ELSEVIER

The Spine Journal 5 (2005) 395–403

THE SPINE JOURNAL

Treating acute low back pain with continuous low-level heat wrap therapy and/or exercise: a randomized controlled trial

John M. Mayer, PhD[a,*], Lee Ralph, MD[b], Michele Look, MD[b], Geetha N. Erasala, MS[c], Joe L. Verna, DC[a], Leonard N. Matheson, PhD[a], Vert Mooney, MD[a]

[a]*U.S. Spine & Sport Foundation, 344 Kearny Villa Road, Suite 307, San Diego, CA 92123, USA*
[b]*San Diego Sports Medicine and Family Health Center, 6699 Alvarado Road, Suite 2100, San Diego, CA 92120, USA*
[c]*The Procter & Gamble Health Sciences Institute, 700 Mason-Montgomery Road, Mason, OH 45040, USA*

Received 12 November 2004; accepted 2 March 2005

Abstract

BACKGROUND CONTEXT: Restorative exercise and palliative modalities are frequently used together for the treatment of acute low back pain. However, little is known about the effects of combining these treatments.

PURPOSE: To evaluate the efficacy of combining continuous low-level heat wrap therapy with directional preference-based exercise on the functional ability of patients with acute low back pain.

STUDY DESIGN/SETTING: A randomized controlled trial was conducted at three outpatient medical facilities.

PATIENT SAMPLE: One hundred individuals (age 31.2±10.6 years) with low back pain of less than 3 months duration.

OUTCOME MEASURES: The primary outcome measure was functional ability assessed by the Multidimensional Task Ability Profile questionnaire. Secondary outcomes were disability assessed by the Roland-Morris Disability Questionnaire and pain relief assessed by a 6-point verbal rating scale.

METHODS: Participants were randomized to one of four groups: Heat wrap therapy alone (heat wrap, n=25); directional preference-based exercise alone (exercise, n=25); combination of heat wrap therapy and exercise (heat+exercise, n=24); or control (booklet, n=26). Treatment was administered for five consecutive days and included four visits to the study center over 1 week.

RESULTS: At 2 days after the conclusion of treatment (Day 7), functional improvement for heat+exercise was 84%, 95%, and 175% greater than heat wrap, exercise, and booklet, respectively ($p<.05$). Seventy-two percent of the subjects in the heat+exercise group demonstrated a return to pre-injury function compared with 20%, 20%, and 19% for heat wrap, exercise, and booklet, respectively ($p<.05$). Disability reduction for heat+exercise was 93%, 139%, and 400% greater than heat wrap, exercise, and booklet, respectively ($p<.05$). Pain relief for heat+exercise was 70% and 143% greater than exercise and booklet, respectively ($p<.05$).

CONCLUSIONS: Combining continuous low-level heat wrap therapy with directional preference-based exercise during the treatment of acute low back pain significantly improves functional outcomes compared with either intervention alone or control. Either intervention alone tends to be more effective than control.

Keywords: Low back pain; Disability; Heat wrap; Thermotherapy; Exercise

Introduction

Low back pain continues to be highly prevalent and very costly in the United States [1]. In most cases, the symptoms related to acute episodes of low back pain resolve within a few months. Without proper intervention, however, the recurrence rate is high and many individuals are left with residual trunk muscle dysfunction [2]. Thus, maintenance of

FDA device/drug status: approved for this indication (ThermaCare Heat Wrap, The Procter & Gamble Co).

Support in whole or in part was received from The Procter & Gamble Company. Author GNE acknowledges a financial relationship (employee of The Procter & Gamble Co.), which may indirectly relate to the subject of this manuscript.

* Corresponding author. 3444 Kearny Villa Rd., Ste. 307, San Diego, CA 92123. Tel.: (858) 279-7548; fax: (858) 874-0582.
E-mail address: jmayer2@san.rr.com (J.M. Mayer)

1529-9430/05/$ – see front matter
doi:10.1016/j.spinee.2005.03.009

physical activity [3] and early initiation of rehabilitative exercises [4] are recommended to prevent functional loss after acute episodes. There are few guidelines on how to best achieve early return to function.

Passive modalities, such as topical heat therapy, are commonly used in conjunction with physical exercise during low back rehabilitation. Most forms of topical heat, including hydroculator packs and heating pads, do not allow the patient to remain mobile during treatment [5]. Therefore, their use for the treatment of acute low back pain may oppose current recommendations. Recently, a lightweight disposable heat wrap has been developed to administer continuous low-level topical heat to the low back, while allowing the user to remain mobile during wear. Previous work has demonstrated that continuous low-level heat wrap therapy is effective for the treatment of acute low back pain in terms of providing pain relief and decreasing muscle soreness and disability [5,6]. It is unknown, however, if continuous low-level heat wrap therapy improves functional ability or results in additional functional benefits when combined with rehabilitative exercise.

The alleviation of acute low back pain is particularly important when the functional consequences of low back pain limit an individual's ability to perform key tasks at home, at work, or during sports. Recognizing that early return to function is a reasonable goal, this study utilized the Multidimensional Task Ability Profile (MTAP) [7,8], a new self-report instrument, to assess functional ability. The MTAP is a computerized pictorial activity and task sort that uses drawings and captions depicting progressively demanding physical tasks of daily living and work to quantify an individual's perception of his or her functional ability (Fig. 1).

The purpose of this study was to evaluate the efficacy of continuous low-level heat wrap therapy alone and combined with active exercise versus active exercise alone and control on the functional ability of patients with acute low back pain.

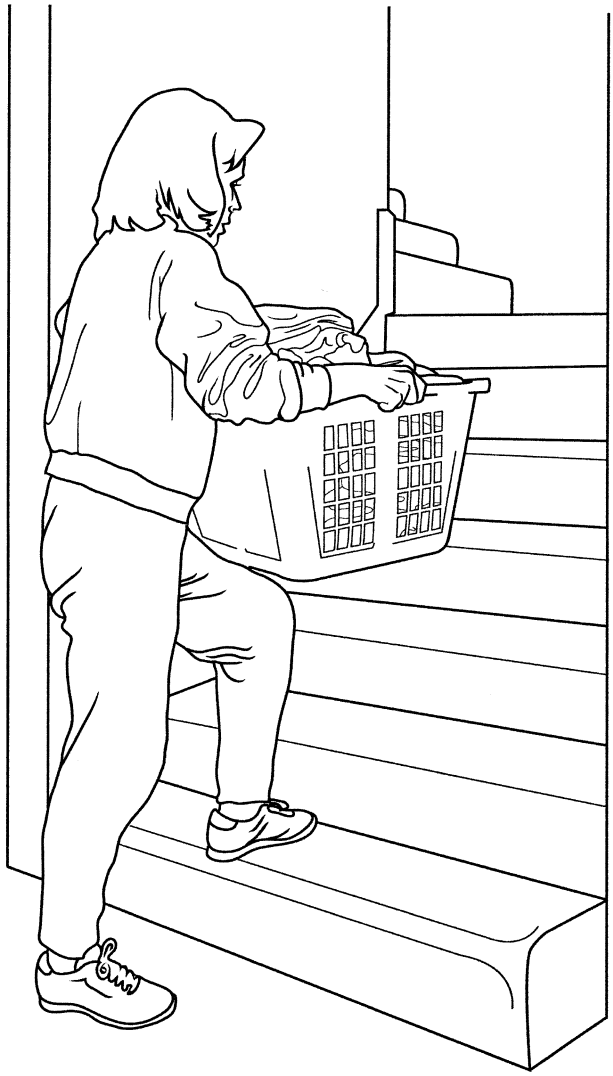

Fig. 1. Sample Multidimensional Task Ability Profile (MTAP) item: Carry a load of laundry upstairs.

Methods

A prospective, randomized, controlled, parallel study was conducted at three outpatient medical facilities in San Diego, California. Subjects were recruited by various written advertisements, word of mouth, and referral from primary care physicians. The study's protocol was approved by BioMed Institutional Review Board (San Diego, CA) and each subject gave written informed consent before participation.

Participants

Individuals with acute nonspecific low back pain were invited to participate. Inclusion criteria were: The subject was between the ages of 18–55 years; had acute nonspecific low back pain of greater than 2 days and less than 3 months duration with at least a 2-month pain-free period before the current episode, which was atraumatic (ie, no traumatic injury within 48 hours of enrollment) and not related to any medical disease that may indicate a pathology; had a low back pain intensity score of moderate or greater on a 6-point verbal rating scale (0=none, 1=mild, 2=moderate, 3=moderately severe, 4=severe, 5=extreme) [6]; had a rating of perceived capacity from the MTAP of less than 70%; had less than three Waddell's Non-Organic Signs [9]; was a candidate for active exercise; was ambulatory; and female subject of child-bearing potential had a negative urine pregnancy test and was using an acceptable form of contraception.

Potential subjects were excluded from participation if they had evidence or history of radiculopathy (eg, numbness, tingling, or shooting pain extending below the knee) or other neurological deficits (eg, abnormal straight leg raise test, patellar reflexes, and/or bowel and bladder function); history of spinal surgery, kidney problems, neuromuscular disorders, fibromyalgia, osteoporosis, diabetes mellitus, bleeding

diseases, arthritis, malignancy, systemic disease, inflammatory disease, abnormal heat or cold sensitivity, poor circulation, peripheral vascular disorders; active tuberculosis; skin lesions (eg, rash, bruising, laceration) on the low back region, or skin conditions in other regions that were spreading (eg, poison ivy, urticaria); psychiatric or psychological disorders; history of alcohol and/or drug abuse within the past year; cardiovascular or orthopedic contraindications to flexibility exercise; resting blood pressure values outside of 90–140/60–90 mm Hg; applied topical medication to the low back within 24 hours of enrollment; current involvement in a workers' compensation, disability, or personal injury claim; spinal injection treatment within 6 months before enrollment; participated in an investigational drug or device trial within 4 weeks of enrollment.

Procedures

Visit 1

Screening. After reading and signing an informed consent document, volunteers completed a health history questionnaire and pain drawing, and female volunteers completed a urine pregnancy test. Next, a licensed doctor performed a lumbar spine evaluation on each volunteer using McKenzie evaluation principles [10]. Then, qualified volunteers completed the study's baseline assessments, which included the MTAP two times (time 1—based on current functional levels (baseline test); time 2—based on functional levels before the onset of low back pain or injury (pre-injury test), the Roland Morris Disability Questionnaire (RMDQ) [11], and the 6-point pain intensity verbal rating scale.

Randomization and group assignment. Immediately after initial assessment, qualified participants were randomized using a computer-generated randomization sheet to one of four groups: Heat wrap alone (heat wrap, n=25); exercise alone (exercise, n=25); combination of heat wrap and exercise (heat+exercise, n=24); or control (booklet, n=26). Interventions were as follows:

Heat wrap: Immediately after randomization, participants applied a heat wrap (ThermaCare, Procter & Gamble, Cincinnati, OH) to the low back region in a manner previously described [6]. Participants were given four additional disposable heat wraps and instructed to wear the heat wrap for 8 hours per day for five consecutive days. The heat wrap is made of layers of cloth-like material that contain heat-generating ingredients (iron, charcoal, table salt, and water) that heat up when exposed to oxygen. The heat wrap reaches its therapeutic temperature of 104°F (40°C) within 30 minutes and delivers at least 8 hours of controlled heat.

Exercise: Immediately after randomization, participants performed a series of directional preference-based exercises at the study site under the supervision of a therapist. The exercise protocol was customized for each participant and consisted of standardized full range of motion movements stressing the end range in the directional preference that was displayed at the initial evaluation according to McKenzie concepts [10]. The exercises included low back extension (prone press-up and standing extension), flexion (supine knee to chest and seated flexion), or a combination of both movements [10]. These exercises have been shown to be beneficial for the treatment of acute low back pain [12]. Of the 49 participants randomized to the exercise and heat+exercise groups, 43 displayed a directional preference for low back extension, two displayed a flexion directional preference, and four did not display a directional preference. The participants performed 1–2 sets of 15–20 repetitions for each exercise at study Visits 1, 2, and 3 under the supervision of a therapist, and were instructed to perform the same exercises at home one time every hour while awake for five consecutive days.

Heat+Exercise: Participants wore the heat wrap in the same manner as the heat wrap group and performed the same exercises as the exercise group. Immediately after randomization, the participants applied the heat wrap to the low back region. Participants wore the heat wrap for at least 1 hour before performing exercise on Visit 1 and were advised to wear the heat wrap for 4 hours before performing exercises on Visits 2 and 3.

Booklet: Immediately after randomization, participants were given an educational booklet titled, "Acute Low Back Problems in Adults, Patient Guide: Understanding Acute Low Back Problems" [3]. A therapist reviewed the booklet with the participants and advised the participants to thoroughly read the booklet at home. The participants were advised to closely follow the recommendations in the booklet, except that they were asked to refrain from performing specific exercises for the low back, using heat or cold modalities, and receiving spinal manipulation.

Home instructions. At the end of Visit 1, participants were given group-specific home instruction sheets and a general home instruction sheet about use of other therapies, warnings signs of a serious low back condition, and a number to call in case of adverse event. Participants were advised to abstain from use of other forms of heat and ice therapy, massage therapy, spinal manipulation, herbal and holistic therapies, sauna, spa baths, steam rooms, and therapeutic hot showers while participating in this study. They were also instructed to refrain from performing specific exercises for the low back other than those assigned for the study and to refrain from performing strenuous activities outside of normal activities of daily living. No recommendations or restrictions were given regarding medication use.

Visits 2, 3, and 4 (Days 2, 4, and 7)

Two days, 4 days, and 7 days after Visit 1, the participants returned to the study site for mid-trial and final assessments, which included the MTAP (based on the current

functional ability level), RMDQ, 6-point pain intensity verbal rating scale, and a 6-point pain relief verbal rating scale [6].

Outcome measures

Functional improvement was the primary outcome measure and was derived from the 0–200 Rating of Perceived Capacity–Spine (RPC-S) from the MTAP as the difference between post-baseline and baseline scores. On the MTAP, the evaluee ranks his or her ability to perform 111 common physical tasks on a 6-point scale with choices of 1=able, 2=slightly restricted, 3=restricted, 4=very restricted, 5=unable, and 6=don't know [7]. An overall RPC-S is calculated from individual MTAP item scores that involve spinal function. The MTAP has been shown to be a reliable and valid self-report measure of functional ability [8].

Deficit from pre-injury function, disability reduction, and pain relief were secondary outcome measures. Deficit from pre-injury function was derived from RPC-S as the difference between post-baseline and pre-injury scores. Disability reduction was derived from the 24-question RMDQ as the difference between post-baseline and pre-injury scores. Pain relief was assessed with a 6-point verbal rating scale with choices of 0=no relief, 1=a little relief, 2=less than half relief, 3=more than half relief, 4=a lot of relief, and 5=complete relief [6].

The following incidence variables were derived by subject and time point based on clinically meaningful cutoff points: Functional improvement was calculated from a cutoff of ≥27-point improvement from baseline RPC-S. Return to function was calculated from a cutoff of <27-point deficit from pre-injury RPC-S. Previous work by the present study's investigators with related pictorial activity and task sorts has shown that 27 points (13.5%) is a reasonable cutoff for clinical relevance [13]. Pain relief was calculated from a cutoff of ≥2 ("less than half relief") [14]. Disability reduction was calculated from a cutoff of ≥3-point reduction from baseline RMDQ [15].

Data analysis

Based on pilot work with the MTAP and published research with related pictorial activity and task sorts [13], we estimated the change in mean value after treatment, standard deviation, and effect size for RPC-S to be 22, 30, and 0.73, respectively. Therefore, we estimated that 96 subjects in four groups of 24 were adequate to establish statistical significance with a one-tailed test, at the 0.05 alpha level, and a power of 0.80.

Change from baseline scores (or change from pre-injury scores for deficit from pre-injury function) for day 2, 4, and 7 assessments for RPC-S (functional improvement from baseline), RPC-S (deficit from pre-injury function), and RMDQ (disability reduction) were evaluated for group main effects by analysis of covariance using baseline scores as covariates. Pain relief scores for day 2, 4, and 7 assessments were evaluated for group and gender main effects and group by gender interactions by analysis of variance. Post hoc, pairwise comparisons of group means were conducted using two-tailed *t* tests with Bonferroni's adjustment for multiple tests. Incidence variables were analyzed by time point for group effects by analogous logistic regression adjusted for gender or baseline, as appropriate. Statistical significance was accepted at the 0.05 alpha level. Because there was no significant study site by treatment group interaction for any of the outcome measures, data were pooled among study sites for all analyses.

Results

Disposition of the subjects

Baseline characteristics of the subjects are shown in Table 1, and disposition of the subjects is provided in Figure 2. One hundred subjects were enrolled, and 92 completed the study. There were no adverse events reported. At baseline, there were no significant differences in age, height, weight, and functional ability, disability, and pain intensity among the groups. A greater number of females were enrolled in the booklet group compared with the other three groups, despite random assignment. There were no significant gender main effects or gender by group interactions for any of the outcome measures ($p>.05$).

Functional improvement

At baseline, the mean RPC-S score was 95.6 (out of 200) for all evaluable subjects. Adjusted mean RPC-S scores by group and time point are shown in Figure 3. At day 2, there was no significant difference among the groups in the functional improvement scores ($F(3, 91)=1.602$, $p=.194$). At days 4 and 7, there was a significant difference among the groups in the functional improvement scores ($F(3, 82)=3.687$, $p=.0152$; and $F(3, 87)=8.976$, $p<.0001$, respectively), with post hoc findings as follows: At day 4, heat+exercise was greater than exercise ($p=.018$) and booklet ($p=.002$), with relative increases for heat+exercise compared with exercise and booklet of 72% and 119%, respectively. At day 7, heat+exercise was greater than heat wrap ($p=.0007$), exercise ($p=.0003$), and booklet ($p<.0001$), with relative increases for heat+exercise compared with heat wrap, exercise, and booklet of 84%, 95%, and 175%, respectively. At day 7, heat+exercise displayed a higher incidence of functional improvement compared with booklet (90.4% vs. 48.0%, respectively; odds ratio=10.19, $p=.005$).

Deficit from pre-injury function

The mean pre-injury RPC-S score was 180.3 (out of 200) for all evaluable subjects. At days 2 and 4, there was no significant difference among the groups in the deficit from pre-injury function scores ($F(3, 75)=1.063$, $p=.370$; and

Table 1
Baseline characteristics of intent-to-treat subjects

	Heat wrap n=25 17 F, 8 M	Exercise n=25 15 F, 10 M	Heat+Exer n=24 15 F, 9 M	Booklet n=26 24 F, 2 M	Overall N=100 71 F, 29 M
Age (yr)	29.3±9.9	32.6±10.3	31.8±11.8	31.3±10.9	31.2±10.6
Height (cm)	168.7±10.3	169.7±11.2	168.3±9.4	165.8±9.4	168.1±9.6
Weight (kg)	71.0±15.7	82.5±23.7	71.2±13.0	70.2±15.9	73.9±18.1
Function(0–200)*	100.5±28.8	91.9±24.2	100.0±32.4	85.7±37.4	94.4±31.3
Disability (0–24)†	9.1±5.0	9.1±4.8	7.4±3.9	10.7±3.9	9.1±4.8
Pain intensity (0–5)	3.0±0.7	2.8±0.8	2.5±0.6	2.9±0.8	2.8±0.7

Values are means±SD.
* Rating of Perceived Capacity–Spine from the Multidimensional Task Ability Profile.
† Roland Morris Disability Questionnaire.

F(3, 69)=.778, p=.510, respectively). At day 7, there was a significant difference among the groups in the deficit from pre-injury function scores (F(3, 74)=5.579, p=.002), with post hoc findings as follows: Heat+exercise was less than heat wrap (p=.0035), exercise (p=.0029), and booklet (p=.0003), with relative decreases for heat+exercise compared with heat wrap, exercise, and booklet of 56%, 56%, and 62%, respectively. At day 7, heat+exercise displayed a higher incidence of return to function compared with booklet (72.2% vs. 19.0%, respectively; odds ratio=11.05, p=.003).

Disability reduction

At baseline, the mean RMDQ score was 9.0 (out of 24) for all evaluable subjects. Adjusted mean RMDQ scores by group and time point are shown in Figure 4. At day 2, there was no significant difference among the groups in the disability reduction scores (F(3, 91)=1.585, p=.198). At days 4 and 7, there was a significant difference among the groups in the disability reduction scores (F(3, 82)=3.231, p=.027; and F(3, 82)=4.958, p=.003, respectively), with post hoc findings as follows: At day 4, heat+exercise and heat wrap were greater than booklet (p=.007 and p=.0123, respectively). At day 7, heat+exercise was greater than heat wrap (p=.0267), exercise (p=.0066), and booklet (p=.0003), with relative increases for heat+exercise compared with heat wrap, exercise, and booklet of 93%, 139%, and 400%, respectively. At day 7, heat+exercise displayed a higher incidence of disability compared with booklet (71.4% vs. 44.0%, respectively; odds ratio=3.18, p=.028).

Pain relief

Pain relief scores by group and time point are shown in Figure 5. At day 2, there was no significant difference among the groups in the pain relief scores (F(3, 88)=2.064,

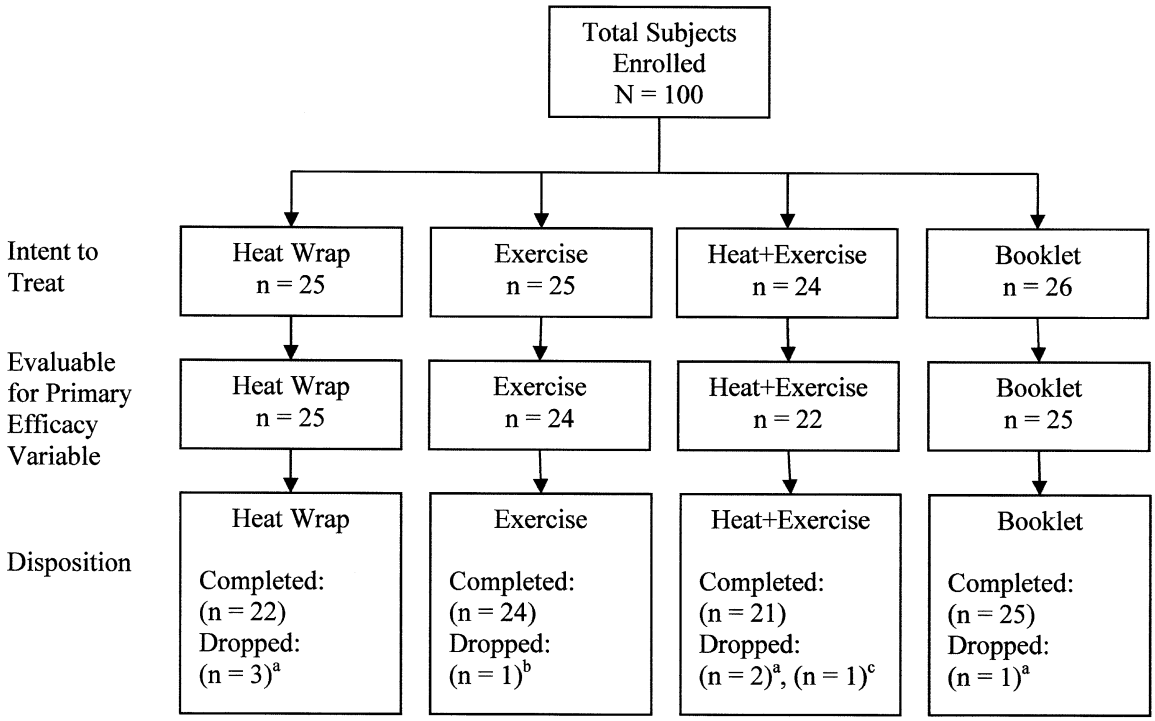

Fig. 2. Randomization schedule and subject disposition. Description of dropped subjects: [a]Missed or out of sequence study visits; [b]Voluntary withdrawal, lack of efficacy; [c]Voluntary withdrawal, noncompliance.

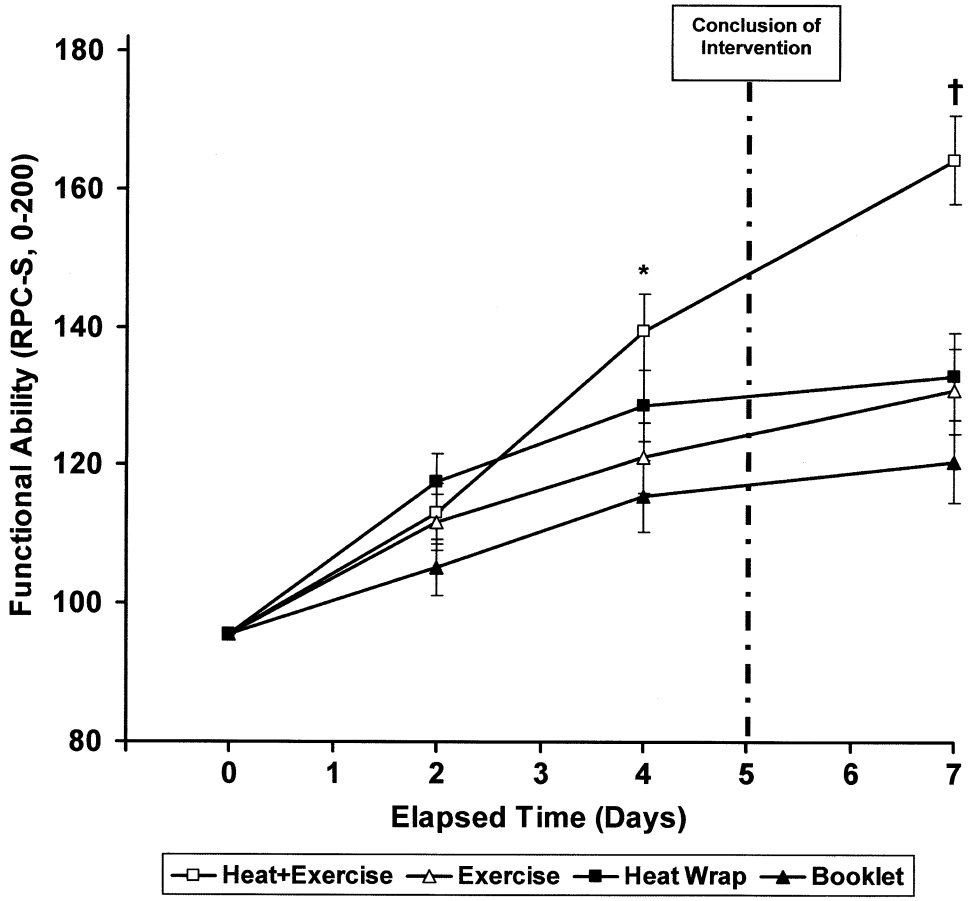

Fig. 3. Functional ability: Rating of Perceived Capacity–Spine (RPC-S) scores (adjusted means±SE) plotted by group and time point. *Heat+Exercise> Exercise, Booklet; †Heat+Exercise>Heat Wrap, Exercise, Booklet; $p<.05$.

$p=.111$). At days 4 and 7, there was a significant difference among the groups in the pain relief scores ($F(3, 79)=3.612$, $p=.017$; and $F(3, 83)=7.282$, $p=.000$, respectively), with post hoc findings as follows: At day 4, heat+exercise and heat wrap were greater than booklet ($p=.000$ and $p=.026$, respectively), with relative increases for heat+exercise and heat wrap compared with booklet of 178% and 122%, respectively. At day 7, heat+exercise was greater than exercise and booklet ($p=.007$ and $p<.0001$, respectively), with relative increases for heat+exercise compared with exercise and booklet of 70% and 143%, respectively. At day 7, heat+exercise displayed a higher incidence of pain relief compared with booklet (95.2% vs. 40.0%, respectively; odds ratio=29.85, $p=.003$).

Specificity of effect

Specificity of effect was investigated through the use of scales in the MTAP for functional constructs that should not have been substantially affected by the interventions of this study. The MTAP questionnaire clearly identified specific functional restrictions related to acute low back pain and functional improvements related to treatment. A comparison of RPC scores among various functional constructs derived from the MTAP indicates that the effect of intervention was specific. At day 7 for the heat+exercise group, for example, the mean percent improvement from baseline RPC for lifting and lowering tasks was greater than finger dexterity tasks (340.3±89.5 vs. 27.5±33.2, respectively, $p<.0001$).

Discussion

The present study was the first known to evaluate the efficacy of combining continuous low-level heat wrap therapy and directional preference-based exercise for improving the functional ability of patients with acute low back pain. Thus, no comparative data are available. Specific findings are discussed below.

Combination therapy provided superior functional improvement, disability reduction, and pain relief. The most compelling finding of the present study is that combining heat wrap therapy and exercise resulted in significantly superior functional gains compared with heat wrap therapy alone and exercise alone; and these gains became most evident at the study's final assessment (day 7), rather than at the first mid-trial assessment (day 2), as originally hypothesized. We anticipated that any relative benefits of combined

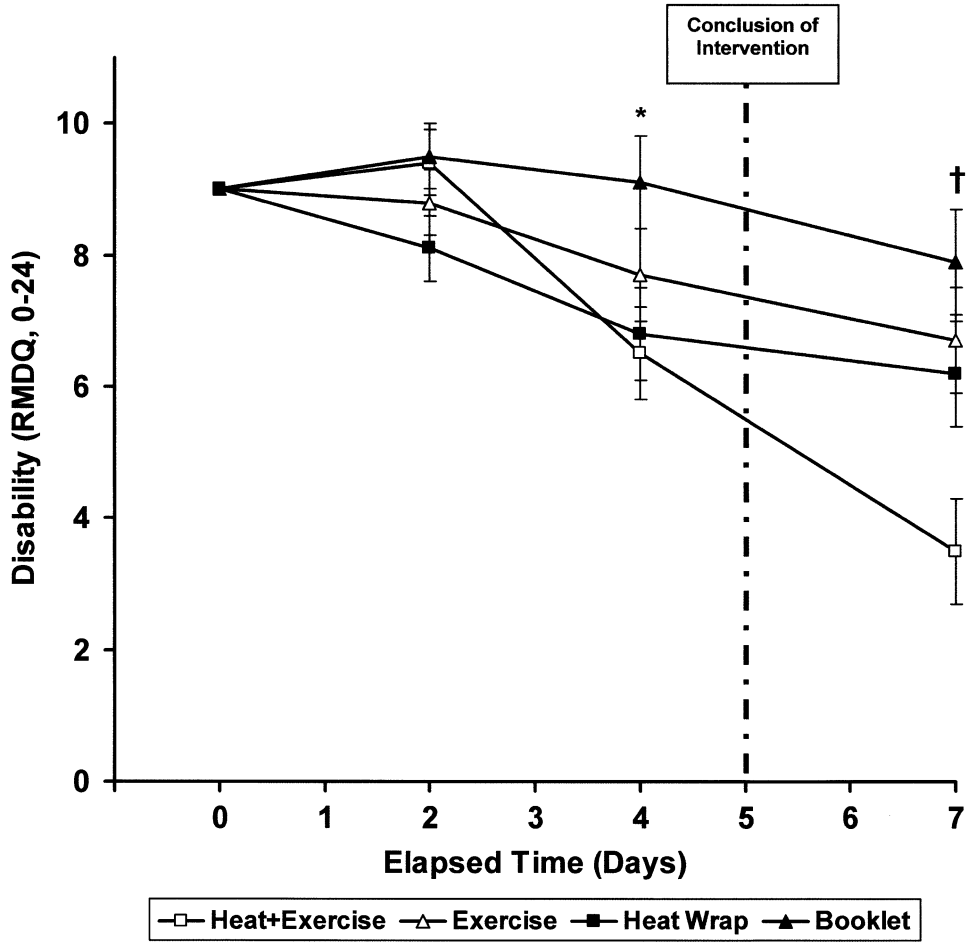

Fig. 4. Disability: Roland-Morris Disability Questionnaire (RMDQ) scores (adjusted means±SE) plotted by group and time point. *Booklet>Heat Wrap, Heat+Exercise; †Heat Wrap, Exercise, Booklet>Heat+Exercise; $p<.05$.

therapy would become apparent early in the trial period and would disappear by the study's conclusion. However, at day 7 (2 days after the conclusion of treatment) functional improvement and disability reduction scores for the combined therapy group were nearly twice the magnitude of heat wrap therapy alone or exercise alone, and three to four times greater than control. Also, the combined therapy group was the only treatment group to display higher incidences of clinically meaningful functional improvement, return to pre-injury function, disability reduction, and pain relief compared with control at this time point. Notably, 72% of the subjects in the combined therapy group demonstrated a return to pre-injury function compared with 20%, 20%, and 19% of the heat wrap alone, exercise alone, and control subjects, respectively.

A plausible reason why combining heat wrap therapy and supervised exercise therapy considerably enhances functional outcomes during acute low back pain treatment is that patients receiving the combined therapy are able to wear the heat wrap while performing the specific therapeutic exercises and also remaining active in meaningful activities. The combination of physiological benefit with the opportunity to minimize the disruption in life activities often reported by persons who experience acute low back pain may result in a powerful effect on treatment outcome.

From a physiological perspective, continuous low-level heat wrap therapy [5,6] and supervised directional preference-based exercises [12] have been shown to provide symptomatic relief for acute low back pain, and the benefits of each are likely the result of different mechanisms. Topical heat elevates the temperature of muscle tissue, which increases connective tissue extensibility, increases the resistance of muscle tissue to tearing, improves motor unit recruitment, and allows for smoother muscle contraction [16]. Topical heat also inhibits pain signals and increases proprioception [5]. Furthermore, the heat wrap supports the lower torso region [5] and may compress the lumbar muscles. Maintenance of physical activity during the treatment of acute low back pain is usually associated with superior outcomes compared with bed rest and passive modalities [3]. Moreover, directional preference-based exercise helps to alleviate fear avoidance patterns related to activity and restore lumbar range of motion and strength [10]. Though not specifically assessed in the current study, topical heat application during the performance of exercise may have improved the patient's pain tolerance and allowed for better execution of the exercise movements at end range.

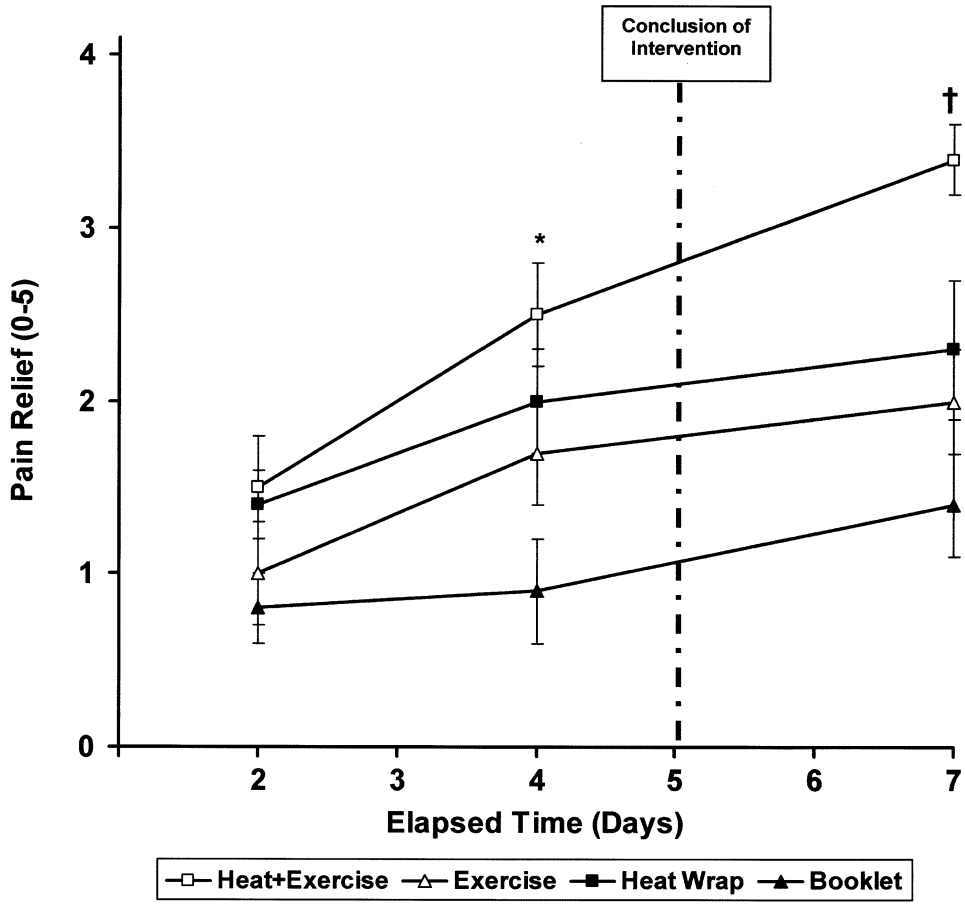

Fig. 5. Pain relief scores (means±SE) plotted by group and time point. *Heat+Exercise, Heat Wrap>Booklet; †Heat+Exercise>Exercise, Booklet; p<.05.

From a psychological perspective, the opportunity to remain active in meaningful activities despite severe pain is thought to be implicated in avoiding depression and loss of self-efficacy [17,18]. At the least, it seems to be impossible to separate the effects of exercise from the effects of participation in meaningful activities [19]. The "portability" of the heat wrap system appears to allow ongoing participation in meaningful activities, which may contribute to these psychological benefits as well. Further study on this issue is warranted.

The MTAP identified specific functional improvements related to treatment. The positive effect of combining heat wrap therapy and exercise was especially noteworthy with lifting and lowering tasks, which are often important work tasks and frequently restricted by acute low back pain. The MTAP scores of subjects in the combined therapy group demonstrated the greatest functional improvement in lifting and lowering tasks (340%) as a consequence of treatment. The MTAP scores for finger dexterity tasks, on the other hand, showed much less improvement (28%). This is consistent with research using the Spinal Function Sort, in which functional improvement was found in persons who received spinal surgery compared with exercise alone for low back pain [20], and another study in which persons who were able to centralize spinal pain were found to have greater functional improvement [21].

Clinical applications

The present study may have important clinical implications because it provides preliminary support for using a passive modality that does not hinder function in conjunction with rehabilitative exercise. Specifically, the present study strongly suggests that clinicians who aim to improve function and reduce disability levels during the treatment of acute low back pain should consider using continuous low-level heat wrap therapy and directional preference-based exercise together, rather than one or the other.

Limitations and future study

The primary limitation of this study is its small sample size, which limits the generalizability of the benefits of combining heat wrap therapy and exercise. Another limitation of the study is that, despite randomization, a greater number of females were assigned to the control group compared with the three treatment groups. Even though we adjusted for the gender imbalance in the statistical analyses, this gender imbalance may have biased the outcomes. However, because

the three treatment groups had similar gender characteristics, the gender imbalance related to the control group does not weaken the study's major finding that combining heat wrap therapy with exercise produced superior outcomes compared with either treatment alone. A third limitation is that long-term outcomes were not assessed. Future research with larger sample sizes, gender-balanced designs, and assessment of long-term outcomes is warranted.

A fourth limitation of the present study is that placebo effects cannot be ruled out as possible mechanisms to explain the superiority of the combined therapy versus either treatment alone in terms of functional improvement and disability reduction. The subjects were not blinded to the treatments, because fully masking the treatments (heat modality and physical exercise) was impossible owing to the present study's design. Further, the subjects in the combined therapy group received approximately twice the amount of intervention and attention compared with either treatment alone. Previous researchers discussed the importance of balancing intervention times among treatment groups in prospective randomized clinical trials, but admitted that deliberately balancing intervention times may not be pragmatic [22]. Nevertheless, future research with blinded treatment group assignment and equal intervention and attention times among groups would be useful to clarify the mechanisms underlying the efficacy of combined therapy.

Conclusions

Combining continuous low-level heat wrap therapy with directional preference-based exercise therapy offers distinct advantages over either therapy alone for the treatment of acute low back pain. Specifically, combined therapy results in significantly larger gains in functional improvement, return to function, and disability reduction compared with either treatment alone or control. Either intervention alone tends to be more effective than control. Physicians and therapists should consider using continuous low-level heat wrap therapy in conjunction with exercise therapy during the early stages of care for acute low back pain in order to achieve optimal functional improvements during recovery.

References

[1] Luo Z, Pietrobon R, Sun SX, Liu GG, Hey L. Estimates and patterns of direct health care expenditures among individuals with back pain in the United States. Spine 2004;29(1):79–86.

[2] Hides JA, Stokes MJ, Jull GA, Cooper DH. Evidence of multifidus wasting ipsilateral to symptoms in patients with acute/subacute low back pain. Spine 1994;19(2):165–72.

[3] Bigos SJ, Bower OR, Braen GR, et al., eds. Clinical practice guideline #14: Acute low back problems in adults. Rockville, MD: Public Health Service, 1994.

[4] Hides JA, Richardson CA, Jull GA. Multifidus recovery is not automatic after resolution of acute, first episode low back pain. Spine 1996;21(23):2763–9.

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

[6] Nadler SF, Steiner DJ, Erasala GN, et al. Continuous low-level heatwrap therapy provides more efficacy than ibuprofen and acetaminophen for acute low back pain. Spine 2002;27(10):1012–7.

[7] Matheson LN. History, design characteristics, and uses of the pictorial activity and task sorts. J Occup Rehabil 2004;14(3):175–95.

[8] Mayer JM, Mooney V, Matheson LN, et al. The reliability and validity of a new computerized pictorial activity and task sort. J Occup Rehabil 2005;15(2):185–95.

[9] Waddell G, McCulloch JA, Kummel E, Venner RM. Nonorganic physical signs in low-back pain. Spine 1980;5(5):117–25.

[10] Jacob G, Heffner S, Medcalf R, Barenburg D, Starler S. Evaluating the patient using the McKenzie approach. In: Stude D, ed. Spinal rehabilitation. Stamford, CT: Appleton & Lange, 1999.

[11] Roland M, Morris R. A study of the natural history of low back pain: Part 1. Development of a reliable and sensitive measure of disability in low back pain. Spine 1983;8:141–4.

[12] Stankovic R, Johnell O. Conservative treatment of acute low-back pain. A prospective randomized trial: McKenzie method of treatment versus patient education in mini back school. Spine 1990;15:120–3.

[13] Matheson LN, Matheson ML, Grant J. Development of a measure of perceived ability. J Occup Rehabil 1993;3(1):15–30.

[14] Farrar JT, Portenoy RK, Berlin JA, Kinman JL, Strom BL. Defining the clinically important differences in pain outcome measures. Pain 2000;88:287–94.

[15] Bombardier C, Hayden J, Beaton DE. Minimal clinically important difference: low back pain outcome measures. J Rheumatol 2001;28: 431–438.

[16] Szymanski DJ. Recommendations for the avoidance of delayed onset muscle soreness. Strength Cond J 2001;23:7–13.

[17] Matheson L. Functional goal setting: foundation of the rehabilitation relationship. Am Pain Soc J 1994;3(2):111–4.

[18] Matheson L. Getting a handle on motivation: self-efficacy in rehabilitation. In: Isernhagen S, ed. Work injury management: the comprehensive spectrum. Rockville, MD: Apsen, 1994.

[19] Ojanen M. Can the effects of exercise on psychological variables be separated from placebo effects? Int J Sport Psych 1994;25(1):63–80.

[20] Robinson RC, Kishino N, Matheson LN, et al. Improvement in postoperative and nonoperative spinal patients on a self-report measure of disability: the Spinal Function Sort (SFS). J Occup Rehabil 2003; 13(2):107–13.

[21] Sufka A, Hauger B, Trenary M, et al. Centralization of low back pain and perceived functional outcome. J Orthop Sports Phys Ther 1998;27(3):205–12.

[22] Bronfort G, Evans R, Nelson B, Aker PD, Goldsmith CH, Vernon H. A randomized controlled trial of exercise and spinal manipulation for patients with chronic neck pain. Spine 2001;26:788–99.