral trunk flexibility, and subjective measures of sleep quality and difficulty in sleep onset. The primary efficacy variable was pain relief, as measured by a 6-point verbal rating scale (VRS) (0=none, 1=a little relief, 2=less than half relief, 3=more than half relief, 4=a lot of relief, 5=complete relief).[11] Muscle stiffness was quantified with a 101-point numeric rating scale (NRS) in which a score of 0 equaled "no muscle stiffness in my low back" and a score of 100 equaled "worst possible muscle stiffness in my low back." Pain affect was evaluated with a 101-point NRS in which 0 equaled "not unpleasant at all" and 100 equaled "the most unpleasant feeling possible for me." LBP disability was assessed with the Roland-Morris Disability Questionnaire[12] (RMDQ).

For a discussion of how the lateral trunk flexibility score was derived, consult the complementary article.[13]

Sleep quality was evaluated with a 6-point VRS in response to the question "How well did you sleep last night?" (0=very poorly, 1=poorly, 2=fair, 3=well, 4=very well, 5=excellently). The onset of sleep difficulty rating was assessed with a 6-point VRS in response to the question "How much difficulty did you have getting to sleep last night?" (0=no difficulty, 1=a little difficulty, 2=some difficulty, 3=moderate difficulty, 4=a lot of difficulty, 5=extreme difficulty).

At visit 1, informed consent documents were signed, medical histories were taken, and physical examinations, including skin assessments at the area of back wrap application, were performed. Subjects were instructed about treatments and completion of diary entries, to be completed before bed each night and on arising in the morning. Diary measures before bed included time of treatment initiation, time into bed, muscle stiffness, and pain affect; subjects were also instructed to record any times out of bed and the reasons, and times back to bed. Morning diary measures were completed in the following order: time out of bed, pain relief, pain affect, muscle stiffness, onset of sleep difficulty, and quality of sleep. Diary entries for pain relief, pain affect, and muscle stiffness were completed on days 2, 3, and 4 at hours 2, 4, 6, and 8 after getting out of bed. Skin quality was assessed with a 4-point scale (0=normal color, 1=faint pink to definite pink, 2=definite redness, 3=very intense redness) on days 1, 2, 3, and 5. Lateral trunk flexibility and disability were measured on days 4 (morning) and 5 (afternoon).

Statistical Procedures

The primary comparison was between the heatwrap and oral placebo groups for the overall day 2 through 4 mean morning pain relief score (hour 0). Secondary study endpoints compared the heatwrap and oral placebo groups for extended pain relief on days 4 and 5 and the mean morning muscle stiffness score (hour 0) on days 2 through 4. Additional study endpoints included the mean daytime pain relief score on days 2 through 4 over hours 0 through 8, the mean morning pain affect score on days 2 through 4, the mean quality of sleep score on days 2 through 4, the mean onset of sleep difficulty score on days 2 through 4, the overall low back disability score on day 4, and the lateral trunk flexibility score on day 4.

Primary and secondary analyses were conducted on a per protocol (evaluable) data set, which was determined before unblinding the database. Evaluability criteria were outlined in the study protocol. Reasons for exclusion from evaluable data set analyses included failure to meet study protocol criteria, voluntary study withdrawal, and protocol violations such as treatment noncompliance, multiple missing and off-schedule diary evaluations, and missing and off-schedule site visits.

Data Analysis

Power analysis determined that based on a standard deviation (SD) estimate of 1.07 (for a 0–5-point scale), a sample size of approximately 30 evaluable subjects per efficacy group would provide at least 80% power to detect a meaningful difference in the primary efficacy variable equal to .70 at the .05 level of significance using a 1-tailed *t* test.

The mean morning (hour 0) pain relief scores on days 2 through 4 were calculated by averaging the 3 individual evaluations recorded immediately on getting out of bed over days 2 through 4. These scores were analyzed with an analysis of variance procedure, which examined effects for site, sleep position, baseline pain intensity, gender, and treatment. Sleep position was grouped as either "back" or "side/stomach." Secondary pain relief parameters were calculated and averaged similarly. All other secondary efficacy parameters were analyzed with analysis of covariance procedures, which examined effects for site, sleep position, visit 1 baseline, gender, and treatment. To control the experiment-wise error rate, the primary variable was first tested at the .05 significance level by using a 1-tailed *t* test. Secondary variables were subsequently tested at the .05 level of significance by using 1-tailed *t* tests.

RESULTS

A total of 76 subjects enrolled in the study. Demographic information for the subjects (table 1) and baseline characteristics (table 2) are presented. By treatment group, the intent-to-treat sample sizes were as follows: heatwrap (n=33), oral placebo (n=34), oral ibuprofen (n=4), and unheated wrap (n=5) (fig 1).

Table 1: Demographics of Study Subjects, by Treatment Group; Intent-to-Treat Subjects, All Sites

	Heatwrap (n=33)		Oral Placebo (n=34)		Oral Ibuprofen (n=4)		Unheated Wrap (n=5)		Total (N=76)	
Variable	n	%	n	%	n	%	n	%	n	%
Age (y)										
18–29	5	15.2	5	14.7	0	0.0	1	20.0	11	14.5
30–39	3	9.1	7	20.6	0	0.0	2	40.0	12	15.8
40–49	18	54.5	14	41.2	4	100.0	2	40.0	38	50.0
50–55	7	21.2	8	23.5	0	0.0	0	0.0	15	19.7
Gender										
Female	21	63.6	21	61.8	3	75.0	4	80.0	49	64.5
Male	12	36.4	13	38.2	1	25.0	1	20.0	27	35.5
Race										
Asian Indian	0	0.0	1	2.9	0	0.0	0	0.0	1	1.3
Black	0	0.0	1	2.9	0	0.0	0	0.0	1	1.3
White	32	97.0	30	88.2	4	100.0	4	80.0	70	92.1
Hispanic	1	3.0	1	2.9	0	0.0	1	20.0	3	3.9
Multiracial	0	0.0	1	2.9	0	0.0	0	0.0	1	1.3
Pain intensity										
Moderate pain	22	66.7	24	70.6	3	75.0	4	80.0	53	69.7
>Moderate pain	11	33.3	10	29.4	1	25.0	1	20.0	23	30.3
Sleep position										
Side or stomach	27	81.8	26	76.5	4	100.0	5	100.0	62	81.6
Back	6	18.2	8	23.5	0	0.0	0	0.0	14	18.4

Pain Relief

The primary study endpoint, the day 2 through 4 mean morning (hour 0) pain relief score after 3 nights of treatment, was significantly greater for the heatwrap (mean, 2.75±.25) versus placebo (mean, 1.45±.23; $P=.00005$), a 90% increase (fig 2). Pain relief for the heatwrap was significantly higher than for placebo at each of the 20 individual time points collected throughout days 2 through 5 ($P\leq.003$ for each). Mean pain relief score on day 2, hours 0 through 8 (representing next-day pain relief), was significantly higher for the heatwrap (mean, 2.36±.36) versus placebo (mean, 1.28±.24; $P<.001$). Mean daytime pain relief score on days 2 through 4 (8h after waking) for the heatwrap group (mean, 2.69±.24) was significantly higher than for placebo (mean, 1.46±.23;

Table 2: Demographic and Baseline Characteristics; Intent to Treat Subjects, All Sites

Variable	Heatwrap (n=113)	Oral Placebo (n=113)	Oral Ibuprofen (n=106)	Unheated Wrap (n=19)	Overall (N=371)
Age (y)					
Mean	42.21	41.53	42.50	34.00	41.38
SD	9.38	9.76	2.65	8.37	9.35
Weight (kg)					
Mean	77.44	78.3	61.6	76.82	76.95
SD	17.8	18.03	17.23	24.95	18.36
Waist size (cm)					
Mean	95.86	95.15	82.88	93.47	94.69
SD	10.87	12.34	11.43	18.42	12.22
Muscle stiffness (0–100 scale)					
Mean	58.00	55.41	61.25	60.00	57.14
SD	18.34	19.86	17.62	25.56	19.17
Lateral flexibility (cm)					
Mean	16.65	16.75	16.69	16.28	16.68
SD	4.82	4.34	1.94	4.95	4.44
RMDQ disability (0–24 score)					
Mean	9.54	8.79	7.75	8.06	9.02
SD	4.32	5.16	4.99	8.27	4.96
Pain affect (0–100 scale)					
Mean	60.09	55.56	41.25	58.00	56.93
SD	17.96	21.08	29.26	33.28	21.09
Sleep quality					
Mean	2.27	2.21	3.00	1.60	2.24
SD	.67	.73	1.15	1.14	.78

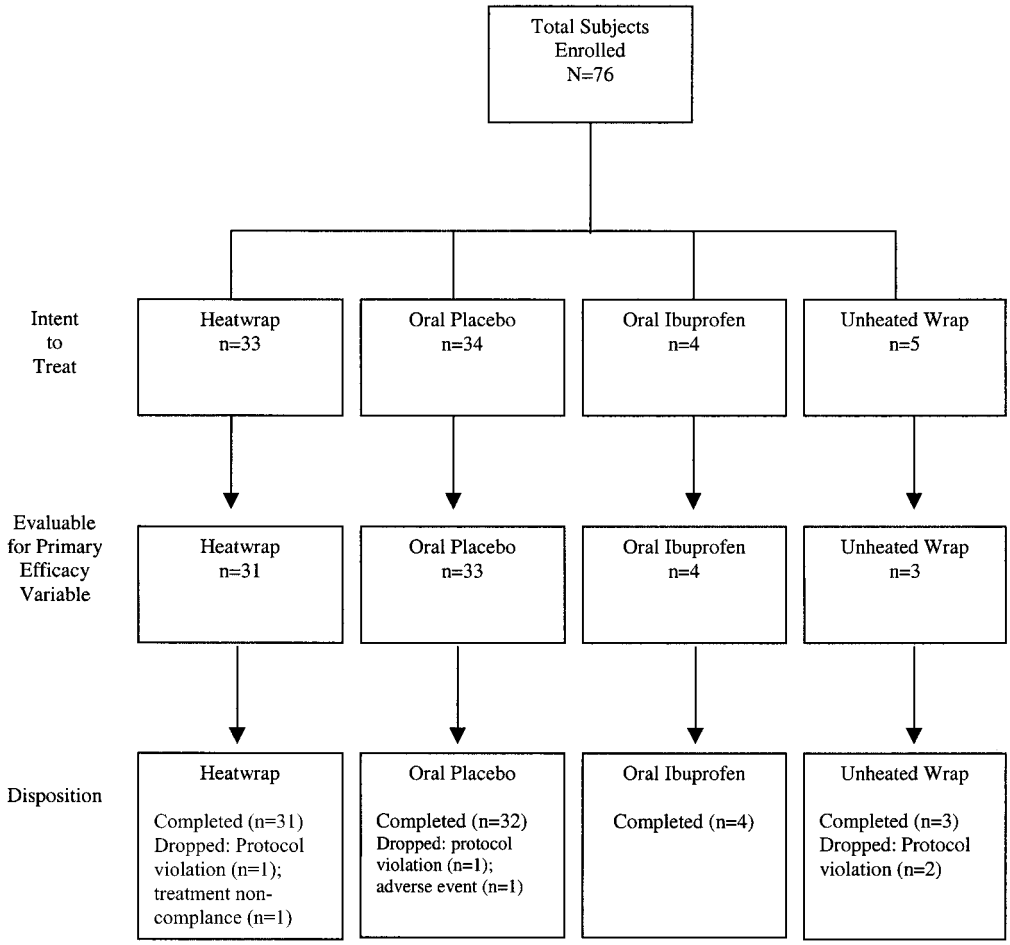

Fig 1. Randomization schedule and patient disposition.

$P=.00005$), an 84% increase. Extended pain relief on the 2 days of follow-up after the final treatment day (mean pain relief score on days 4 and 5) was also significantly higher for the heatwrap (mean, 2.90±.29) than for placebo (mean, 1.60±.27; $P=.0001$).

Muscle Stiffness

At baseline, muscle stiffness was rated 56.3 out of 100 on average by evaluable subjects. Muscle stiffness was significantly lower for heatwrap when compared with placebo at each of the 20 individual time points evaluated ($P\leq.02$ for each) (fig 3). Morning (hour 0) muscle stiffness score on days 2 through 4 was significantly lower for the heatwrap (mean, 36.3±3.1) than for placebo (mean, 47.9±2.9; $P<.001$), a 24% decrease. Mean daytime muscle stiffness scores on day 2 (representing the next-day period) were significantly lower for the heatwrap (mean, 40.0±3.3) than for placebo (mean, 50.8±3.1; $P<.003$). The level of muscle stiffness remained lower with the heatwrap (mean, 32.5±3.3) during the follow-up evaluation period (mean muscle stiffness scores on days 4 and 5) than with placebo (mean, 46.9±3.1; $P<.001$).

Pain Affect

Mean morning pain affect score on days 2 through 4 at hour 0 for the heatwrap (mean, 34.4±2.9) was significantly lower than for placebo (mean, 47.9±2.7; $P=.00005$), a 28% decrease. Additionally, pain affect scores were significantly lower for the heatwrap group when compared with placebo at each of the 20 individual time points evaluated throughout days 2 through 5 ($P\leq.007$ for each). Further, the mean next-day pain affect for day 2, hours 0 through 8, was significantly lower for the heatwrap (mean, 38.6±3.1) when compared with placebo (mean, 48.8±2.9; $P<.003$).

Disability

Among evaluable subjects, the mean day 1 baseline RMDQ score was 9.1 out of 24. Disability on the morning of day 4, the end of the treatment period, was significantly reduced for the heatwrap (mean, 3.6±0.7) versus placebo (mean, 5.8±0.7; $P=.005$) (fig 4). This was a 38% reduction in disability relative to placebo. Disability was also significantly lower for the heatwrap (mean, 3.2±0.8) on the afternoon of day 5 versus placebo (mean, 5.8±0.7; $P=.003$), a 44% difference. RMDQ data were also evaluated by individual questions, with the heatwrap group significantly better on day 4 when compared with the placebo group for the following items: "I find it difficult to turn over in bed because of my back" ($P<.02$), "I have trouble putting on my socks/stockings because of my back" ($P<.01$), "I only walk short distances because of my back" ($P<.04$), and "I sleep less well because of my back" ($P<.03$).

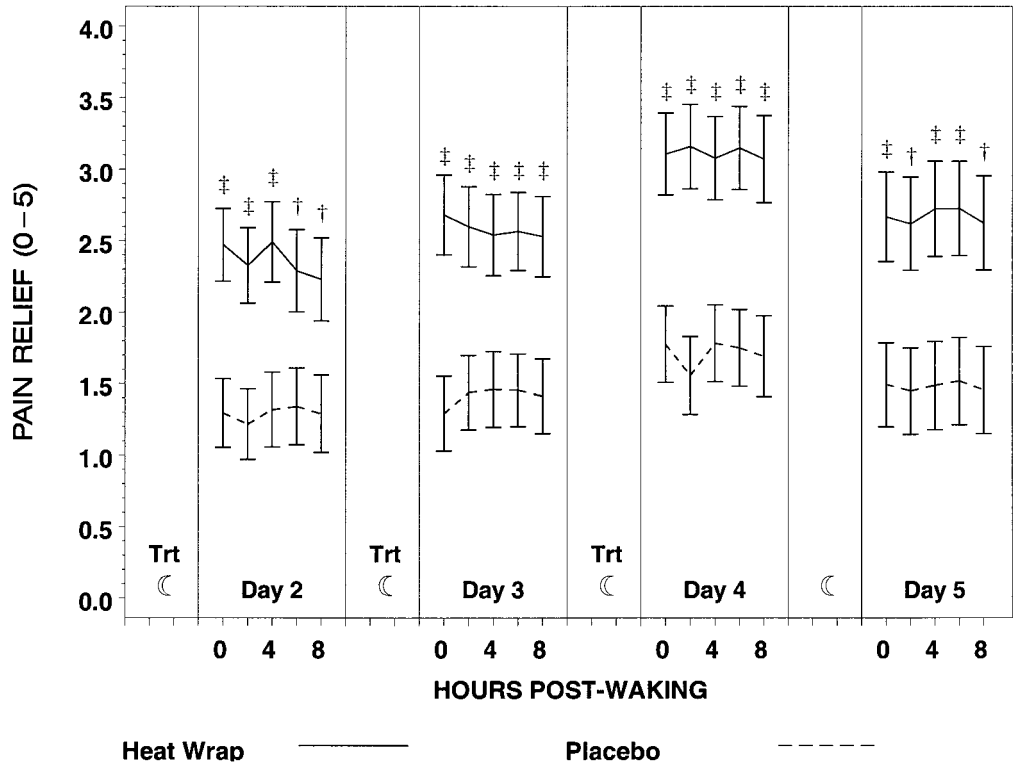

Fig 2. Mean pain relief scores for the heatwrap group and the oral placebo group during the daytime after overnight treatment (days 2–4) and during follow-up (day 5). Abbreviation: Trt, treatment. **P*<.05; †*P*<.01; ‡*P*<.001.

Lateral Trunk Flexibility

Before treatment initialization, the evaluable subjects' mean lateral flexibility was 16.6cm. Lateral flexibility score on day 4 was significantly greater for the heatwrap (mean, 20.0±0.9cm) when compared with placebo (mean, 17.0±0.8cm; $P<.002$), a relative 18% increase over placebo.

In contrast to the day 4 (morning) results, lateral trunk flexibility for the heatwrap (mean, 18.8±0.8cm) was direction-

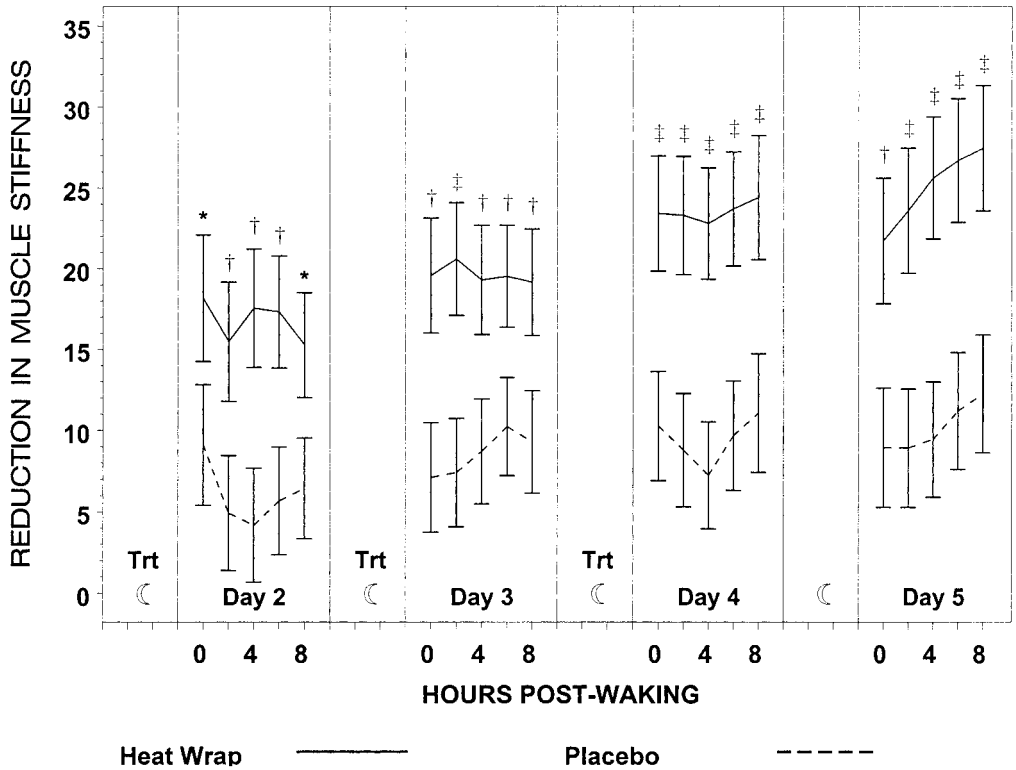

Fig 3. Mean muscle stiffness scores for the heatwrap group and the oral placebo group during the daytime after overnight treatment (days 2–4) and during follow-up (day 5). **P*<.05; †*P*<.01; ‡*P*<.001.

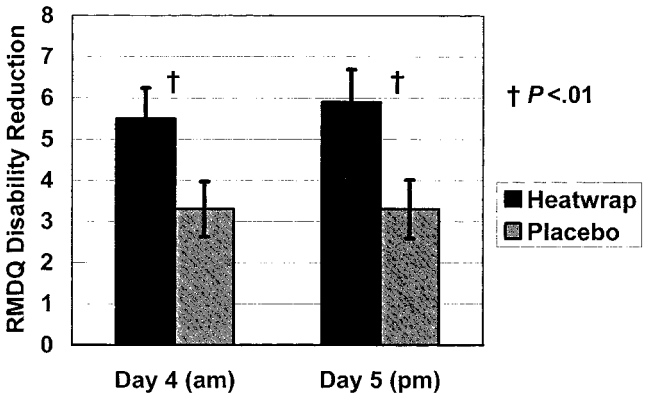

Fig 4. Mean reduction in RMDQ scores on day 4 and day 5.

ally but not statistically significantly lower than placebo (mean, 17.6±0.8cm; $P=.11$) on the afternoon of day 5.

Sleep Variables

Quality of sleep score on days 2 through 4 for the heatwrap (mean, 2.81±.14) was significantly higher than for placebo (mean, 2.42±.13; $P<.01$) by 16%. The reported quality of sleep was significantly higher for the heatwrap on the mornings of day 2 ($P<.01$), day 4 ($P<.01$), and day 5 ($P<.001$), but not on the morning of day 3 ($P=.29$). For the assessment of the onset of sleep difficulty, the mean score on days 2 through 4 was significantly improved with the heatwrap (mean, .73±.14) versus placebo (mean, 1.06±.12; $P<.02$), an observed 31.1% improvement. On the individual mornings, the heatwrap onset of sleep difficulty scores for the previous night were significantly improved versus placebo on day 2 ($P<.04$), day 3 ($P<.05$), and day 5 ($P<.03$), but not on day 4 ($P=.10$).

Safety

There were no serious adverse events during this study. Only 2 subjects (placebo group) withdrew because of an adverse event (nausea, vomiting). The number of adverse events reported in the heatwrap group was similar to that in the placebo group. Systemic adverse events were more common in the ibuprofen group (25%) than in the primary treatment groups, with the most common adverse events reported for each group as follows: for the heat wrap group, application-site reaction (15%); for placebo, headache (12%); and for ibuprofen, abdominal pain (25%). On the skin-quality assessments, 5 subjects (15%) in the heatwrap group and 1 subject in the oral placebo group experienced faint skin pinkness, with 1 heatwrap subject progressing to moderate erythema. All application-site reactions resolved without treatment within 1 to 2 days.

DISCUSSION

LBP is a highly prevalent condition that results in diminished quality of life for patients and high cost for employers.[14] Clinical practice guidelines support a variety of self-care measures, including use of NSAIDs, acetaminophen, and self-administered heat or cold therapy. Activity modification, including rest, is routinely recommended for 2 to 4 days in treatment of acute LBP. Prolonged bedrest, however, is not recommended.[4] These guidelines do not address the effect of acute LBP on sleep or the role of restful sleep during recovery from injury.

The positive daytime benefits of nighttime heatwrap therapy may have several explanations, including an interference with nociception (gate control theory) along with the influences of improved sleep. The gate control theory of pain inhibition involves inhibition ("gating") of nociception in the dorsal horn of the spinal cord, providing a plausible rationale for the pain relief benefit of topical heat.[15] Warming the skin increases mechanoreceptor sensitivity, an effect that is enhanced by the physical support of the backwrap, resulting in increased large myelinated (A beta) fiber activity.[16-18] The gate control theory is widely accepted by researchers in the field of pain management as the primary mechanism responsible for the pain relief provided by topical heat therapy.[19,20]

However, the observed extension of therapeutic benefits well beyond the duration of heatwrap treatment is an interesting phenomenon, which may be explained mechanistically by inference from research with transcutaneous electric nerve stimulation (TENS), another topical modality thought to provide therapeutic benefits via gate control. Treatment effects lasting for 12 to 24 hours were observed after 20 minutes of TENS treatment in a rat model.[21,22] Increased blood and cerebrospinal fluid concentrations of β-endorphin were reported in healthy human subjects after TENS treatment.[23,24] The prolonged pain relief that occurs with continuous low-level topical heat therapy may be associated with β-endorphin release, because long-term stimulation of small-diameter afferent neurons with TENS has been reported to increase the release of β-endorphins from the central nervous system and provide prolonged analgesic effects.[25]

Sleep disturbance is a prevalent complaint in those who have LBP, with reports of impaired sleep affecting up to 70% of patients with chronic LBP.[26-30] Sleep is essential to physical and emotional health and plays a strong role in recovery from illness and injury. Interference with immune function through impaired cellular and hormonal influences has been noted in those with sleep deprivation,[31] with these effects on the immune system thought to play a major role in recovery from tissue injury.[31] Hormones released during the sleep cycle—melatonin and growth hormone—function to stimulate and enhance the immune system, supporting the hypothesis that sleep deprivation may have a negative effect on tissue healing and recovery from an acute episode of LBP.

This study supports a temporal association between sleep and improvement in pain relief and muscle stiffness. As opposed to the influence of a cool bath, subjects given a warm bath had significantly increased sleepiness at bedtime, with increased slow-wave and stage 4 sleep.[32] For subjects with insomnia, baths with a temperature between 40° and 40.5°C showed significantly increased slow-wave sleep and subjectively improved deeper and more restful sleep as compared with baths in the range of 37.5° to 38.5°C.[33] On the basis of the results of our study, the heatwrap may provide benefits for individuals with LBP that interferes with their ability to sleep comfortably and restoratively, loosely categorized as insomnia.

The lack of improvement in lateral flexibility after day 4 was inconsistent with the observed improvements for muscle stiffness and the reduction in disability scores during treatment and follow-up. This finding may indicate the potential variability of nighttime treatment relative to observations made with the passive use of nonportable heat modalities, which may have limited effectiveness.[34] Heat use during normal activities has been previously shown to provide significant therapeutic benefits.[10] Future research may evaluate the combined effects of night and daytime use.

Skin burns are a major safety concern when commonly used heat-producing physical modalities are used therapeutically.

These products often produce temperatures exceeding the threshold for tissue damage (45°C),[35] requiring that patients using these modalities remain awake and alert and limit use to less than 30 minutes to avoid the risk of skin burns.[36] Factors that contribute to burn risk include an attenuation of the processing of pain stimuli during sleep[37]; increased pressure on the skin; inhibition of skin blood flow and heat dissipation; or intrinsic factors such as insensate skin in diabetics, spinal cord injury, and communication problems (infants or adults with altered cognitive functioning). Despite the known risks, more than 1500 burns per year are treated in emergency rooms, and approximately 8 deaths per year occur secondary to the use of high-intensity electric heating pads.[36] In contrast to these concerns, the safety profile for overnight use of continuous, low-level heatwrap therapy used for 3 consecutive nights during sleep was excellent. Heatwrap compliance was outstanding, with no instances of heatwrap removal for any reason during any of the 8-hour wear times. Mild erythema, without blister formation, was noted in 4 subjects who wore the heatwrap, all resolving without intervention. A potential limitation of this study was the lack of measurement of hormone levels or stages of sleep, which may have provided further insight into the effects of nighttime heatwrap usage.

In our experimental design, we included 2 small blinding groups to minimize potential subject and investigator biases associated with the random assignment of subjects to a topical modality treatment that provides a detectable sensate (heat). To minimize expected biases, the subjects were instructed in the informed consent that they would receive a back wrap that may or may not generate heat or an oral tablet that may or may not be an analgesic. Because these treatments were used simply for blinding purposes and were not powered for statistical comparison, we did not present all these data in the article.

CONCLUSION

Continuous low-level heatwrap therapy was shown to provide effective daytime pain relief after overnight use in subjects with acute nonspecific LBP. Additional therapeutic benefits included reduction of muscle stiffness, increased trunk flexibility, decreased disability, and improved sleep quality and onset of sleep. The heatwrap showed a good safety profile when worn during sleep and should be considered as an initial treatment strategy for patients with acute LBP.

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