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ORIGINAL ARTICLE

Effect of Cryotherapy After Elbow Arthrolysis: A Prospective, Single-Blinded, Randomized Controlled Study

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Abstract

Objective: To investigate the effect of cryotherapy after elbow arthrolysis on elbow pain, blood loss, analgesic consumption, range of motion, and long-term elbow function.

Design: Prospective, single-blinded, randomized controlled study.

Setting: University hospital.

Participants: Patients (N=59; 27 women, 32 men) who received elbow arthrolysis.

Interventions: Patients were randomly assigned into a cryotherapy group (n=31, cryotherapy plus standard care) or a control group (n=28, standard care).

Main Outcome Measures: Elbow pain at rest and in motion were measured using a visual analog scale (VAS) on postoperative day (POD) 1 to POD 7 and at 2 weeks and 3 months after surgery. Blood loss and analgesic consumption were recorded postoperatively. Elbow range of motion (ROM) was measured before surgery and on POD 1, POD 7, and 3 months after surgery. The Mayo Elbow Performance Score (MEPS) was evaluated preoperatively and 3 months postoperatively.

Results: VAS scores were significantly lower in the cryotherapy group during the first 7 PODs, both at rest and in motion ($P<.05$). There were no significant differences between the 2 groups in VAS scores at 2 weeks and 3 months after surgery. Less sufentanil was consumed by the cryotherapy group than the control group for pain relief ($P<.01$). No significant differences were found in blood loss, ROM, and MEPS between the 2 groups ($P>.05$).

Conclusions: Cryotherapy is effective in relieving pain and reducing analgesic consumption for patients received elbow arthrolysis. The application of cryotherapy will not affect blood loss, ROM, or elbow function.

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Elbow stiffness is a common complication after elbow trauma.[1] Risk factors of posttraumatic stiffness include immobilization, pain, soft tissue contracture, and osseous congruency disruption.[2] Surgical intervention by open or arthroscopic release has proven to be effective in dealing with severe elbow stiffness if nonoperative management fails.[3-5] Early-stage flexion-extension exercises are encouraged postoperatively to maintain the arc of motion achieved during surgery. However, pain is a dominant patient complaint in the early phase after elbow arthrolysis and affects postoperative rehabilitation. Pain intervention improves patient quality of life.[6]

Cryotherapy is the local use of low temperatures in medical therapy, and it was first mentioned by Hippocrates.[7] It is an effective option in relieving pain and swelling in various acute injuries. The application of cold has several physiological effects, including lowering skin temperature,[8] reducing blood flow through local vasoconstriction,[9] and decreasing nerve conduction.[10] It also has the effects of decreasing tissue metabolism and reducing cytokine levels, which may have some anti-inflammatory properties.[11]

Several studies on the postoperative effects of cryotherapy have been conducted, but the results are still controversial. Previous randomized trials of cryotherapy after total knee

The cryotherapy device was owned by the Department of Orthopaedics of our hospital, and we used it free of charge during the study.

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arthroplasty (TKA) show small benefits in blood loss and knee range of movement (ROM) on discharge, but they do not show significant changes in pain, swelling, or analgesia requirements.[12] The postoperative application of local cooling in the hip and shoulder proved to be effective in relieving pain in the early stages after surgeries.[13,14] However, there have been no reports on postoperative cryotherapy applied after elbow arthrolysis. To our knowledge, this is the first study to examine the clinical effects of cryotherapy on the postoperative rehabilitation of patients with elbow stiffness.

This study aimed to investigate the clinical effect of postoperative cryotherapy after elbow arthrolysis. It is expected that cryotherapy can reduce elbow pain, blood loss, and analgesic consumption and can improve elbow ROM and long-term elbow function.

Methods

A prospective, single-blinded, randomized controlled study was conducted at our institution between November 2012 and June 2013. Patients with elbow stiffness who were between the ages of 18 and 70 years and requiring elbow arthrolysis were included in the study. The exclusion criteria were as follows: stiffness associated with local loss of sensation, rheumatoid arthritis, Raynaud disease, peripheral vascular disease, or cold intolerance. Written informed consent was obtained from all patients. The study conformed to the Declaration of Helsinki and was approved by the ethical committee of Shanghai Jiao Tong University Affiliated Sixth People's Hospital.

On preoperative day 1, patients were randomly assigned to 1 of 2 groups: cryotherapy group or control group. Randomization was carried out by the researchers using computer-generated random numbers. Patients in different groups were arranged into different wards to ensure that the patients were blinded to the study.

Surgery was performed under brachial plexus anesthesia in a supine position. For all patients, open arthrolysis and hinged external fixation was performed by the same surgeon. A suction drain was left in place before skin closure. Sufentanil at a dose of 100μg was placed in a continuous intravenous infusion device and was administered on patient's demand in the first 2 days after surgery for pain relief. The analgesic was given at a rate of 2μg/h, and the maximum dose in a 24-hour period was 48μg. When the patients decided to stop using sufentanil, the actual dose of analgesic consumption was recorded. The patients were prescribed 25mg of indomethacin 3 times daily for 6 weeks postoperatively to prevent heterotopic ossification.

In the cryotherapy group, the Cryo/Cuff system[a] was applied to operated elbows as a way of postoperative cooling. The system is a cooler device linked to a specialized cuff by a tube. The cuff covers the gauze wrapped around the operated elbow (fig 1). The cooler contains ice water, and the cuff is filled after the elevation of the cooler for about 30 seconds. The system provides continuous cooling combined with pulsing compression (30mmHg) at 30-second intervals. Therefore, cryotherapy was administered in combination with compression in this study. The Cryo/Cuff system was used for at least 3 sessions of 60min/d for 1 week, starting from the day of operation. The combined cooling and compression was strictly applied even if there was not sufficient time for patients to carry on postoperative exercising. All patients were hospitalized during the study period.

List of abbreviations:

MEPS	**Mayo Elbow Performance Score**
POD	**postoperative day**
ROM	**range of motion**
TKA	**total knee arthroplasty**
VAS	**visual analog scale**

Fig 1 The Cryo/Cuff system is a cooler connected to a specialized cuff. The cuff covers the gauze wrapped around the operated elbow.

In the control group, the same postoperative management as the cryotherapy group was carried out with the exception of the cryotherapy treatment.

All patients were treated by the same physical therapist and started an exercise program on postoperative day (POD) 1. Postoperative exercises consisted of active, assisted, and passive elbow flexion and extension movements. The exercises were gradually increased as much as tolerable for the patient to a period of 1 hour for each session. The fixator was locked for about 10 minutes when the elbow reached its extreme of flexion or extension after each session of exercise. The patient was encouraged to take a total of 4 hours of exercises; however, the exact time of exercising was not recorded. The progressive exercise program was continued with the help of the fixator after the patient was discharged from the hospital. The fixator was removed 6 to 8 weeks after arthrolysis as an outpatient procedure.

Pain was measured on a visual analog scale (VAS) by the physical therapist. The scale is a 10-cm horizontal line, with a description of no pain on the left end and very severe pain on the right. Patients were instructed to draw a mark on the line that represents the intensity of the pain they felt during exercise and the rest of the day. The VAS score was determined by the distance between the left end of the line and the patient's mark (cm). Pain was recorded from POD 1 to POD 7 and at 2 weeks and 3 months postoperatively.

Blood loss during the first 72 hours postoperatively was measured by the drain discharge. The total doses of sufentanil administered for pain relief were recorded. ROM for flexion and extension was recorded with a goniometer preoperatively on PODs 1 and 7 and at 3 months postoperatively. The Mayo Elbow Performance Score (MEPS)[15] was evaluated preoperatively and at 3 months postoperatively. This score is a comprehensive evaluation of elbow function, including pain (45 points), motion (20 points), stability (10 points), and function (25 points).

Statistical tests were selected based on the distribution and type of data. Statistical analyses of demographics, blood loss, and ROM were performed with use of an unpaired *t* test. Pain scores,

analgesic consumption, and MEPS were analyzed via the Mann-Whitney U test. A P value $\leq$.05 was regarded as statistically significant. Cohen d effect size was calculated. All statistical analyses were performed with use of statistical software SPSS version 19.0.[b]

Results

Sixty-one patients met the inclusion criteria. Two patients refused to participate after being informed about the trial; therefore, 59 patients were enrolled in this study, including 27 women and 32 men. Thirty-one patients (14 women, 17 men) were assigned to the cryotherapy group, and 28 (13 women, 15 men) patients were assigned to the control group. No patients dropped out during the study. There were no missing data for all the demographics and outcome variables under consideration. There were no significant differences between patients in the cryotherapy and control groups (P>.05) in terms of age, height, body weight, or duration of surgery. Table 1 shows the patient demographics and surgery time for the 2 groups.

VAS scores from PODs 1 through 7 in the cryotherapy group were significantly lower (P<.05) than those in the control group, both at rest and in motion. Pain levels at 2 weeks and 3 months postoperatively were not significantly different (P>.05) between the 2 groups (fig 2 and table 2).

With regard to analgesic consumption, the cryotherapy group consumed less sufentanil than the control group. The mean analgesic consumption was 86.5±18.0μg for the cryotherapy group and 93.1±13.2μg for the control group (P<.01) (table 3).

The mean volume of drainage output in the cryotherapy group was 132.6±76.9mL in the first 24 hours after surgery and 304.4±134.4mL in total for the 72 hours postoperatively compared with 168.9±104.7mL and 341.0±166.6mL, respectively, in the control group (see table 2). There was no statistically significant difference (P>.05) regarding the postoperative blood loss between the cryotherapy group and control group.

There was no significant difference between the cryotherapy group and control group with respect to ROM (36.8°±26.8° vs 37.3°±31.8°) and MEPS (60.6°±7.3° vs 60.9°±8.5°) preoperatively. Both groups had significantly increased ROM on POD 1 compared with preoperative values and improved ROM on POD 7. There was no difference between the 2 groups. At the 3-month follow-up, they had similar (P>.05) ROM (125.0°±13.2° vs 123.4°±10.8°) and MEPS (93.1°±4.2° vs 92.5°±4.0°) (see table 2).

One patient in the control group had a blood transfusion. No frostbite, neuroparalysis, or other cold-related complications were observed during the study. There was no difference in terms of wound healing between groups.

Table 1 Demographics and duration of surgery for the cryotherapy group and control group

Demographics	Cryotherapy Group	Control Group
No. of elbows	31	28
Sex, F/M	14/17	13/15
Age (y)	37.5±13.3	34.9±10.6
Height (cm)	165.4±6.7	167.8±7.3
Weight (kg)	60.0±8.3	64.4±10.8
Duration of surgery (h)	2.8±0.7	2.7±0.7

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviations: F, female; M, male.

Discussion

Our results suggest that cryotherapy relieves pain after elbow release. The cryotherapy group had a significantly lower postoperative pain score and lower analgesic consumption than the control group, indicating the importance of cryotherapy in the early phase after surgery. However, no significant difference was observed in terms of postoperative blood loss, ROM, and elbow function.

Postoperative recovery and complaints can be influenced by factors such as age and sex, preoperative status, surgical trauma, surgeon experience, duration of surgery, and postoperative medication. All patients in the current study were operated on by an experienced surgeon and received a standardized inpatient treatment protocol after surgery, except for the cooling intervention. Furthermore, there was no significant difference in patient demographics and surgery time; therefore, the results collected from the cryotherapy group and control group are comparable.

Researchers have conducted clinical trials to study the efficacy of postoperative cryotherapy for the knee,[16-20] hip,[14] shoulder,[13,21,22] and wrist[23] joints. However, to our knowledge, cryotherapy after elbow surgery, especially elbow arthrolysis, was not studied in any of these trials. Our present findings are consistent with the previous studies on pain control.

In a prospective randomized study carried out by Morsi,[17] 30 patients who received bilateral TKA were studied with the objective of discovering the impact of continuous-flow cold therapy on pain. Morsi found that the patients in the cold therapy group suffered less pain and used fewer pain medications than those in the control group. A similar pain-relieving effect was noted by Saito et al.[14] In their work, patients who received total hip arthroplasty and were administered continuous local cooling were compared with a control group. In contrast, no significant difference in postoperative pain between cryotherapy-treated patients and controls was found in the study conducted by Hölmstrom and Härdin.[18] However, they found that morphine consumption was significantly greater in the control group.

The efficacy of cryotherapy in reducing postoperative blood loss is controversial. Leutz and Harris[16] found significant decreases in blood loss in a continuous cold therapy group compared with controls; however, the patients were grouped according to surgeon preference instead of random allocation. A systematic review conducted by Adie et al[12] showed a slight benefit from cryotherapy treatment in blood loss after TKA; however, the transfusion rate was not significantly changed. These benefits were not found in trials performed on shoulders or hips.[13,14,21,22] In the current study, we found no significant difference in postoperative hemovac output, but the drain discharge in the first 24 hours postoperatively was slightly less in the cryotherapy group than in the control group.

Despite the noticeable pain relief after surgery, no significant difference was seen in postoperative ROM and elbow function. This indicates that postoperative rehabilitation is influenced by multiple factors and not just pain. Early postoperative elbow joint mobilization was emphasized to maintain the degree of elbow flexion and extension movements gained during elbow arthrolysis. The hinged external fixator provided stability to the elbow joint, which allowed for early exercise to prevent intra-articular and muscle adhesion around the joint.[24] Good compliance was

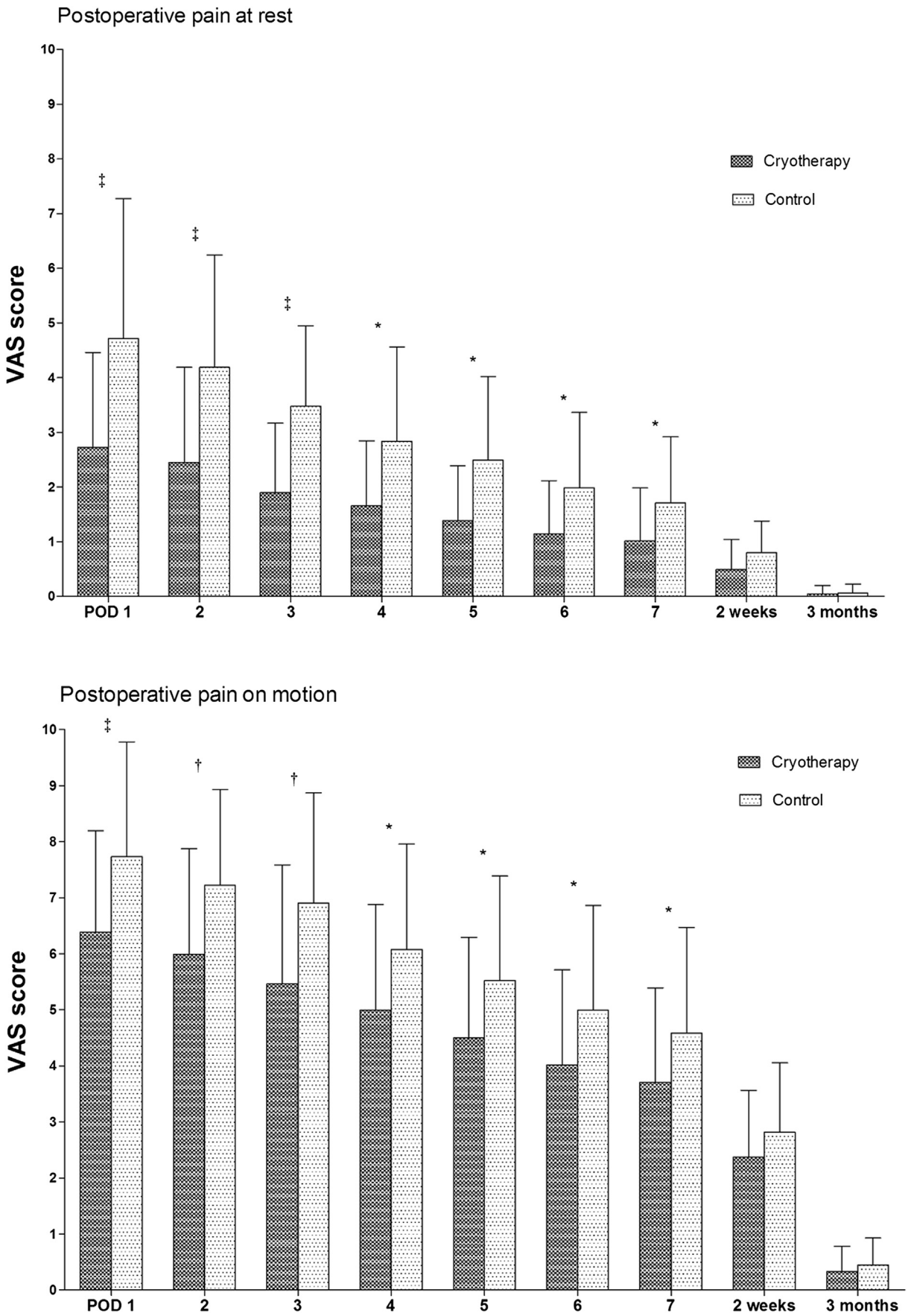

Fig 2 VAS scores for elbow pain at rest and in motion from PODs 1 through 7 and at 2 weeks and 3 months for the cryotherapy group and control group. *$P<.05$; †$P<.01$; ‡$P<.001$.

Table 2 Comparison of postoperative pain levels between the cryotherapy group and control group

	At Rest				In Motion			
Time	Cryotherapy	Control	*P*	ES	Cryotherapy	Control	*P*	ES
POD 1	2.7±1.7	4.7±2.6	.001	0.91	6.4±1.8	7.7±2.1	.001	.66
POD 2	2.5±1.7	4.2±2.1	.001	0.89	6.0±1.9	7.2±1.2	.007	.76
POD 3	1.9±1.3	3.5±1.5	<.001	1.14	5.5±2.1	6.9±1.5	.009	.77
POD 4	1.7±1.2	2.8±1.7	.015	0.75	5.0±1.9	6.1±1.7	.034	.61
POD 5	1.4±1.0	2.5±1.5	.012	0.86	4.5±1.8	5.5±1.8	.033	.56
POD 6	1.1±1.0	2.0±1.4	.042	0.74	4.0±1.7	5.0±1.9	.030	.55
POD 7	1.0±1.0	1.7±1.2	.043	0.63	3.7±1.7	4.6±2.0	.037	.48
2wk	0.5±0.5	0.8±0.6	.053	0.54	2.4±1.2	2.8±1.3	.198	.32
3mo	0.1±0.2	0.1±0.2	.616	0.00	0.3±0.5	0.4±0.5	.396	.20

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviation: ES, effect size.

important for the rehabilitation procedure and the recovery of elbow function in patients. One advantage of our study was that all the patients enrolled were inpatients, and postoperative care was well applied during the early phase of rehabilitation. The outcomes may be influenced if patients do not receive such targeted physical therapy intervention.

Various methods of local cooling have been reported in previous studies. Plastic ice bags and refreezable silica gel packs are widely used traditional forms of cryotherapy in orthopedics and sports medicine. The Robert-Jones bandage[20] and a continuous-flow cold therapy device[17] were applied after TKA. Complex methods (eg, hyperbaric gaseous cryotherapy) were introduced to achieve a thermal shock effect.[25,26] We used a Cryo/Cuff system in the present study. Compared with traditional cooling methods, the Cryo/Cuff system provides a continuous cooling effect and stable temperature control with a temperature gauge. The Cryo/Cuff system is convenient to use because the iced water in the cooler is changed less often than in traditional ways of cooling. Moreover, the device combines cryotherapy with compression, which may contribute to pain and swelling relief when compared with cryotherapy alone.[27,28] In this work, the Cryo/Cuff system was applied intermittently instead of continuously after surgery to make early exercising executable. This might be a reason for the lack of effect on blood loss, ROM, and elbow function. The cost of Cryo/Cuff application was not calculated in our study because the device was used free of charge for the study purpose. However, this issue should be carefully considered in future studies comparing the Cryo/Cuff system with different ice modalities.

Table 3 Postoperative comparison between the cryotherapy group and control group for blood loss, analgesic consumption, ROM, and elbow function

Variables	Cryotherapy Group	Control Group	*P*	ES
Postoperative blood loss (mL)				
Hour 24	132.6±76.9	168.9±104.7	.280*	.40
Hour 48	105.3±55.0	106±62	.783*	.01
Hour 72	66.5±34.5	65.9±42.3	.285*	.02
Total	304.4±134.4	341.0±166.6	.331*	.24
Mean dose of sufentanil (μg)	86.5±18.0	93.1±13.2	.002†	.42
ROM (deg)				
Preoperative	36.8±25.8	37.3±31.8	.184*	.02
POD 1	103.7±14.6	102.0±15.6	.341*	.11
POD 7	118.6±14.5	118.0±11.2	.412*	.05
3mo	125.0±13.2	123.4±10.8	.632*	.13
MEPS				
Preoperative	60.6±7.3	60.9±8.5	.994†	.04
3mo	93.1±4.2	92.5±4.0	.613†	.15

NOTE. Values are mean ± SD or as otherwise indicated.
Abbreviation: ES, effect size.
* Unpaired *t* test.
† Mann-Whitney *U* test.

Study limitations

Certain limitations in the present study should be mentioned. First, the statistical power was limited because of the small sample size. Although the number of patients enrolled in this study was comparable with other studies on postoperative cryotherapy,[14,17] a larger sample size may provide more convinced results. A fair number of statistical tests were conducted at $\alpha = .05$, which might increase the chance of type I error. In addition, complete blinding is difficult to achieve in the implementation of the study. Although patients of different groups were admitted into different wards, the patients in the control group could recognize that they were not in the therapeutic group because no specific intervention was administered to them during rehabilitation. As previously mentioned, the issue of cost was not taken into consideration in the current work, but it is important for clinical application of cryotherapy in the future. Furthermore, because the patients in the cryotherapy group were educated to use the cooling device on their own, there was no guarantee that every patient strictly followed our prescription.

Conclusions

Cryotherapy is effective in relieving pain and reducing analgesic consumption postoperatively, indicating its benefit for patients undergoing elbow arthrolysis, despite there being no significant effects on blood loss and improvement in range of motion or elbow function. In the future, multicenter studies should be performed that include a larger sample size and a comparison of the effects and costs of various forms of cryotherapy after elbow surgery.

Suppliers

a. Aircast Inc, 92 River Rd, Summit, NJ 07901-1421.
b. SPSS Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606-6307.

Keywords

Cryotherapy; Elbow; Pain; Rehabilitation

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