

Continuous-Flow Cold Therapy for Outpatient Anterior Cruciate Ligament Reconstruction

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Summary: This prospective, randomized study evaluated continuous-flow cold therapy for postoperative pain in outpatient arthroscopic anterior cruciate ligament (ACL) reconstructions. In group 1, cold therapy was constant for 3 days then as needed in days 4 through 7. Group 2 had no cold therapy. Evaluations and diaries were kept at 1, 2, and 8 hours after surgery, and then daily. Pain was assessed using the VAS and Likert scales. There were 51 cold and 49 noncold patients included. Continuous passive movement (CPM) use averaged 54 hours for cold and 41 hours for noncold groups ($P = .003$). Prone hangs were done for 192 minutes in the cold group and 151 minutes in the noncold group. Motion at 1 week averaged 5/88 for the cold group and 5/79 the noncold group. The noncold group average visual analog scale (VAS) pain and Likert pain scores were always greater than the cold group. The noncold group average Vicodin use (Knoll, Mt. Olive, NJ) was always greater than the cold group use ($P = .001$). Continuous-flow cold therapy lowered VAS and Likert scores, reduced Vicodin use, increased prone hangs, CPM, and knee flexion. Continuous-flow cold therapy is safe and effective for outpatient ACL reconstruction reducing pain medication requirements. **Key Words:** Cold therapy—Pain management—ACL reconstruction.

The benefit of cold on the reduction of pain and swelling has been established. Several methods for the application of cold exist, including ice bags, reusable cold packs, and sophisticated refrigeration devices. The recent development of portable constant-flow cold therapy devices permits the continuous application of cold to the operated or injured area in the outpatient setting. Several studies have looked at the postoperative effectiveness of continuous-flow cold therapy using hospitalized patients.¹⁻⁸ However, changing treatment patterns are reducing the frequency of postoperative hospitalization. Studies on the

effectiveness of continuous-flow cold therapy that include patient randomization and standardized treatment protocols are lacking for the outpatient setting. The purpose of this study is to evaluate the benefit and efficacy of portable continuous-flow cold therapy in such an outpatient setting.

METHODS

A prospective, randomized series of consecutive patients undergoing outpatient anterior cruciate ligament (ACL) reconstruction using a patellar tendon autograft were assigned to either group 1 (cold therapy) or group 2 (no cold therapy). Randomization was based on the last digit of their social security number. Subjects with even numbers received cold therapy and odd numbers received no cold therapy. Subjects selected for postoperative cold therapy had a sterile cold bladder included in the immediate postoperative dressing separated from the skin by a thin absorbent dressing. The pain-producing procedure was an arthro-

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scopically assisted single-incision, central third patellar tendon autograft, ACL reconstruction fixed with BioScrews (Linvatec, Largo, FL). No drains were used. The continuous-flow cold therapy unit was worn constantly by the subject for 3 days. After the initial 3 days, the unit was used by the subject in conjunction with the continuous passive motion (CPM) machine (usually 6 to 8 hours each day) and at other times as the subject desired. The target enrollment was 100 subjects at two sites.

Subject inclusion criteria included the ability to speak and understand English, at least 16 years of age, to be undergoing an arthroscopically assisted ACL reconstruction incorporating a patellar tendon autograft, able to complete the 2-hour evaluation while at the surgicenter before going home, be available for follow-up phone evaluation for the duration of the study, be willing to comply with the therapeutic regimen, and agree to complete and return the postoperative evaluation diary. Patients with acute ACL injuries were rehabilitated for several weeks (usually 6 weeks) until several objective criteria were met: no existing effusion, full extension, and knee flexion to at least 120°.

Exclusion criteria included a known allergy to hydrocodone bitartrate with acetaminophen (Vicodin; Knoll, Mt. Olive, NJ), oxycodone hydrochloride with acetaminophen (Percocet; DuPont, Wilmington, DE), or acetaminophen and codeine phosphate (Tylenol with codeine; McNeil, Raritan, NJ), have a significant coexisting injury or illness which contraindicates administration of cold therapy, have any serious concomitant injury, be undergoing multiple ligament reconstructions, not make the inclusion criteria, or be undergoing revision ACL surgery.

A constant-flow, portable cold therapy unit (Orthopedic Technology, Tracy, CA; Aircast Inc, Summit, NJ) was used for group 1 subjects (Fig 1). The unit had a water reservoir into which a combination of ice and water was placed. This was maintained by the patient and provided a constant flow of cold water ranging from 35°F to 50°F through insulated tubing to a sterile rubber pad held with a compressive dressing at the knee operative site. This flow was maintained constantly including during knee flexion and extension by a mechanical, electrically powered pump attached to the water reservoir. To control for the effect of compression which may be a confounding variable,¹ those not receiving the cold therapy had their dressing held in place by the same compressive dressing as those receiving the cold therapy bladders. An empty water bladder or a bladder filled with room tempera-

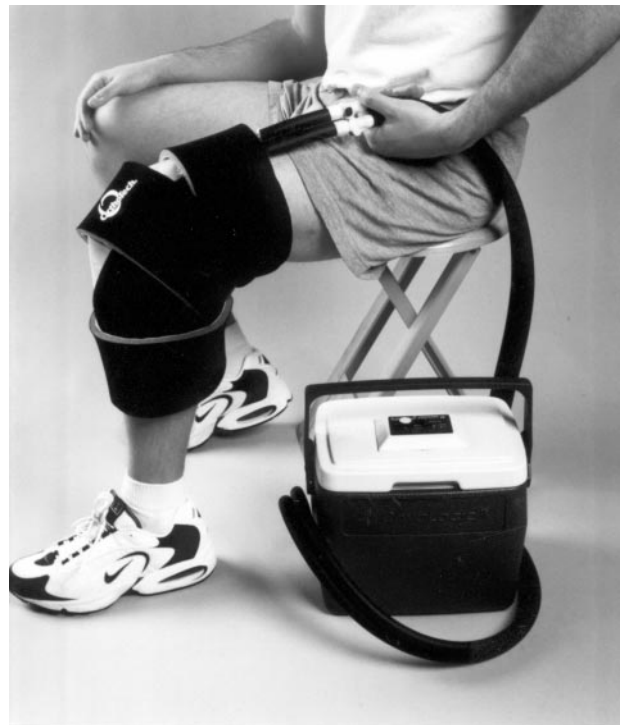


FIGURE 1. The continuous-flow cold therapy unit pumps ice water from a reservoir through a rubber pad held at the operative site by a compressive dressing.

ture water were not felt to be valid controls, but rather would be provocative of pain,² and were not used.

Evaluations were conducted at 1, 2, and 8 hours after completion of the surgery, followed by daily evaluations for the entire study period (lasting up to 1 week) after surgery. Evaluations at hours 1 and 2 were conducted in person at the surgicenter by research personnel after which time the patients were discharged home. Subsequent evaluations were made daily by phone to monitor and document progress and to reinforce subject diary completion and protocol compliance. These records included two separate evaluations of the pain: a Visual Analog Scale (VAS)⁹ and categorical pain scale.¹⁰ The VAS was a 10-cm long rectangular bar, with polar descriptors at both ends, that the subject marked to reflect the discomfort experienced during the prior evaluation period. The lowest or minimal pain was located at the left, while the maximum or worst possible pain designator located at the right end of the bar. The patients were asked to place a mark on the bar that best indicated their personal experience in relationship to the two extremes. The patients' response on the VAS was converted to a number based on its distance from the left side of the 10-cm bar. The Likert categorical pain

score included four pain descriptions from no pain to severe pain that were also marked by the subject at each follow-up interval. For the subjects in group 1, questions also concerned the effectiveness of the cold therapy device. Subjects completed these evaluations at home in a diary. Daily phone contact by the research coordinator insured a contemporary completion of the diaries. Subjects brought their diaries to the office for the 1 week follow-up visit. Each subject received a \$50 honorarium to compensate them for their inconvenience with the necessary phone calls and daily log completion.

Analgesics and all other medications consumed during these intervals were recorded. The intraoperative and immediately postoperative medications were standardized for all cases at the two sites. At the completion of the surgery, intra-articular morphine was administered to each patient,¹¹ the wound margins infiltrated with Marcaine (Sanofi Winthrop, New York, NY), and an intramuscular injection of Toradol (Roche, Nutley, NJ) given. Subjects were educated to avoid taking analgesics as preventative maintenance for pain (in anticipation of pain), but rather as needed for moderate pain levels. Two prescriptions of medications were provided each patient (Percocet and Vicodin). The patients were instructed to take two Vicodin initially for pain relief only after they began to experience significant discomfort. The instructions emphasized that pain medication should be taken only *after* pain was perceived, and not in the anticipation of pain developing. Only after the Vicodin proved insufficient should a single Percocet be taken. When the patient was comfortable enough, a transition to plain Tylenol was permitted.

For the postoperative period, all patients were instructed in knee extension exercises (prone hangs and bridging). The use of the CPM machine was 6 to 8 hour per day starting with a comfortable range (all in full extension) and increasing flexion 5° per day to increase the motion. Crutches were provided, but the patients instructed to weight bear as tolerated. A clinical follow-up examination was performed by the surgeon approximately 1 week postoperatively. Knee stability (Lachman), range of motion (supine goniometer), wound healing, and swelling were measured.

Statistical comparisons of categorical variables were performed using Fisher's Exact Test and Mantel-Haenszel χ -square test while continuous variables were compared by the Student's *t* test. All data summaries and statistical comparisons were performed by Statistical Analysis System (SAS) version 6.09. Statistical significance was assigned at $P < .05$.

RESULTS

A total of 100 patients were enrolled in the study; 51 were randomized to group 1 and received the postoperative cold therapy. Another 49 were randomized to group 2 and received no cold therapy. The average age for both groups was 34 years (range, 16 to 53 years). In group 1, there were 34 male and 17 female subjects, and in group 2 there were 40 male and 9 female subjects. CPM use varied between the groups and averaged 54 hours for the cold group and 41 hours for the noncold group (this difference was significant, $P = .003$). Prone hangs were done more often in the cold group (192 min) than the noncold group (151 min) ($P = .055$). Bridging exercises were done on average for 81 minutes for the cold group and 78 minutes for the noncold group ($P = .7$). No infections occurred in either group.

Pain was assessed by two established tools: a VAS and a categorical pain scale (Likert). The average VAS at each data collection interval was plotted over time after surgery (Fig 2). While the differences between groups 1 and 2 narrow as the time from surgery approaches 1 week, at no point during the study period did the group 1 average VAS pain report reach or exceed the group 2 VAS pain report. Noncold patients' average VAS pain was 25% more in the first postoperative day than the cold patients' VAS pain ($P = .059$), but approached the cold patients' pain by postoperative day 6. Noncold average categorical pain (Likert) was also always greater than the cold group categorical pain varying from 40% more with significant pain in the first postoperative day ($P = .053$) to 10% more at day 6 (Fig 3).

Pain perception may be influenced by medication, and medication usage is another indicator of pain. Consequently, postoperative pain medication use was monitored. Patients usually found it necessary to take Percocet at first, but later transitioned to Vicodin. The

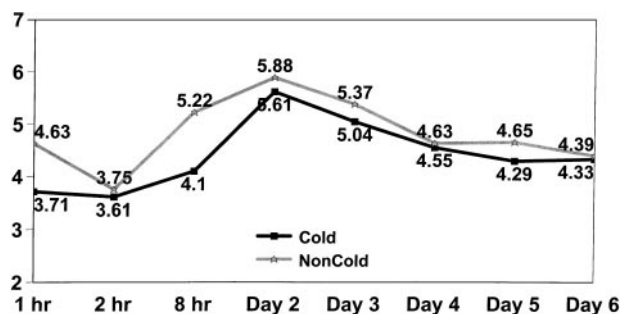


FIGURE 2. VAS pain scores for the noncold group were always greater than those receiving cold therapy.

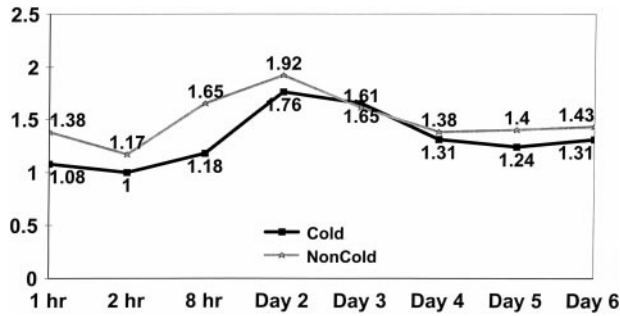


FIGURE 3. Likert pain scores for the noncold therapy group varied from 40% more than those of the cold therapy group in the first postoperative day to 10% more at postoperative day 6.

average Percocet usage data shows no difference between either group. Vicodin usage increased over time as Percocet use declined (Fig 4). Noncold patients' average postoperative Vicodin use was always greater than the cold patients' use ($P = .013$) varying from 125% more on day 2 ($P = .001$) to 5% more on day 7 (Fig 5).

Physical examinations were conducted 1 week after surgery. No instability or wounds healing differences were noted. No difference was noted in the incidence of subjects that failed to achieve full extension. Twenty-four of 49 (49%) in the noncold group 2 failed full extension by at least 5°. Eleven of these failed full extension by 10°. Twenty-seven of 51 (53%) of cold therapy group 1 also failed full extension by at least 5° and 13 failed full extension by 10°. The average knee flexion for the cold group was 88° (flexion range, 48° to 155°) and for the noncold group, 77° (flexion range 25° to 125°) ($P = .058$). No differences in swelling were noted ($P = .76$).

Patients in group 1 were questioned with a categorical scale as to their tolerance of the cold therapy and the performance of the cold therapy unit. As for tolerating the cold therapy, 57% categorized their tolerance as excellent, 29% as very good, 10% as

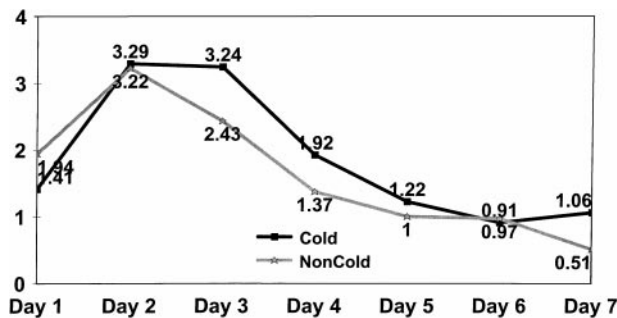


FIGURE 4. There was no significant difference in Percocet use between groups.

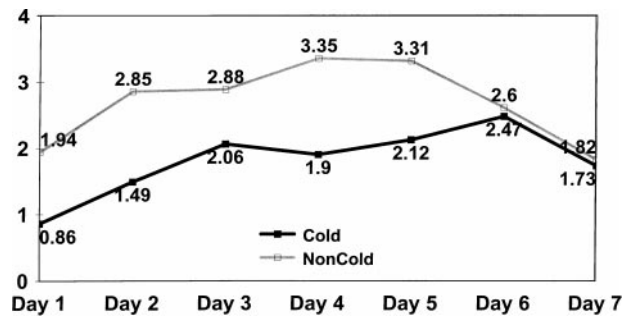


FIGURE 5. Vicodin use was always greater in the noncold therapy group than the cold therapy group varying from 125% more on postoperative day 2 to 5% more on postoperative day 7.

good, and 4% as fair. This group also evaluated the performance of the cold therapy unit by a similar categorical scale and 61% thought the performance was excellent, 29% very good, 4% good, and 6% fair. The principal problem resulting in a reduced opinion of the performance was water bladder leakage. Using a VAS for cold therapy tolerance and unit performance (10 was the highest rank) 57% reported their tolerance to be a 10, and 59% reported the unit performance as a 10. Only 10% gave rankings for either question below a level 8 VAS. No reports of cold therapy related complications were observed. Specifically, no instances of frostbite or transient nerve palsies^{3,12} were observed. Cold therapy was used constantly during the first 3 days after surgery by all but 5 subjects of the 51 in group 1 (90%). The average total cold unit use from day 4 through day 6 was 48 hours indicating a high continued voluntary use.

Cold therapy tolerance was excellent. Patient compliance with continuous usage in the first 3 days (72 hours) was found in 90% of the cold therapy group. After the first 3 days, the patients were allowed to use the cold therapy as needed. Over that 72-hour period (the voluntary phase), average cold therapy use was 48 hours. Patient acceptance averaged 9.0 on the VAS with 29 of 51 rating it a 10. Using the four-point Likert scale, the patient acceptance of cold therapy averaged 3.45 with 31 of 51 rating it at the 4.0 level. In contrast to other reports,^{1,12} no cases of thermal injury, such as frostbite, or nerve palsy were observed.

DISCUSSION

Cold has been used to treat pain and swelling for centuries, although the mechanism by which cold decreases pain and swelling is not well understood. It is thought that locally induced vasoconstriction contributes to a reduction in bleeding, edema, and local

inflammatory response. Local cooling reduces neuronal pain signal transmission, inhibits the stretch reflex, and reduces muscle spindle activity.⁴ Cold therapy initiation shortly after the injury is more effective.¹³

Surgery causes cell trauma and interstitial space leakage of arachidonic acid. Cyclooxygenase catalyzes the reaction of arachidonic acid, which eventually leads to the formation of prostaglandins. Prostaglandins stimulate the pain receptors resulting in a pain impulse which goes to a synapse in the dorsal horn of the spinal cord. Substance P is then released at this location, and the pain impulse enters the central nervous system. The pain impulse is then transmitted to the brain via ascending pathways. Cold therapy slows the velocity of this pain impulse as it traverses the peripheral nervous system.⁵ Most published reports evaluate the use of cold therapy on inpatient ACL reconstructions or total joint replacements.⁶ A study of continuous cold therapy (Hot/Ice Blanket; Thermo Temp Inc, Tampa, Florida) for hip and knee arthroplasty failed to show a difference in narcotic use, but did show that continuous cold therapy patients were discharged 1.5 days earlier than noncold patients.⁵ The lack of discharge criteria makes it hard to determine if the discharge decisions were indeed influenced by this single factor. The lack of drug administration criteria raises concerns that medication usage may not reflect the cold therapy effect.

The earliest report using the patellar tendon autograft (PTA) ACL reconstruction as a pain model followed 54 inpatients for about 3.5 days. The two-incision reconstruction was augmented with an iliotibial band tenodesis. Hemovac drains were used in all cases. The cumulative dose of medication was recorded rather than a day-by-day use pattern. Pain was not objectively recorded by VAS. Patients using the continuous cold therapy (Hot/Ice machine) used statistically less Vistaril (Pfizer, New York, NY) and Demerol (Sanofi Winthrop).³ A later report on inpatient PTA ACL reconstructions confirmed this reduction in pain medication. That study compared the Cryocuff (Aircast) with crushed ice.⁷ The Cryocuff is not a continuous-flow device. A container holding ice water is raised or lowered to allow ice water to flow into and drain out of bladders placed about the treated area.

The Cryocuff was compared with both no Cryocuff and to "room temperature" water in a Cryocuff in a study of 71 inpatient arthroscopic PTA ACL reconstruction patients. A patient-controlled analgesia (PCA) system was used postoperatively. VAS pain reports were collected daily for an average of 3 hospitalized

days. No differences were shown among the three groups. The PCA may have influenced the medication use. The authors are repeating this study with the Autochill cuff.⁴ In a series of various shoulder procedure inpatients receiving lidocaine interscalene blocks for anesthesia and hospitalized for at least 1 night, pain symptoms were measured by VAS at day 1 and day 10. The VAS showed less pain, more comfort lying in bed, easier sleeping, less pain frequency, and less perception of the need to use narcotics on the first day in those using the Cryocuff than those not using the Cryocuff. On day 10, the VAS showed that those receiving the Cryocuff hurt less often, had less severe pain, less pain during rehabilitation exercises, and perceived less shoulder stiffness than those not using the Cryocuff.²

Groups of inpatient PTA ACL reconstructions treated with continuous-flow cold therapy (DuoTemp; Seabrook Medical, Cincinnati, OH) at four different temperature settings failed to show a difference among the different temperature settings.⁸ Pain medication usage was evaluated by converting various medications to a standard pain medication unit. In this three-day inpatient study, it is not clear if medication was administered after pain was experienced or at routine time intervals in anticipation of the pain. These authors subsequently indicated they still use a cold therapy device if the patient is willing to purchase one.¹⁴

A one-day inpatient study of arthroscopic PTA ACL reconstructions using postoperative drains compared the continuous flow Polar Care unit (Breg Inc, Vista, CA) with three other groups: room temperature water in the continuous flow bladder, ice packs, and nothing. Skin temperature was significantly lower for both the ice pack and continuous-flow cold therapy groups. No difference in total pain medication used or length of hospitalization was shown among these groups. However, discharge criteria and criteria for the administration of medication were not clearly established.¹

Measuring pain by inpatient medication use is dependent on both the patient and the nurse. The patient may request medication in anticipation of pain. The nurse may administer the medication at the minimum time interval ordered, rather than when the patient complains of pain.

Effective pain management and modalities that enhance rehabilitation play an essential role in outpatient ACL reconstruction.¹⁵ We wished to explore the hypothesis that continuous cold therapy could make a positive contribution in outpatient surgery. No cold therapy was selected as the control because we felt, as

do others,² that using an empty cryotherapy device or one filled with warm water at room temperature would be provocative in causing pain.

Postoperative narcotic pain medications for the study patients were limited to only two drugs: Percocet and Vicodin. These were recorded daily, both in phone interviews and patient completed diaries. This study looked at four areas: pain perception, medication usage, physical effects, and toleration of the cold therapy. Pain perception was measured objectively by VAS and Likert categorical questionnaires. Perceived pain was at its highest levels on the second postoperative day. This time interval reflects the importance of the first 36 hours in establishing pain relief.¹³ In the initial 24 hours after surgery, pain levels were less than on days 2 and 3. The decline in pain was steady after that point. The lower pain levels documented by this study for the first 24 hours may explain the inability of some studies to show a difference in pain when looking exclusively at the first postoperative day,¹ but when a longer time interval is considered, differences are shown.^{3,7} Narcotic medication use coincided with this pain pattern. Total narcotic usage on the second day was twice that of the first day. Interestingly, despite greater Vicodin consumption, the noncold group still had higher VAS pain scores.

The application of cold has many effects on injured soft tissue including influencing circulation, pain reduction, muscle spasm reduction, reduced metabolic activity, inflammation suppression, and increased tissue stiffness.² The data of this study demonstrate that continuous-flow cold therapy results in the consumption of less Vicodin. Continuous-flow cold therapy is a safe and effective modality for an outpatient ACL reconstruction, and results in a measurable reduction in medication use.

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