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Continuous Low-Level Heat Wrap Therapy Provides More Efficacy Than Ibuprofen and Acetaminophen for Acute Low Back Pain

Scott F. Nadler, DO,* Deborah J. Steiner, MD, MS,† Geetha N. Erasala, MS,‡ David A. Hengehold, MS,‡ Robert T. Hinkle, BS,‡ Mary Beth Goodale, BS,‡ Susan B. Abeln, BS,‡ and Kurt W. Weingand, DVM, PhD‡

Study Design. A prospective, randomized, single (investigator) blind, comparative efficacy trial was conducted.

Objective. To compare the efficacy of continuous low-level heat wrap therapy (40 C, 8 hours/day) with that of ibuprofen (1200 mg/day) and acetaminophen (4000 mg/day) in subjects with acute nonspecific low back pain.

Summary of Background Data. The efficacy of topical heat methods, as compared with oral analgesic treatment of low back pain, has not been established.

Methods. Subjects (n = 371) were randomly assigned to heat wrap (n = 113), acetaminophen (n = 113), or ibuprofen (n = 106) for efficacy evaluation, or to oral placebo (n = 20) or unheated back wrap (n = 19) for blinding. Outcome measures included pain relief, muscle stiffness, lateral trunk flexibility, and disability. Efficacy was measured over two treatment days and two follow-up days.

Results. Day 1 pain relief for the heat wrap (mean, 2) was higher than for ibuprofen (mean, 1.51; $P = 0.0007$) or acetaminophen (mean, 1.32; $P = 0.0001$). Extended mean pain relief (Days 3 to 4) for the heat wrap (mean, 2.61) also was higher than for ibuprofen (mean, 1.68; $P = 0.0001$) or acetaminophen (mean, 1.95; $P = 0.0009$). Lateral trunk flexibility was improved with the heat wrap (mean change, 4.28 cm) during treatment ($P \leq 0.009$ *vs* acetaminophen [mean change, 2.93 cm], $P \leq 0.001$ *vs* ibuprofen [mean change, 2.51 cm]). The results were similar on Day 4. Day 1 reduction in muscle stiffness with the heat wrap (mean, 16.3) was greater than with acetaminophen (mean, 10.5; $P = 0.001$). Disability was reduced with the heat wrap (mean, 4.9), as compared with ibuprofen (mean, 2.7; $P = 0.01$) and acetaminophen (mean, 2.9; $P = 0.0007$), on Day 4. None of the adverse events were serious. The highest rate (10.4%) was reported in the ibuprofen group.

Conclusion. Continuous low-level heat wrap therapy was superior to both acetaminophen and ibuprofen for treating low back pain. [Key words: acetaminophen, analgesia, heatwrap, ibuprofen, low back pain, musculoskeletal, thermotherapy] **Spine 2002;27:1012–1017**

Low back pain (LBP) commonly occurs in the general population, with an annual incidence of 5% and a lifetime prevalence of 60% to 90%.[2,11,25] Approximately one half of the patients seen in the primary care setting self-treat for a given episode of low back pain before their first visit.[7,27] Acetaminophen and ibuprofen are the two most commonly used nonprescription drugs in the United States.[15] Both of these analgesics have been advocated as a first-line treatment for acute episodes of LBP,[3,6,13] but their efficacy is questioned.[16,19,23] A systematic review concluded that these drugs are effective for short-term symptomatic improvement of patients with acute LBP, but efficacy of nonsteroidal antiinflammatory drugs as compared with other therapies remains unclear.[26] Concerns persist about the potential risks of these analgesics in terms of renal, hepatic and gastrointestinal complications.[4,5,21,22,24,31]

Clinical practice guidelines in the United States and the United Kingdom have recommended the use of self-administered topical heat therapy in the treatment of acute LBP.[3,28] A recent confirmatory study demonstrated the efficacy of a continuous, low-level heat wrap therapy for the treatment of acute muscular low back pain (Nadler et al, submitted separately). This study was undertaken to compare the efficacy of this heat wrap to the maximum recommended nonprescription dosages of ibuprofen and acetaminophen for self-treatment of acute nonspecific LBP.

Methods

This study was a randomized, actively controlled, multicenter, single (investigator) blind study involving 2 days of treatment and 2 days of additional follow-up evaluation. The study was conducted at 11 sites and approved by an Investigational Review Board. All clinical assessments were standardized. As shown in Figure 1, 371 subjects with acute nonspecific LBP of at least moderate pain intensity were enrolled and randomized. Pain of moderate or greater intensity (2 or more on a 6-point scale) was required for inclusion. Additional inclusion criteria

From the *Department of Physical Medicine and Rehabilitation, UMDNJ-NJ Medical School, the †Research Testing Laboratories, Great Neck, New York, and the ‡the Procter and Gamble Health Sciences Institute, Cincinnati, Ohio.
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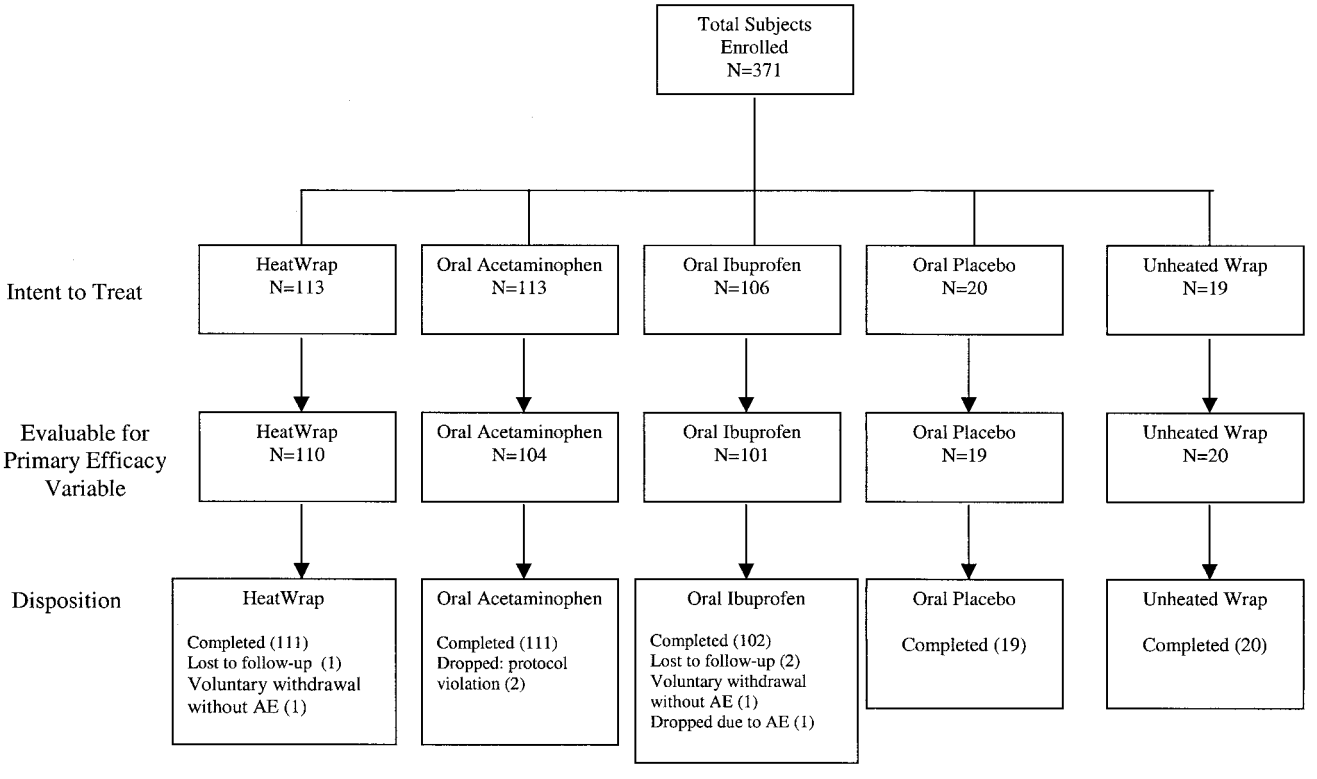

Figure 1. Intent to treat, primary efficacy variables, and disposition of the 371 enrolled patients.

required an age of 18 to 55 years (inclusive), ambulatory status, no low back trauma within the preceding 48 hours, and an answer of "yes" to the question "Do the muscles in your low back hurt?" Women of childbearing potential were required to undergo negative urine pregnancy tests, and if heterosexually active, to adopt the use an acceptable method of birth control. Subjects were asked not to use other treatments.

Subjects were excluded from the study if they had any evidence or history of radiculopathy or other neurologic deficits (*e.g.*, abnormal straight-leg-raise test results, patellar reflexes, or bowel or bladder function), or a 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 (*e.g.*, warfarin), daily back pain for more than three consecutive months, or hypersensitivity to acetaminophen, nonsteroidal antiinflammatory drugs, or heat.

Before randomization, qualified subjects were stratified according to baseline pain intensity, gender, and study site. Within each stratum, the subjects were randomized to treatment by a ratio of 6:6:6:1:1. Of the five treatment groups, three were considered the primary efficacy treatment groups: heat wrap (ThermaCare Heat Wrap; Procter and Gamble, Cincinnati, OH), which wraps around the lumbar region of the torso and uses a velco-like closure, heats to 104 F (40 C) within 30 minutes of exposure to air, and maintains this temperature continuously for 8-hours of wear; oral ibuprofen (two tablets three times daily for a total dose of 1200 mg, with oral placebo one time daily for blinding from the acetaminophen group); or oral acetaminophen (two tablets four times daily for a total of 4000 mg dose total). Two small sample-size groups were included for blinding and reduction of bias on assignment of treatment: oral placebo (two tablets four times daily) or unheated back wrap. Subjects assigned a back wrap were required to wear the device for approximately 8 hours per day, with all treatments administered on two consecutive days. Four visits to the study site were required, with prescreening initiated by telephone before the first study visit. Baseline measures for efficacy evaluation included tests for muscle stiffness, disability (Roland–Morris Disability Questionnaire[20]), and lateral trunk flexibility.

The primary efficacy variable was pain relief, as measured by a 6-point verbal rating scale.[1] Muscle stiffness was quantified with a 101-point numerical rating scale. Disability was calculated by subject as the percentage of "yes" responses to the 24 questions comprising the questionnaire; back transformed to a maximum score of 24. 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 right trunk flexion, the subject was instructed to stand erect with scapulae against a wall, arms hanging straight down, and palms on the lateral surface of the thighs. With the subject in this neutral position, a piece of masking tape was placed on the skin of each side of the thighs to mark the fingertip ends of the third digits (middle fingers). The subject then was 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 middle finger tip on the lateral side of the right leg at the maximum extent of right trunk flexion. With the subject standing in the neutral position, right trunk flexion was measured by tape measure as the distance in centimeters between the tops of the two pieces of masking tape on the

Table 1. Demographics of Study Subjects, by Treatment Group

	Heat Wrap (N = 113)		Oral Acetaminophen (N = 113)		Oral Ibuprofen (N = 106)		Unheated Wrap (N = 19)		Oral Placebo (N = 20)		Total (N = 371)	
	N	%	N	%	N	%	N	%	N	%	N	%
Age (years)												
18–29	34	30.1	42	37.2	32	30.2	4	21.1	4	20.0	116	31.3
30–39	27	23.9	28	24.8	28	26.4	6	31.6	7	35.0	96	25.9
40–49	40	35.4	32	28.3	33	31.1	8	42.1	7	35.0	120	32.3
50–55	12	10.6	8	7.1	13	12.3	1	5.3	2	10.0	36	9.7
>55	0	0.0	3	2.7	0.0	0.0	0	0.0	0	0.0	3	0.8
Gender												
Female	66	58.4	64	56.6	63	59.4	11	57.9	12	60.0	216	58.2
Male	47	41.6	49	43.4	43	40.6	8	42.1	8	40.0	155	41.8
Pain Intensity												
Moderate pain	63	55.8	63	55.8	60	56.6	11	57.9	11	55.0	208	56.1
More than moderate pain	50	44.2	50	44.2	46	43.4	8	42.1	9	45.0	163	43.9

lateral side of the right leg. This procedure was subsequently repeated on the left side.

At the first visit, informed consent documents were signed, medical histories taken, and physical examinations performed, including neurologic assessments and skin assessments at the area of back wrap application. The study participants were given treatment instructions as well as diaries and questionnaires to complete. On Day 4, the participants returned to the site, where lateral trunk flexibility and disability were assessed. The skin quality of all the participants was assessed at visits 1 and 4 using a 4-point scale with the following range of choices: 0 (normal color), 1 (faint pink to definite pink), 2 (definite redness), 3 (very intense redness).

As designated by the protocol, the primary comparison was between the Day 1 pain relief scores of the heat wrap group and the groups actively treated with ibuprofen and acetaminophen. Secondary study end points compared the heat wrap and oral analgesic treatment groups for Days 3 to 4 mean "extended" pain relief, Day 1 mean muscle stiffness reduction, Day 1 mean increase in lateral trunk flexibility and disability reduction. Primary and secondary analyses were conducted on both the intent-to-treat population and a per-protocol ("evaluable") data set, which was determined before the database was unblinded. 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 or off-schedule diary evaluations, and missing or off-schedule site visits.

Statistical Analysis. It was determined that given a standard deviation estimate of 1.01 for a 0- to 5-point scale, a sample size of approximately 105 evaluable subjects per efficacy group would provide 90% power to detect meaningful differences versus heat wrap in the day 1 mean pain relief scores of 0.5, with a significance level of 0.025.

Day 1 baseline measurements were used to calculate change from baseline scores. Day 1 mean pain relief (primary) and 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 3 to 4 mean "extended" pain relief scores and mean "extended" muscle stiffness reduction were calculated from evaluations taken approximately 24 and 48 hours after visit 3 on Day 2. Pain relief was analyzed using analysis of variance (ANOVA), including effects for study site, baseline pain intensity, gender, and treatment. Muscle stiffness reduction, disability reduction, and lateral flexibility data were analyzed using analysis of covariance (ANCOVA).

For all primary and secondary variables, two-tailed Student *t* tests of the null hypothesis of no treatment difference were conducted between the heat wrap group and both of the oral analgesic groups. To hold the Type 1 experiment error rate to 5%, Hochberg's procedure was used to adjust and test the two primary variable treatment comparisons before any secondary variable was tested.[14]

■ Results

This study enrolled 371 participants (155 men and 216 women) (Table 1). The baseline characteristics of the intent-to-treat population are provided in Table 2, and the disposition of the subjects is provided in Figure 1. The results of statistical analyses for the intent-to-treat population matched the results of the analyses of protocol-defined evaluable subjects for all primary and additional variables. Therefore, the results of the evaluable subject population are reported.

Primary Efficacy Variable: Day 1 Pain Relief

The Day 1 mean pain relief score for the heat wrap (mean, 2) was significantly higher than for either acetaminophen (mean, 1.32; $P = 0.0001$) and or ibuprofen (mean, 1.51; $P = 0.0007$) (Figure 2). This observed treatment difference for the heat wrap was 51.5% higher than for acetaminophen and 32.5% higher than for ibuprofen. Significant differences ($P < 0.05$) were observed at individual hourly time points comprising the primary end point. The heat wrap exhibited significantly greater pain relief than either acetaminophen (at hours 2 through 8) or ibuprofen (hours 3 through 8).

Other Efficacy Variables

Pain Relief Evaluations: Other Time Points. The Day 2 mean pain relief results corroborated those observed on Day 1. The heat wrap scores (mean, 2.78) were significantly greater than those for either acetaminophen (mean, 2;

Table 2. Demographic and Baseline Characteristics

	Heat Wrap (N = 113)	Oral Acetaminophen (N = 113)	Oral Ibuprofen (N = 106)	Unheated Wrap (N = 19)	Oral Placebo (N = 20)	Overall (N = 371)
Age (years)						
Mean	35.82	34.90	36.61	36.79	38.00	35.94
Standard deviation	10.54	11.29	10.4	9.32	9.07	10.59
Weight (pounds)						
Mean	173.44	171.81	177.41	160.68	180.05	173.78
Standard deviation	40.51	37.28	40.83	27.84	49.83	39.64
Muscle stiffness (0–100 scale)						
Mean	61.32	62.58	60.39	69.47	70.6	62.35
Standard deviation	16.22	16.97	19.3	15.98	16.56	17.51
Lateral flexibility (cm)						
Mean	13.81	14.19	13.8	13.64	15.93	14.02
Standard deviation	5.35	5.49	6.63	4.58	4.8	5.72
Disability (%)						
Mean	46.9	46.24	42.38	51.1	48.33	45.7
Standard deviation	20.79	20.92	21.47	22.86	14.58	20.88

$P = 0.0001$) or ibuprofen (mean, 2.06; $P = 0.0001$). The mean "extended" pain relief score for Days 3 to 4 was significantly higher for the heat wrap (mean, 2.61) than for either acetaminophen (mean, 1.95; $P = 0.0009$) or ibuprofen (mean, 1.68; $P = 0.0001$). This was an observed treatment difference of 33.8% between the heat wrap and acetaminophen, and a 55.4% difference between the heat wrap and ibuprofen. The treatment differences were significant ($P < 0.05$) between these groups for both time points comprising this end point.

Muscle Stiffness. All three primary treatment groups provided significant reductions in the muscle stiffness, as compared with the mean baseline score at each of the hourly time points evaluated throughout the study ($P \leq 0.001$ for all). The reduction in the Day 1 mean muscle stiffness score was significantly greater with the heat wrap (mean, 16.3) than with the acetaminophen (mean, 10.5; $P = 0.001$), and directionally greater than with ibuprofen (mean, 13.3; $P = 0.10$) (Figure 3). This represented a 55.2% greater mean reduction for the heat wrap than for acetaminophen, as compared with a 22.6% greater reduction for the heat wrap than for ibuprofen. Despite the mixed outcome overall on Day 1, the heat wrap was associated with a significantly greater reduction in the muscle stiffness scores ($P < 0.05$) than either acetaminophen or ibuprofen at individual time points from hours 4 through 8 on Day 1.

On Day 2, the muscle stiffness findings were added to those observed on Day 1, with significantly greater reductions in the mean muscle stiffness scores for the heat wrap (mean, 26.6) than for either acetaminophen (mean, 19.7; $P = 0.006$) or ibuprofen (mean, 17.6; $P = 0.009$). Similarly, over the entire treatment period, the heat wrap (mean, 21.3) showed significantly greater reductions in mean muscle stiffness scores on Days 1 to 2 than either acetaminophen (mean, 15.2; $P = 0.002$) or ibuprofen (mean, 16.4; $P = 0.01$).

In addition, the mean "extended" muscle stiffness reduction score on Days 3 to 4 for the heat wrap (mean, 26.6) was significantly greater than for either acetaminophen (mean, 17.1; $P = 0.001$) or ibuprofen (mean, 14.8; $P = 0.0001$). On Day 4, the muscle relaxation score peaked for the heat wrap (mean, 27.3), marked by a 44.5% decrease from the baseline score.

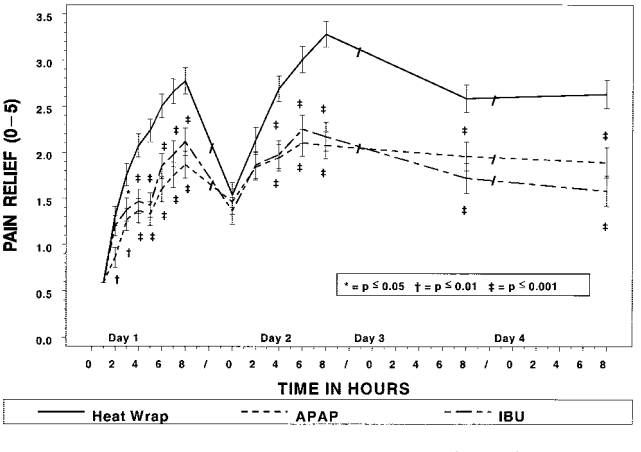

Figure 2. Primary efficacy variable pain relief (Day 1).

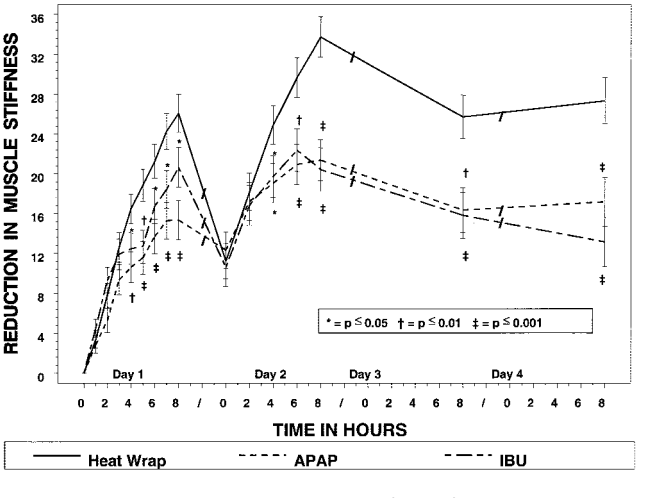

Figure 3. Reduction in muscle stiffness (Day 1).

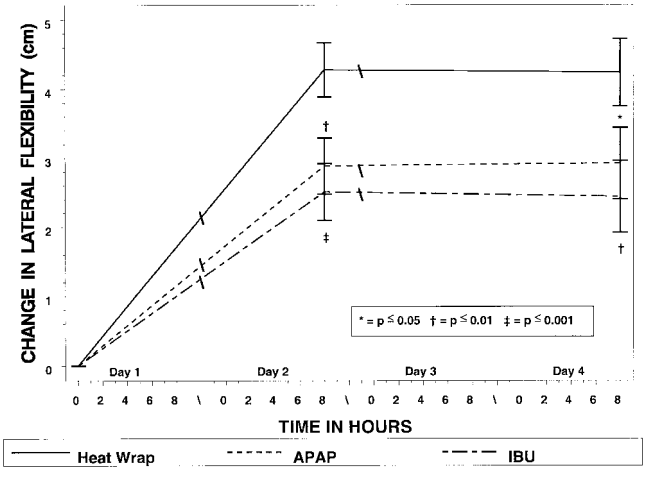

Figure 4. Assessment of lateral trunk flexibility.

Assessment of Lateral Trunk Flexibility: Range of Motion

All three primary treatment groups were associated with significant increases ($P \leq 0.0001$ for all) in lateral trunk flexibility on Days 2 and 4, as compared with baseline values. However, after 2 days of treatment, the change in lateral flexibility was significantly greater for the heat wrap (mean, 4.28 cm) than for either acetaminophen (mean, 2.93 cm; $P = 0.009$) or ibuprofen (mean, 2.51 cm; $P = 0.001$) (Figure 4). This was an observed treatment difference of 48.1% between the heat wrap and acetaminophen, and of 70.5% between the heat wrap and ibuprofen. Findings were similar on Day 4.

Roland–Morris Disability Assessment

Significant reductions in disability scores were observed for all three main groups on both Days 2 and 4, as compared with baseline scores ($P \leq 0.0001$ for all) (Figure 5). On Day 2, the reduction in the disability score for the heat wrap (mean, 3.9) was directionally greater than for acetaminophen (mean, 3; $P = 0.08$), and significantly greater than for ibuprofen (mean, 2.6; $P = 0.009$). By Day 4, the reduction in the disability score for the heat wrap (mean, 4.9) was significant as compared with either acetaminophen (mean, 2.9; $P = 0.0007$) or ibuprofen (mean, 2.7; $P = 0.0001$).

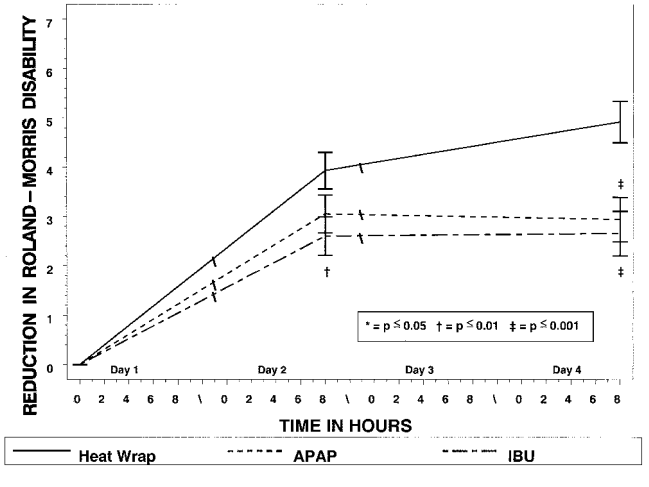

Figure 5. Assessment of reduction in Roland–Morris disability scores.

Safety

No serious adverse events occurred during this study. Systemic adverse events were more common in the ibuprofen group (10.4%) than in the other primary treatment groups (6.2% for the heat wrap and 4.4% for acetaminophen). Nausea was the most frequently reported adverse event in all the groups. Only one participant dropped out of the study because of an adverse event, an upper respiratory infection in the ibuprofen group. The heat wrap was well tolerated over the study period. One participant in the heat wrap group experienced minor redness in the area of wrap application on Day 2. However, this resolved spontaneously 1 hour after wrap removal.

■ Discussion

Self-medication using nonprescription acetaminophen or ibuprofen is now a standard strategy for acute LBP management.[3,9,12,26,29] Topical heat is less commonly used, possibly because of the need for assistance with the placement of heat packs or immobility imposed by use. This conflicts with recommendations for activity in the weeks after an acute episode, with neither bed rest nor exercise recommended in the acute phase.[3,10,30] Workers with LBP instructed to maintain a tolerable level of normal activity had a more rapid recovery than control subjects who received either 2 days of bed rest or back mobilizing exercises.[18] Minimizing the impact of LBP on the maintenance of activities of daily living is key to successful treatment.[8,17]

In this study, the heat wrap group demonstrated significant improvements in pain relief, lateral trunk flexibility, and disability reduction, as compared with the ibuprofen group. Comparison of the heat wrap with acetaminophen showed similar improvements in pain relief, lateral trunk flexibility, and muscle stiffness with the heat wrap. These findings were sustained in the heat wrap group more than 48 hours after the heat wrap was removed, which is consistent with a separate report of heat wrap efficacy, supporting the long-lasting effects of topical heat treatment (Nadler et al, submitted separately). The therapeutic benefit of the low-intensity, long-duration wearable heat wrap results partly from the continuous use of heat combined with the ability to maintain normal activity levels. No serious adverse events were noted over the course of this 4-day study.

■ Conclusion

According to the findings, continuous low-level topical heat wrap therapy is superior to both acetaminophen and ibuprofen, supporting its recommendation as a first-

line therapy for the treatment of acute muscular low back pain.

■ Key Points

- Continuous low-level heat wrap therapy was shown to be superior to maximum nonprescription dosages of acetaminophen and ibuprofen for the treatment of acute nonspecific low back pain.
- Heat wrap therapy was superior for pain relief, reduction in muscle stiffness, improved flexibility, and reduction in Roland–Morris disability, as compared with both acetaminophen and ibuprofen.
- The heat wrap studied allows patients with low back pain to receive pain relief and return to normal activity.

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Address reprint requests to

Scott F. Nadler, DO
Department of Physical Medicine and Rehabilitation
UMDNJ-NJ Medical School
90 Bergen Street (Suite 3100)
Newark, NJ 07103
E-mail: sfnadler@cs.com