

Review Article

The Efficacy of Cryotherapy for Improving Functional Outcomes Following Lateral Ankle Sprains

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OPEN ACCESS**Keywords**

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- Athletic training
- Sports injury
- Cold therapy
- Recovery

Abstract

Cryotherapy is frequently used to treat acute injuries despite minimal outcomes-based evidence supporting this practice. A thorough review of the literature was conducted to ascertain the efficacy of cryotherapy for improving function after acute lateral ankle sprain (ALAS). Three studies met the inclusion criteria and were selected for review. None of the reviewed studies demonstrated that cryotherapy is more efficacious than control interventions for improving function after ALAS, although their poor methodology, impractical cryotherapy application parameters, and incomplete statistical reporting make it challenging to draw conclusions with any degree of confidence. Despite these methodological shortcomings, the reviewed studies are frequently cited to support the use of cryotherapy as a treatment agent for ALAS. Since the use of cryotherapy is ubiquitous, and a therapeutic “gold standard” against which other interventions are sometimes compared, there is a need to scrutinize its efficacy with high quality outcomes-based research instead of relying on historical convention or anecdotal reports.

ABBREVIATIONS

ALAS: Acute Lateral Ankle Sprain; RCT: Randomized Control Trial; ROM: Range of Motion

INTRODUCTION

Cryotherapy has long been an accepted mainstay in the treatment of acute soft-tissue injuries to help reduce pain and edema. While the immediate physiologic effects of cryotherapy (e.g. vasoconstriction) [1] have been clearly elucidated, the impact of cryotherapy on injury recovery is less certain. Despite cryotherapy’s widespread use, some have questioned its efficacy and proposed that it may actually delay recovery from certain conditions [2]. Given this, a critical appraisal of research-based evidence regarding the efficacy of cryotherapy as a therapeutic agent was performed. The scope of this review was limited to acute lateral ankle sprains (ALAS) as these are so commonplace. Functional outcomes (as opposed to simply pain, swelling, etc.) were selected as indicators of treatment efficacy.

FOCUSED CLINICAL QUESTION

Does cryotherapy improve functional outcomes after ALAS?

Summary of Search, “Best Evidence” appraised, and Key Findings

- The literature was searched for studies on the impact of

cryotherapy on functional outcomes following ALAS.

- Two low-quality randomized control trials (RCTs) and one low-quality quasi-experimental design study were retrieved.
- Two studies reported no difference in functional outcomes with cryotherapy compared to control interventions. The third study reported a trend favoring cryotherapy, although inexplicably no statistical analysis was reported.

Clinical Bottom Line

None of the reviewed studies demonstrated that cryotherapy is more efficacious than control interventions for improving function following ALAS.

Strength of Recommendation. Level 3 and 4 evidence suggests that cryotherapy is no more effective than control interventions for improving function after ALAS.

Search Strategy**Terms Used to Guide Search Strategy:**

- Patient/Client Group: *acute lateral ankle sprains*
- Intervention (or Assessment): *cryotherapy or ice or icing or cold treatment or cooling*

- Comparison: *no cryotherapy* or *no intervention* or *control*
- Outcome: *function* and *pain* or *edema* or *range of motion*

Sources of Evidence Searched:

- PubMed
- The Cochrane Library
- CINAHL Plus
- Medline
- Additional resources obtained via manual search of reference lists.

Inclusion and Exclusion Criteria

Inclusion:

- Acute lateral ankle sprains in humans
- Cryotherapy (ice pack, ice bath, ice cup, cooling anklet, frozen gel pack) initiated within 72 hours of injury
- Control group that did not receive cryotherapy
- Functional outcome measure(s)

Exclusion:

- Non-English language studies
- Animal studies
- Ankle fractures
- Topical cooling agents/gels or vapocoolant sprays

RESULTS OF SEARCH

Three studies were identified that satisfied the search criteria. These studies are categorized in (Table 1) (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011).

SUMMARY OF BEST EVIDENCE

Two RCTs [2,3] and one quasi-experimental design [4] were identified as the 'best' evidence and selected for inclusion in this review. These studies are summarized in (Table 2). In accordance with Centre for Evidence Based Medicine recommendations all three studies were downgraded due to poor quality.

IMPLICATIONS FOR PRACTICE, EDUCATION AND FUTURE RESEARCH

Despite an exhaustive search effort, only three studies were identified that addressed the clinical question. Data from these studies suggest that cryotherapy is no more effective than control interventions for improving function after ALAS. The studies were of relatively low-quality and their inherent shortcomings make it difficult to draw firm conclusions with confidence.

Laba et al. [4] and Basur et al. [5] neglected to report any statistical analysis of their data, and the data that was reported were substantially limited. Despite this, Basur et al. [5] concluded that cryotherapy was an effective intervention for their subjects. In separate RCTs, Sloan et al. [3] and Laba and colleagues [4] studied the effects of a single ice application on various outcome measures, though in clinical settings patients are commonly

Table 1: Summary of Study Designs of Articles Retrieved.

Level of Evidence	Study Design/ Methodology	Number Located	Author (Year)
3	Randomized-controlled trial	2	Sloan et al. (1989) [3] Laba et al. (1989) [4]
4	Quasi-experimental design	1	Basur et al. (1976) [5]

advised to use ice frequently for several days following acute injury. Laba et al. [4] reported that changes in pain, swelling, and recovery rate were no different between subjects who received a single, 20-minute ice-pack application and those that did not. However, both groups also received a pulsed ultrasound treatment and were furthermore asked to perform daily ROM and strengthening exercises. Roughly half of the participants in the Laba et al. [4] study had already received cryotherapy prior to entering the study, introducing another confounding variable.

Similar to Laba et al. [4], Sloan and colleagues [3] did not control for the confounding influence of co-interventions between groups—in this case pneumatic compression, elevation, and medication—and delayed follow-up for one week after the single cryotherapy or control treatment. Also of note, both groups received doses of ibuprofen and were advised to utilize paracetamol (acetaminophen) as needed for additional analgesia. Due to these variables it is difficult to estimate treatment causality.

The quasi-experimental study by Basur et al. [5] also had several limitations. For one, it is not clear from the study methodology if subjects received cryotherapy every four hours (as interpreted by Collins [6]), or if subjects received cryotherapy continuously for 48 hours with ice packs replaced every fourth hour, as interpreted from the original text. The feasibility of the latter scenario is difficult to conceive clinically and likely to result in poor adherence. Beyond this, such methodological ambiguity precludes study replication.

Given the poor methodology of the available studies, it is difficult to draw firm conclusions regarding the use of cryotherapy for acute ankle sprain. The utilization of co-interventions, unconventional single ice pack applications, ambiguous methodologies, and lack of statistical analyses introduce uncertainty regarding treatment efficacy. There is a need for well-designed prospective studies that allow for more clinically applicable intervention periods with longer follow-up.

The impetus for this review was a recent study by Tseng and colleagues [2] regarding the effects of cryotherapy on exercise-induced muscle damage. The authors reported that topical icing did not enhance, and moreover seemed to delay, the return to normal of muscle damage markers after eccentric exercise. Though Tseng et al. [2] examined a different locale and catalyst for injury, their work raises important questions about the efficacy of cryotherapy for the treatment of acute soft tissue injuries in general.

In the initial phase of this review, an attempt was made to retrieve articles comparing cryotherapy to no treatment at all. Despite a multi-person, multi-database search and manual searching of reference lists no suitable studies were found.

Table 2: Characteristics of included studies.

Study Design	Sloan et al. (1989) [3] RCT	Laba et al. (1989) [4] RCT	Basur et al. (1976) [5] Quasi-experimental design
Participants	<p>143 male (79%) and female subjects (age 16-50 years old; median 24 years old). Presented to emergency care with acute ankle sprain within 24 hours of injury (median 17.5 hours), 53% were sport related injuries and 50% were unable to bear weight.</p> <p>116 patients completed study. Subjects were excluded if they had a history of asthma, gastrointestinal disturbance, ankle fractures, and/or chronic ankle instability. Randomly assigned to groups by a predetermined sequence.</p> <p>Authors did not provide information on the 27 dropouts.</p>	<p>30 male and female subjects (age 13-56 years old).</p> <p>Referred from emergency department with diagnosis of an inversion ankle sprain within the previous 48 hours. All subjects had functional grades 3 or 4 ankle sprains (Grade 3 = subject able to stand without pain but ascending 4 stairs or taking 10 steps is greatly limited by pain; Grade 4 = unable to stand or weight bear due to pain).</p> <p>Patients were randomly assigned (coin toss) to one of two groups; crushed ice (n=14) or no ice (n=16).</p> <p>Authors did not report dropouts. 43.3% of subjects received ice treatment prior to enrolling in study.</p>	<p>60 subjects ("more than half the patients in the present series were between 10 and 30 years old") who sustained an ankle sprain (injury severity not reported).</p> <p>Subjects were excluded if injury to cartilage was apparent from radiographs.</p> <p>Patients were non-randomly assigned into two groups; cold pack (n=30) and control (n=30).</p> <p>Authors did not report dropouts.</p>
Intervention Investigated	<p>Treatment group: One session of cryotherapy using a pneumatic 15-20°C freon-cooled ankle inflated to 30 mmHg.) for 30 minutes. Ankle was elevated 45° during cryotherapy treatment.</p> <p>Control group: One session using a non-inflated room temperature cooling ankle for 30 minutes with the ankle not elevated (i.e. heart level). Both groups received an immediate dose of 1200 mg ibuprofen and 2400 mg dosage of ibuprofen on subsequent days. 500 mg paracetamol tablets were provided as needed for additional analgesia. All subjects received the same written instructions regarding compression and elevation and were provided elastic support to be worn at home. Subjects were blinded to treatment options. Single assessor was blinded.</p>	<p>Treatment group: One 20 minute session of ice-pack application (2 liters of finely crushed ice spread over a 30 cm by 15 cm area, wrapped in a single layer of damp towel, and secured by a crepe bandage).</p> <p>Control group: No ice-pack application.</p> <p>Both groups received pulsed ultrasound (1.5 W/cm², 5 min/session), as well as ROM and strengthening exercises based on grade of sprain.</p> <p>Neither subjects nor assessors were blinded to treatments.</p>	<p>Treatment group: Application of cold pack (10-30°C) filled with non-solidifying crystallizing cooling gel continuously for the first 48 hours followed by compression with crepe bandaging. Tubigrip® was applied under cold pack to avoid direct skin contact.</p> <p>Control group: Compression with crepe bandaging.</p> <p>Neither subjects nor assessors were blinded to treatments.</p>
Outcome Measure(s)	<p>Daily journal entries regarding their pain, reaction to treatment, and readiness to weight bear were kept by each subject. Seven days after initial treatment 3 objective outcome measures were taken: severity of sprain (linear analogue scale), ROM, and swelling as measured by a soft tissue swelling index calculated from radiographs. Subjects were either discharged at 7 days, or returned at 14 days for the same objective measurements, not including radiographs.</p>	<p>All outcomes were assessed daily; swelling as measured by displacement volumetry, pain scale (1-5 likert scale), function grading as described above, time (in days) to reach functional level 2 (able to climb 4 stairs, walk 10 steps, and jump 5 times on both feet with only mild to moderate discomfort).</p> <p>Upon reaching functional level 2, subjects were discontinued from study.</p>	<p>Subjects were assigned a score on a 7-point scale (0= no pain or restrictions) based on a combination of ankle circumference, pain, weight bearing status, and walking status. Subjects' scores in each group were summed at beginning of study and after 2, 7, and 14 days. Reduction in score over time was converted to a percentage of recovery.</p> <p>Investigators also tracked number of days before returning to work and number of patients requiring 2-week follow-up.</p>

Main Findings	No between-group differences in swelling at 7-day follow-up (P=0.07; 46% reduction in treatment group vs. 40% in control). No between-group differences in injury severity at 7-day follow-up (P=0.15). No between-group differences in weight bearing tolerance at 7-day follow-up (P=0.64). No between-group differences in ROM measurements at 7-day follow-up (no statistical test results reported). No between-group differences in pain after 1 hour of treatment or at 7-day follow-up (no statistical test provided). No between-group differences in time needed for follow-up (no statistical test provided).	No difference in the rate of recovery, swelling, or level of pain in those treated with ice or without ice (no statistical test provided). Regression analysis was performed with the following 3 factors; number of days between sprain and treatment, history of ankle sprain, and application of ice prior to entering study. These factors did not predict functional outcomes (no statistical test results reported).	Mean period of disability: 9.7 days in the treatment group and 14.8 days in control group. Treatment group demonstrated 42.1% and 84.2% recovery on the 2nd and 7th day, respectively, compared to 29.1% on the 2nd day and 60.6% on the 7th for the compression group (no statistical test results reported).
Level of Evidence	3	3	4
Validity Score	PEDro 3/10 [7]	PEDro 3/10 [7,8]	PEDro 2/10 [8]
Conclusion	After 7 days post intervention and with a background of NSAIDs in each group, cryotherapy with compression and elevation for 30 minutes was no more effective than a 30-minute control treatment for subjects with acute ankle sprains.	The treatment and control groups recovered at a similar rate. No difference was found in swelling or level of pain between those who received cryotherapy and those that did not.	Cryotherapy is beneficial in treating acute ankle sprains, especially when the sprain is incomplete. Cryotherapy reduces edema, pain, disability, and recovery time.

Consequently, the focus of this review was altered. The reviewed studies represent the best-available alternative at this time for comparing cryotherapy to no treatment. Several articles commonly cited to rationalize cryotherapy were analyzed for their potential inclusion in this review. However, the use of additional interventions in these studies impedes assessment of isolated cryotherapy effects. Hocutt et al. [7] compared cryotherapy to thermotherapy, Bleakley et al. [8] compared two different cryotherapy protocols against one another, and Wilkerson et al. [9] administered cryotherapy and other therapeutic modalities to all study participants, thus precluding between-group comparisons of cryotherapy alone. Clearly none of those authors examined cryotherapy effects against a non-treatment control (i.e. the natural healing process). Conceivably a study of this nature has not been conducted because there is currently no effective method for blinding subjects to cold exposure in a laboratory setting. Still, substitute materials can be employed and concealed to mimic the mechanical feel of crushed ice (e.g. dried corn) and applied with a standardized force to control for compressive effects. Since cryotherapy is ubiquitous, and a therapeutic “gold standard” against which other interventions are sometimes compared, there is a need to scrutinize its efficacy with sound research instead of relying on historical convention or anecdotal reports.

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