Preoperative Cryotherapy Use in Anterior Cruciate Ligament Reconstruction

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Abstract

Unrelieved postoperative pain may impair rehabilitation, compromise functional outcomes, and lead to patient dissatisfaction. Preemptive multimodal analgesic techniques may improve outcomes after surgery. We hypothesized that patients using preoperative cryotherapy plus a standardized postoperative treatment plan will have lower pain scores and require less pain medication compared with patients receiving a standardized postoperative treatment plan alone after arthroscopically assisted anterior cruciate ligament reconstruction (ACLR). A total of 53 consecutive patients undergoing arthroscopically assisted ACLR performed by one of seven surgeons were randomly assigned to one of two groups. Group 1 received no preoperative cryotherapy and group 2 received 30 to 90 minutes of preoperative cryotherapy to the operative leg using a commercial noncompressive cryotherapy unit. Visual analog scale pain scores and narcotic use were recorded for the first 4 days postoperatively. Total hours of cold therapy and continuous passive motion (CPM) use and highest degree of flexion achieved were recorded as well. Group 1 consisted of 26 patients (15 allograft Achilles tendon and 11 autograft bone patellar tendon bone [BPTB]), and group 2 consisted of 27 patients (16 allograft Achilles tendon and 11 autograft BPTB). Group 2 patients reported less pain (average 1.3 units, $p < 0.02$) and used less narcotic use (average 1.7 tablets, $p < 0.02$) for the first 36 hours compared with group 1. No statistically significant differences were identified between the two groups with regard to demographics, hours of postoperative cryotherapy, hours of CPM use, or maximum knee flexion achieved. Complications did not occur in either group. This is the first report we are aware of showing the postoperative effects of preoperative cryotherapy. Our results support the safety and efficacy of preoperative cryotherapy in a multimodal pain regimen for patients undergoing ACL reconstruction.

Keywords
- cryotherapy
- multimodal pain management
- ACLR
- cold therapy

The effective use of ice or cryotherapy for postoperative pain control has been well documented.[1] In fact, the benefits of cryotherapy have been shown to extend beyond a simple reduction in pain and include shortened hospital stays, lower prescription medication consumption, diminished swelling and inflammation, reduced postsurgical drainage, increased range of motion, increased compliance with rehabilitation, and improved weight-bearing status.[1–3]

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Preemptive anesthesia is defined as an antinociceptive treatment that prevents the establishment of altered central processing of afferent input, which amplifies postoperative pain.[4] The concept of preemptive analgesia to reduce postoperative pain became popularized after a series of successful animal experiments confirmed central nervous system plasticity and sensitization after nociception.[5,6] By decreasing the altered central sensory processing, preemptive anesthesia is thought to consequently decrease the incidence of hyperalgesia and allodynia after surgery. The emphasis of preemptive anesthesia is on the pathophysiologic phenomenon that it should prevent altered sensory processing.

The objective of cryotherapy is to lower the temperature of the tissue and in turn achieve a therapeutic benefit by suppressing the metabolic changes induced by trauma. When the metabolism of tissues is suppressed by cooling, tissue damage caused by hypoxia is prevented. In addition, vasoconstriction is induced, which reduces bleeding and edema in damaged tissues.[7] Other potential mechanisms by which cryotherapy may elevate the pain threshold include an antinociceptive effect on the so-called gate control system, a decrease in nerve conduction, and a reduction in muscle spasms.[1]

The microscopic iatrogenic effects produced from the trauma of surgery are well documented. Tissue injury produces stress, which leads to the release of chemical mediators from the injury site, the adrenal cortex, and the immune system, all of which, in turn, interact with mediators of pain.[8] Surgical trauma can initiate an entire cascade of inflammatory mediators including hydrogen ions, histamines, purines, leukotrienes, norepinephrine, potassium ions, cytokines, nerve growth factors, bradykinin, prostaglandins, 5-hydroxytryptophan, and neuropeptides. Accordingly, if cryotherapy's beneficial effect in lowering tissue metabolism and suppressing bleeding can be expected after surgical trauma, then it may be possible to show a beneficial clinical effect from the application of cryotherapy before surgery.

Beyond the use of local frost anesthesia preceding injections and minor procedures, we do not know of any studies employing the use of preoperative cryotherapy for the control of postoperative pain. The purpose of this study is to prospectively evaluate preoperative cryotherapy for the control of postoperative pain in patients undergoing arthroscopically assisted anterior cruciate ligament reconstruction (ACLR). We hypothesize that patients using preoperative cryotherapy plus a standardized postoperative treatment plan will have lower pain scores and require less pain medication compared with patients receiving the standardized postoperative treatment alone.

Materials and Methods

Study Design

The study was a prospective, randomized, controlled trial. The study protocols, including methodologies, patient selection criteria, surgical techniques, and postoperative assessments, were approved by an Institutional Review Board before patient enrollment. The trial was conducted at a single orthopedic surgery center and involved a collaboration of seven sports medicine fellowship trained surgeons. Patient enrollment occurred over a 5-month period.

Patient Selection

A prospective series of consecutive patients undergoing primary ACLR were recruited from a preoperative log of patients seeing one of seven sports medicine fellowship trained surgeons within our group. Patients undergoing primary unilateral ACLR, either with bone patellar tendon bone autograft or Achilles tendon allograft, were included in the study. Patients were enrolled regardless of activity level, mechanism of injury, or chronicity of injury. Each patient underwent a general medical clearance before surgery, ensuring that each subject was in good general overall health, with no apparent limiting factors, no appreciable effusion or swelling, and no notable deficits in knee range of motion. Patients were excluded from the study if they (1) were undergoing multiligament or revision reconstructions, (2) were taking any routine preoperative pain medication, (3) had a known intolerance to ice or cryotherapy, (4) had experienced any sensory dysesthesias in the effected extremity, or (5) had a known allergy to any of the medications or anesthetics used in the study.

Study Groups

After consenting to participate, subjects were randomized into one of two groups. A random-number table was used to generate 30 odd (control group) and 30 even (experimental group) numbers. The numbers were assigned by a phone call to a blinded assistant after subjects were consented. Group 1 (control) patients underwent routine arthroscopically assisted ACLR surgery with a standardized postoperative protocol described below. Group 2 (experimental) patients underwent the same procedures with the same postoperative protocols as group 1 patients, with the addition of a preoperative cold therapy session to the operative extremity by way of a commercial cryotherapy unit. There were no placebo treatments offered and the surgeons and operative staff were not blinded to the subject's group or preoperative care, as the operative extremity was often still palpably cool at the start of surgery.

Preoperative Care

Before surgery, all patients were supplied noncompressive cryotherapy units and continuous passive motion (CPM) machines, as well as a training session on the proper use of each device by the appropriate device sales representatives. Patients randomized to group 2 were told to arrive 1.5 hours before their scheduled surgery time (vs. 1 hour early for the control group) to undergo a preoperative cooling session. A single, standardized cooling unit (Don Joy Iceman, Vista, CA) was kept in the preanesthesia waiting area and used for all preoperative group 2 patients. The cooling unit was applied per the manufacture's protocol with the exception of the cooling pad being applied to operative leg over a thin absorbent skin barrier, to avoid any contamination of the pad used between patients. Total cooling time was recorded in the

patient's chart and required to last a minimum of 30 minutes and a maximum of 90 minutes. The cooling unit was kept on the leg until the patient was taken into the operating room. A delay of no more than 20 minutes was allowed from the time the cryotherapy unit was removed to the time of surgery. All patients were given preoperative regional (femoral nerve) blocks by the anesthesia team. A nerve stimulator was used to localize proximity to the femoral nerve, followed by an infusion of 30 mL of 0.5% Marcaine (Hospira, Lake Forest, IL).

Operative Treatments

Intraoperative and postoperative care was standardized between both groups. Anesthesia was provided via laryngeal mask airway. An air tourniquet was applied at the beginning of the procedure (in all but four patients described below) and insufflated to 275 mm/Hg. After routine arthroscopic evaluation, arthroscopic ACLRs were performed using interference screw fixation on both the femur and tibia. Concomitant procedures were performed and recorded. Patients undergoing partial medial and/or lateral meniscectomies, all inside meniscal repairs, and or abrasion chondroplasties were allowed in the study. Patients undergoing multiligament reconstructions, chondral microfracture procedures, inside-out, or outside-in meniscal repair were excluded intraoperatively. At the conclusion of the case, each patient received a dry sterile dressing, followed by a compressive wrap and a hinged knee brace locked in extension. There were no drains, pain pumps, or nerve stimulators (transcutaneous electrical nerve stimulation units) used.

Postoperative Care

All patients were discharged home from the surgery center on the same day (within 2 hours) after the completion of their operative procedure. Regardless of surgical group, patients were allowed to bear weight as tolerated using crutches only as needed. Patients were sent home with a postoperative diary to record pain, Percocet use (Endo Health Solutions, Malvern, PA), cryotherapy and CPM use, and their daily maximum knee flexion. Postoperative pain was recorded using a previously validated[9] standardized visual analog scale (VAS), which included a nonhatched 10 cm line ranging from "no pain at all" to "worst possible pain." Patients were asked to rate their most severe pain each morning and night for 4 consecutive postoperative days (PODs), starting in the postanesthesia recovery room. Postoperative pain medication was standardized to Percocet 7.5/325 mg tablets to be taken 1 to 2 tablets every 4 to 6 hours as needed for pain control. A log of the time and amount of medication taken each day for 4 PODs was kept and recorded by the patients. Each patient was instructed to use their commercial cryotherapy unit postoperatively as their pain required and tolerated, up to 24 hours/day if needed. The cooling pads were placed over the operative dressing but under the operative brace. The CPM machines were also used by each patient starting postoperatively at a comfortable range and increasing the flexion at a rate of 5 degrees/day or as comfort allows achieving maximal flexion. Each day patients recorded the total number of hours of cold therapy use, the total hours of CPM use, and maximum flexion achieved for 5 consecutive PODs. Patients returned for their first postoperative visit between 7 and 10 days after surgery, where their pain/ice diaries were collected and a clinical evaluation was performed and recorded by the operating surgeon.

Statistical Methods

The mean scores and their 95% confidence intervals were determined and compared between the two treatment groups for each corresponding time period. All data were statistically analyzed using Student two-tailed *t*-test for the intragroup (i.e., paired) and intergroup (i.e., unpaired) analysis, with a significance value set at $p < 0.05$.

A pre hoc power analysis was performed with respect to VAS pain. Our hope was to control a significance level (type I error) of 5% ($\alpha = 0.05$). With a power of 80%, a sample size for each group of at least 25 patients was calculated as being appropriate. We set a goal of 30 patients for each group to allow for possible patient exclusion or loss of retention.

Results

Cohort Analysis

A total of 59 patients were screened and consented for the study. Of the 59 patients, 30 patients were randomized to group 1 (the control group) and received standardized care; 29 patients were randomized to group 2 (the experimental group) and received a preoperative cryotherapy session. Six patients were excluded from the study; four from group 1 and two from group 2. In group 1, three patients were excluded for lost or missing forms and one patient was excluded after he underwent a microfracture procedure. One patient from group 2 was excluded because of a lost form and another experimental patient was excluded because of an excessive delay (> 20 minutes) between the preoperative cooling session and the induction of surgery.

In the final pool of 53 patients, there were 30 males and 23 females, with an average age of 29 (range, 14–55) years. Of the 26 group 1 patients, 15 (58%) underwent allograft and 11 (42%) underwent autograft reconstructions. Of the 27 group 2 patients, 16 (59%) underwent allograft and 11 (41%) underwent autograft reconstructions. There were no statistically significant differences between the patient groups for age, gender, height, weight, graft type, number of concomitant procedures, operative times, tourniquet times, hours of postoperative cryotherapy, hours of CPM use, or maximum knee flexion achieved. Four patients (one from group 1, and three from group 2) did not have a tourniquet used during surgery because of either surgeon preference or a patient history of deep vein thrombosis.

Visual Analog Scale Pain Scores and Pain Medication Use

Overall, group 2 (experimental) patients reported less pain (average 1.3 units, $p < 0.02$) and used less narcotics (average 1.7 tablets, $p < 0.02$) for the first 36 hours compared with the control group 1. The average VAS at each data collection interval was plotted over time after surgery (►**Fig. 1**). Group 2 reported average VAS that were 22% ($p = 0.02$), 22%

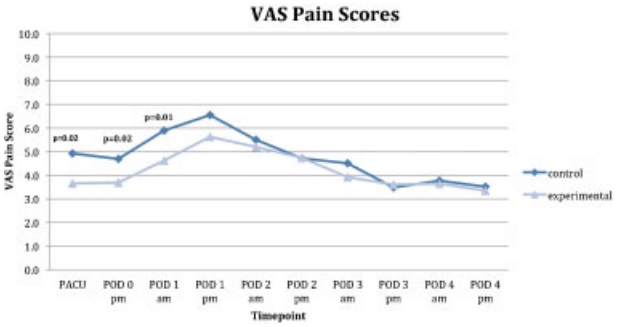

Fig. 1 VAS pain scores depicted over time. At three time points, the experimental group showed a statistically significant decrease in pain score; immediately postoperative in the PACU, POD 0 PM, and POD 1 AM The general trend continued through POD 3 but was not statistically significant at later time points. PACU, postanesthesia care unit; POD, postoperative day; VAS, visual analog scale.

($p = 0.02$), and 26% ($p = 0.01$) lower than the group 1 for the first three time periods after surgery (postanesthesia care unit [PACU], POD 0 PM, and POD 1 AM). These differences in reported pain between groups narrow as the time from surgery advances, and there were no statistically significant differences in VAS after POD 1 PM for the individual time points.

The average pain medication usage at each data collection interval was plotted over time (►**Fig. 2**). Group 2 reported 23% ($p = 0.01$) less pain medication use on the day of surgery and 26% ($p = 0.001$) less medication use on postoperative day 1. There was no significant difference in medication use between the groups during PODs 2 through 4.

The average duration of preoperative cryotherapy in the experimental group was 60 minutes (± 18, range, 31–90). The amount of time (dose) of preoperative cryotherapy was analyzed for a possible dose response. No correlation was found between the duration of cryotherapy and pain scores or pain medication use.

Complications and Ease of Administration

Complications did not occur in either group. Preoperative cryotherapy was easily administered by the staff and was well tolerated by the patients. There were no pre- or postoperative adverse reactions to the use of cryotherapy and no episodes of intolerance. Specifically, there were no episodes of frostbite and no evidence of increased erythema, wound drainage, delayed wound healing, or other wound-related troubles. There were no nerve palsies, transient or otherwise, in either group.

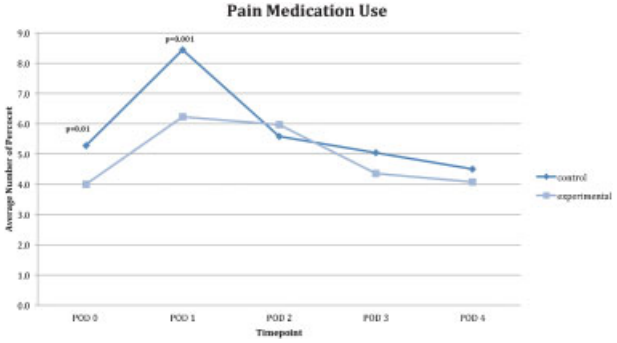

Fig. 2 Pain medication use depicted over time. At POD 0 and 1, the experimental group showed a statistically significant decrease in pain medication use. POD, postoperative day.

Discussion

In this study, we have shown an improvement in postoperative VAS scores and pain medicine consumption in patients who received cryotherapy versus those who did not before undergoing ALCR. Specifically, there was a statistically significant difference in VAS scores in the first 36 hours after surgery and a trend that continued through the third postoperative day. A statistically significant decrease in pain medicine consumption was also shown in the experimental group in the first 36 hours. To our knowledge, this is the first study to test and/or show a therapeutic benefit of preoperative cryotherapy in patients undergoing an orthopedic procedure.

The historic treatment of pain with high doses of unimodal agents has proven insufficient in providing optimal pain management. There is a trend toward increasing utilization of multimodal analgesia in orthopedic surgery and for the management of musculoskeletal injury.[10] A combination of approaches, both pharmacologic and nonpharmacologic, can be used to address multiple mechanisms of pain, with the added benefit of reducing side effects through the use of lower doses of individual modalities.

Relatedly, advances in perioperative anesthesia have so dramatically improved patient pain control as to allow most of our arthroscopic procedures, including ACLR, to be almost exclusively performed in a same day surgery setting. Regional pain blocks, laryngeal air masks, combinations of local anesthetics, and indwelling pain pumps have all played a role in various modern multimodal pain plans.[11] Preoperative cold therapy has the makings of an ideal component of a multimodal pain plan as it is readily available, universally accepted, inexpensive, and has minimal side effects when used appropriately.[1] It could also aid in attempts to lower pain medication doses due to intolerance, comorbidities (i.e., sleep apnea), or history of dependence.

This study has several limitations, the most important one being the lack of blinding. Because the patients receiving the treatment were aware of it, they may have been biased toward reporting lower pain scores. However, they did also consume less pain medication adding weight to the notion of a true benefit of the therapy.

Second, while there was a control, there was not a placebo group per se. Ideally, the patients in both groups would have worn the cooling device with cold water used in the experimental group and room temperature water in the control group. Ethically, we could not rationalize inducing anesthesia significantly before the procedure so that the patients would be blinded and hence have a true placebo group.

Finally, despite the fact that the assessment of pain with a VAS is well validated and widely accepted, it does fail to

account for the subjective, multidimensional characteristics of pain, including affective qualities. Future studies should use a more detailed assessment encompassing the multifaceted nature of pain.

Our study has shown a benefit to preoperative cryotherapy in patients undergoing ACLR. Although the benefit did not last more than 36 hours, it may have lead to a more pleasant postoperative experience for the experimental group and could positively impact the initial recovery after surgery. Future efforts should focus on blinding, a placebo treatment, a larger patient cohort, and longer follow-up.

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