The efficacy of continuous cryotherapy on the postoperative shoulder: A prospective, randomized investigation

Hardayal Singh, MD,[a] Daryl C. Osbahr, BS,[b] Thomas F. Holovacs, MD,[a]
Patrick W. Cawley, DSc, OPA, RT,[c] and Kevin P. Speer, MD,[d]
Durham and Cary, NC, and Vista, Calif

This prospective, randomized investigation evaluated the efficacy of cryotherapy on subjective responses after both open and arthroscopic procedures on the shoulder. Seventy patients were randomly assigned to one of two study groups: (1) continuous cryotherapy group and (2) age-matched control group. Visual analog scales were used to assess subjective responses on postoperative days 1, 7, 14, and 21. On day 1, patients receiving cryotherapy reported significantly less pain during sleep and significantly more comfort in bed and rated their sleep as more restful than the control subjects. During days 7 through 21, cryotherapy subjects reported a significant reduction in frequency and intensity of pain, as well as less pain during shoulder rehabilitation, than the control subjects. These results indicate that cryotherapy is an effective method for postoperative pain control because it decreases the severity and frequency of pain and allows a return to normal sleep patterns while increasing overall postoperative comfort and satisfaction. (J Shoulder Elbow Surg 2001;10:522-5.)

INTRODUCTION

The use of cold for analgesia is a practice that dates to the time of Hippocrates in the 4th century BC.[8] Ice was commonly used as a preoperative anesthetic agent in the Middle Ages.[6] Although cryotherapy is in common use in the athletic training and rehabilitative environments to control pain and swelling after injury,[1-5,7-9,11] its use for control of pain after surgical procedures is not universally accepted. This lack of acceptance stems in part from a lack of carefully controlled clinical research. A number of deficiencies in the current research on cryotherapy exist, including a lack of standardized methodology, variability in the methods of cold application, and failure to quantify subjective variables that affect outcome.[1,2,11] In a recent investigation, Speer et al[10] demonstrated that the use of continuous cold therapy postoperatively was effective in reducing recovery time after shoulder surgery. The purpose of this investigation was to determine the efficacy of continuous cryotherapy on subjective responses after both open and arthroscopic procedures on the shoulder.

MATERIALS AND METHODS

Institutional review board approval was obtained before this investigation was begun, and all patients who agreed to participate signed an informed consent declaration. Seventy patients scheduled for either arthroscopic (38 patients) or open (32 patients) shoulder surgical procedures were recruited for this investigation. Thirty-two patients (15 open and 17 arthroscopic procedures) were randomly assigned to receive continuous cryotherapy, and 32 patients (15 open and 17 arthroscopic procedures) received no postoperative cryotherapy and served as the control group. A third group of 5 age-matched patients who received body temperature (warm) water in the continuous cryotherapy unit served as additional control subjects.

Open surgical procedures consisted of rotator cuff repair, anterior shoulder stabilization, posterior shoulder stabilization, and biceps tenodesis. Arthroscopic procedures included subacromial decompression, biceps tenotomy, capsulorrhaphy, and labral repair. Surgical anesthesia was standardized for both the open and arthroscopic groups as an interscalene block with 40 to 50 mL of 1% lidocaine in all patients with adjuvant intravenous sedation. All patients were operated on by the senior author (K.P.S.) to ensure that a standardized operative technique was used. Continuous cryotherapy was standardized through use of the Polar Care unit (Breg, Inc, Vista, Calif). All cryotherapy pads were fitted by one author (D.C.O.) to ensure consistency. Figure 1 shows a patient fitted with a continuous cryotherapy shoulder pad. The continuous

From the Division of Orthopaedic Surgery,[a] and the Coach Michael W. Krzyzewski Human Performance Research Laboratory, Division of Orthopaedic Surgery, Section of Sports Medicine,[b] Duke University Medical Center, Durham, NC; Breg, Inc, Vista, Calif[c]; and Cary Orthopaedics and Sports Medicine Specialists, Cary, NC.[d]

Reprint requests: Kevin P. Speer, MD, Southeastern Orthopedics, Sports Medicine, & Shoulder Center, 3404 Wake Forest Rd, Suite 101, Raleigh, NC 27609.

Copyright © 2001 by *Journal of Shoulder and Elbow Surgery* Board of Trustees.

1058-2746/2001/$35.00 + 0 **32/1/118415**
doi:10.1067/mse.2001.118415

cryotherapy system consists of a reservoir containing ice and water that are continuously circulated through the pad by means of an electrical pump to provide a constant temperature. Patients in the cryotherapy subgroup and home caregivers were instructed on the use of the continuous cryotherapy unit and were instructed to replenish the reservoir with ice every 4 to 6 hours as needed to ensure maintenance of the desired temperature.

Before this study was initiated, the subjective responses of 9 male and female volunteers were used to validate appropriate temperatures for the continuous cryotherapy system. Surface temperatures were monitored by thermocouples at 10 different locations about the subjects' shoulders. On the basis of subjective responses from these volunteers regarding comfort, a temperature range of 7.2°C to 13°C (45°F-55°F) was chosen as optimal for the continuously circulating water in the study subjects. For the warm-water control subjects, the reservoir was filled with warm tap water and the pump was turned on until the pad was filled. The pump was then turned off, and the water in the cryotherapy pad was allowed to equilibrate to body temperature. The pump was left off for the remainder of treatment in this group. Other than the addition of either continuous cryotherapy or water-filled arm pads, postoperative protocols were identical for all patients in this investigation. For both the warm-water control subjects and the continuous cryotherapy subjects, pad use was standardized as follows: first 48 hours postoperatively, the pad was applied continuously; days 2 through 7, the pad was applied while subjects were sleeping at night; and days 8 through 21, the pad was applied after rehabilitation exercise for 2 to 4 hours.

After surgery, each patient was provided with a diary to be filled out on the evening of postoperative days 1, 7, 14, and 21. Using standardized 100-mm visual analog scales, patients were asked to detail their subjective impressions of pain frequency, pain intensity, energy level during the day, sleep, and pain during exercise. Subjects were contacted regularly by an investigator and reminded to complete diary entries. On the visual analog scales, a higher percentage response indicated less pain, more comfort, etc. Visual analog scores were calculated by a blinded investigator. Between and within group differences were evaluated with repeated measures analysis of variance. When differences were identified, data were further characterized with a paired *t* test.

RESULTS

Only 5 patients were recruited for the warm-water control group. The application of pads filled with warm water proved to be provocative, with all patients in this group complaining of intolerable discomfort when the pads were applied. For ethical reasons, this subgroup was eliminated from the investigation.

Day 1 results

The mean results for questions administered on the first postoperative day are shown in Figure 2. As shown, cryotherapy subjects who underwent open procedures reported substantially less pain, significantly more comfort, significantly more restful sleep, and significantly reduced pain frequency than control subjects.

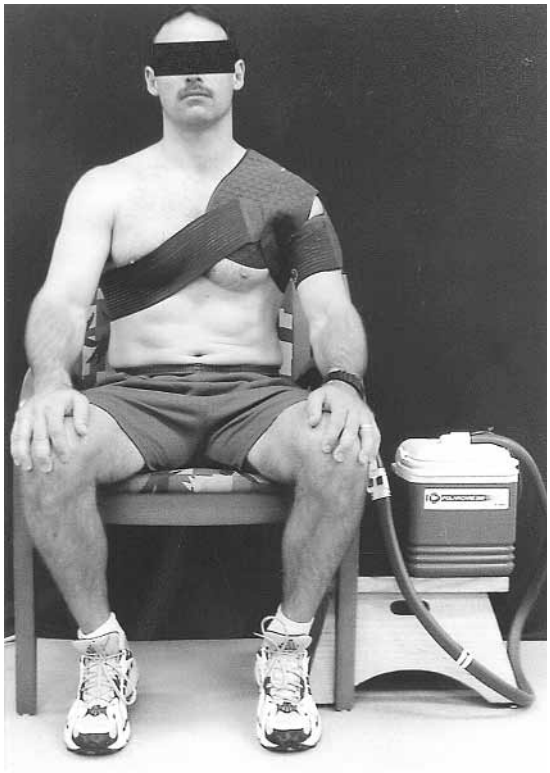

Figure 1 Photograph showing a patient fitted with the Polar-Care shoulder cuff.

As shown in Figure 2, *A*, the differences between cryotherapy and control subjects who underwent open procedures were statistically significant for the categories evaluating comfort, restful sleep, and pain frequency.

Day 7, 14, and 21 results

The subjective assessment of pain frequency in open procedure subjects for days 7 through 21 of the evaluation revealed that both control and cryotherapy subjects demonstrated a reduction in pain frequency from day 7 through day 21. Reductions for cryotherapy subjects were greater at all intervals and were statistically better at the day 14 interval ($P = .041$). These curves begin to converge by day 21. Cryotherapy subjects who underwent arthroscopic procedures demonstrated substantially better reduction in pain intensity than control subjects throughout the 21-day evaluation. In contrast to open procedure subjects, the curve for arthroscopic subjects and control subjects diverges over the 3 intervals, with a statistically significant reduction in pain frequency demonstrated by cryotherapy subjects at 21 days.

Subjective impressions of pain intensity for days 7 through 21 revealed that the cryotherapy subjects who underwent open procedures demonstrated less pain

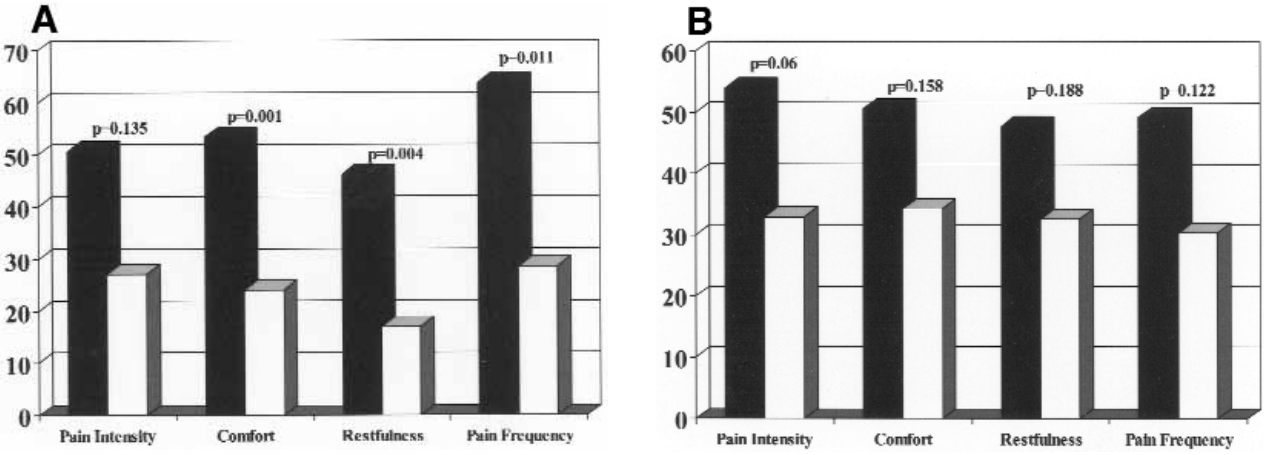

Figure 2 Bar graphs comparing patients receiving cryotherapy *(black bars)* versus the control subjects (*white bars*) for all of the day 1 questions for the open (**A**) and arthroscopic (**B**) groups.

intensity than control subjects, although these differences were not statistically significant at the 3 evaluation intervals. However, the results were dramatically different for cryotherapy subjects who underwent arthroscopic procedures. At day 7, control subjects reported lower pain intensities than cryotherapy subjects. However, by day 14, cryotherapy subjects demonstrated a significant and dramatic reduction in pain intensity ($P = .043$). At day 21, cryotherapy subjects continued to demonstrate substantial decreasing reductions in pain intensity, whereas the control subjects demonstrated a slight increase in pain intensity. This difference was nearly significant at .06.

Trends for pain associated with exercise nearly mirror those reported for pain intensity. Again, cryotherapy subjects who underwent open procedures reported less pain than control subjects at each evaluation, although these differences were not statistically significant. As noted for pain intensity, the curves for open procedure subjects tended to converge by day 21. At day 7, control subjects who underwent arthroscopic procedures reported slightly less pain than cryotherapy patients. However, by day 14, cryotherapy subjects reported significantly less pain during exercise than control subjects ($P = .040$). This trend continued through day 21, at which the cryotherapy subjects reported continued and significant improvement, whereas control subjects reported little improvement during this interval ($P = .044$).

The results for subjective responses concerning energy levels for the days 7 through 21 revealed that cryotherapy subjects in both the open procedure and arthroscopic procedure groups demonstrated better energy levels than control subjects at any interval. These differences were not statistically significant.

DISCUSSION

The goal of this investigation was to build on the earlier study by Speer et al[10] of the impact of cryotherapy on the postoperative shoulder. In that study the use of cryotherapy was assessed only in postoperative open surgical shoulder cases and with a manual delivery system that needed cold water to be replenished every 60 to 90 minutes. The data showed that cryotherapy was effective in providing a significant improvement in the postoperative recovery. The current study used an advanced motorized continuous cryotherapy delivery system and evaluated its utility in both arthroscopic and open surgical procedures by using visual analog scales to assess patients' subjective postoperative sensations and responses for 28 postoperative days.

This investigation tested 2 hypotheses: (1) there is a significant decrease in postoperative shoulder pain in patients who use continuous cryotherapy, and (2) the application of cryotherapy increases overall patient comfort and satisfaction. When compared with the control group during the first night after surgery, patients in the cryotherapy group stated that their shoulders hurt less frequently (open and arthroscopic surgeries), they could lie more comfortably in bed (open surgery), and their sleep was more restful (open and arthroscopic surgeries). Because these differences were significant on the very first night after surgery, it can be safely inferred that cryotherapy attains its efficacy very early on in its application and continues throughout the course of the study.

Therefore we feel that the 2 hypotheses were illustrated adequately. First, cryotherapy reduced the amount of pain and discomfort perceived by patients. The patients slept longer and more comfortably and thus were able to re-establish their normal daily pattern

quickly after surgery. This establishment of a normal pattern allowed better and faster rehabilitation in these patients. Thus overall patient satisfaction and comfort were increased by the application of cryotherapy.

As is the case with many studies, there are methodological factors that should be taken into account when evaluating our results. Although our patients were age-matched, the population of patients was diverse, with varying demographic characteristics and ages. In addition, all patients were not standardized in terms of the same orthopaedic procedure. However, our patients were grouped according to the overall classification of either an arthroscopic or open procedure, and all surgeries were performed the same author (K.P.S.).

There are many theories regarding the mechanism of action of cryotherapy. It is thought to work as a local anesthetic agent, causing the pain threshold of the nerve fibers to be raised by the lowered temperature. Through early application of cryotherapy, hemorrhaging, initial swelling, and inflammation may be reduced by reflex capillary constriction. Also, the basal metabolism and cell metabolism speeds are retarded by reduced tissue temperature.

In the 48 hours after surgery or trauma to the shoulder, the major benefits of cryotherapy are likely to be its effects on metabolism and inflammation and its analgesic effects. The direct analgesic effects of cold may actually be the most pertinent effects of cryotherapy. Pain reduction occurs after cooling tissue temperatures to 50°F to 60°F. The mechanism of this pain relief is unclear but is thought to be the breaking of the pain cycle, whereby pain provokes muscle spasm, which then causes pain. Thus, in the course of clinical progress, continuous cryotherapy leads to a reduction in the negative psychological consequences of the injury and helps lead to an acceleration of the healing process.

Continuous cryotherapy is an efficacious and safe adjunct to postoperative pain control. It has been objectively shown to have a positive impact on subjective comfort variables such as pain, comfort, and sleep. The delivery of cryotherapy with a continuous motor-driven system renders easier use in patients with one immobilized shoulder or arm.

REFERENCES

1. Basur RL, Shephard E, Mouzas GL. A cooling method in the treatment of ankle sprains. Practitioner 1976;216:708-11.
2. Hocutt JE Jr, Jaffe R, Rylander CR, Beebe JK. Cryotherapy in ankle sprains. Am J Sports Med 1982;10:316-9.
3. Knight KL. Cryotherapy: theory, technique, and physiology. Chattanooga (TN): Chattanooga Corporation; 1985.
4. Lehmann JF, Warren CG, Scham SM. Therapeutic heat and cold. Clin Orthop 1974;99:207-45.
5. McMaster WC, Liddle S, Waugh TR. Laboratory evaluation of various cold therapy modalities. Am J Sports Med 1978;6:291-4.
6. McDonald WD, Guthrie JD Jr. Cryotherapy in the postoperative setting. J Foot Surg 1985;24:438-41.
7. McDowell JH, McFarland EG, Nalli BJ. Use of cryotherapy for orthopaedic patients. Orthop Nurs 1994;13:21-30.
8. Meeusen R, Lievens P. The use of cryotherapy in sports injuries. Sports Med 1986;3:398-414.
9. Omer GE Jr, Brobeck AG. An evaluation of ice application with postoperative dressings. Clin Orthop 1971;81:117-21.
10. Speer KP, Warren RF, Horowitz L. The efficacy of cryotherapy in the postoperative shoulder. J Shoulder Elbow Surg 1996;5:62-8.
11. Starkey JA. Treatment of ankle sprains by simultaneous use of intermittent compression and ice packs. Am J Sports Med 1976;4:142-4