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Comparison of a Cryopneumatic Compression Device and Ice Packs for Cryotherapy Following Anterior Cruciate Ligament Reconstruction

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Background: The purpose of the current study was to evaluate and compare the effectiveness of a cryopneumatic compression device with that of standard ice packs following arthroscopic anterior cruciate ligament (ACL) reconstruction, with a primary focus on early postoperative pain.

Methods: Participants were divided into two groups: cryopneumatic compression device group (CC group) and standard ice pack group (IP group). Patients in the CC Group (28 patients) received a cryopneumatic compression device (CTC-7, Daesung Maref) treatment, while patients in the IP group (28 patients) received standard ice pack cryotherapy postoperatively. All cryotherapy was applied three times (every 8 hours) per day for 20 minutes until discharge (postoperative day 7). Pain scores were assessed preoperatively and at 4, 7, and 14 days after surgery, and the primary outcome for analysis was pain at postoperative day 4 assessed using a visual analog scale (VAS). Other variables were opioid and rescue medication use, knee and thigh circumferences, postoperative drainage, and joint effusion quantified by a three-dimensional magnetic resonance imaging (MRI) reconstruction model.

Results: The mean pain VAS score and difference in VAS relative to the preoperative measurements for postoperative day 4 were significantly lower in the CC group than in the IP group ($p = 0.001$ and $p = 0.007$, respectively). The sum of postoperative drainage and effusion quantified by MRI showed a significant reduction of postoperative effusion in the CC group compared to the IP group ($p = 0.015$). The average total rescue medication consumption was comparable between the two groups. Circumferential measurements at days 7 and 14 postoperatively relative to those at day 4 (index day) demonstrated no significant differences between the groups.

Conclusions: Compared to standard ice packs, application of cryopneumatic compression was associated with a significant reduction in VAS pain scores and joint effusion during the early postoperative period following ACL reconstruction.

Keywords: *Knee, Anterior cruciate ligament reconstruction, Cryotherapy, Magnetic resonance imaging*

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Cryotherapy is one of the most common adjunctive treatment modalities in early postoperative care in orthopedic surgery.[1,2] Cryotherapy aims to decrease edema, pain, and inflammation. Decreases in edema and inflammation are thought to occur through vasoconstriction and reduction in secondary hypoxic injury by lowering the metabolic demand of the injured tissues.[1,3,4] An analgesic effect of cryotherapy is thought to occur by lowering the tissue

temperature below 15°C, producing a decrease in nerve conduction velocity.[5]

In the early postoperative period after anterior cruciate ligament (ACL) reconstruction, pain and knee effusion must be controlled to avoid delay in functional recovery and the quadriceps inhibition phenomenon.[6-8] Cryotherapy is one of the most widely used modalities after ACL reconstruction as it is inexpensive, easy to use, and rarely associated with adverse events.[2,4] Cryotherapy includes standard ice packs (IP), crushed-ice bags, and cold compression devices (cryopneumatic compression [CC] devices), although there is no consensus on which of these modalities is most effective. Cold compression devices have been introduced and maintain a constant temperature by circulating cold water to fill the cuff and to simultaneously offer compression to increase pressure gradients in the venous and lymphatics systems, counteracting edema and inflammation.[9,10] In a meta-analysis following ACL reconstruction, use of cold compression devices resulted in a significant reduction in pain scores and did not increase the risk of adverse events in the first 48 hours after surgery compared to no cryotherapy.[4] However, the outcome studies are limited and were not able to identify definitive conclusions on the effectiveness of cold compression devices on other important clinical parameters, such as edema, opioid use, postoperative blood loss, and effusion following ACL reconstruction surgery. Furthermore, it is not clear whether CC devices have any advantages over traditional IPs.

The purpose of the current study was to evaluate and compare the effectiveness of a CC device with that of standard IPs following arthroscopic ACL reconstruction, with a primary focus on early postoperative pain. Other variables of interest were opioid and rescue medication use, edema, postoperative drainage, and joint effusion. It was hypothesized that a CC device would produce decreased postoperative pain and effusion compared with standard IPs.

METHODS

Research Ethics Approval

The Institutional Review Board of Hanyang University Hospital approved this study (No. 2019-07-011), and all patients provided informed consent. The trial was registered at ClinicalTrials.gov (a service of the U.S. National Institutes of Health) with a trial identification number of NCT04222933.

Participants

Between April 2019 and March 2020, 71 consecutive patients who underwent primary ACL reconstruction performed by a single surgeon (JKL) were assessed for eligibility for this prospective, randomized, controlled trial. Exclusion criteria were patient age less than 18 years, multiligamentous knee injury requiring concomitant surgical treatment, contraindications to compressive or cold therapy (history of deep vein thrombosis, vascular ischemic disease, or cold allergy),[11,12] and history of long-term analgesic therapy or treatment for anxiety disorder. Excluding 15 patients, a total of 56 patients were enrolled in the study (Fig 1).

Interventions

ACL reconstructions were performed using a transportal technique by a single surgeon (JKL).[13] Patients were ran-

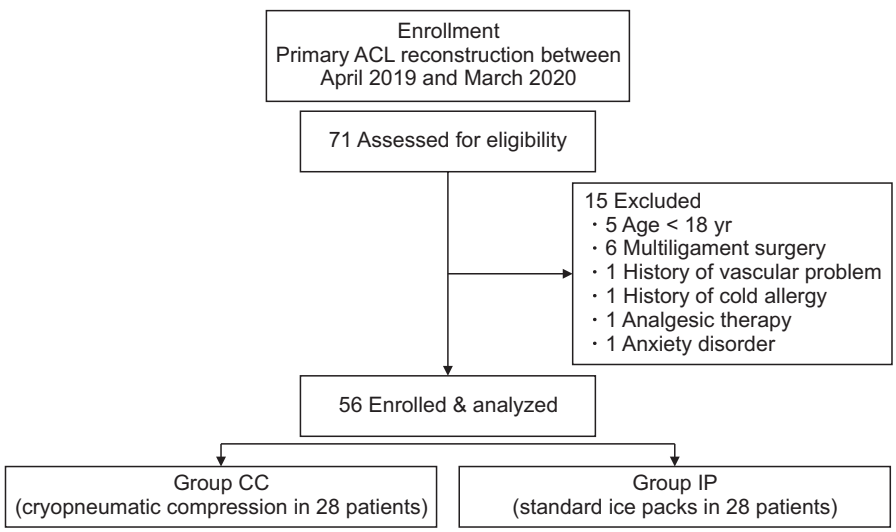

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart. ACL: anterior cruciate ligament.

domized into two groups using a computer-generated random sequence. Because of the nature of the study, both patients and physicians were aware of study group assignments. However, the single assessor collecting the outcome data (MKL) was blinded to the study group assignments.

Twenty-eight patients (28 knees) treated with a CC device were assigned to group CC, while another 28 patients (28 knees) who received standard IP cryotherapy postoperatively were assigned to group IP. All cryotherapy began as soon as patients returned to the wardroom after surgery and was applied three times (every 8 hours) per day for 20 minutes until discharge (postoperative day 7). For the IP group, an IP was applied on each side of the knee to maximize coverage. For the CC group, a CC device (CTC-7; Daesung Maref, Gunpo, Korea) was applied with a knee wrap and set to a temperature of 10°C and a compression pressure of 30 mmHg.[14] The same standard postoperative ACL rehabilitation protocol was used in both groups. Active assisted range of motion was allowed up to 90° during hospital stay, and braced weight bearing in extension was allowed as tolerated.

Outcome Measures

The primary outcome for analysis was postoperative pain assessed using a visual analog scale (VAS) with a range of 0 (no pain at all) to 10 (worst possible pain). Pain scores were assessed preoperatively and at 4, 7, and 14 days after surgery. For pain control, all patients received fentanyl-based, intravenous (IV) patient-controlled analgesia (PCA) that consisted of a 20-μg loading dose of fentanyl. The PCA device was set to deliver 10-μg boluses of IV fentanyl with a lockout period of 10 minutes at a basal background infusion rate of 10 μg/hr. The PCA regimen was continued for 48 hours when patients were transitioned to oral medications (tramadol/acetaminophen 37.5 mg/325 mg every 12 hours) until discharge. IV PCA fentanyl consumption was assessed during the first 48 hours. Rescue medication (tramadol 50 mg/ampule) was administered intramuscularly upon patient request or when VAS pain score exceeded 4.

Circumferential measurements were performed at the knee (mid-patella) and thigh (10 cm proximal to the upper patellar margin) with the knee in full extension.[15] Measurements were performed at 4, 7, and 14 days after surgery. As there was large variation in circumferential measurements between sexes and according to the level of patient sport participation and activity, differences in measurements at days 7 and 14 relative to the index day (day 4) were compared between the groups. All measurements were repeated three times by a single assessor (MKL), and a mean value was used for analysis.

Postoperative closed suction drainage (intra-articular bleeding) was measured at 48 hours after surgery, and joint effusion was quantified using a three-dimensional (3D) magnetic resonance imaging (MRI) reconstruction model obtained at postoperative day 6. The sum of postoperative drainage and effusion quantified by MRI, which represented the volume of total effusion that occurred during the first 6 days after surgery, was compared between groups.

3D MRI Reconstruction Model Protocol

A trained researcher with 3D modeling expertise (EC) segmented the knee MRIs of patients under supervision of a knee specialist (JKL). Digital Imaging and Communications in Medicine (DICOM) images consisting of sagittal T2-weighted Dixon sequences were used as inputs.[16] Version 4.10.2 3D Slicer software (Brigham and Women's Hospital and The Slicer Community, Boston, MA, USA) was used for segmentation.[17] Bony structures (femur, tibia, and patella) were segmented primarily in 3D Mask View MRI though an artificial intelligence (AI)-based algorithm to set the boundary of the knee joint, and effusion was segmented though a threshold-based image processing algorithm (Fig. 2).[18,19] The segment for effusion was calculated as a product of Boolean data acquired through threshold-based image processing from the region of interest mask data deduced from bone segment data produced though AI training.[20] Finally, effusion segment data were imported into 3D Slicer software, and the closed surface volume was calculated by the segment statistics function of the software (Fig. 3).[17] To validate the algorithm, saline loading (30 mL initially, then increased incrementally up to 60 mL) was performed in two cadaveric knees, and correla-

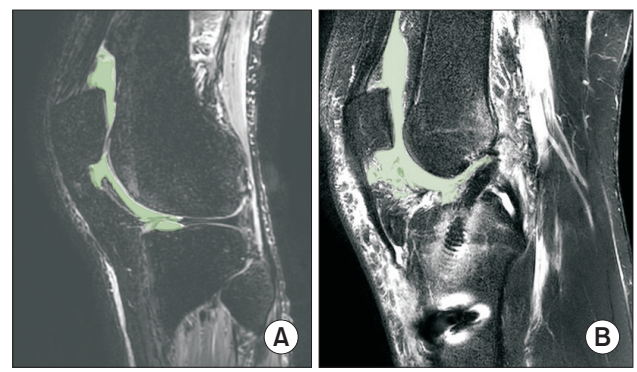

Fig. 2. Joint effusion segmentation. Joint effusion segmentation process of sagittal T2-weighted magnetic resonance imaging slices obtained from cadaveric (A) and anterior cruciate ligament-reconstructed (B) knees.

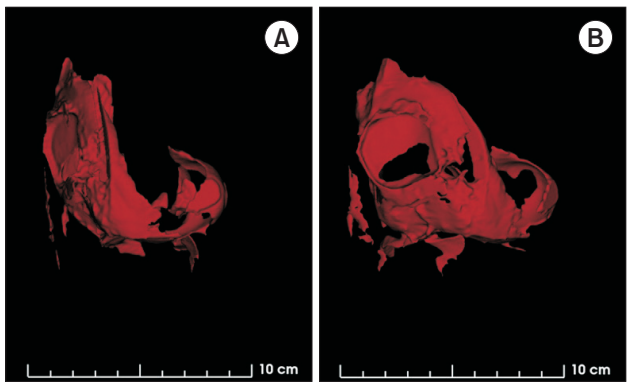

Fig. 3. Final three-dimensional magnetic resonance imaging reconstructed effusion model. Anterolateral (A) and anterior (B) aspects of the knee.

tion with calculated effusion volume was performed. The calculated effusion volume in the 3D MRI reconstructed model showed excellent correlation with the known saline load, with an *r*-value of 0.990 ($p = 0.003$).

Statistical Analysis

Statistical analysis was performed with SAS software ver. 9.4 (SAS Institute Inc., Cary, NC, USA). Groups were compared statistically using the independent *t*-test, chi-square test, Fisher's exact test, Wilcoxon rank-sum test, and linear mixed model as appropriate. The VAS pain scores were presented with a least square means analysis and tested with a linear mixed model analysis for repeated measures. This was a pilot study, and a pre-study power analysis was not performed; however, a post hoc power analysis for difference in VAS pain scores at postoperative day 4 was conducted. With the alpha level set at 0.05, the post hoc analysis revealed that a sample size of 56 (28 in each group) had a statistical power of 0.95 for detecting a significant difference.

RESULTS

Demographic and clinical parameters of patient sex, age, body mass index, side of operation, type of graft used (allograft or hamstring autograft), and frequency of associated meniscal surgery (partial meniscectomy or meniscal repair) were comparable between the two groups ($p > 0.05$) (Table 1). Baseline preoperative measures for the VAS pain scores were comparable between the two groups. The mean VAS pain scores and differences in VAS relative to baseline measurements for postoperative day 4 were significantly lower in the CC group compared to the IP group ($p = 0.001$ and $p = 0.007$, respectively). However,

Table 1. Patient Characteristics and Clinical Data

Variable	CC group (n = 28)	IP group (n = 28)	*p*-value
Age (yr)	26 (19–34)	24.5 (21.5–30.5)	0.724*
Sex (male)	23 (82.1)	23 (82.1)	1.000†
Body mass index (kg/m^2)	25.5 ± 2.9	26.28 ± 4.3	0.433†
Affected side (right)	16 (57.1)	13 (46.4)	0.422†
Graft type			0.611†
Allograft	1 (3.6)	3 (10.7)	
Hamstring autograft	27 (96.4)	25 (89.3)	
Combined meniscus surgery (partial meniscectomy or repair)	15 (53.6)	18 (64.3)	0.415†

Values are presented as median (interquartile range), number (%), or mean ± standard deviation. CC group: cryopneumatic compression device group, IP group: ice pack group.
*Wilcoxon rank-sum test. †Chi-square test or Fisher's exact test.

Table 2. Comparison of VAS Pain Scores between Groups

Variable	CC group (n = 28)	IP group (n = 28)	*p*-value
VAS preop	2.0 ± 1.5	2.1 ± 0.9	0.596
VAS (day 4)	2.1 ± 1.4	3.3 ± 1.3	0.001
VAS (day 7)	1.5 ± 1.3	2.0 ± 0.9	0.078
VAS (day 14)	1.3 ± 1.1	1.3 ± 0.8	0.980
ΔVAS (day 4)	0.1 ± 1.4	1.2 ± 1.4	0.007
ΔVAS (day 7)	–0.5 ± 1.7	–0.1 ± 1.2	0.363
ΔVAS (day 14)	–0.6 ± 1.5	–0.8 ± 1.1	0.577

Values are presented as mean ± standard deviation. VAS scores are presented as a least square mean and were tested by linear mixed model analyses for repeated measures. CC group: cryopneumatic compression device group, IP group: ice pack group.
VAS: visual analog scale, ΔVAS: changes in VAS postoperatively relative to preoperative measurements.

VAS pain scores at postoperative days 7 and 14 revealed no statistically significant differences between the two groups (Table 2). Cumulative fentanyl consumption during 48 hours of PCA was higher in the IP group compared to the CC group, though the difference was not statistically significant during any of the time intervals (0–6 hours, 0–12 hours, 0–24 hours, and 0–48 hours) (Table 3). Average total rescue medication consumption was comparable between the two groups. Circumferential measurements at days 7 and 14 postoperatively relative to those at day 4 (in-

Table 3. Comparison of Cumulative Fentanyl Consumption (mL) and Rescue Medication (Ampules) between the Groups

Variable	CC group (n = 28)	IP group (n = 28)	*p*-value
Rescue medication	0.6 ± 1.4	0.5 ± 1.0	0.657
Fentanyl (6 hr)	220.9 ± 106.7	208.2 ± 80.5	0.626
Fentanyl (12 hr)	370.6 ± 156.7	352.7 ± 120.0	0.647
Fentanyl (24 hr)	561.1 ± 223.3	584.4 ± 209.0	0.705
Fentanyl (48 hr)	840.6 ± 297.5	987.4 ± 343.6	0.136

Values are presented as mean ± standard deviation. CC group: cryopneumatic compression device group, IP group: ice pack group.

Table 4. Comparison of Circumferential Measurements (cm) at Mid-Patellar and Thigh Levels between the Groups

Variable	CC group (n = 28)	IP group (n = 28)	*p*-value
Patella (day 7)	1.1 ± 1.6	1.2 ± 1.5	0.899
Patella (day 14)	0.9 ± 1.8	0.6 ± 1.6	0.508
Thigh (day 7)	–0.4 ± 1.8	0.2 ± 1.5	0.134
Thigh (day 14)	–1.0 ± 2.9	0.1 ± 1.4	0.120

Values are presented as mean ± standard deviation and represent the difference in circumferential measurements (cm) at 7 and 14 days postoperatively relative to index measurements at day 4. CC group: cryopneumatic compression device group, IP group: ice pack group.

dex day) demonstrated no significant differences between the two groups (Table 4).

Mean postoperative drainage was higher in the IP group compared to the CC group, though the difference was not statistically significant (Table 5). Forty-three of the 56 patients (21 in the CC group and 22 in the IP group) underwent MRI evaluation on postoperative day 6. Effusion volume quantified by a 3D MRI reconstruction model was higher in the IP group than in the CC group, although the difference was not significant (Table 5). The sum of postoperative drainage and effusion quantified by MRI showed a significant reduction of postoperative effusion in the CC group compared to the IP group (p = 0.015). No cold-related complications such as frostbite or transient nerve palsy occurred in patients in either the CC group or IP group.[11,12] All patients completed cryotherapy as prescribed, and none discontinued cryotherapy for any reason.

Table 5. Comparison of effusion (mL) Measured by Drainage and 3D MRI Reconstruction between the Groups

Variable	CC group (n = 28)	IP group (n = 28)	*p*-value
Drainage	148.2 ± 102.8 (28)	171.3 ± 64.8 (28)	0.324
MRI effusion	47.1 ± 11.9 (21)	51.8 ± 16.0 (22)	0.280
Total effusion	175.2 ± 83.4 (21)	239.7 ± 78.8 (22)	0.015

Values are presented as mean ± standard deviation (number of patients assessed). CC group: cryopneumatic compression device group, IP group: ice pack group.
3D: three-dimensional, MRI: magnetic resonance imaging.

DISCUSSION

In this study, the effect of CC was compared to that of standard IPs in patients undergoing arthroscopic ACL reconstruction. The results demonstrated that patients who received CC showed significantly improved VAS pain scores at postoperative day 4. However, there was no difference in VAS pain scores at postoperative day 7 or 14. Furthermore, the sum of postoperative drainage and effusion quantified by MRI showed significant reduction of postoperative effusion in the CC group compared to the IP group.

Cryotherapy is widely accepted as a beneficial approach for decreasing edema, pain, and inflammation through localized vasoconstriction and reduction in secondary hypoxia by lowering the metabolic demands of injured tissue.[1-5] While the optimal modality, duration, and frequency of cryotherapy are under debate, it is accepted that pain, effusion, and edema must be controlled to avoid delay in functional recovery and to minimize muscle spasm (quadriceps inhibition phenomenon), accelerating postoperative rehabilitation.[6] Compression is thought to counteract edema, and it can help reduce tissue temperature by increasing pressure gradients in venous and lymphatic systems.[21] Several clinical studies have demonstrated improvement in outcomes when various cryotherapy modalities were applied after ACL reconstruction surgery. Waterman et al.[10] compared the effects of combined compression and cryotherapy with those of traditional ice therapy following ACL reconstruction and concluded that the combined compression and cryotherapy group had significantly lower VAS pain scores by 6 weeks after operation. Barber et al.[22] compared continuous-flow cryotherapy with no cryotherapy controls after ACL reconstruction and found improved VAS pain scores, reduced oral narcotics use, and improved range of knee motion with cryotherapy. A recent systematic review conducted by Martimbianco et al.[4] concluded that use of cold com-

pression devices produced a significant reduction in pain scores at 48 hours after ACL reconstruction compared to no cryotherapy. However, the review could not draw definitive conclusions on the effects of cryotherapy for other outcomes, including edema, effusion, postoperative blood loss, analgesic medication use, or patient satisfaction. In the present study, the use of a CC device produced a significant reduction in VAS pain scores at day 4 after operation compared to that of standard IPs; however, the difference was relatively small between the two groups (2.1 ± 1.4 vs. 3.3 ± 1.3). Furthermore, there was no difference in VAS pain scores assessed at postoperative day 7 or 14 regardless of cryotherapy modality. The findings of Waterman et al.[10] indicate that CC devices should be used for longer periods of time as an analgesic effect was evident in more subacute periods (6 weeks postoperatively). However, the study was limited by significantly different baseline VAS pain scores between groups.

Uncontrolled joint effusion has been suggested as a main cause of the quadriceps inhibition phenomenon following ACL reconstruction.[23] Furthermore, laboratory studies involving artificial knee joint effusion models concluded that cryotherapy was effective in reducing inhibition of quadriceps muscle induced by swelling or joint effusion.[24,25] However, no previous studies have quantified or assessed the effectiveness of cryotherapy on reducing the volume of knee joint effusion after ACL reconstruction. In the present study, the sum of postoperative drainage and effusion quantified by MRI showed a significant reduction in the CC group compared to the IP group, indicating that CC devices have an advantage over standard IPs in reducing early postoperative drainage and joint effusion following ACL reconstruction.

Our study has several limitations. First, this is a pilot clinical trial, and pre-study power analysis was not performed; however, post hoc power analysis revealed that the sample size of 56 would have a statistical power of 0.95 for detecting a difference in VAS pain score at postoperative day 4. Second, although there was a statistically significant difference in VAS pain score on postoperative day 4, the difference in the VAS pain score was relatively small (2.1 ± 1.4 vs. 3.3 ± 1.3) between the two groups. It could be considered that the clinical impact of cryotherapy, regardless of its modality, is limited in terms of early postoperative pain reduction. Third, the difference in parameters of fentanyl consumption, circumferential measurements, postoperative drainage, and effusion quantified by the MRI model lacked statistical significance with the given number of patients. Although the sum of postoperative drainage and effusion quantified by MRI showed a significant reduction, the data were acquired in only 43 patients (of 56 total) who had undergone MRI evaluation. Fourth, the effect of CC on long-term functional recovery remains unknown. Finally, the cost-effectiveness of such CC devices is unknown. These issues should be addressed in a future study with a larger number of patients. Despite some limitations, compared to standard IPs, the application of CC was associated with a significant reduction in VAS pain scores and joint effusion during the early postoperative period following ACL reconstruction.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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