

Continuous Cryotherapy vs Ice Following Total Shoulder Arthroplasty: A Randomized Control Trial

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Author Affiliation | **Disclosures**

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Take-Home Points

- CC has been proposed as a means of improving postoperative pain control.
- CC represents a cost typically not covered by insurances.
- No difference was noted between the 2 groups in quality of sleep, satisfaction with the cold therapy, or narcotic usage at any time interval.
- While CC may offer convenience advantages, the increased cost associated with this type of unit may not be justified.
- The mechanism for CC for pain control is poorly understood.

The number of total shoulder arthroplasties (TSAs) performed annually is increasing dramatically.¹ At the same time, there has been a push toward decreased length of hospital stay and earlier mobilization following joint replacement surgery. Central to these goals is adequate pain control. Multimodal pain pathways exist, and one of the safest and cheapest methods of pain control is cold therapy, which can be accomplished with continuous cryotherapy (CC) or plain ice (ICE).

The mechanism of cryotherapy for controlling pain is poorly understood. Cryotherapy reduces leukocyte migration

and slows down nerve signal transmission, which reduces inflammation, thereby producing a short-term analgesic effect. Stalman and colleagues² reported on a randomized control study that evaluated the effects of postoperative cooling after knee arthroscopy. Measurements of metabolic and inflammatory markers in the synovial membrane were used to assess whether cryotherapy provides a temperature-sensitive release of prostaglandin E₂.

Cryotherapy lowered the temperature in the postoperative knee, and synovial prostaglandin concentrations were correlated with temperature. Because prostaglandin is a marker of inflammation and pain, the conclusion was that postoperative cooling appeared to have an anti-inflammatory effect.

The knee literature contains multiple studies that have examined the benefits of cryotherapy after both arthroscopic and arthroplasty procedures. The clinical benefits on pain have been equivocal with some studies showing improvements using cryotherapy^{3,4} and others showing no difference in the treatment group.^{5,6}

Few studies have examined cryotherapy for the shoulder. Speer and colleagues⁷ demonstrated that postoperative use of CC was effective in reducing recovery time after shoulder surgery. However; they did not provide an ICE comparative group and did not focus specifically on TSA. In another study, Kraeutler and colleagues⁸ examined only arthroscopic shoulder surgery cases in a randomized prospective trial and found no significant difference between CC and ICE. They concluded that there did not appear to be a significant benefit in using CC over ICE for arthroscopic shoulder procedures.

The purpose of this study is to prospectively evaluate CC and ICE following TSA. The hypothesis was that CC leads to improved pain control, less narcotic consumption, and improved quality of sleep compared to ICE in the immediate postoperative period following TSA.

Materials and Methods

This was a prospective randomized control study of patients undergoing TSA receiving either CC or ICE postoperatively. Institutional Review Board approval was obtained before commencement of the study. Inclusion criteria included patients aged 30 to 90 years old undergoing a primary or revision shoulder arthroplasty procedure between June 2015 and January 2016. Exclusion criteria included hemiarthroplasty procedures.

Three patients refused to participate in the study. Enrollment was performed until 40 patients were enrolled in the study (20 patients in each group). Randomization was performed with a random number generator, and patients were assigned to a treatment group following consent to participate. Complete follow-up was available for all patients. There were 13 (65%) male patients in the CC group. The average age of the CC group at the time of surgery was 68.7 years (range). There were 11 male patients in the ICE group. The average age of the ICE group at the time of surgery was 73.2 years (range). The dominant extremity was involved in 9 (45%) patients in the CC group and in 11 patients (55%) in the ICE group. Surgical case specifics are summarized in **Table 1**.

All surgeries were performed by Dr. Denard. All patients received a single-shot interscalene nerve block prior to the procedure. A deltopectoral approach was utilized, and the subscapularis was managed with the peel technique.⁹ All patients were admitted to the hospital following surgery. Standard postoperative pain control consisted of as-needed intravenous morphine (1-2 mg every 2 hours, as needed) or an oral narcotic (hydrocodone/acetaminophen 5/325mg, 1-2 every 4 hours, as needed) which was also provided at discharge. However, total narcotic usage was recorded in morphine equivalents to account for substitutions. No non-steroidal anti-inflammatory drugs were allowed until 3 months postoperatively.

The CC group received treatment from a commercially available cryotherapy unit (Polar Care; Breg). All patients received instructions by a medical professional on how to use the unit. The unit was applied immediately

postoperatively and set at a temperature of 45°F to 55°F. Patients were instructed to use the unit continuously during postoperative days 0 to 3. This cryotherapy was administered by a nurse while in the hospital but was left to the responsibility of the patient upon discharge. Patients were instructed to use the unit as needed for pain control during the day and continuously while asleep from days 4 to 14.

The ICE group used standard ice packs postoperatively. The patients were instructed to apply an ice pack for 20 min every 2 hours while awake during days 0 to 3. This therapy was administered by a nurse while in the hospital but left to the responsibility of the patient upon discharge. Patients were instructed to use ice packs as needed for pain control during the day at a maximum of 20 minutes per hour on postoperative days 4 to 14. Compliance by both groups was monitored using a patient survey after hospital discharge. The number of hours that patients used either the CC or ICE per 24-hour period was recorded at 24 hours, 3 days, 7 days, and 14 days. The nursing staff recorded the number of hours of use of either cold modality for each patient prior to hospital discharge. The average length of stay as an inpatient was 1.2 days for the CC group and 1.3 days for the ICE group.

Visual analog scales (VAS) for pain, satisfaction with the cold therapy, and quality of sleep were recorded preoperatively and postoperatively at 24 hours, 3 days, 7 days, and 14 days following surgery.

Statistical Method

The Wilcoxon rank-sum test was used to assess whether scores changed significantly from the preoperative period to the different postoperative time intervals, as well as to assess the values for pain, quality of sleep, and patient satisfaction. *P*-values <.05 were considered significant.

Results

No differences were observed in the baseline characteristics between the 2 groups. Both groups showed improvements in pain, quality of sleep, and satisfaction with the cold therapy from the preoperative period to the final follow-up.

The VAS pain scores were not different between the CC and ICE groups preoperatively (5.9 vs 6.8; *P* = .121) or postoperatively at 24 hours (4.2 vs 4.3; *P* = .989), 3 days (4.8 vs 4.7; *P* = .944), 7 days (2.9 vs 3.3; *P* = .593), or 14 days (2.5 vs 2.7; *P* = .742). Both cohorts demonstrated improved overall pain throughout the study period. These findings are summarized in **Table 2**.

The number of morphine equivalents of pain medication was not different between the CC and ICE groups postoperatively at 24 hours (43 vs 38 mg; *P* = .579), 3 days (149 vs 116 mg; *P* = .201), 7 days (308 vs 228 mg; *P* = .181), or 14 days (431 vs 348 mg; *P* = .213). Both groups showed increased narcotic consumption from 24 hours postoperatively until the 2-week follow-up. Narcotic consumption is summarized in **Table 3**.

VAS for quality of sleep improved in both groups from 24 hours postoperatively until the final follow-up. However, no significant differences in sleep quality were observed between the CC and ICE groups postoperatively at 24 hours (5.1 vs 4.3; *P* = .382), 3 days (5.1 vs 5.3; *P* = .601), 7 days (6.0 vs 6.7; *P* = .319), or 14 days (6.5 vs 7.1; *P* = .348). The VAS scores for sleep quality are reported in **Table 4**.

Finally, VAS patient satisfaction scores were not different between the CC and ICE groups postoperatively at 24 hours (7.3 vs 6.1; *P* = .315), 3 days (6.1 vs 6.6; *P* = .698), 7 days (6.6 vs 6.9; *P* = .670), or 14 days (7.1 vs 6.3; *P* = .288).

While compliance within each group utilizing the randomly assigned cold modality was similar, the usage by the CC group was consistently higher at all time points recorded. No complications or reoperations were observed in either group.

Discussion

The optimal method for managing postoperative pain from an arthroplasty procedure is controversial. This prospective randomized study attempted to confirm the hypothesis that CC infers better pain control, improves quality of sleep, and decreases narcotic usage compared to ICE in the first 2 weeks after a TSA procedure. The results of this study refuted our hypothesis, demonstrating no significant difference in pain control, satisfaction, narcotic usage, or sleep quality between the CC and ICE cohorts at all time points studied.

Studies on knees and lower extremities demonstrate equivocal results for the role CC plays in providing improved postoperative pain control. Thienpont¹⁰ evaluated CC in a randomized control trial comparing plain ice packs postoperatively in patients who underwent TKA. The author found no significant difference in VAS for pain or narcotic consumption in morphine equivalents. Thienpont¹⁰ recommended that CC not be used for outpatient knee arthroplasty as it is an additional cost that does not improve pain significantly. Healy and colleagues⁵ reported similar results that CC did not demonstrate a difference in narcotic requirement or pain control compared to plain ice packs, as well as no difference in local postoperative swelling or wound drainage. However, a recently published randomized trial by Su and colleagues¹¹ comparing a cryopneumatic device and ICE with static compression in patients who underwent TKA demonstrated significantly lower narcotic consumption and increased ambulation distances in the treatment group. The treatment group consumed approximately 170 mg morphine equivalents less than the control group between discharge and the 2-week postoperative visit. In addition, a significant difference was observed in the satisfaction scores in the treatment group.¹¹ Similarly, a meta-analysis by Raynor and colleagues¹² on randomized clinical trials comparing cryotherapy to a placebo group after anterior cruciate ligament reconstruction showed that cryotherapy is associated with significantly lower postoperative pain ($P = .02$), but demonstrated no difference in postoperative drainage ($P = .23$) or range of motion ($P = .25$).

Although multiple studies have been published regarding the efficacy of cryotherapy after knee surgery, very few studies have compared CC to conventional ICE after shoulder surgery. A prospective randomized trial was performed by Singh and colleagues¹³ to compare CC vs no ICE in open and arthroscopic shoulder surgery patients. Both the open and arthroscopic groups receiving CC demonstrated significant reductions in pain frequency and more restful sleep at the 7-day, 14-day, and 21-day intervals compared to the control group. However, they did not compare the commercial unit to ICE. In contrast, a study by Kraeutler and colleagues⁸ randomized 46 patients to receive either CC or ICE in the setting of arthroscopic shoulder surgery. Although no significant difference was observed in morphine equivalent dosage between the 2 groups, the CC group used more pain medication on every postoperative day during the first week after surgery. They found no difference between the 2 groups with regards to narcotic consumption or pain scores. The results of this study mirror those by Kraeutler and colleagues,⁸ demonstrating no difference in pain scores, sleep quality, or narcotic consumption.

With rising costs in the US healthcare system, a great deal of interest has developed in the application of value-based principles to healthcare. Value can be defined as a gain in benefits over the costs expended.¹⁴ The average cost for a commercial CC unit used in this study was \$260. A pack of ICE is a nominal cost. Based on the results of this study, the cost of the commercial CC device may not be justified when compared to the cost of an ice pack.

The major strengths of this study are the randomized design and multiple data points during the early

postoperative period. However, there are several limitations. First, we did not objectively measure compliance of either therapy and relied only on a patient survey. Usage of the commercial CC unit in hours decreased over half between days 3 and 14. This occurred despite training on the application and specific instructions. We believe this reflects “real-world” usage, but it is possible that compliance affected our results. Second, all patients in this study had a single-shot interscalene block. While this is standard at our institution, it is possible that either CC or ICE would have a more significant effect in the absence of an interscalene block. Finally, we did not evaluate final outcomes in this study and therefore cannot determine if the final outcome was different between the 2 groups. Our goal was simply to evaluate the first 2 weeks following surgery, as this is the most painful period following TSA.

Conclusion

There was no difference between CC and ICE in terms of pain control, quality of sleep, patient satisfaction, or narcotic consumption following TSA. CC may offer convenience advantages, but the increased cost associated with this type of unit may not be justified.

Key Info

Figures/Tables

Figures / Tables:

Table 1. Summary of Surgical Cases

	CC group (n = 20)	ICE group (n = 20)
Primary TSA	7 (35%)	9 (45%)
Primary RSA	12 (60%)	9 (45%)
Revision arthroplasty	1 (5%)	2 (10%)

Abbreviations: CC, continuous cryotherapy; ICE, plain ice; RSA, reverse shoulder arthroplasty; TSA, total shoulder arthroplasty.

Table 2. Summary of VAS Pain Scores With Cold Therapy

	CC group (mean ± SD)	ICE group (mean ± SD)	P value	95% CI
Preoperative	5.9 ± 4.1	6.8 ± 5.3	.121	3.3-8.3
24 hours	4.2 ± 3.0	4.3 ± 3.1	.989	2.9-5.7
3 days	4.8 ± 2.7	4.7 ± 3.2	.944	3.2-6.3
7 days	2.9 ± 1.8	3.3 ± 2.5	.593	2.1-4.4
14 days	2.5 ± 2.1	2.7 ± 1.8	.742	1.5-3.6

Abbreviations: CC, continuous cryotherapy; CI, confidence interval; ICE, plain ice; VAS, visual analog

scales.

Table 3. Summary of Narcotic Consumption in Morphine Equivalents

	CC group (mean ± SD)	ICE group (mean ± SD)	P value	95% CI
24 hours	43.0 ± 36.7	38.0 ± 42.9	.579	17.9-60.1
3 days	149.0 ± 106.5	116.3 ± 108.9	.201	63.4-198.7
7 days	308.1 ± 234.0	228 ± 258.3	.181	107.1-348.9
14 days	430.8 ± 384.2	347.5 ± 493.4	.213	116.6-610.6

Abbreviations: CC, continuous cryotherapy; CI, confidence interval; ICE, plain ice.

Table 4. Summary of VAS Sleep Quality With Cold Therapy^a

	CC group (mean ± SD)	ICE group (mean ± SD)	P value	95% CI
24 hours	5.1 ± 2.8	4.3 ± 2.4	.382	3.2-6.4
3 days	5.1 ± 1.9	5.3 ± 2.3	.601	4.2-6.5
7 days	6.0 ± 2.3	6.7 ± 2.1	.319	4.9-7.7
14 days	6.5 ± 2.3	7.1 ± 2.5	.348	5.3-8.4

^a0-10 rating with 10 being the highest possible score.

Abbreviations: CC, continuous cryotherapy; CI, confidence interval; ICE, plain ice; VAS, visual analog scales.

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