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Compressive cryotherapy versus ice—a prospective, randomized study on postoperative pain in patients undergoing arthroscopic rotator cuff repair or subacromial decompression

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Background: The purpose of this study was to compare the effect of compressive cryotherapy (CC) vs. ice on postoperative pain in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression. A commercial device was used for postoperative CC. A standard ice wrap (IW) was used for postoperative cryotherapy alone.

Methods: Patients scheduled for rotator cuff repair or subacromial decompression were consented and randomized to 1 of 2 groups; patients were randomized to use either CC or a standard IW for the first postoperative week. All patients were asked to complete a ''diary'' each day, which included visual analog scale scores based on average daily pain and worst daily pain as well as total pain medication usage. Pain medications were then converted to a morphine equivalent dosage.

Results: Forty-six patients completed the study and were available for analysis; 25 patients were randomized to CC and 21 patients were randomized to standard IW. No significant differences were found in average pain, worst pain, or morphine equivalent dosage on any day.

Conclusion: There does not appear to be a significant benefit to use of CC over standard IW in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression. Further study is needed to determine if CC devices are a cost-effective option for postoperative pain management in this population of patients.

Level of evidence: Level II, Randomized Controlled Trial, Treatment Study.

Keywords: Compressive cryotherapy; cold compression; cryotherapy; postoperative pain; shoulder arthroscopy; rotator cuff repair; subacromial decompression; morphine equivalent dosage

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The Colorado Multiple Institutional Review Board granted approval for this study: Protocol 07-0403.

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Postoperative pain control remains an issue in patients undergoing rotator cuff repair[1,4,5,16,19] and subacromial decompression.[6-8,12] Cryotherapy has been used for centuries in the management of pain. The physiologic benefits of cryotherapy are well documented in the literature and range from local modulation of blood flow and oxygen

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utilization[18] to spinal cord–mediated reflex arcs.[2,9] Compression has often been used to decrease local edema formation after musculoskeletal injury and has also been shown to decrease pain and muscle spasms through proprioceptive feedback loops. Cryotherapy has been shown to reduce pain in the early postoperative period for patients undergoing open rotator cuff repair,[14,15] shoulder stabilization,[14,15] biceps tenodesis,[14] total shoulder arthroplasty,[15] and arthroscopic subacromial decompression[14] compared with control groups receiving no cryotherapy. In addition, compressive cryotherapy (CC) has been shown to reduce postoperative pain scores after total knee replacement,[10] anterior cruciate ligament reconstruction,[13] and wrist arthroscopy.[11]

Although prior studies have shown that CC is effective compared with no cryotherapy, no studies have compared CC with cryotherapy or ice alone.

A commercial device, the Game Ready (CoolSystems, Inc., Concord, CA, USA), provides active, continuous cryotherapy and intermittent pneumatic compression to the postoperative shoulder, which may provide better treatment than standard ice wrap (IW) alone. The purpose of this study was to compare the effect of CC vs. ice on pain during the immediate postoperative week in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression. We hypothesized that both pain and narcotic use would be lower in the CC group.

Materials and methods

Institutional Review Board approval for this study was obtained before beginning of the study. Patients undergoing arthroscopic rotator cuff repair or subacromial decompression by the senior surgeon were prospectively identified and offered participation in the research study. Inclusion criteria included men and women 18 to 75 years old undergoing unilateral rotator cuff repair or subacromial decompression. Exclusion criteria included nonambulatory patients; patients with any bleeding coagulopathies; and patients with a history of congestive heart failure, deep venous thrombosis, pulmonary embolism, pulmonary edema, vascular impairment, thrombophlebitis, or compromised local circulation.

After informed consent was obtained, patients were randomized to 1 of 2 treatment groups on the basis of computer randomization. Randomization was performed before study initiation using the random number generator function in Microsoft Excel. The CC group used the Game Ready device for the first postoperative week (days 0-7). The cryotherapy alone (IW) group used a standard IW during the same period. Patients were instructed to apply their respective cryotherapy for 1 hour followed by 1 hour of no treatment for the first 72 hours postoperatively (days 0-2) during all waking hours of the day. For days 3 to 7, patients were instructed to apply their cryotherapy 2 or 3 times per day, any time of day, for 1 hour each time.

The standard IW consisted of zip lock bags that were used for the ice and an ACE bandage (3M, St. Paul, MN, USA) that was wrapped over the ice bag and around the shoulder and body (Fig. 1).

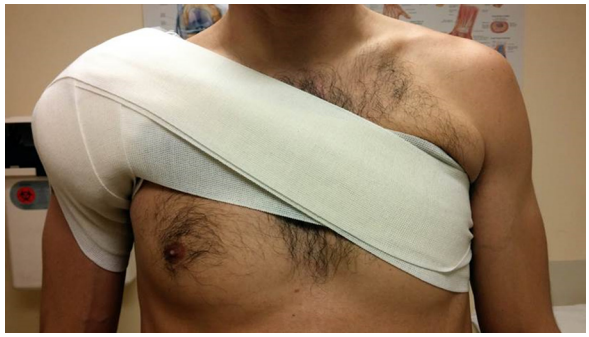

Figure 1 ACE shoulder bandage.

Figure 2 Game Ready shoulder wrap.

The Game Ready device consists of an inflatable shoulder wrap (Fig. 2) with an electrical pump that fills the wrap with compressed air and ice water. The shoulder wrap, which comes in different sizes to best fit the patient, is connected to a control unit (Fig. 3) into which water and ice are added. The control unit allows patients to manage compression level, temperature, and treatment time. Before their operation, patients were shown how to use the Game Ready device and were given the device to begin use immediately after surgery. Patients were instructed to adjust the compression level according to their comfort and to set the temperature to the coldest temperature tolerated.

All patients were asked to complete a ''diary'' each day. In this diary, patients marked their pain level on a 10-cm visual analog scale (''no pain'' to ''extreme pain'') twice each day. Pain scores were then measured to the nearest millimeter for a score of 0 (no

Figure 3 Game Ready control unit.

pain) to 100 (extreme pain). Patients were also instructed to document all narcotics taken throughout the duration of the study. Finally, patients recorded the number of times that cryotherapy was applied each day and the duration of each application. At the first postoperative appointment (7-10 days postoperatively), each patient was asked to complete a modified version of the acute 12-Item Short Form Health Survey (SF-12, version 2), in which questions regarding the "past 4 weeks" were changed to the "past week."

Statistical analysis

Visual analog scale scores were measured and scored on a scale of 0 to 100. Medications were converted to morphine equivalent dosage (MED) according to the conversions shown in Table I. Student *t* tests were used to compare numerical data between CC and IW groups. A P value $< .05$ was considered statistically significant.

Results

Fifty-seven patients were consented and enrolled in this study. Eleven (11 of 57, 19%) of these patients were excluded for an incomplete diary or nonadherence to the research protocol, leaving 46 patients for data analysis. Twenty-five patients remained who had been randomized to the CC group and 21 patients who had been randomized to the IW group. Average age at the time of surgery was 55.4 years in the CC group and 55.8 years in the IW group ($P = .91$). A list of procedures performed is shown in Table II.

Table I Equianalgesic dosages

Medication	Equianalgesic dosage
Morphine	3 mg
Oxycodone	2 mg
Hydrocodone	3 mg

The patients' medications were converted to a morphine equivalent: 1 mg of oral morphine = 1 morphine equivalent.

Table II Surgical procedures

Procedure	CC	IW
Subacromial decompression	23 (92%)	16 (76%)
Rotator cuff repair	17 (68%)	15 (71%)
Distal clavicle excision	15 (60%)	4 (19%)
Biceps tenodesis	9 (36%)	8 (38%)
Débridement of glenohumeral joint	6 (24%)	6 (29%)
Biceps tenotomy	4 (16%)	2 (10%)
Débridement of labrum	3 (12%)	3 (14%)

CC, cold compression; *IW*, ice wrap.
Forty-six patients underwent a total of 131 procedures. Included in each column is the number of patients who underwent each procedure. Numbers in parentheses indicate the percentage of patients in each group who underwent each procedure. Every patient in the study underwent arthroscopic rotator cuff repair and/or subacromial decompression.

Average scores for the SF-12 physical subscore were 33.9 and 34.2 for the CC and IW groups, respectively ($P = .93$). Average scores for the SF-12 mental subscore were 45.8 and 51.7 for the CC and IW groups, respectively ($P = .10$). No significant differences were noted regarding pain on the day or night of surgery (Table III). In addition, no significant differences were found in average pain, worst pain, or MED on days 0 to 7 (Fig. 4). The CC group used a higher MED every day, although this difference was not statistically significant on any single day. The average total MED during postoperative days 0 to 7 was also higher in the CC group (201 vs. 154), although this was not statistically significant ($P = .28$).

Patients were then stratified on the basis of the procedures performed. Among patients who underwent rotator cuff repair (with or without subacromial decompression), no significant differences were found in terms of average pain, worst pain, or MED on any postoperative day between the CC and IW groups. Likewise, no significant differences were found in these variables among patients who underwent subacromial decompression (with or without rotator cuff repair).

Patients were also stratified on the basis of placement of a peripheral nerve block as part of their operative anesthesia. These data were available for 45 patients (45 of 46, 98%), of whom 25 received a peripheral nerve block and 20 did not. No significant differences were found on the basis

Table III Questions answered by patients on postoperative day 0

Question	CC score (0-100)	IW score (0-100)	*P* value
Pain 4 to 6 hours postoperatively	30	24	.53
Worst pain on night of surgery	40	32	.40
Could you lay comfortably in bed on night of surgery?	46	40	.62
Were you able to sleep on night of surgery?	35.0	35.5	.96
How often does your shoulder hurt? (day 0)	41	38	.83
How bad is your pain? (day 0)	45	41	.67

CC, cold compression; *IW*, ice wrap.
All questions were answered on a visual analog scale.

of peripheral nerve block in terms of age at surgery, SF-12 scores, average or worst pain, or MED on any postoperative day. Furthermore, there was no significant difference found in terms of the percentage of patients receiving a nerve block in either treatment group ($P = .95$).

A post hoc power analysis was performed using published data from a prior study analyzing the effect of a cryotherapy device without compression (Aircast Cryo/Cuff; DJO Global, Vista, CA, USA) vs. no cryotherapy after shoulder surgery.[15] From this study, visual analog scale scores (0-100) of the worst pain experienced on the night of the operation (31.33 in the cryotherapy group, 56.49 in the noncryotherapy group) were used for the means in the power analysis. Because this study did not report standard deviations of these visual analog scale scores, we used the standard deviation of our own patients' visual analog scale scores of pain 4 to 6 hours postoperatively (32.20). A 2-sided test was performed with $\alpha = .05$ and power = 0.80. With use of these data, a desired sample size of 13 patients from each group was calculated.

Discussion

Rotator cuff tears are relatively common, with an incidence up to 51% in individuals older than 80 years.[3] Acromioplasties are performed in approximately 101.9 per 100,000 people in the general population.[17] Nearly 5.9% of acromioplasties are associated with complete rupture of the rotator cuff, whereas another 13.6% of acromioplasties are associated with sprains or strains of the rotator cuff.[17] Because of the frequency of these procedures, it is important to find the most effective postoperative pain reduction system.

Previous studies have compared the effect of cryotherapy vs. no cryotherapy after open rotator cuff repair[14,15] as well as after arthroscopic subacromial decompression.[14] In a study by Speer et al,[15] a Cryo/Cuff was used. This is a cryotherapy device that provides cold water into a shoulder wrap without pneumatic compression. Each patient filled out a questionnaire that included a visual analog scale regarding pain level. However, rather than marking their pain level each day, patients filled out a visual analog scale only on postoperative days 1 and 10. Pain levels were significantly lower in the cryotherapy group compared with the noncryotherapy group on days 1 and 10.

In another study,[14] a Polar Care unit (Breg Inc., Vista, CA, USA) was used, another non-CC device. Again, rather than having patients fill out a set of visual analog scales on a daily basis, the patients in this study marked their pain levels only on postoperative days 1, 7, 14, and 21. In patients undergoing arthroscopic procedures, pain intensity was significantly lower in the cryotherapy group compared with the noncryotherapy group on day 14. On days 1 and 21, pain intensity was lower in the cryotherapy group, but this was not statistically significant.

Both of the previous studies demonstrated that the use of cryotherapy provided a greater reduction in pain after various shoulder procedures compared with no cryotherapy. The current study investigated a comparison of CC vs. ice. We did not find any reduction of pain in comparing the 2 modalities. With these findings, it makes it difficult to recommend the use of a CC device such as Game Ready after arthroscopic rotator cuff repair or subacromial decompression. In addition, CC devices can be heavy to move about and are somewhat awkward and more complex to use than IWs. Furthermore, they are often not covered by insurance companies, and the cost to rent the Game Ready device is $190 for 9 days at our institution.

Although no statistically significant difference was found in MED between the 2 groups, the CC group used a higher amount of pain medication on every postoperative day for the week after surgery. Although not statistically significant, the difference in MED was clinically significant on days 5 to 7.

There are limitations to this study. Eleven patients (19%) were excluded for failing to fill out their pain diaries. Patients were not observed during treatment; thus, compliance with correct application of the respective cryotherapy is difficult to determine. There is also some inherent recall bias in asking a patient to fill out a diary. In addition, the power analysis was performed retrospectively

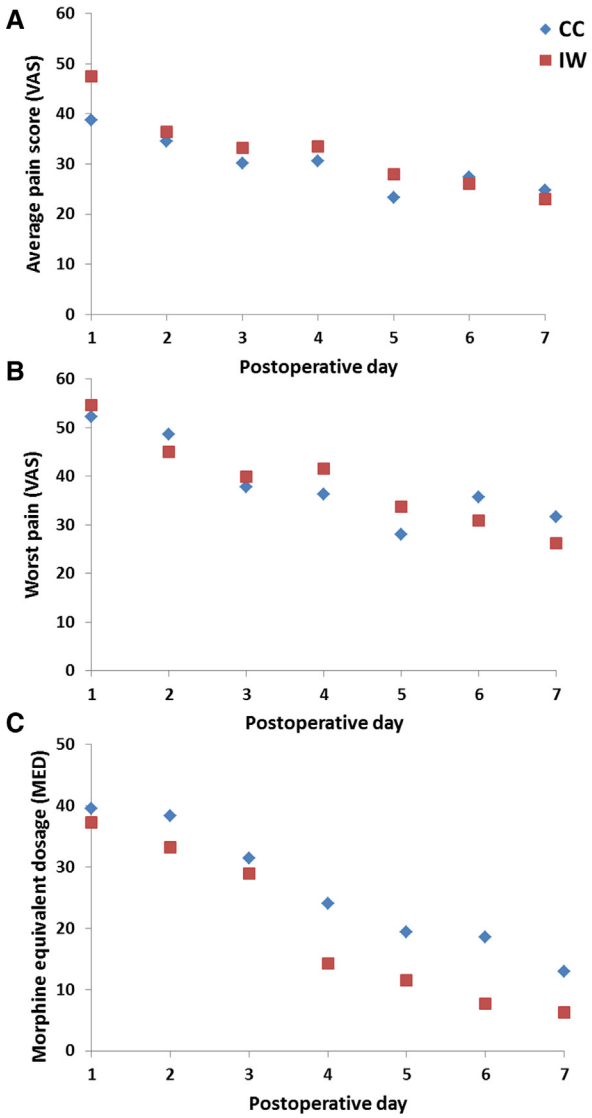

Figure 4 (**A**) Average pain scores, (**B**) worst pain scores, and (**C**) morphine equivalent dosage (*MED*). Pain scores were measured on a visual analog scale (*VAS*) from 0 (no pain) to 100 (extreme pain). *CC*, patients who used cold compression during days 0 to 7; *IW*, patients who used ice wraps during days 0 to 7.

to incorporate a reliable standard deviation into the analysis.

Strengths include the randomized study design as well as its being the first study comparing the use of CC to cryotherapy alone.

Conclusions

CC using the Game Ready device did not demonstrate significant reduction in postoperative pain or narcotic use in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression. On the basis of these results, we cannot recommend routine use of CC over standard IWs after shoulder arthroscopy.

Disclaimer

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