Continuous Low-Level Heatwrap Therapy for Treating Acute Nonspecific Low Back Pain

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ABSTRACT. Nadler SF, Steiner DJ, Erasala GN, Hengehold DA, Abeln SB, Weingand KW. Continuous low-level heatwrap therapy for treating acute nonspecific low back pain. Arch Phys Med Rehabil 2003;84:329-34.

Objective: To evaluate the efficacy of 8 hours of continuous low-level heatwrap therapy for the treatment of acute nonspecific low back pain (LBP).

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

Setting: Five community-based research facilities.

Participants: Two-hundred nineteen subjects, aged 18 to 55 years, with acute nonspecific LBP.

Intervention: Subjects were stratified by baseline pain intensity and gender and randomized to one of the following groups: evaluation of efficacy (heatwrap, n=95; oral placebo, n=96) and blinding (oral ibuprofen, n=12; unheated back, wrap n=16). All treatments were administered for 3 consecutive days with 2 days of follow-up.

Main Outcome Measures: Primary: day 1 mean pain relief (0- to 5-point verbal response scale). Secondary: muscle stiffness (101-point numeric rating scale), lateral trunk flexibility (fingertip-floor distance), and Roland-Morris Disability Questionnaire over 3 days of treatment and 2 days of follow-up.

Results: Heatwrap therapy was shown to provide significant therapeutic benefits when compared with placebo during both the treatment and follow-up period. On day 1, the heatwrap group had greater pain relief (1.76±.10 vs 1.05±.11, $P<.001$), less muscle stiffness (43.1±1.21 vs 47.6±1.21, $P=.008$), and increased flexibility (18.6±.44cm vs 16.5±.45cm, $P=.001$) compared with placebo. Disability was also reduced in the heatwrap group (5.3 vs 7.4, $P=.0002$). Adverse events were mild and infrequent.

Conclusion: Continuous low-level heatwrap therapy was shown to be effective for the treatment of acute, nonspecific LBP.

Key Words: Analgesia; Low back pain; Musculoskeletal system; Rehabilitation; Thermotherapy.

LOW BACK PAIN (LBP) has been described as a 20th-century medical disaster.[1] This common condition has a significant economic effect on society, with annual cost estimates in the United States varying from $16 to $30 billion in the injured worker population.[2,3] Although most patients show improvement within 3 months, up to 75% of patients with a history of LBP have 1 or more relapses, and 72% continue to have pain 1 year after the initial occurrence.[2,4,5]

Various self-administered treatments, including oral analgesics, exercise, and topical heat therapy,[6,7] have been recommended in the management of acute LBP, although the efficacy of these therapies remains questionable after a comprehensive review of published studies.[8] Application of topical heat (thermotherapy) is commonly used to relieve pain and muscle spasm and, additionally, to increase blood flow and facilitate tissue healing.[9] Unfortunately, heating pads, hydrocollators, and other forms of topical heat have limitations, because they are cumbersome and restrict mobility. Research has clearly shown that individuals with LBP should be encouraged to remain active in the ensuing weeks after an acute episode.[10,11] The ability of a patient to apply a wearable, mobile source of topical heat would therefore be preferable to the traditional heat modality. This study was undertaken to evaluate the therapeutic benefits of a new form of continuous, low-level heatwrap therapy for the treatment of acute nonspecific LBP.

METHODS

This study was a randomized, placebo-controlled, single-blind (investigator), parallel study conducted at 5 freestanding clinical research testing sites: Huntington, NY; Great Neck, NY; Bryan, TX; Dallas, TX, and Columbus, OH. Each clinical testing site had a primary investigator who was blinded to the treatments, as were all of the individuals who participated in the study. Subjects were recruited from the clinic database and via print advertising. The study was approved by an institutional review board, and all subjects provided informed consent.

Participants

Subjects with acute nonspecific LBP were recruited for participation. To qualify for study participation, pain intensity was assessed with a 6-point categoric scale (0=none, 1=mild, 2=moderate, 3=moderately severe, 4=severe, 5=very severe); pain intensity of moderate or higher was required for inclusion. Additional inclusion criteria included age from 18 to 55 years; ambulatory; and nonspecific LBP of atraumatic origin (ie, no traumatic injury within the previous 48h) not caused by, or related to, any medical diseases that may indicate a pathologic cause of LBP, with an answer "yes" to the question, "Do the muscles in your low back hurt?" Women of child-bearing potential were required to have negative urine pregnancy tests and, if heterosexually active, to agree to use an acceptable

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method of birth control. Subjects were required to abstain from the use of therapeutic interventions with the potential to confound the evaluation of efficacy.

Prospective subjects were excluded from the study if they had any evidence or history of radiculopathy (eg, sciatica extending below the knee [numbness, tingling, shooting pain]) or other neurologic deficits (eg, abnormal straight-leg raising test, patellar reflexes, bowel and/or bladder function), history of back surgery, fibromyalgia, diabetes mellitus, 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 (eg, warfarin). Prospective subjects with any serious medical diseases were excluded at the investigator's discretion, as were subjects enrolled in any investigational drug or device trials. Individuals were also excluded it they had any skin lesions (eg, rash, bruising, swelling, irritation, laceration, excoriation, ulceration) on the lumbar region. Additional exclusion criteria were a history of alcohol and/or drug abuse, involvement in active litigation or a worker's compensation claim involving low back disability, back pain daily for more than 3 consecutive months, or hypersensitivity to nonsteroidal anti-inflammatory drugs (NSAIDs) or heat.

Procedures

Qualified subjects were stratified according to baseline categoric pain intensity, gender, and study site and then were randomized to 1 of 4 treatment groups: (1) 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 at least 8 hours of wear; (2) oral placebo (2 tablets, 3 times daily, spaced 6h apart); (3) oral analgesic (ibuprofen 200mg, 2 tablets, 3 times daily, spaced 6h apart); or (4) unheated wrap in a randomized ratio of 6:6:1:1. Unequal sample sizes were planned because the primary treatment comparison was between the heatwrap and the oral placebo; the other treatment groups were included to enhance blinding. Back wraps were worn for approximately 8 hours daily for 3 consecutive days.

Measures

Pretreatment baseline measures for efficacy evaluation included muscle stiffness, lateral trunk flexibility, and disability assessment (Roland-Morris Disability Questionnaire[12] [RMDQ]). The treatment efficacy variables included pain relief, muscle stiffness, lateral trunk flexibility, and disability. The primary efficacy variable was pain relief, as measured by a 6-point verbal rating scale (0=none, 1=a little relief, 2=less than half relief, 3=more than half relief, 4=a lot of relief, 5=complete relief).[13] Muscle stiffness was quantified with a 101-point numeric rating scale with a score of 0 equal to "no muscle stiffness in my low back" and a score of 100 equal to "worst possible muscle stiffness in my low back."[14]

Lateral trunk flexibility was a derived score, calculated as the within-subject mean measure of trunk flexion for the left and right sides. To measure the extent of trunk flexion to the right (TFR), the subject was instructed to stand erect with his/her upper back (scapulae) against a wall and arms hanging straight down, with the palms on the lateral surface of the thighs. After the subject was positioned, a piece of masking tape was used to mark the position of the fingertips. The subject was then instructed to bend first to the right from the waist, as far as possible, keeping both legs straight and extending a straightened right arm and hand down along the lateral surface of the right leg as far as possible. A second piece of masking tape was used to mark the location of the tip of the middle finger on the lateral side of the right leg at the maximum extent of TFR. TFR was measured by tape measure, as the distance (centimeters) between the tops of the 2 pieces of masking tape on the lateral side of the right leg, with the subject standing in the neutral position. This procedure was subsequently repeated on the left side to measure trunk flexion to the left.

At visit 1 (a morning visit on the first study day), informed consent documents were signed, medical histories were taken, and physical examinations, including neurologic assessments and skin assessments at the area of back wrap application, were performed. Subjects were instructed in the use of back wraps or oral treatment and provided with diaries for recording pain relief and muscle stiffness measurements at specified times. Treatments were administered immediately after this visit. Subjects returned to the site in the afternoon for visit 2, approximately 8 hours after the initiation of treatment.

At each clinical study visit, lateral trunk flexibility was measured, and diary data were recorded. On days 3 and 5, disability was also evaluated. 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) at visits 1 and 5 on all subjects.

Statistical Procedures

The primary comparison was between the heatwrap and oral placebo groups for the day 1 mean pain relief score over 8 hours (analogous to total area under the pain relief curve). Secondary study endpoints compared the heatwrap and oral placebo treatment groups for days 4 and 5 mean "extended" pain relief, day 1 mean muscle stiffness, and day 1 lateral trunk range of motion (ROM). 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 the 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, on the basis of a standard deviation (SD) estimate of 1.01 (for a 0–5-point scale), a sample size of approximately 86 evaluable subjects per efficacy group would provide 90% power to detect a meaningful difference in the day 1 mean pain relief scores equal to .50 at the .05 level of significance.

Day 1 mean pain relief (primary) and day 1 mean muscle stiffness scores were calculated for each subject by taking a mean of the individual hourly evaluations recorded at hours 1 through 8 on day 1. Days 4 and 5 mean "extended" pain relief scores were calculated from evaluations taken approximately 24 and 48 hours after visit 4 on day 3. Both sets of pain relief scores were analyzed with an analysis of variance procedure, examining effects for study site, baseline pain intensity (grouped as moderate or greater than moderate), gender, and treatment. Day 1 mean muscle stiffness scores and day 1 lateral trunk flexibility data were analyzed by using analysis of covariance (ANCOVA) procedures, examining effects for baseline, study site, gender, and treatment. For all primary and secondary outcome measures, 2-tailed t tests of the null hypothesis of no treatment difference were conducted between the heatwrap and the oral placebo groups at the .05 level of significance, and all efficacy results and figures corresponded to model-adjusted least-squares means. To control the experi-

Table 1: Demographic and Baseline Characteristics: Intent-to-Treat Subjects, All Sites

Statistic	Heatwrap (n=95)	Oral Placebo (n=96)	Oral Ibuprofen (n=12)	Unheated Wrap (n=16)	Overall (N=219)
Age (y)					
Mean	35.55	36.73	36.25	34.88	36.05
SD	11.57	10.82	11.56	11.32	11.17
Weight (kg)					
Mean	79.68	79.44	80.91	67.64	78.77
SD	18.97	15.35	15.15	14.3	17.13
Height (cm)					
Mean	171.96	170.89	174.42	166.52	171.22
SD	10.03	9.65	9.55	6.91	9.70
Waist size (cm)					
Mean	91.34	91.67	90.07	82.60	90.78
SD	12.14	12.47	10.03	12.32	12.34
Muscle stiffness (0–100 scale)					
Mean	52.67	55.13	58.58	57.50	54.42
SD	19.69	19.14	11.66	16.43	18.86
Flexibility (cm)					
Mean	15.46	15.41	16.93	13.51	15.38
SD	4.23	4.64	7.07	3.33	4.56
Disability (0–24)					
Mean	8.81	10.17	10.02	9.88	9.55
SD	4.92	5.04	4.18	4.92	4.95
Baseline pain intensity (0–6 scale) (%)					
Moderate	69.5	69.8	83.3	68.8	70.3
>Moderate	30.5	30.2	16.7	31.3	29.7

ment-wise error rate, the primary outcome measure was tested before the additional study variables.

For the disability questionnaire, the percentage of "yes" responses from among the 24 questions comprising the questionnaire was calculated by subject and by day. Percentage scores were analyzed by day by use of ANCOVA methodology as described previously. Results were back-transformed to a maximum score of 24.

The incidence rates of complete relief—as defined by 1 or more pain relief diary ratings equal to 5—were compared by using a logistic regression model adjusted for study site, baseline pain intensity, gender, and treatment. Additionally, Pearson correlation coefficients were calculated among the efficacy parameters to explore the strengths of their associations with each other. The change from baseline scores after 3 days of treatment were used for this correlation analysis, with the exception of pain relief, for which the day 3 mean score was used. Day 3 data was chosen for this analysis because all 4 parameters had data collected on this day.

RESULTS

The final study population included 219 subjects (table 1); 119 (54.3%) were women and 100 (45.7%) were men. Only 13 subjects (5.9%) were excluded from the evaluable data set for the primary analysis. Disposition of the subjects is provided in figure 1.

An intent-to-treat analysis was also performed among all subjects with any efficacy data. Identical statistical conclusions (ie, $P<.05$ or $P>.05$) were reached in both sets of analyses overall; however, the heatwrap group displayed significantly greater pain relief versus placebo at 2 additional time points (day 1/hour 1, day 2/hour 2) in the intent-to-treat analysis.

Pain Relief

The primary study endpoint—the day 1 mean pain relief score—was significantly higher for the heatwrap (mean, 1.76±.10) compared with placebo (mean, 1.05±.11; $P<.001$), an observed treatment difference of .71 (67.6% relative increase). Mean pain relief scores for the heatwrap were significantly higher ($P<.05$) than placebo for 16 of the 20 individual time points evaluated (fig 2). The incidence of complete pain relief over days 1 through 5 was significantly greater for the heatwrap (15.4% incidence) compared with placebo (6.6% incidence; $P=.04$; odds ratio=2.89). The days 4 and 5 mean "extended" pain relief scores, calculated from evaluations taken approximately 24 and 48 hours after treatment ended, were also significantly higher for the heatwrap (mean, 2.50±.16) than for placebo (mean, 1.56±.18; $P<.0001$).

Muscle Stiffness

At baseline, the mean muscle stiffness score was 54.1 (out of 100) for all evaluable subjects. The day 1 mean muscle stiffness score was significantly lower for the heatwrap (mean, 43.1±1.21) than for placebo (mean, 47.6±1.21; $P=.008$), an observed 4.5 treatment mean difference (9.6% decrease relative to placebo, 20.4% decrease from baseline). The mean muscle stiffness scores for the heatwrap were significantly lower ($P<.05$) than for placebo for 15 of the 20 individual time points evaluated (fig 3). Extended muscle stiffness was also observed; the days 4 and 5 mean muscle stiffness score for the heatwrap (mean, 32.2±1.99) was significantly lower than for placebo (mean, 43.1±2.03; $P<.0002$).

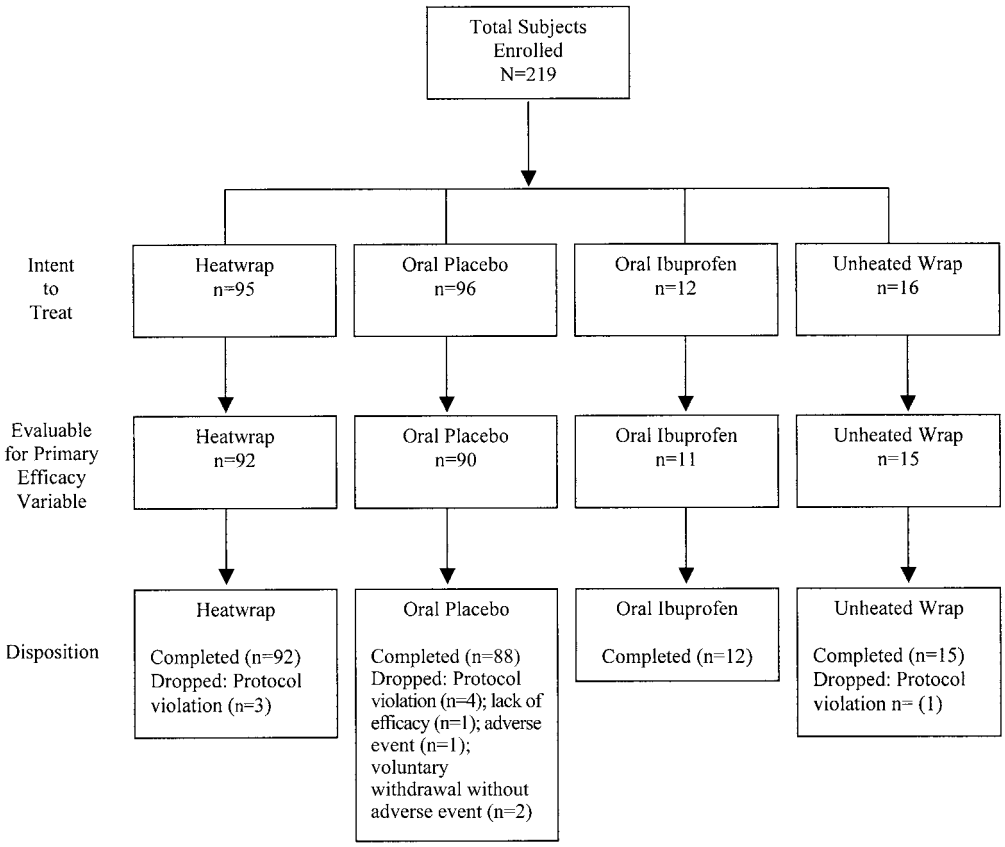

Fig 1. Randomization schedule and patient disposition.

Lateral Trunk Flexibility

Lateral trunk flexibility scores for the heatwrap were significantly higher ($P<.01$) than for placebo at all time points (fig 4). The significant increase in the lateral trunk flexibility scores persisted with the heatwrap (mean, 18.6±.44cm) as compared with placebo (mean, 16.5±.45cm; $P=.001$) during the follow-up period.

Roland-Morris Disability Questionnaire

At baseline, the mean disability score was 9.3 (out of 24) across evaluable subjects. The day 3 mean disability scores for the heatwrap (mean, 5.3) were significantly lower than for placebo (mean, 7.4; $P<.0002$) (fig 5). Additionally, the day 5 mean disability scores for the heatwrap (mean, 4.6) were significantly lower than for placebo (mean, 6.7; $P<.001$).

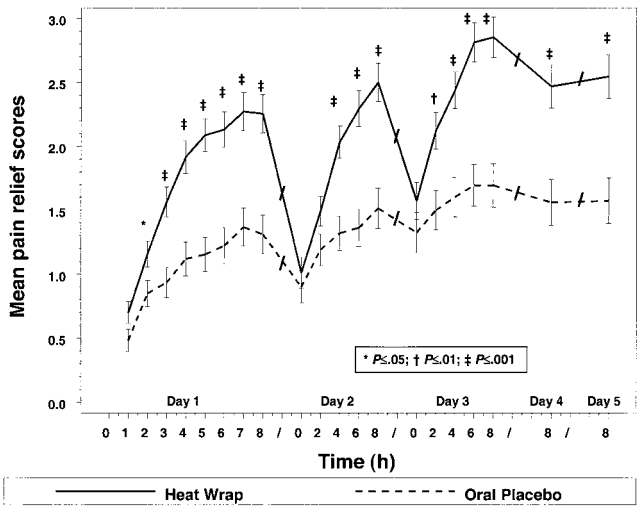

Fig 2. Mean pain relief scores for the heatwrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4 and 5).

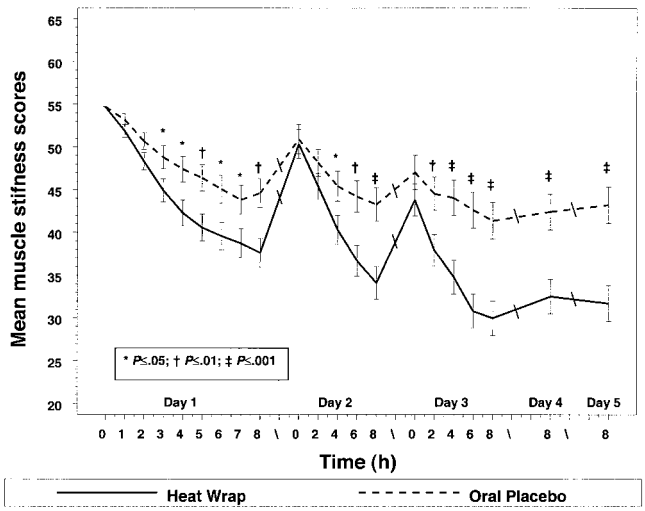

Fig 3. Mean muscle stiffness scores for the heatwrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4 and 5).

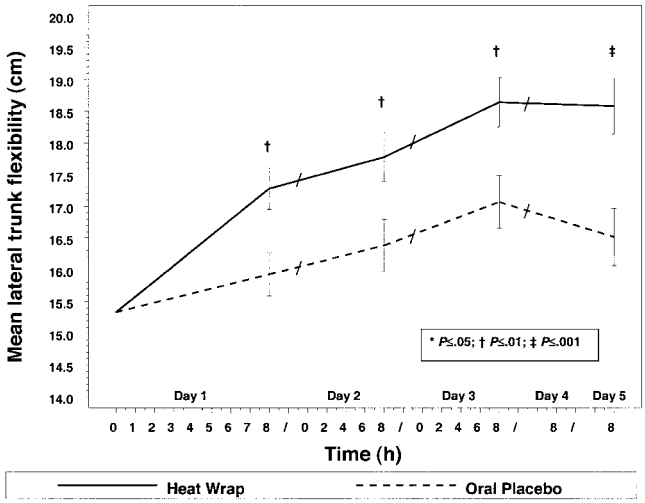

Fig 4. Mean lateral trunk flexibility scores for the heatwrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4 and 5).

Correlations Between Efficacy Parameters

In subjects treated with heatwrap, day 3 pain relief correlated significantly with each of the other efficacy parameters: lateral trunk flexibility ($R=.32$, $P=.0027$), muscle stiffness ($R=-.79$, $P<.0001$), and disability ($R=-.30$, $P=.0047$). In addition, muscle stiffness was correlated significantly with trunk flexibility ($R=-.25$, $P=.021$) and disability ($R=.30$, $P=.005$).

Safety

No serious adverse events occurred during this study. Only 1 subject (in the oral placebo group) withdrew due to an adverse event, and this event was unrelated to study products or procedures (hip pain caused by slipping on ice).

The heatwrap was well tolerated over the wear period among 94 of the 95 subjects randomized to the heatwrap group. One subject, a 52-year-old woman, entered the study with normal skin color, which progressed to definite redness by study day 5; this resolved without treatment.

DISCUSSION

LBP ranks fifth as a reason for all physician visits, accounting for more than 15 million office visits in 1990 in the United States.[15] Because most LBP is purported to resolve in 12 weeks, clinical practice guidelines advocate simple conservative measures as the mainstay of treatment, including NSAIDs, acetaminophen, spinal manipulation, self-administered heat or cold modalities, and activity modification, including rest for up to 4 days.[6] In this study, continuous low-level heat therapy provided effective pain relief when compared with placebo, in addition to decreased muscle stiffness and improved lateral trunk flexibility. These results were consistent with scores on the RMDQ, indicating improved function and decreased disability in the heatwrap group.

Determination of the clinical significance of statistical differences can be based on a number of factors, including how a treatment or intervention affects overall symptoms and quality of life.[16] In a report[17] on the clinical significance associated with commonly used pain outcome measures, relative treatment differences between 33% and 50% were considered clinically meaningful. We observed a 67.6% higher mean pain relief, well above this range, for the heatwrap compared with placebo. Considering the effect on quality of life, the heatwrap was associated with a reduction in RMDQ disability of 4.0 points (from baseline) on day 3 and 4.7 points on day 5—both significantly higher than placebo and well above the 2- to 3-point difference advocated as the minimum clinically important change.[18]

The benefits of heatwrap therapy are related to the therapeutic effects of topical heat applied during the performance of normal work and recreational activities. Passive use of heat modalities has historically been associated with poor treatment outcomes for LBP. Significantly improved pain relief, reduced disability, and improved lumbar muscle endurance have been reported in individuals with LBP after 12 weeks of active rehabilitation, as compared with a group receiving passive treatment, massage, and thermotherapy.[19] This result supported a previous multicenter study[20] that found that subjects treated for LBP who received passive heat or cold modalities had a poorer outcome than those who performed endurance exercises. In contrast, our results suggest that continuous low-level heat therapy in a form worn during activity may be superior to passive heat therapy for the treatment of most cases of LBP. We are unaware of any other study using an active-modality group in the experimental design.

The therapeutic effects of topical heat treatment are mediated via neurologic, vascular, and biopsychosocial mechanisms. Topical heat increases small nonmyelinated C-fiber activity that inhibits nociceptive signals in the spinal cord and increases proprioception.[21-24] Heat therapy may also stimulate various regions of the brain, supporting psychosomatic effects.[25,26] The benefit of the heatwrap is thus indirectly mediated in the brain via skin warming, combined with the physical support of body regions affected with pain. Additionally, the psychologic effects of comfort and relaxation have been associated with topical heat therapy, mitigating central integration and coherence of the pain experience.[25]

The 1 objective evaluation included in this study was trunk flexibility, as measured by the ROM of lateral bending. ROM of the spine is an objective, reproducible measurement commonly used to assess impairment and disability.[27] Lateral bending was chosen, because it has been previously shown, along with axial rotation, to be the most sensitive measure for detecting between-group differences for treatment effects as com-

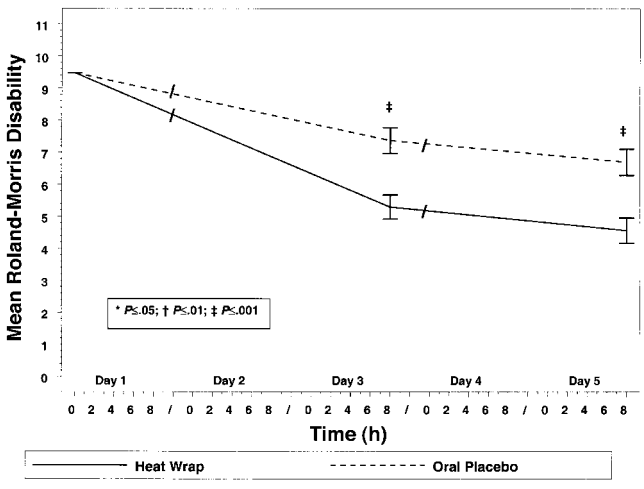

Fig 5. Mean disability scores for the heatwrap group and the oral placebo group over the treatment study period (days 1–3) and follow-up period (days 4 and 5).

pared with flexion and extension.[28] Additional research[29-31] has shown lateral bending to be predictive of outcome or future occurrence of LBP. In our study, lateral flexibility for the heatwrap group was significantly greater than for the placebo group at all time points and may be explained by increased muscle relaxation.

In this study, the selection of the appropriate negative control group to establish the efficacy of the heatwrap involved several factors. The total therapeutic benefits of the heatwrap are derived from the sum of the heat generated chemically by the device and the physical support and insulation provided by the wrap. Unheated back wraps provide a mild effect on pain relief, and, as such, unheated back wraps were not considered a true negative control treatment. Comparison of heatwraps with unheated back wraps, therefore, does not allow evaluation of the total therapeutic benefits of the heatwrap. We included the small unheated wrap group to minimize potential subject biases associated with random assignment of a modality treatment that provides a physical sensate (heat) and to blind the investigator to the treatment groups.

Comparison of the unheated wrap group with the heatwrap group for pain relief, the primary variable of the study, found that the level of pain relief was significantly ($P=.018$) higher in the heated wrap group over the 3-day treatment period. Additionally, comparison of the heatwrap group with the small oral ibuprofen group indicated a statistically significant difference in the level of pain relief ($P=.008$) in favor of the heatwrap. These small blinding groups were not powered for statistical comparison, so we did not present data herein for these groups.

CONCLUSION

Continuous low-level heatwrap therapy was shown to provide significant therapeutic benefits in patients with acute nonspecific LBP, as indicated by increased pain relief and trunk flexibility, and it provided decreased muscle stiffness and disability when compared with placebo. No serious or significant adverse effects were observed during the use of the heatwrap.

Research is under way to evaluate heatwrap therapy in college and elite athletes, as well as in recreational golfers, with LBP. This study supports the efficacy of continuous low-level heatwrap therapy in the treatment of acute nonspecific LBP.

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