A Cochrane Review of Superficial Heat or Cold for Low Back Pain

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Study Design. Cochrane systematic review.

Objective. To assess the effects of superficial heat and cold therapy for low back pain in adults.

Summary of Background Data. Heat and cold are commonly used in the treatment of low back pain.

Methods. We searched electronic databases from inception to October 2005. Two authors independently assessed inclusion, methodologic quality, and extracted data, using the criteria recommended by the Cochrane Back Review Group.

Results. Nine trials involving 1,117 participants were included. In two trials of 258 participants with a mix of acute and subacute low back pain, heat wrap therapy significantly reduced pain after 5 days (weighted mean difference [WMD], 1.06; 95% confidence interval [CI], 0.68–1.45, scale range, 0–5) compared with oral placebo. One trial of 90 participants with acute low back pain found that a heated blanket significantly decreased pain immediately after application (WMD, −32.20; 95% CI, −38.69 to −25.71; scale range, 0–100). One trial of 100 participants with a mix of acute and subacute low back pain examined the additional effects of adding exercise to heat wrap and found that it reduced pain after 7 days.

Conclusions. The evidence base to support the common practice of superficial heat and cold for low back pain is limited, and there is a need for future high-quality randomized controlled trials. There is moderate evidence in a small number of trials that heat wrap therapy provides a small short-term reduction in pain and disability in a population with a mix of acute and subacute low back pain, and that the addition of exercise further reduces pain and improves function. There is insufficient evidence to evaluate the effects of cold for low back pain and conflicting evidence for any differences between heat and cold for low back pain.

Key words: systematic review, Cochrane Collaboration, heat, cold, low back pain.

Low back pain is a common complaint with the lifetime prevalence reported as ranging from 11% to 84%. The cause of pain is nonspecific in about 95% of people presenting with acute low back pain, with serious conditions being rare. Chronic low back pain is a well-documented disabling condition, costly to both individuals and society.

Different healthcare disciplines commonly use heat and cold treatments for the treatment of low back pain. Both therapies are simple to apply and are inexpensive. They may be used by people with low back pain at home or may be employed by practitioners as part of a treatment regimen.

Traditionally, ice has been recommended for acute injury and heat has been recommended for longer-term injuries. Superficial heat methods convey heat by conduction or convection. Superficial heat elevates the temperature of tissues and provides the greatest effect at 0.5 cm or less from the surface of the skin. However, deep heating is achieved by converting another form of energy to heat, for example, shortwave diathermy, microwave diathermy, and ultrasound. Superficial heat includes such methods as hot water bottles, heated stones, soft heated packs filled with grain, poultices, hot towels, hot baths, saunas, steam, heat wraps, heat pads, electric heat pads, and infra-red heat lamps. Cold therapy is used to reduce inflammation, pain, and edema. Superficial cold includes cryotherapy, ice, cold towels, cold gel packs, ice packs, and ice massage.

Various national guidelines for the management of low back pain have conflicting recommendation for heat and cold therapy. The U.S. Agency for Healthcare Research and Quality guidelines found no evidence of benefit from the application of ice or heat for acute low back pain, however, recommended self-application of heat or cold for patients to provide temporary relief of symptoms. Other guidelines give different recommendations.

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The device(s)/drug(s) is/are FDA-approved or approved by corresponding national agency for this indication.

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There is consensus among the Editorial Board of the Back Review Group that strong evidence can only be provided by multiple higher quality trials that replicate findings of other researchers in other settings.

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©2006, Lippincott Williams & Wilkins, Inc.
Objectives. The objective of this review was to determine the efficacy of superficial hot or cold therapies in reducing pain and disability in low back pain in adults, aged 18 and older.

Criteria for Considering Studies for This Review

Types of Studies. We included randomized controlled trials (RCTs) and nonrandomized controlled clinical trials (CCTs) comparing superficial hot or cold therapy to placebo, no therapy, or to other therapies.

Types of Participants. Studies were selected that included participants 18 years of age or older, with the complaint of nonspecific low back pain. Trials that included participants with pathologic causes of low back pain and low back pain with radiculopathy were excluded. For the purpose of this review, the duration of back pain was defined as acute (<6 weeks), subacute (6–12 weeks), or chronic (>12 weeks), as defined by the Cochrane Back Review Group.

Types of Interventions. Trials were included in which superficial heat or cold therapy was administered to at least one group within the trial. Trials in which cointerventions (e.g., exercise) were given were only included if the cointerventions were similar across comparison groups. If cointerventions were given, trials were excluded if we could not isolate the effects of heat or cold from the effects of the other therapies delivered. Trials of spa therapy (balneotherapy) were excluded because that intervention is being assessed by another Cochrane review. At the time of publication of our review, the protocol for the balneotherapy review had only proceeded to the editorial review stage.

Types of Outcome Measures. Trials were included that used at least one of the five outcomes considered to be important in low back pain research: pain (e.g., measured by visual analogue scale), disability/function (e.g., measured by Oswestry, Roland Disability Scale), overall improvement, patient satisfaction, and adverse effects. The primary outcomes for this review were pain and physical functional status. Some included trials measured other outcomes, e.g., trunk flexibility or skin temperature; however, these results are not included in the analysis because they are out of the scope of this review.

Search Strategy for Identification of Studies

Data Sources. The following sources were accessed and searched:

1. The Cochrane Controlled Trials Register (CENTRAL) (Cochrane Library Issue 3, 2005)
2. MEDLINE (1966 to October 2005)
3. EMBASE (1980 to October 2005)
4. CINAH (1982 to October 2005)
7. SPORTDiscus (1830 to October 2005)
8. OLDMEDLINE (1950 to 1965, searched October 2005)

Search Strategy. The search strategy was based on that recommended by the Cochrane Back Review Group.

Methods of the Review

Selection of Studies. One author (S.D.F.) conducted the searches and compiled all of the abstracts retrieved by the above search strategy. Two authors (S.D.F., B.F.W.) then independently applied the inclusion criteria to all of these abstracts. If the eligibility of the study was not clear from the abstract, then the full text of the article was obtained and assessed independently by the two authors. Any disagreement between the authors was resolved by discussion and consensus.

Data Extraction and Management. Two authors (S.D.F. and M.C.) independently extracted the data onto a standard form. The data extraction form was pilot tested on one trial to minimize misinterpretation. Any disagreement between the authors was resolved by discussion and consensus. We requested additional study details and data from trial authors when the data reported were incomplete. Some data from the Nadler studies and from the Mayer study were received from the authors and were incorporated into the table of included studies (Table 2) and the results.

Assessment of Methodologic Quality of Included Studies. The methodologic quality of the included trials was independently assessed by two authors (S.D.F., M.C.) and checked by a third author (J.W.R.). The assessment of methodologic quality was performed according to the methodologic criteria list recommended by the Cochrane Back Review Group and scored as a “yes (Y),” “no (N),” or “don’t know (DK).” There were 11 criteria relevant to the internal validity of the study, against which each trial was assessed, including selection bias, performance bias, attrition bias, and detection bias. The methodologic quality assessment of the trials was used to grade the strength of the evidence. Higher-quality trials were defined as fulfilling 6 or more of the 11 methodologic quality criteria. Lower-quality trials were defined as fulfilling fewer than 6 criteria.

Data Analysis. Only a small proportion of the data in the included trials were available for pooling. For the majority of comparisons and outcomes, it was not possible to pool results. A qualitative method recommended by the Cochrane Back Review Group using Levels of Evidence for data synthesis was performed:

- Strong evidence: consistent findings among multiple high-quality RCTs
- Moderate evidence: consistent findings among multiple low-quality RCTs or CCTs and/or one high-quality RCT
- Limited evidence: one low-quality RCT and/or CCT
- Conflicting evidence: inconsistent findings among multiple trials (RCTs and/or CCTs)
- No evidence from trials: no RCTs or CCTs

Clinical Relevance. Two authors (S.D.F., J.W.R.) independently judged the clinical relevance of each trial, using the five questions recommended by the Cochrane Back Review Group and scored each one as a yes, no, or don’t know:

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

### Results

The search strategy identified 1,178 potentially eligible studies. Of these, 123 were retrieved in full text. We identified nine trials involving 1,117 participants suitable for inclusion. All nine trials were published in English. Only 4 of these trials had pain data in a form that could be extracted and combined in a meta-analysis, and this was only possible after obtaining further data from the authors of the studies. All of these trials examined a heat wrap as the main intervention. One trial had pain data that could be extracted; however, it was absolute pain data as compared with change in pain data used in the other heat wrap trials. The remaining four trials did not present data in a form that could be extracted for meta-analysis. Despite attempts to con-
Table 2. Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants and settings</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Authors’ Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landen et al. (1967)</td>
<td>143 participants with mix of acute and chronic LBP; gender and age, not described; 117 participants completed follow-up; definite diagnosis of disc herniation excluded; setting: U.S. Army General Hospital, Germany</td>
<td>1. Hot packs: twice daily for 20 min, across lumbosacral area (n = 58) 2. Ice massage: twice daily with cubes of ice across lumbosacral area until numb, usually 16–12 min (n = 58) Conterventions: all participants also performed flexion exercises</td>
<td>1. Pain: participant reported change in symptoms: minimal, moderate, or marked increase or decrease in pain, or no change 2. Length of hospitalization 3. Muscular spasm: not described how measured Timing of outcome measures: time of discharge</td>
<td>Ice massage and hot packs seem equally effective in the symptomatic relief of low back pain</td>
</tr>
<tr>
<td>Mayer et al. (2005)</td>
<td>100 participants (29 male, 71 female) with acute (&gt;2 days, &lt;3 mo) nonspecific LBP without radiation below the knee and normal neurologic examination, no comorbidities; duration of pain not reported; mean age, 31.2 yr; setting: outpatient medical facilities in California</td>
<td>1. Heat wrap alone (ThermaCare Heat Wrap; Procter and Gamble, Cincinnati, OH), applied to lumbar area, 40 C for 8 hr per day for 5 consecutive days (n = 25) 2. McKenzie exercise alone (n = 25) 3. Heat wrap plus McKenzie exercise (n = 24) 4. Educational booklet. Participants were advised to closely follow the recommendations, except that they were asked to refrain from performing specific exercises for the low back, using heat or cold modalities, and receiving spinal manipulation (n = 26) Conterventions not allowed, except for medication as required</td>
<td>1. Functional improvement: MTAP 2. Disability: Roland Morris 3. Pain relief: 6-point verbal rating scale Timing of outcome measures: 2 days, 4 days and 7 days after randomization</td>
<td>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</td>
</tr>
<tr>
<td>Melzack et al. (1980)</td>
<td>44 participants (23 male, 21 female) with chronic LBP, unresponsive to conventional care; mean duration of pain 7.4 yr; age, 18–73 yr Majority of participants had undergone previous surgery Exclusion criteria: severe emotional problems as determined by Minnesota Multiphasic Personality Inventory; setting: Pain centre, Canada</td>
<td>1. Ice massage: ice cube gently massaged on skin for a max 7 min at 3 sites (midline low back, lateral malleolus, and popliteal space) with 3 min between applications, total treatment time of 30 min; ice massage was administered by a “technician” 2. TES: 2 treatments of TES at the same 3 sites and time interval for 30 min; interventions were administered on 2 occasions at 1- to 2-wk intervals Treatment for each group was reversed after the initial 2 treatment sessions with a further 2 treatments of the alternate intervention Conterventions not reported</td>
<td>1. Pain: McGill pain questionnaire; measured immediately after treatment sessions 2. Preferred treatment Timing of outcome measures: pain measured before and after each treatment session, then 1–12 mo after completing treatment</td>
<td>Ice massage is an effective therapeutic tool and is more effective than TES for some patients</td>
</tr>
<tr>
<td>Nadler et al. (2002)</td>
<td>371 participants (155 male, 216 female) with acute (&lt;3 mo) nonspecific LBP without radiation below the knee and normal neurologic examination, no comorbidities; duration of pain not reported; mean age, 36.0 yr; setting: clinical research sites</td>
<td>1. Heat wrap (ThermaCare Heat Wrap; Procter and Gamble, Cincinnati, OH) for approximately 8 hr per day (n = 113) 2. Oral ibuprofen: 2 tablets 3 times daily for a total dose of 1,200 mg, plus oral placebo 1 time daily (n = 106) 3. Oral acetaminophen: 2 tablets 4 times daily for a total of 4,000-mg dose (n = 113) 4. Oral placebo: 2 tablets 4 times daily (n = 20) 5. Unheated back wrap: (n = 19) Conterventions not reported</td>
<td>1. Pain: 6-point verbal scale of pain relief 2. Muscle stiffness: 101-point scale 3. Disability: Roland-Morris (0–24 scale) 4. Lateral trunk flexibility 5. Adverse effects Timing of outcome measures: pain relief and disability measured daily for 4 days post-randomization</td>
<td>Continuous low-level topical heat wrap therapy is superior to both acetaminophen and ibuprofen</td>
</tr>
<tr>
<td>Nadler et al. (2003)</td>
<td>219 participants (100 male, 119 female) with acute (&lt;3 mo) nonspecific LBP without radiation below the knee and normal neurologic examination, no comorbidities; duration of pain not reported; mean age, 36.1 yr; setting: clinical research sites</td>
<td>1. Heat wrap (ThermaCare Heat Wrap; Procter and Gamble, Cincinnati, OH) for 3 consecutive days, approximately 8 hr per day (n = 95) 2. Oral placebo: 2 tablets, 3 times daily, spaced 8 hr apart (n = 98) 3. Oral ibuprofen: 200 mg, 2 tablets, 3 times daily, spaced 8 hr apart (n = 12) 4. Unheated wrap: (n = 16) Conterventions not allowed</td>
<td>1. Pain: 6-point verbal scale of pain relief 2. Muscle stiffness: 101-point scale 3. Disability: Roland-Morris (0–24) 4. Lateral trunk flexibility 5. Skin quality: 4-point scale Timing of outcome measures: pain relief and disability measured daily for 4 days post-randomization</td>
<td>Continuous low-level heat wrap therapy was shown to provide significant therapeutic benefits in patients with acute nonspecific LBP No serious or significant adverse effects were observed during the use of the heat wrap</td>
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(Continued)
Table 2. (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants and settings</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Authors’ Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nadler et al(^{29}) (2003)</td>
<td>76 participants (27 male, 49 female) with acute (&lt;3 mo) nonspecific LBP without radiation below the knee and normal neurologic examination, no comorbidities; duration of pain not reported; mean age, 41.4 yr; setting: clinical research sites</td>
<td>1. Heat wrap (ThermaCare Heat Wrap; Procter and Gamble, Cincinnati, OH) worn during sleep for approximately 8 hr each night for 3 consecutive nights (n = 33)</td>
<td>1. Pain relief: 6-point verbal rating scale</td>
<td>Continuous low-level heat wrap therapy was shown to provide effective daytime pain relief after overnight use in subjects with acute nonspecific LBP</td>
</tr>
<tr>
<td>Nuhr et al(^{27}) (2004)</td>
<td>90 participants (57 male, 33 female) with first episode acute (&lt;6 hr) LBP without radiation below the knee and normal neurologic examination, no comorbidities; mean age, 36.9 yr (±8.2 yr); setting: emergency site in Austria</td>
<td>1. Resistive heating of 42 C via a carbon-fiber electric heating blanket (ThermaMed GmbH, Bad Oeynhausen, Germany) covered by a single woolen blanket; the active heating component covered an area of 148 × 40 cm; mean duration of treatment, 24.8 ± 9.1 min (n = 47)</td>
<td>1. Pain: 100 point VAS</td>
<td>The heat wrap showed a good safety profile when worn during sleep</td>
</tr>
<tr>
<td>Roberts et al(^{30}) (1992)</td>
<td>36 participants (17 male, 19 female), with chronic low back pain; mean duration of pain, 4.6 yr; age, 24–72 yr (mean, 40.4 yr); all participants had failed to respond to traditional medical management; setting: Pain centre, United States</td>
<td>1. Hot pack (160 F) with 6–8 layers of towels for 20 min</td>
<td>1. Pain: VAS (0–20) immediately after and 1 hr after intervention</td>
<td>Local active warming is an easy and effective way to learn emergency care treatment for acute low back pain that could be used by emergency physicians as well as by paramedical personnel</td>
</tr>
<tr>
<td>St. John Dixon et al(^{31}) (1972)</td>
<td>38 participants (12 male, 24 female) with chronic nonspecific low back pain; mean duration of pain, 17 yr (range, 0.5–46 yr); age, 30–80 yr (mean, 61 yr) setting: orthopaedic outpatient department in United Kingdom</td>
<td>1. Medima angora wool body belt (“giving insulation and warmth without support”)</td>
<td>1. Preference for type of support</td>
<td>Ice massage was found to be significantly more effective than either hot packs or cold packs for relief of chronic low back pain</td>
</tr>
</tbody>
</table>

The nature of the interventions differed between the trials. Two trials compared hot packs to ice massage,\(^{28,30}\) one trial compared ice massage to transcutaneous electrical stimulation,\(^{29}\) one trial compared a full body active warming electric blanket to passive warming by way of a wool

\(^{RCT}\) = randomized controlled trial; \(^{CCT}\) = controlled clinical trial; \(^{LBP}\) = low back pain; \(^{NSAIDs}\) = nonsteroidal anti-inflammatory drugs; \(^{VAS}\) = visual analogue scale; \(^{MTAP}\) = Multidimensional Task Ability Profile; \(^{TES}\) = transcutaneous electrical stimulation.

The findings of this study call into question the common practice of prescribing a lumbar sacral support for chronic, nonspecific, low back pain; many patients fare equally well with a simple warm body belt.
important prognostic indicators? D

A

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different participants.

completely separate studies with each of them including

from the authors indicated that these three trials are

manufactures the heat wrap device. Correspondence

either employees or paid consultants of the company that

heat wrap device. The authors of each of these trials were

search team and were funded by the manufacturer of the

three Nadler trials were all conducted by the same re-

faction.

trials assessed overall improvement or participant satis-

ity measure was used in four trials. 23–26 None of the

criteria, 28,29 and two trials did not state exclusion crite-

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ria. 30,31 Allocation concealment was adequate in only one of the trials, 27 and in the remaining trials was either not reported or was inadequate. Blinded outcome assessment was carried out in four trials 23–25,27 and was either not done or was unclear in the remaining five trials. Blinding of participants to the interventions of heat or cold was not possible in most cases. Most trials had an acceptable loss to follow-up; however, only three of the trials reported an intention-to-treat analysis was undertaken. 23–25

Methodologic Quality of Included Studies

The included trials were of varying methodologic quality (Table 3). Applying the criteria of six or more equalling a high-quality study, five of the trials were of high quality (range, 6–8) and four low quality (range, 1–5). Five of the trials were reported as randomized. 23–27 In the Nadler series of trials, the method of randomization was not described. One trial was a nonrandomized CCT 28 and three were nonrandomized crossover trials. 29–31 Wash-out of the interventions was not considered in any of the crossover trials. Trial population sizes were generally small (median sample size, 90; range, 36–371). Five of the trials reported clear inclusion and exclusion criteria, 23–27 two trials reported brief inclusion and exclusion criteria, 28,29 and two trials did not state exclusion criteria. 30,31 Allocation concealment was adequate in only one of the trials, 27 and in the remaining trials was either not reported or was inadequate. Blinded outcome assessment was carried out in four trials 23–25,27 and was either not done or was unclear in the remaining five trials. Blinding of participants to the interventions of heat or cold was not possible in most cases. Most trials had an acceptable loss to follow-up; however, only three of the trials reported an intention-to-treat analysis was undertaken. 23–25

Comparison 1: Heated Wrap Versus Oral Placebo or Nonheated Wrap

Four higher-quality trials assessed a heated wrap or heated blanket versus either an oral placebo tablet, or a nonheated wrap 23–25,27 in participants with a mix of acute and subacute (<3 months) low back pain. It was only possible to combine the data from a maximum of two trials.

Pain relief data were extracted from two of the trials with 258 participants that compared a heated wrap to oral placebo. 24,25 The short-term pain relief was significantly greater for the heated back wrap than for the oral placebo (weighted mean difference [WMD], 1.06; 95% confidence interval [CI], 0.68 to 1.45 scale; range, 0–5). Pain relief was only measured for up to 5 days after

Table 3. Methodologic Quality Assessment of Included Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
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<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>Summary Scores and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landen 20 (1967)</td>
<td>N</td>
<td>N</td>
<td>DK</td>
<td>N</td>
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<td>N</td>
<td>DK</td>
<td>Y</td>
<td>Y</td>
<td>DK</td>
<td>N</td>
<td>Score = 2 (low)</td>
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<tr>
<td>Mayer et al 20 (2005)</td>
<td>Y</td>
<td>DK</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>DK</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Score = 6 (high)</td>
</tr>
<tr>
<td>Melzack et al 20 (1990)</td>
<td>N</td>
<td>N</td>
<td>DK</td>
<td>N</td>
<td>N</td>
<td>DK</td>
<td>Y</td>
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<td>DK</td>
<td>Y</td>
<td>N</td>
<td>Score = 2 (low)</td>
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<tr>
<td>Nadler et al 20 (2002)</td>
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<td>DK</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
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<td>Nadler et al 20 (2003)</td>
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<td>Y</td>
<td>Y</td>
<td>Score = 6 (high)</td>
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<td>Nuhr et al 20 (2004)</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
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<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Score = 8 (high)</td>
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<tr>
<td>Roberts et al 20 (1992)</td>
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<td>DK</td>
<td>Y</td>
<td>N</td>
<td>Score = 1 (low)</td>
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<tr>
<td>St. John Dixon et al 20 (1972)</td>
<td>DK</td>
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<td>N</td>
<td>DK</td>
<td>DK</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Score = 2 (low)</td>
</tr>
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</table>

Y = yes; N = no; DK = don’t know.

A = Was the method of randomization adequate? B = Was the treatment allocation concealed? C = Were the groups similar at baseline regarding the most important prognostic indicators? D = Was the patient blinded to the intervention? E = Was the provider blinded to the intervention? F = Was the outcome assessor blinded to the intervention? G = Were co-interventions avoided or similar? H = Was the compliance acceptable in all groups? I = Was the dropout rate described and acceptable? J = Was the timing of the outcome assessment in all groups similar? K = Did the analysis include an intention-to-treat analysis?

blanket, 27 and one trial compared a wool body belt that provided warmth to a lumbar corset. 31

Four trials assessed the effect of a disposable heated lumbar wrap (ThermaCare Heat Wrap; Procter and Gamble, Cincinnati, OH) compared with various interventions. Three of these trials compared the heated wrap with pain relief medication and with a nonheated wrap, 23–25 and one trial compared the heated wrap alone with exercise alone, with heat plus exercise, and with an educational booklet. 26 The heat wrap is a disposable product made of layers of cloth-like material that contain heat-generating ingredients (iron, charcoal, table salt, and water). These ingredients heat up when exposed to oxygen and provide heat (40°C) for at least 8 hours. The heat wrap is applied to the lumbar region of the torso and is secured with a Velcro-like closure, thus allowing it to be worn while remaining mobile. It can be worn during the day or night. The single use heat wrap costs approximately U.S. $6.00 to $8.00 for a packet of two.

The outcomes assessed and the timing of outcomes varied. Pain was assessed in all trials, however, for only five trials were pain data available for meta-analysis. Three trials only measured pain immediately after the treatment, 27,29,30 four trials measured pain over 4 to 7 days, 23–26 one trial measured pain at the time of hospital discharge, 28 and one after 2 weeks. 31 A validated disability measure was used in four trials. 23–26 None of the trials assessed overall improvement or participant satisfaction.

Four of the trials declared industry funding. 23–26 The three Nadler trials were all conducted by the same research team and were funded by the manufacturer of the heat wrap device. The authors of each of these trials were either employees or paid consultants of the company that manufactures the heat wrap device. Correspondence from the authors indicated that these three trials are completely separate studies with each of them including different participants.

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randomization. This result indicates an approximate 17% reduction in pain after 5 days with a heated back wrap compared with oral placebo. Pain data measuring the degree of “unpleasantness” were only available for one trial23 and indicated a significant decrease in the short-term (WMD, −13.50; 95% CI, −21.27 to −5.73; scale range, 0–100).

Absolute pain data were only available in one trial of 90 participants.27 This trial demonstrated a statistically significant benefit of a heated blanket compared with a nonheated blanket immediately after treatment in acute (<6 hours) low back pain (WMD, −32.20; 95% CI, −38.69 to −25.71; scale range, 0–100). Pain was only measured immediately after the heat was applied for approximately 25 minutes, and no further follow-up occurred.

Only two trials provided data on disability,24,25 measured with the Roland-Morris Disability Questionnaire. The short-term (4 days) reduction in disability was significantly greater for the heated back wrap than for oral placebo (WMD, −2.10; 95% CI, −3.19 to −1.01; scale range, 0–24).

Adverse effects were minor for the heated back wrap. Two trials provided data on the adverse effect of “skin pinkness” after use of the heated wrap.24,25 A total of 6 of 128 participants experienced this outcome in the heated back wrap group, compared with 1 participant out of 130 in the placebo group.

No trials were located that examined this comparison for chronic low back pain or for the medium- or long-term effects of this intervention.

**Comparison 2: Cold Versus Placebo or No Cold**

No studies were located that examined this comparison.

**Comparison 3: Heat Versus Cold**

Two lower-quality trials evaluated heat versus cold in the form of hot packs versus ice massage.28,30 Unfortunately, there were very little data available in either of these trials to extract. Both of these trials were nonrandomized: one a controlled trial28 and the other a crossover trial.30 One trial concluded that hot packs and ice massage were not significantly different for participants with a mix of acute, subacute, and chronic low back pain. The other concluded that ice massage was superior to hot packs in participants with chronic low back pain.

**Comparison 4: Heat Versus Other Interventions**

Three higher-quality trials compared a heated back wrap with oral ibuprofen,23–25 and one of these trials also included a comparison group that took oral acetaminophen.23 Unfortunately, none of these trials presented data in a way that could be combined in a meta-analysis. One trial23 found that a heated back wrap provided significantly greater pain relief and improved function than oral ibuprofen and oral acetaminophen after both 1 day and 4 days of treatment. The other two Nadler trials did not provide results for this comparison.

One high-quality trial of 100 participants compared a heated back wrap alone with exercise alone and with an education booklet.26 Measured at 1 and 4 days after randomization, the heat wrap provided significantly more pain relief than an educational booklet (day 2: WMD, 0.60; 95% CI, 0.05 to 1.15; scale range, 0–5; day 4: WMD, 1.10; 95% CI, 0.55 to 1.65) but not more than McKenzie exercise (day 2: WMD, 0.40; 95% CI, −1.15 to 0.95; day 4: WMD, 0.30; 95% CI, −0.41 to 1.01). At 7 days after randomization, there were no significant differences in pain relief between the groups. The heat wrap provided significantly improved function compared with an educational booklet at day 2 (WMD, −1.40; 95% CI, −2.79 to −0.01; scale range, 0–24) and day 4 (WMD, −2.30; 95% CI, −4.24 to −0.36) but not at day 7 (WMD, −1.70; 95% CI, −3.92 to 0.52). There was no significant difference in function between heat wrap and McKenzie exercise at day 2, day 4, or day 7.

One lower-quality nonrandomized crossover trial compared a wool body belt providing warmth to a lumbar corset in chronic low back pain participants.31 No pain results were provided.

**Comparison 5: Cold Versus Other Interventions**

Only one low-quality nonrandomized crossover trial examined this comparison.29 This trial compared ice massage with transcutaneous electrical stimulation (TES) in chronic low back pain participants. The trial concluded that ice massage and TES were equally effective in reducing pain.

**Comparison 6: Heat Plus Exercise Versus Other Interventions**

One higher-quality trial of 100 participants combined a heated back wrap with exercise and compared this to heat alone, exercise alone, and to an educational booklet, in participants with a mix of subacute and acute low back pain.26 Heat wrap plus exercise provided significantly more pain relief than an educational booklet at day 4 (WMD, 1.60; 95% CI, 0.89 to 2.31; scale range, 0–5) and day 7 (WMD, 2.00; 95% CI, 1.29 to 2.71), and also for function (Roland Morris) (day 4: WMD, −2.60; 95% CI, −4.54 to −0.66; day 7: WMD, −4.40; 95% CI, −6.62 to −2.18). Heat wrap plus exercise also provided significantly more pain relief and improvement in function than either heat or exercise alone at day 7. This improvement in pain and function was not evident at the earlier time periods measured (day 2 or day 4).

**Clinical Relevance**

The median score for the trials was 3 of 5. The higher-quality trials generally had a higher clinical relevance score.

**Discussion**

Only a few studies have been published evaluating the effects of superficial heat or cold for low back pain. We found nine trials involving 1,117 participants that were suitable for inclusion in this review. Of these, six trials
examined heat compared with no heat or other interventions, one compared cold to another intervention, and two trials compared heat to cold. The included trials were very heterogeneous in terms of interventions used, control treatments, outcome measures, timing of follow-up, and presentation of data. Therefore, it was not possible to perform any meaningful meta-analyses, and it was difficult to reach firm conclusions for most types of treatments.

According to the qualitative criteria for levels of evidence, for a mixed population with acute and subacute low back pain, there is moderate evidence that a heated wrap applied for 8 hours, or an electric blanket applied for 25 minutes, are both better than no heat for pain in the short-term (4 days). There is moderate evidence (one small high-quality RCT) that heat wrap is better for pain and function than an educational booklet during the early stages of treatment (days 2–4), but not after 7 days. There is moderate evidence that combining heat wrap with McKenzie exercises is better for pain relief and function after 7 days than an educational booklet and either heat wrap or exercise alone. The effect of these treatments was small. If the short-term beneficial effects of this therapy can be verified in further high-quality trials, then its use would be valuable.

There is empirical data that indicate that industry-funded studies are more likely to be positive than non-funded studies.32–34 The results of the Nadler series of studies and the Mayer study of heat wrap therapy should be considered with this in mind, and independent studies would be useful to verify their results. Also, considering the cost of the disposable heat wraps, it would be useful to include a cost-effectiveness analysis in future trials.

No RCTs were located that examined the effects of cold for low back pain. Given that it is a commonly held belief that cold is beneficial for recent onset musculoskeletal injuries,35 it was surprising that no studies were located that applied cold treatment to acute low back pain. Indeed, in the trials conducted with participants with acute and subacute low back pain, heat was applied. The trials that were located for cold treatment used cold for chronic low back pain and were of poor methodologic quality. No conclusions can be drawn for the use of cold treatment in low back pain.

There is conflicting evidence when comparing heat treatment to cold treatment. Two low-quality nonrandomized trials of chronic low back pain participants were located. One concluded that hot packs and cold packs were equally effective, and the other concluded that ice massage was better than either hot packs or cold packs.

There were no major adverse events reported in any of the trials. Some minor events were reported with the heat wrap therapy, in the form of “skin pinkness” that resolved quickly.

There are methodologic challenges when conducting high-quality trials into these therapies. For example, it is questionable whether or not participants can be blinded to these interventions. The Nadler series of studies23–25 and the Nuhr study27 attempted to blind participants by including a nonheated wrap or blanket and an oral placebo group; however, the investigators did not measure whether participants could determine if they were receiving an active therapy or not. Also, outcome assessors should be blinded to the allocation of the participants to at least improve the quality of this aspect of the trials. It is recommended that these methodologic issues are considered in future trials.

Heat and cold are methods that are commonly used in practice in conjunction with other interventions, especially in the physical therapy professions. We only found one small study that evaluated the use of heat combined with exercise, and we found no study that examined cold in this context. Thus, no conclusions can be drawn regarding the use of heat or cold in combination with other therapies, other than in combination with exercise.

Conclusion

Implications for Practice

Heat and cold are commonly recommended by clinicians for low back pain. The evidence base to support this common practice is not strong. There is moderate evidence that continuous heat wrap therapy reduces pain and disability in the short-term, in a mixed population with acute and subacute low back pain (up to 3 months) and that the addition of exercise to heat wrap therapy further reduces pain and improves function. This evidence is limited to a small number of trials using a relatively small number of participants, and the size of the effect is small. The application of cold treatment to low back pain is even more limited, with only three poor-quality studies located. No conclusions can be drawn about the use of cold for low back pain. There is conflicting evidence to determine the differences between heat and cold for low back pain.

Implications for Research

Many of the studies were of poor methodologic quality, and there certainly is a need for future higher-quality RCTs. Also, many trials were poorly reported, and we recommend that authors use the CONSORT statement as a model for reporting RCTs (www.consort-statement.org). The results of the majority of the studies could not be pooled with other studies because of the way the authors reported the results. Therefore, we suggest that the publications of future trials report, for continuous measures, means with standard deviations or means with standard error of means, and for dichotomous measures, number of events and total participants analyzed.

Future research should focus on areas where there are few or no trials, for example, simple heat applications like hot water bottles, ice massage versus no cold and heat versus cold treatment, and trials in chronic low back pain participants. The classification of duration of low
back pain was not consistent in the different studies, and in the future, authors should be clear on the definition of acute, subacute, and chronic low back pain and report the duration of pain in their results. Future studies should be adequately powered and have both a short-term follow-up (for acute pain) and a long-term follow-up (for chronic pain).

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References
3. Carey TS, Evans A, Hadler N, et al. Care-seeking among individuals with low back pain that lasts for less than 3 months. The relief has only been shown to occur for a short time and the effect is relatively small. The addition of exercise to heat wrap therapy appears to provide additional benefit.
4. There is insufficient evidence about the effect of heat for back pain that lasts longer than 3 months.
5. There is insufficient evidence about the effect of the application of cold for low back pain of any duration.

Key Points
- Nine trials involving 1,117 participants were included in this systematic review.
- There is moderate evidence that heat wrap therapy reduces pain and disability for patients with back pain that lasts for less than 3 months. The relief has only been shown to occur for a short time and the effect is relatively small. The addition of exercise to heat wrap therapy appears to provide additional benefit.
- There is insufficient evidence about the effect of heat for back pain that lasts longer than 3 months.
- There is insufficient evidence about the effect of the application of cold for low back pain of any duration.