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Intraoperative Arthroscopic Cold Irrigation Solution Does Not Affect Postoperative Pain and Swelling

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Objective: To determine what effect using a cold irrigating solution during arthroscopic knee surgery would have on postoperative pain intensity, pain-medicine consumption, and knee joint swelling.

Design and Setting: We employed a randomized, controlled trial design. Subjects were randomly assigned to either the cold (4°C) irrigating saline group or room-temperature (18°C) irrigating saline (control) group. Subjects were blinded to group assignment. All surgeries were performed at the same hospital by the same surgeon.

Subjects: The sample was 93 physically active patients (32 women, 61 men, mean age = 47.4 ± 15.1 years) who had knee injuries requiring surgery. Those with cold sensitivities or contraindications to the use of cold were excluded.

Measurements: A 10-cm horizontal visual analog scale was used to measure postoperative pain intensity. Postoperative pain-medicine consumption was recorded using a daily log. Knee joint swelling (girth) was measured at midpatella and 2 in (5.08 cm) above midpatella. Pain and swelling measures were collected before and after surgery.

Results: No statistical or clinical differences were found between the cold-saline and control groups for pain, pain-medicine consumption, and postoperative swelling across the first 4 postoperative days.

Conclusions: Our results suggest that using intra-articular cold saline to irrigate the knee joint during arthroscopic surgery had no statistically or clinically significant effect on postoperative pain, medication usage, or swelling in the first 4 postoperative days.

Key Words: cryotherapy, knee, controlled trial

Physically active persons are usually eager to return to activity after arthroscopic knee surgery. Return to activity, however, is often delayed by the pain and swelling experienced after knee surgery. Postoperative pain and swelling often inhibit quadriceps function, which may delay the initiation and progression of rehabilitation. Clinicians continually seek methods for improving the management of postoperative pain and swelling in an effort to hasten return to normal activity and improve outcomes. Cryotherapy is a very common postoperative intervention used to relieve postoperative pain and swelling; however, researchers have failed to consistently demonstrate its therapeutic effectiveness.[1–6] Most of the reported inconsistencies associated with postoperative cryotherapy can be attributed to one or more of the following factors: (1) the variation in methods used to apply postoperative cold, (2) the temperatures used, (3) the length of time between surgery and initial cold application, (4) the duration and frequency of cold applications, and (5) the thickness of surgical dressings over which cold was applied. Each of these factors can significantly influence the therapeutic effectiveness of cryotherapy[7] and make comparisons among studies difficult.

Dahlstedt et al[8] reported that skin temperature had to be lowered to about 20°C (68°F) to produce demonstrable changes in knee intra-articular temperatures. These findings suggest that for cryotherapy to effectively reduce postoperative pain and swelling, which is believed to stem from trauma to the intra-articular tissues, skin temperatures should be reduced to at least 20°C. This magnitude of change in skin temperature is difficult to accomplish in the postoperative setting because of the barrier of protective bandaging.[9,10] Of the authors who have reported skin temperatures resulting from postoperative cryotherapy, none have attained temperatures as low as 20°C.[2,4]

Our purpose was to examine what effect, if any, intraoperative cryotherapy during arthroscopic knee surgery would have on postoperative pain intensity, pain-medicine consumption, and knee joint swelling. Intraoperative cryotherapy enables therapeutic cold to be applied directly to the intra-articular tissues, thus regulating the temperature of the specific target tissue. Our study was based on the theoretic assumptions that postoperative pain and swelling are attributable to surgical injury of intra-articular tissues and lowering the metabolism of the intra-articular tissues during surgery would decrease those tissues' need for oxygen during and immediately after surgery.[7] This would, in turn, decrease the amount of second-

ary hypoxic injury produced during surgery. Decreased tissue damage should lead to lower tissue oncotic and capillary filtration pressures that should, in turn, lead to less edema formation.[7] Lessened tissue damage and edema should also effectively reduce the amount of postoperative pain.

METHODS

Experimental Design

In this randomized, controlled trial, subjects were randomly assigned by coin toss to either the cold saline group (4°C) or the control group (18°C, room-temperature saline). Subjects were blinded to treatment group assignment, but the surgeon and principal investigator were not. The dependent variables were postoperative pain intensity, pain-medicine consumption, and knee joint swelling (girth). Approval for the use of human subjects was obtained from the facility's institutional review board.

We conducted an a priori power analysis to estimate the sample size required for detecting a large effect ($\geq$0.10).[11] With alpha set at 0.05 and power equal to 0.80, a sample size of 17 patients per group was calculated. Because there were 3 dependent variables, the calculated sample size was tripled to ensure adequate power. An additional 10% was added to the 51 subjects per group calculation to counter potential subject attrition, for a final minimum group size of 56 subjects.

Subjects

We recruited 122 consecutive patients who had a knee injury requiring arthroscopic surgery from the orthopaedic practice of a study coinvestigator. Patients requiring an arthroscopically assisted anterior cruciate ligament reconstruction or a lateral retinacular release were excluded. A Cold Sensitivity Questionnaire was created for this study and used to screen all potential subjects for sensitivities or conditions that might contraindicate the use of cold.[1,12–15] Patients without known cold sensitivities or contraindicating conditions consented to participate in this study by signing the informed consent form. Informed consent was provided by the parents of subjects who were minors (under age 18 years). All subjects were given an explanation of the study procedures and the potential risks to participants.

Instrumentation and Procedures

The principal investigator met with patients on the morning of their surgery to collect baseline pain and swelling measures. A 10-cm horizontal visual analog scale (VAS) with verbal anchors of ''no pain'' and ''worst pain possible'' was used to measure postoperative pain intensity.[16]

Subjects were instructed to make a single vertical mark that crossed the VAS at the point between the 2 extremes that represented their peak pain over the previous 24 hours. The VAS has been widely reported to be reliable and valid for measuring pain intensity[17,18] and has been specifically recommended for measuring pain during recovery from knee surgery.[17,19] Before surgery, subjects completed their baseline VAS rating of knee pain intensity. Subjects were also given a packet containing 4 additional VAS instruments and were instructed to complete them once per day at 6 hours (day 1), 24 hours (day 2), 48 hours (day 3), and 72 hours (day 4) after surgery. This measurement schedule for the VAS followed those previously described in the literature for patients with postoperative knee pain.[17,19] Subjects were instructed how to record their prescription pain medication consumption (either hydrocodone bitartrate 5 mg and acetaminophen 500 mg or codeine phosphate 30 mg and acetaminophen 500 mg; both are schedule III narcotics) using a preprinted pain-medicine log for postoperative days 1 through 4. Quantifying postoperative pain-medicine consumption provides a reliable, simple, objective, and reproducible indication of pain.[20]

A Lufkin tape measure with a Gulick spring-loaded attachment (Cooper Industries, Inc, Houston, TX) was used to assess knee joint girth. Girth measures were collected for both knees at midpatella and 2 in (5.8 cm) above midpatella. Side-to-side comparative girth measures were used as indicators of knee joint swelling. A swelling score was calculated for each measurement site (surgical knee [cm]–nonsurgical knee [cm]), and the swelling scores for each site were summed for an overall rating of swelling.

After instructions and baseline measures, the subjects were randomly assigned by coin toss to either the cold-saline group or the control group. Making the random assignment after collecting the baseline measures ensured that group assignment did not bias the delivery of instructions to subjects. The subject's group assignment was documented on the surgical schedule to enable the circulating nurses to prepare and hang the appropriate bags of irrigating saline.

All surgeries were performed at the same hospital by the same surgeon (a study coinvestigator). All arthroscopies were done on an outpatient basis using general anesthesia. The gravity method was used to administer a continuous flow of the saline irrigating solution during all the arthroscopic procedures. The circulating nurse monitored the level of saline throughout the case and hung additional bags of the appropriate solution as needed.

Bags of normal saline were cooled to 4°C (39.2°F) in 2 commercial-grade, hazardous-location refrigerators (Grainger, Houston, TX) that were located in the substerile storage room just outside the operating room suite. The temperatures of the refrigerators and the saline bag supply were checked daily. Two neoprene sleeves were made to insulate the bags of saline during arthroscopic surgery. The sleeves were constructed such that they could easily be slipped onto the bags of saline before hanging, maintaining the temperature of the cold saline during the surgical procedure. The bags of room-temperature saline (18°C [64.4°F]) were stored on a shelf in the same substerile storage room.

Knee intra-articular temperature was recorded at the beginning and end of every arthroscopic procedure using a sterile temperature probe and digital temperature monitor (Mallinckrodt, Inc, Irving, TX). To standardize the procedure, the temperature probe was inserted through the anterior portal and directed such that the tip rested in the anterior intercondylar notch.[21] The probe was held in this position for 1 minute, and then the temperature reading was recorded. The first measurement was taken as soon as the portal incisions were made and the arthroscopic instruments were inserted, providing a clear view of the intercondylar notch. The second and final measurement was taken at the conclusion of the surgical procedure, immediately preceding removal of the arthroscopic instruments from the knee.

At the conclusion of all arthroscopic procedures, subjects received an intra-articular injection of bupivacaine (20 mL,

Table 1. Age and Sex Distribution by Treatment Group

Group	Sex	N	Mean Age (SD)	Age Range (y)
Cold saline	Females	20	49.2 (17.9)	15–73
	Males	31	45.3 (14.4)	16–69
	Total	51	46.8 (15.8)	15–73
Control	Female	12	51.0 (17.5)	14–81
	Males	30	47.1 (13.1)	23–74
	Total	42	48.2 (14.4)	14–81
Total		93	47.4 (15.1)	14–81

Table 2. Surgical Procedures by Treatment Group

Procedure	All Subjects (n = 93)	Cold-Saline Group (n = 51)	Control Group (n = 42)
Partial meniscectomy*	74	43	31
Abrasion chondroplasty	62	33	29
Other†	17	12	5
Total‡	153	88	65

*All meniscus surgical procedures were partial meniscectomies. Small (<5 mm) radial tears and small (<5 mm) peripheral tears in the vascular zone received no surgical treatment.
†Other includes loose body, removal of hardware, and partial synovectomy.
‡Totals exceed subject count because many patients underwent 2 or more concomitant arthroscopic procedures.

0.5% with epinephrine, 1:200 000) and morphine (1 mL, 10 mg). This routine was standard practice for all arthroscopic procedures performed by the coinvestigator and was therefore not changed for this study. All patients were instructed to bear weight as tolerated, to use crutches as necessary for balance, and to maintain a normal gait pattern (ie, without a quadriceps-avoidance gait[22]). Patients were instructed in quadriceps-setting exercises, straight-leg raises, and active knee flexion (sitting with the foot of the surgical leg sliding under the chair). Most patients attended at least 2 to 3 rehabilitation sessions on consecutive postoperative days in an outpatient clinic or athletic training room. Patients were informed that they could use ice packs for 15 minutes several times a day, but that this was not required. Neither the surgeon nor the principal investigator had any contact with the subjects between their surgery and first postoperative office visit (usually day 5).

The VAS instruments and pain-medicine logs were collected from the subjects at their first follow-up appointment with the surgeon. Patients who forgot to bring their forms were given a self-addressed, stamped envelope to return their forms. Of the 122 subjects recruited, 93 (32 females, 61 males) completed the study. The remaining 29 subjects returned incomplete data forms. During the first follow-up visit, the principal investigator also reassessed swelling by repeating the girth measurements (centimeters) with the same tape measure that was used for the preoperative measurements.

Statistical Analyses

We computed descriptive statistics for all variables, using means, SDs, and ranges for continuous variables and frequencies for categoric variables. Independent-samples Student *t* tests and χ^2 tests were used as appropriate to compare the independent variables between the treatment groups. Pearson product moment correlation coefficients were calculated for all pairwise relations among VAS ratings, pain-medicine consumption, swelling, and articular temperatures. To address the primary research questions, orthogonal contrasts in a multivariate general linear-model analysis were used to test for group differences in pain (VAS ratings across 4 days), pain-medicine consumption, and swelling. Our 3 hypotheses were tested independently of one another and therefore did not require alpha value corrections, as would be necessary with multiple (dependent) comparisons or tests.

RESULTS

No significant differences were seen in pain ($P = .385$), pain-medicine consumption ($P = .989$), or postoperative swelling ($P = .966$) between the treatment groups. There was no evidence that use of the cold saline irrigating solution during arthroscopy of the knee had any effect on postoperative pain, medication use, or swelling.

The treatment groups did not differ by age ($P = .652$) or sex distribution ($P = .392$, Table 1). Surgical procedures by treatment group are presented in Table 2. Intra-articular temperature between treatment groups was significantly different ($P < .0005$), indicating the cold saline had cooled the knee as intended. The mean intra-articular knee temperature for the cold saline group (7.7°C) was 12.1°C colder than the control group (19.8°C).

The mean pain rating across the 4 postoperative days was significantly correlated with pain-medicine consumption across ($r = 0.29$, $P = .005$) and within groups ($r_{Cold} = 0.28$, $r_{Control} = 0.30$; Table 3). Pain-medicine consumption increased slightly as pain ratings increased, and medication use decreased slightly as pain ratings decreased. Postoperative swelling (increase in girth relative to baseline measure) was not significantly correlated with pain ratings ($r = 0.11$, $P = .280$). Intra-articular knee temperature readings (beginning and end) were also uncorrelated with the pain ratings.

Table 3. Mean (Range) Pain on Visual Analog Scale, Pain-Medicine Use, and Swelling Ratings by Treatment Group

Variable	All Subjects	Cold-Saline Group	Control Group
Visual analog scale			
Day 1 (cm)	3.6 (0.0–10.0)	3.4 (0.0–9.5)	3.8 (0.0–10.0)
Day 2 (cm)	5.0 (0.4–10.0)	4.9 (0.5–10.0)	5.1 (0.4–10.0)
Day 3 (cm)	3.1 (0.0–9.1)	3.7 (0.2–8.8)	3.4 (0.0–9.1)
Day 4 (cm)	2.2 (0.0–8.3)	2.4 (0.3–8.2)	2.3 (0.0–8.3)
Visual analog scale across days (cm)	3.6 (0.4–7.5)	3.4 (0.4–7.5)	3.8 (0.4–7.5)
Pain medicine (number of pills)	8.7 (0–32)	8.8 (0–32)	8.5 (0–27)
Swelling (cm)	2.6 (−3.8–10.1)	2.6 (−2.0–10.1)	2.6 (−3.8–10.1)

DISCUSSION

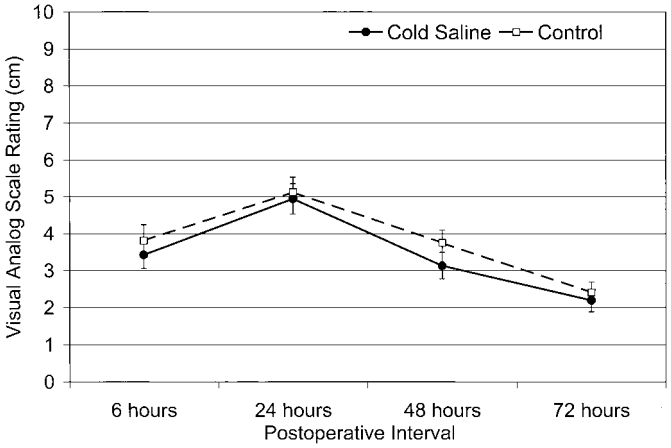
Our results suggest that intra-articular cold saline irrigation during arthroscopic knee surgery had no statistically or clinically significant effect on postoperative pain, medication intake, or swelling. Several potential explanations for the lack of effect exist. First, intra-articular tissue insult may not have been the primary cause of postoperative pain associated with these arthroscopic knee surgeries. The extra-articular tissue insult caused by insertion of the arthroscopic instruments, however, may have created an inflammatory response. The intra-articular cold saline irrigation probably did not alter the temperature of the superficial knee tissues (skin, superficial muscle, etc) and thus would not have affected the signs and symptoms associated with injury of those tissues. Many of the intra-articular procedures did not involve the synovium and therefore may have produced little to no intra-articular inflammation.

Alternately, the cold saline may have been withdrawn from the intra-articular tissues before any inflammatory response had begun. Most of the arthroscopic procedures were less than 30 minutes in duration. The first portion of each procedure consisted of diagnostic arthroscopy of the knee joint. The surgical tissue insults occurred in the latter part of each procedure, just before closing. In many cases, the cold saline irrigation continued for less than 10 minutes after conclusion of the surgical tissue insult (eg, partial meniscectomy). If the knees had continued to be irrigated with cold saline for 10 or 15 minutes after conclusion of the surgical procedure, an effect on one or more of the postoperative measures might have been seen. Unfortunately, the material and financial costs associated with extending operating room time are likely to outweigh any potential benefit that may result from continuing the cold saline irrigation after the conclusion of the procedure.

It is also possible that the treatment provided in the outpatient clinics and athletic training rooms varied somewhat among patients and may have contributed to the lack of an effect. For example, patients with more swelling and pain may have received more intensive treatment to address these problems. The duration, intensity, and specific activities of postoperative rehabilitation were not controlled or measured in this study because there was no reliable way of observing them. We suspect that, as a whole, neither group received more rehabilitative treatment because pain and swelling did not differ between groups. The prospective, randomized, controlled-trial study design we used is the most powerful research design possible for control of factors that are beyond the immediate control of the investigators.

Despite the lack of any detectable treatment effect, our results did demonstrate a few trends. Subjects within both treatment groups demonstrated a consistent pain pattern (Table 3, Figure) with peak pain intensity occurring on day 2. This pattern is similar to that reported by Brown et al[23] and may be common to most patients with arthroscopic knee surgery. The intra-articular injection of bupivacaine and morphine that all subjects received at the conclusion of their surgery may have produced lower VAS scores on day 1 compared with day 2.

During their follow-up examinations, several subjects provided unsolicited, anecdotal comments regarding their postoperative pain. These comments ranged from ''I know I must have received the cold treatment because I really didn't have much pain'' to ''I'm pretty sure I didn't get the 'cold stuff' since my knee really hurt pretty bad.'' After recording each set of anecdotal comments, the principal investigator compared the subject's pain ratings with his or her comments. In no case did the subject's comments and the qualitative interpretation of the pain ratings match. For example, subjects who commented that they had experienced very little pain often produced VAS scores that would be interpreted as moderate to severe (VAS rating = >31 mm[24,25]).



Pain (visual analog scale) ratings by treatment group across the postoperative interval showed no significant differences between groups (bars represent standard errors).

This empirical inconsistency suggests that the single VAS rating per day may not have been representative of the subjects' pain. Jensen and McFarland[26] stated, ''A single rating of pain intensity is not adequately reliable or valid as a measure of average pain'' for persons with chronic pain and recommended that VAS ratings should occur every 2 hours or at least 6 times per day. They suggested that an average of these measures would provide a more reliable and accurate measure of pain. It is not known whether this measurement schedule would be appropriate for persons with acute postsurgical pain. We employed a once-a-day measurement schedule based on currently accepted methods for this population.[17,19]

The use of cold saline produced a very small effect among our subjects. The a priori power analysis to determine sample size was estimated using an effect size of at least 0.10 (ie, cold saline would explain at least 10% of the differences between treatment groups). The largest observed effect size in our analyses was 0.008, corresponding to a mean group difference of only 0.34 cm on the 10-cm VAS scale. The very small effect sizes in the current study were much less than what we had designated as being clinically relevant.

Chilled saline has been shown to be successful in reducing pain in neurosurgical procedures.[27,28] For this reason, the therapeutic effects of intraoperative cold applications should not be discounted for orthopaedic procedures. Future researchers in this area may consider avoiding the use of intra-articular medication immediately after the procedure and collecting more than one VAS reading each day to increase reliability and responsiveness of pain measurement. In addition, prolonged irrigation with cold saline after completion of the procedure may coincide with onset of inflammation, thereby potentially producing a larger effect. Also, probes could be inserted directly into several tissues surrounding the knee to evaluate the degree to which cold saline irrigation lowers their temperature. Finally, we recommend that the intra-articular cold applications be tested with surgical knee procedures that

involve greater intra-articular tissue insult, such as anterior cruciate ligament reconstruction.

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