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ARTHROSCOPY AND SPORTS MEDICINE

Temperature-controlled continuous cold flow device versus traditional icing regimen following anterior cruciate ligament reconstruction: a prospective randomized comparative trial

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Abstract
Introduction Anterior cruciate ligament (ACL) reconstruction requires an intensive rehabilitation program to be completely successful. Cryotherapy has been described to be helpful in reducing post-operative pain and edema. Aim of this prospective randomized study is to compare two homogeneous groups of patients, one receiving traditional icing regimen and the other a temperature-controlled continuous cold flow device, in post-operative setting after ACL reconstruction.
Materials and methods Forty-seven patients treated for ACL reconstruction using "over the top" technique were enrolled for this study. All patients received the same elastocompressive bandage. Regarding the coolant device, 23 patients were randomized to temperature-controlled continuous cold flow device (Hilotherm® group) and 24 patients were randomized to receive ice bag (control group). The two groups were homogenous for pre-operative (age, sex, and time "lesion to surgery") and intra-operative parameters (duration of the procedure, meniscectomy, and chondral damage). NRS (numeric rating scale), blood loss, knee volume increase at three established sites, ROM, and pain killers consumption were assessed. The subjective evaluation of the device including practicality and usefulness of the device was investigated.
Results Hilotherm group resulted in lower pain perception (NRS), blood loss, knee volume increase at the patellar apex and 10 cm proximal to the superior patellar pole, and higher range of motion ($p < 0.05$) in the first post-operative day. No difference in pain killers consumption was noted. Hilotherm device was considered "comfortable" and "useful" by the majority of patients.
Conclusions Hilotherm group showed significant better results in first post-operative day. Further studies with higher number of patients and longer follow-up are required to assess the beneficial effects on rehabilitation and the cost-effectiveness of the routinely use of this device.
Level of evidence: II.

Keywords Hilotherm · Cryotherapy · ACL reconstruction · Continuous cool flow device

Introduction

Anterior cruciate ligament (ACL) ruptures represent a common musculoskeletal injury related to sport activity with estimated 200,000 new cases per year in the United States [1, 2].

In case of young and active patients willing to perform contact sport activities, arthroscopic ACL reconstruction is recommended [3]. However, the post-operative period is generally associated with important clinical symptoms, including local pain, edema, and reduced knee range of motion, which delay functional recovery time [4].

Many authors highlighted the importance of an aggressive rehabilitation protocol focused on the improvement of

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the mid- and long-term clinical outcome following ACL surgery [5]. For this reason, it appears important to adopt measures aimed to reduce pain and edema in the immediate post-operative period to allow early mobilization.

The use of ice, or cryotherapy, is an easily available, low-cost, and popular intervention that has been widely used in post-operative patients [6–8]. By relieving acute symptoms including pain and edema, cryotherapy is believed to accelerate post-operative rehabilitation and the return to regular activities [6–8]. Several studies have tested the effects of cryotherapy in the relief of post-operative pain after knee surgery [6–8]. It has been hypothesized that this effect may be due to decreased release of inflammatory mediators, such as prostaglandin E2, in the synovial membranes [9]. The analgesic effect seems to be also guaranteed by biochemical and physical desensitization of nociceptors associated to the reduction of neural transmit rapidity [10]. Edema reduction is achieved through vasoconstriction as well as by lowering colloid osmotic pressure combined with the normally positive capillary filtration pressure [10].

Cryotherapy can be applied through several different methods such as cold packs, crushed ice bags, and continuous cold flow devices with adjustable temperatures [10]. Cold packs and ice bags are cheap and widely available but can damage skin and soft tissues (e.g., frostbite), the temperature cannot be regulated and it is not constant with need of regular coolant replacement by nursing staff [8].

Continuous cold flow devices permit to regulate temperature maintaining it over time reducing the risk of skin damages as well as the effort from health care workers [8]. These devices are obviously more expensive with respect to ice packs and bags [8].

Some systematic reviews of the literature demonstrated the efficacy of cryotherapy in terms of patients satisfaction and pain reduction but the limited evidence currently available is insufficient to draw definitive conclusions on the effectiveness of cryotherapy for other outcomes [10–12]. In addition, the lack of well-designed randomized trials does not allow to sustain the superiority of continuous cold flow devices with respect to traditional coolants [10].

The aim of this paper is to report the results of a prospective randomized study comparing two homogeneous groups of patients who underwent ACL reconstruction. The control group received traditional coolants (ice bag) in the post-operative period, while a temperature-controlled continuous cold flow device was administered to the study group. Our working hypothesis was that continuous cold flow device may be superior to traditional coolants in terms of pain reduction (primary endpoint), reduction of blood loss, and knee swelling and improvement in knee range of motion.

Materials and methods

Patients data

The study was approved by authors' hospital ethical committee and it was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All the patients involved in the study gave their informed consent prior to their inclusion in the study.

Fifty-six consecutive patients with ACL lesion were enrolled for a prospective randomized comparative study.

The complete clinical history was collected for every patient. A complete physical examination of the knee was conducted in every case. Knee circumference was measured pre-operatively at the patellar apex (S0), 10 cm proximal to the superior patellar pole (S1), and 15 cm distal to the superior patellar pole (S2).

Patients were clinically and radiologically (MRI) diagnosed of unilateral primary ACL lesions and scheduled for ACL reconstruction using an "over the top" technique.

Exclusion criteria were active phlebitis of the injured leg, history of venous thrombosis or pulmonary embolism, presence of vascular disease of the injured leg (e.g., diabetic vasculopathy), presence of cryoglobulinemia, presence of Raynaud syndrome, presence of livedo reticularis or acrocyanosis, sensibility alterations such as hypersensitivity to cold, hives, purpura, or deficit in deep or superficial sensibility. Patients with associated osteochondral lesions graded III or IV in ICRS classification were also excluded from the study.

Forty-seven patients were eventually enrolled for the study.

In the pre-operative settings, using a dedicated device, the 47 patients were randomized in two groups, a control groups (24 cases) in which ice bag was adopted in the post-operative setting and a study group in which a continuous cold flow device (Hilotherm) was administered (23 cases).

Hilotherm (Hilotherm GmbH, Germany) is a temperature-controlled cold continuous flow device working as a coolant. It consists of anatomically adapted thermoplastic polyurethane cuffs and the Hilotherm cooling device control unit (the temperature setting is adjustable from 10 to 30 °C).

The surgical procedure was performed the day after using a semitendinosus and gracilis ACL reconstruction with "over the top" passage, under general or spinal anesthesia, by a senior surgeon expert in ligament reconstruction. After fastening the tourniquet, an arthroscopic evaluation using two standard anterolateral and anteromedial portals was performed: concomitant meniscal tear or minor chondral lesions were visualized and treated. The ACL lesion was visualized and the remnants were

debrided. After the arthroscopic joint evaluation, graft harvesting was performed. Through a vertical incision in the proximal medial tibial metaphysis, the semitendinosus and gracilis tendons were identified and harvested, paying attention not to violate the tibial insertion and the neurovascular network. The residual muscle tissue on tendons was removed; the proximal third of the two tendons was stitched with four non-reabsorbable suture threads (Ethibond no 2).

The entry point on the tibial cortex was positioned at 5 mm medially and 5 mm superiorly to the bone insertion of the gracilis tendon: a tibial tunnel was performed with a guide wire, emerging in the joint at the original tibial footprint of the torn ACL. The tibial tunnel was drilled using a cannulated reamer, depending on the size of the graft.

Through a lateral incision on the lateral femoral condyle, the graft was passed through the tibial tunnel and in the "over the top" position, thanks to messenger wires. The superior fixation of the graft was performed using two titanium staples. The remnants were taken backwards and retrieved outside the tibial tunnel, performing a tenodesis at the pes anserinus using non-reabsorbable stitches. Intra-articular suction drainage was positioned.

After suturing, Hilotherm device was applied in the study group by the senior surgeon in the operating room. In both groups, an elastocompressive bandage was then applied. Hilotherm was set to a constant temperature of 12 °C, as the better pain decrease sensation is afforded between 12 and 15 °C, avoiding nerve conduction impairment [10].

In the post-operative setting, both the groups shared the same fixed-interval analgesic strategy (Paracetamol 1000 mg endovenous administration three times per day), the same elastocompressive bandage and differ only for the cooling agents (traditional cooling agents versus Hilotherm).

Rescue analgesia in case of persistent pain was represented by Tramadol 100 mg endovenous administration for a maximum of three times per day.

Post-operative assessment was performed in the first post-operative day. The evaluation criteria were as follows:

- NRS (numeric rating scale) for subjective pain evaluation (scale range from 0, no pain, to 10, worst pain imaginable);
- Blood loss from the suction drainage;
- Knee circumference at the patellar apex (S0), 10 cm proximal to the superior patellar pole (S1) and 15 cm distal to the superior patellar pole (S2);
- Range of motion (ROM) of the knee. The evaluation of the knee flexion and extension ROM was executed in degrees, through goniometry using a universal goniometer of plastic material. The articular line of the knee was used as an axis to position the goniometer, while the fixed arm remained parallel to the lateral surface of the femur in the direction of the greater trochanter, and the mobile arm remained parallel to the lateral side of the fibula in the direction of the lateral malleolus [13];
- Pain killers consumption;
- A subjective evaluation including the practicality and the usefulness of the device (only Hilotherm device): Practicality (evaluation of subjective feeling of encumbrance and discomfort related to the device) was evaluated as "very comfortable," "quite comfortable," "quite uncomfortable," "completely uncomfortable." Usefulness (evaluation of subjective benefits in terms of pain and knee volume reduction) was described as "very satisfying," "quite satisfying," "quite dissatisfying," "completely dissatisfying";
- Registration and description of any adverse effect observed.

Statistical analysis

Mean ± SD was used to express any continuous data; categorical variables were expressed as frequency and percentages. The Kolmogorov–Smirnov test was performed to test normality of continuous variables. The Levene's test was performed to test the homoscedasticity. The ANOVA test was performed to evaluate the differences of continuous and normally distributed and homoscedastic data between the groups. Otherwise, the Mann–Whitney test was performed. The Kendall tau correlation was used to test the existence of an ordinal by ordinal correlation. For all tests, $p < 0.05$ was considered significant.

All statistical analysis was performed using SPSS v. 19.0 (IBM Corp., Armonk, NY, USA).

Results

No immediate post-operative complications were detected in both the groups. No complications or adverse events related to the use of the Hilotherm device or ice bag were noted.

Both the groups (control and Hilotherm) resulted homogeneous for pre-operative features (age, sex and time elapsed from lesion to surgery) and intra-operative features (duration of surgery, meniscectomy, rate of minor chondral damage) (Table 1).

All the patients were discharged from the department the day after surgery.

Table 1 Homogeneous pre-operative parameters (age, sex, and time elapsed from lesion to surgery) and intra-operative parameters (duration of surgery, meniscectomy, rate of minor chondral damage) were noted in both groups. Non-statistically significative values were obtained ($p > 0.05$)

	Hilotherm group (23 patients)	Control group (24 patients)
Pre-operative parameters		
Age (years)	32.2 ± 6.7	31.4 ± 8.1
Sex (*M*/*F*)	14/9	15/9
Time lesion surgery (months)	3.2 ± 1.1	2.9 ± 0.8
Intra-operative parameters		
Duration of surgery (min)	47.2 ± 10.5	49.7 ± 12.1
Meniscectomy (%)	43.47	50.00
Minor chondral damage (I–II ICRS) (%)	60.87	66.67

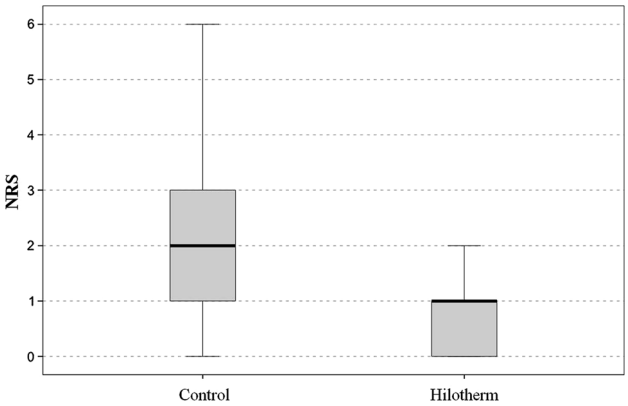

Fig. 1 Pain perception evaluated using NRS showed a significant reduction in Hilotherm group

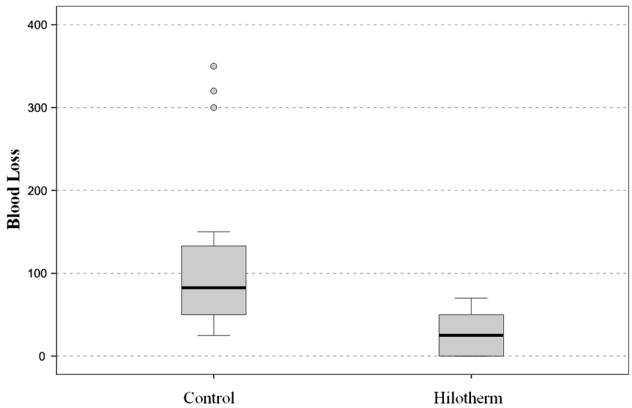

Fig. 2 Blood loss (cc) in a suction drainage was significantly lower in Hilotherm group when compared to control group (also notice the *three outliers*)

NRS evaluation showed a mean value of 0.9 ± 0.8 in the Hilotherm group and 2.4 ± 1.7 in the control group, resulting in a statistically significant reduction of pain in the patients treated with the coolant device ($p < 0.0001$) (Fig. 1).

Blood loss was significantly lower in the Hilotherm group (26.7 ± 27.3 ml) when compared to control group (108.0 ± 91.4 ml) ($p < 0.0001$) (Fig. 2).

The joint volume increase related to hemarthrosis was evaluated measuring the difference between knee circumferences in the pre-operative and post-operative settings at the three different sites (S0, S1, S2). The knee volume increase appeared to be significantly lower in the study group with respect to the control group at S0 and S1 measurements (respectively, $p = 0.013$; $p = 0.001$) (Figs. 3, 4). A positive trend for Hilotherm group was registered at S2, with no significant value.

ROM evaluation showed a complete extension in every patient of the study. The mean flexion value in the Hilotherm was 74.8° ± 22.3°, which was significantly higher than control group (43.3° ± 24.7°) ($p < 0.0001$).

No difference was noted in rescue analgesia consumption between the two groups.

The subjective evaluation of the Hilotherm was generally positive. Nine patients (39 %) considered the device very comfortable, 13 (57 %) rated the device quite comfortable, and only one (4 %) patient complained about the lack of comfort. Five patients (22 %) found Hilotherm very useful, 13 cases (57 %) had positive opinions ("quite satisfying"), three (13 %) patients were quite dissatisfied, and two (9 %) patients were completely dissatisfied.

Discussion

Reduction of post-operative pain and swelling after ACL reconstruction represents a hot topic in sports medicine. Patient wellness in the immediate post-operative period may represent a crucial aspect to obtain a faster recovery through an aggressive rehabilitation [4].

Cryotherapy is frequently used in orthopedics for post-operative analgesia [5–14]. Despite the above-mentioned advantages of cryotherapy, it is not clear which should be the best method to administer cryotherapy to the patients, traditional coolant, or continuous cold flow device.

The present study's objective was to compare a continuous cold flow device named Hilotherm with crushed ice bag in the management of patients operated by ACL reconstruction.

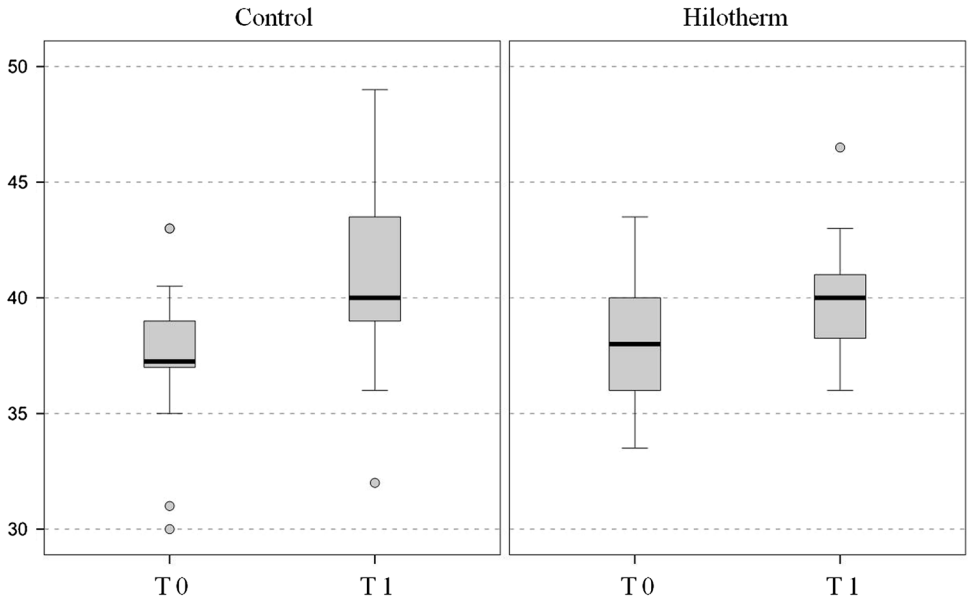

Fig. 3 Knee circumference in cm in pre-operative setting (T0) and in post-operative day 1 (T1) at S0 (patellar apex): significant lower increase of volume in Hilotherm group was noted

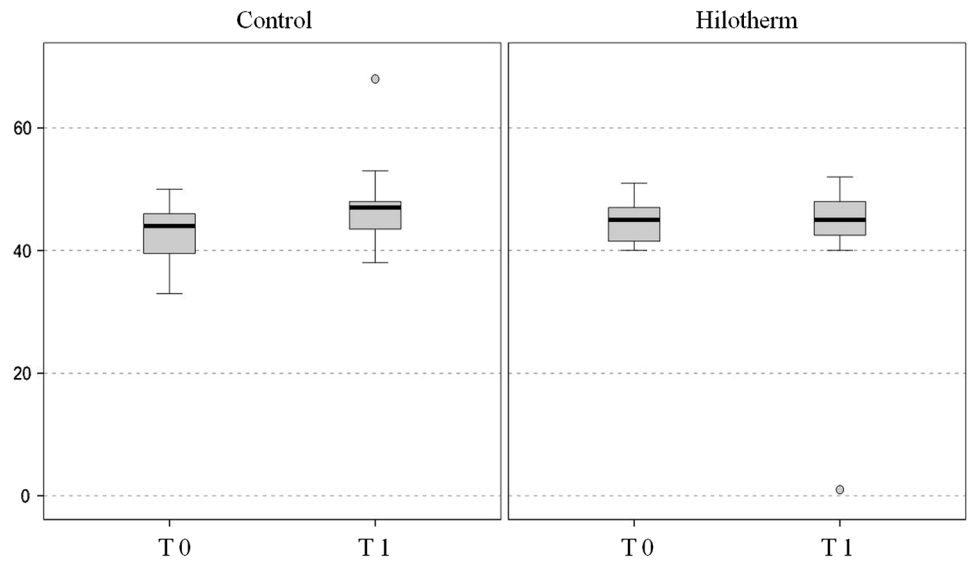

Fig. 4 Knee circumference in cm in pre-operative setting (T0) and in post-operative day 1 (T1) at S1 (10 cm proximal to the superior patellar pole): significant lower increase of volume in Hilotherm group was noted

Hilotherm device is a new temperature-controlled device which has proved to be able to obtain excellent results in terms of pain and edema reduction in maxillo-facial surgery [15–17]. Our hypothesis was that this device should be employed in orthopedic surgery resulting better than a traditional coolant in terms of pain and swelling reduction as well as knee ROM improvement. This hypothesis was confirmed with a statistically significant reduction in the NRS scale, in the blood collected in the drainage and in knee circumference in the study group. Knee ROM also demonstrated to be statistically superior in the study group. In addition to the objective evaluation performed, it has to be noticed that 96 % of the patients found the device comfortable and no adverse effects were reported in the study group. The nursing staff reported an excellent compliance with the device in fact that the patients of the study group required lower effort to be managed.

The results of our study seem to be substantially in line with the papers by Martimbianco et al., Schröder et al., and Barber et al., who compared two groups of patients undergoing cryotherapy with traditional coolant or continuous flow cold devices, after ACL reconstruction [11, 14, 18]. Pain perception and functionality was lowered in the study group using cooling device and, moreover, a reduction in pain killer consumption was also observed. Similarly, Waterman et al. reported reduction of pain killer use, whereas non-statistically significative differences between the two groups were detected [19]. Differently, the reduction in drug use was not evident in our study, and this

is the only result not in line with the current literature regarding cooling device after ACL reconstruction.

The main strength of the present study is that it is a prospective, randomized, controlled trial in a defined patient cohort. The authors tried to reduce all the possible bias that may affect the outcome. The two groups of patients were homogeneous. ACL surgery was performed by the same surgeon with the same technique in all the evaluated patients.

On the other hand, the presented study has some limitations. First of all, the number of patients enrolled is not so high (47 patients). Secondarily, the evaluation of the patients was only limited to the duration of the hospital stay; a clinical evaluation performed in the outpatient clinic at scheduled follow-up steps may improve the findings of the study. In addition, we did not evaluate the medical economic impact of the cooling device. Finally, a methodological limitation is represented by the fact that neither the patients nor the outcome assessors could be blinded due to the nature of the intervention.

In conclusion, this study showed that the examined continuous cold flow device statistically improves the outcome in patients with reconstruction ACL in the first post-operative day with respect to traditional coolants. This symptom improvement may affect hospitalization and may allow a more aggressive rehabilitation in the perioperative period. Further, studies with higher number of patients enrolled as well as longer follow-up are required to validate these findings to assess the effective beneficial effects of the device in terms of speeding up patient rehabilitation. Longer follow-up and higher number of patients should also permit to evaluate in terms of cost effectiveness in the routine employment of this device in ordinary clinical practice.

Conflict of interest The authors declare that they have no conflict of interest.

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