

EFFECTIVENESS OF CRYOTHERAPY AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

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ABSTRACT

Objective: The purpose of this study was to evaluate cryotherapy effectiveness in the immediate postoperative period of ACL reconstruction to improve pain and range of motion (ROM) of the knee. **Methods:** This is a pilot study of a prospective and randomized clinical trial. Patients (n=25) were divided into two groups: Intervention (A) group (n=10): patients were submitted to an inpatient physical therapy protocol and received ice compress for 20 minutes, twice a day; Control (B) group (n=9): patients had the same protocol, twice a day. The pain intensity was evaluated with the visual analogic scale

(VAS) and range of motion was measured with a goniometer. **Results:** The Intervention (A) group had important absolute and percentual improvement when compared with the Control (B) group regarding measures of pain and knee flexion/extension ROM. **Conclusion:** Cryotherapy in the immediate postoperative period of ACL reconstruction was effective to improve pain and range of motion of the knee. **Level of Evidence I, Randomized Clinical Trial.**

Keywords: Cryotherapy. Anterior cruciate ligament. Pain measurement. Range of motion, articular.

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INTRODUCTION

The knee joint is a complex structure, capable of providing stability and mobility to the human body, functions guaranteed mainly by the bone, ligament and muscle structures that compose this articular complex. Nevertheless, this region is constantly exposed to stress, since it absorbs a large part of the bodyweight impact during the movements of the human body, and is considered one of the joints that sustains the most injuries.¹

Knee ligament injuries are very common nowadays, and are considered epidemiological in nature, particularly in sports.² The anterior cruciate ligament (ACL) is the most affected ligament, especially in individuals aged between 15 and 25 years who are assiduous athletes,³ while the incidence of isolated ACL tears is 30% per year and more than 100 thousand surgical reconstruction procedures are performed annually in the United States. ACL injuries are frequently associated with meniscal injuries in 96% of chronic injuries and 82% of acute injuries.⁴⁻⁶ The treatment for ligament injuries is frequently surgical, as it aims to restore the anatomical and functional stability of the knee joint, allowing the individual to return to preoperative activity levels, thus improving their quality of life.^{3,7} ACL reconstruction is a procedure widely researched by the scientific commu-

nity, with a certain degree of controversy still existing. The gold standard for this surgery is performance through arthroscopy, a less invasive technique than open surgery and that affords a more accelerated rehabilitation process.

The rehabilitation process is essential and targets, after ACL reconstruction surgery, the reduction of pain, edema and inflammatory process; improvement of neuromuscular control, muscle strength, range of motion, gait and proprioception.^{4,7} Accelerated rehabilitation protocols have been considered more effective and indicate early mobilization and weight bearing, yet in this phase the pain and edema can interfere in the rehabilitation process, hampering the individual's return to their routine activities and their functionality.⁸

Cryotherapy is a method used to alleviate the pain and to decrease edema during rehabilitation, as a low-cost technique of easy access, commonly employed in musculoskeletal disorders, especially in acute soft-tissue injuries. Some studies demonstrate that after ACL reconstruction surgery, cryotherapy promotes the reduction of pain, drug intake, length of hospital stay, the improvement of knee ROM and the patient's quality of life.⁹⁻¹¹

Despite the widespread use of cryotherapy, there are still differences of opinion in the literature concerning the effectiveness of its various application methods and the quantification of

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variables such as frequency, duration and best time for use. The cryotherapy application time ranges between 10 and 20 minutes, from two to four times a day.^{10,12}

Based on the hypothesis that cryotherapy is effective in reducing pain and improving knee ROM, during the immediate post-ACL reconstruction surgery rehabilitation process, the purpose of this study was to standardize an inpatient physiotherapy protocol associated with the use of cryotherapy.

Objective

To evaluate the effectiveness of cryotherapy in relation to the improvement of pain and knee ROM in adults submitted to ACL reconstruction surgery.

METHODS

Pilot study of a randomized prospective clinical trial, carried out at a tertiary care Public Teaching Hospital located in the city and state of São Paulo.

Sample

The sample followed the inclusion criteria: adult individuals (over 18), both sexes, submitted to elective ACL reconstruction surgery, isolated, or associated with partial or total meniscectomy of one meniscus or both. The exclusion criteria were: complex knee injuries; patients with vasospastic disorders, such as Raynaud's phenomenon, Livedo reticularis or acrocyanosis; sensibility alterations such as hypersensitivity to cold, hives, purpura, or deficit in deep or superficial sensibility, i.e., tactile or painful, detected through previous evaluation.

The individuals were recruited electively for surgery and were invited to take part in the study on the first day of hospitalization (preoperative period), and after acceptance, signed the "Informed Consent Form", and were then randomized to one of the two groups (A - Intervention and B - Control).

The sample size was calculated and consisted of 100 participants; however, as this is a pilot study (which uses at least 10% of the calculated sample), a minimum of 10 participants would be necessary.

Randomization

The generation of the allocation sequence was performed by an individual not involved in the study. The sequential numbers were kept in opaque, non-translucent, sealed envelopes, and were only delivered to the therapist involved in the study at the time of the allocation of the individual, i.e., on the first postoperative day.

Procedures

The procedures and interventions used in the present study are in accordance with ethical principles and were evaluated and approved by the Research Ethics Committee of Universidade Federal de São Paulo – Escola Paulista de Medicina (protocol CEP 1025/10).

The patients included in the study were assessed by an evaluator aware of the survey objectives, on the first postoperative day.

The care protocol prepared by the Physiotherapy Team of the Orthopedic and Traumatology Ward of Hospital São Paulo (UNIFESP-EPM) (Table 1), was applied on the first postoperative day, in both groups (A and B). However, in the Intervention

group (A), the patients received the application of an ice pack (using crushed ice wrapped in sterile plastic material) in the anterior region of the affected knee, with the limb elevated, for 20 minutes.

All the physiotherapy sessions were held twice a day, in the morning and in the afternoon.

Table 1. Post-ACL reconstruction rehabilitation protocol.

Post-ACL reconstruction rehabilitation protocol Orthopedic and Traumatology Ward Unifesp/EPM
Daily Evaluation – ROM and VAS
Patellar Mobilization (laterolateral and craniocaudal)
Isometry of quadriceps and gluteus
Progressive gain of ROM up to 90° of knee flexion
Gain of extension ROM
Exercises to strengthen the lateral rotators and hip abductors
Progressive partial weight bearing, if isolated ACL surgery, with auxiliary device (crutches)
Weight bearing (foot strike), if associated with meniscectomy with auxiliary device (crutches)
Positioning of the limb in elevation and extension
Metabolic exercises of the ankles
Control of pain and edema: Ice wrap in the anterior region of the knee, for 20 minutes (only in the Intervention Group)

Outcomes

The measurement of pain intensity used the Visual Analog Scale (VAS) of pain, at the beginning and at the end of all the physiotherapy sessions, in both groups. VAS is represented by a 100mm dash, and is interpreted as follows: values of 0-4mm can be considered without pain, 5-44 mm medium pain, 45-74mm moderate pain and 75-100mm severe pain.¹³

The evaluation of the knee flexion and extension ROM was executed in degrees, through goniometry,¹⁴ 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. Standard values of 90° for knee flexion and 0° for extension were considered on the first postoperative day.¹⁵

STATISTICAL ANALYSIS

The results were presented through a descriptive analysis, with mean and standard deviation. The evaluation of results was also based on absolute and percentual improvement, with a comparison between the initial and final condition of the individuals after the physiotherapy treatment, for groups (A) Intervention and (B) Control. Absolute improvement demonstrates how many degrees or how many centimeters altogether the patient has improved, i.e., if the initial pain was 5 cm and the final pain 2 cm, the absolute improvement is 3 cm. The percentual improvement demonstrates the improvement in percentage at the end of the physiotherapy treatment. In this example it would have been 60%.

RESULTS

The flowchart of participants is shown in Figure 1 and was based on CONSORT (Consolidated Standard of Reporting Trials, <http://www.consort-statement.org/>).

The total number of study participants was 25 individuals, whereas after randomization the Intervention group was composed of 10 individuals and the Control group of nine individuals. There was loss of 24%, as they did not fulfill the inclusion criteria. The causes for exclusion were: presence of systemic disease (n= 1), other ligament injuries (n= 2), removal of osteochondroma in the same surgery (n=1), did not undergo surgery (n=1) and attended only one physiotherapy session (n=1).

The characteristics of the sample are represented in Table 2. In both groups, the participants received two physiotherapy sessions on the first postoperative day, one of which was in the morning, and the other in the afternoon. The knee flexion and extension ROM goniometric measurement was made at the start and at the end of the physiotherapy sessions, whereas all these measurements were submitted to the calculation of the mean and standard deviation, and can be observed in Tables 3 and 4 and Figures 2 and 3. We can observe that the Intervention group obtained an improvement in mean knee flexion ROM compared to the Control group, and as regards to the mean knee extension ROM the Intervention group started the physiotherapy treatment with a greater knee extension deficit than the Control group. Nevertheless, at the end of the treatment the group achieved an improvement in the mean knee extension goniometry in comparison to the Control group.

The measurement of pain intensity using VAS, performed at the beginning and end of the physiotherapy sessions, was submitted to the calculation of the mean and standard deviation and can be observed in Table 5 and in Figure 4. In the Intervention group there was a decrease in the mean pain intensity at the end of the physiotherapy sessions when compared to the Control group.

As regards the absolute and percentual improvement, in all outcomes the Intervention group obtained an effective absolute and percentual improvement when compared to the Control group. The absolute improvement is represented in Figure 5, for knee flexion ROM. The Intervention group presented an improvement of 26.4° and 17.3° for the Control group, while the improve-

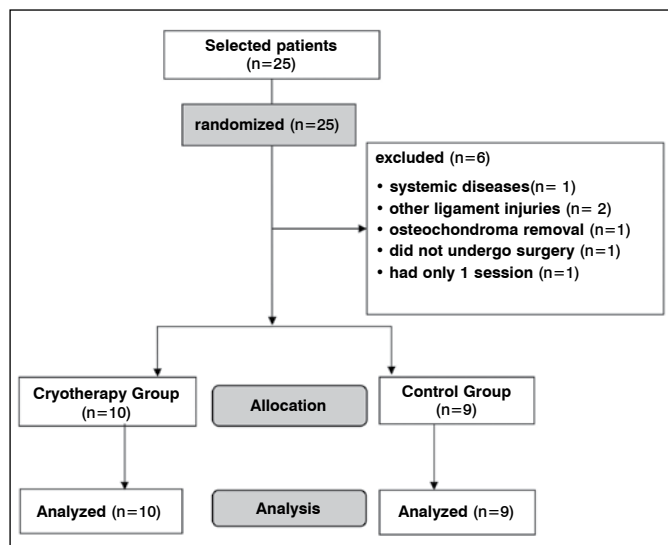


Figure 1. CONSORT Flowchart.

Table 2. Characteristics of the Sample.

Sample	Intervention Group (n=10)	Control Group (n=9)
Average age	31.9 (21-58 years)	27.22 (19-34 years)
Sex		
Male	n=10	n=9
Female	n=0	n=0
Affected limb		
Right	n=5	n=6
Left	n=5	n=3
Type of graft		
Flexor Tendon	n=10	n=9
Meniscal Injury	n=6	n=7
Meniscectomy		
Partial medial	n=3	n=3
Partial medial and lateral	n=2	n=4
Total medial and partial lateral	n=1	
Number of postoperative sessions	n=2	n=2

Table 3. Mean and standard deviation of the range of motion of knee flexion in the Intervention and Control group.

Flexion Intervention Group	Mean (SD)	
1 st IPs	57.3	±18 . 3
1 st FPs	69.3	±22 . 9
2 nd IPs	70.8	±11 . 8
2 nd FPs	83.7	7.9
Flexion Control Group	Mean (SD)	
1 st IPs	53.4	±20 . 8
1 st FPs	69.7	±17 . 2
2 nd IPs	63.7	±11 . 0
2 nd FPs	70.8	±12 . 8

IPs: Initial physiotherapy session, FPs: Final physiotherapy session, SD: Standard Deviation.

Table 4. Mean and standard deviation of the range of motion of knee extension in the Intervention and Control group.

Extension Intervention Group	Mean (SD)	
1 st IPs	-13.7	±11 . 9
1 st FPs	-9.8	±8 . 1
2 nd IPs	-10.1	±8 . 5
2 nd FPs	-7.8	±7 . 2
Extension Control Group	Mean (SD)	
1 st IPs	-7.3	±4 . 5
1 st FPs	-6.1	±4 . 0
2 nd IPs	-7.0	±7 . 1
2 nd FPs	-5.8	±5 . 8

IPs: Initial physiotherapy session, FPs: Final physiotherapy session, SD: Standard Deviation.

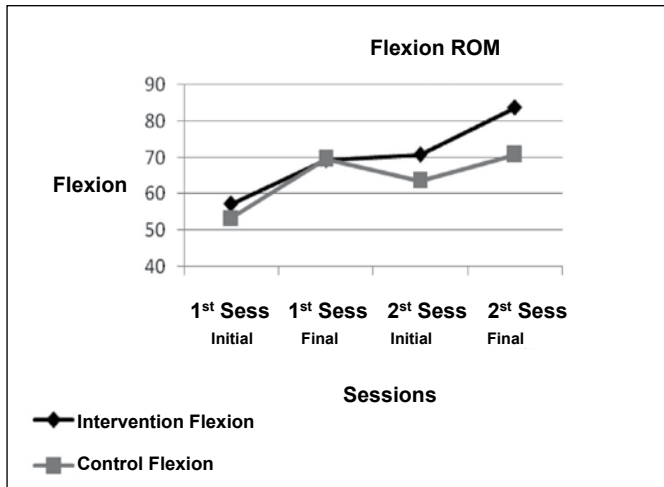


Figure 2. Mean range of motion of knee flexion in the Intervention and Control groups.

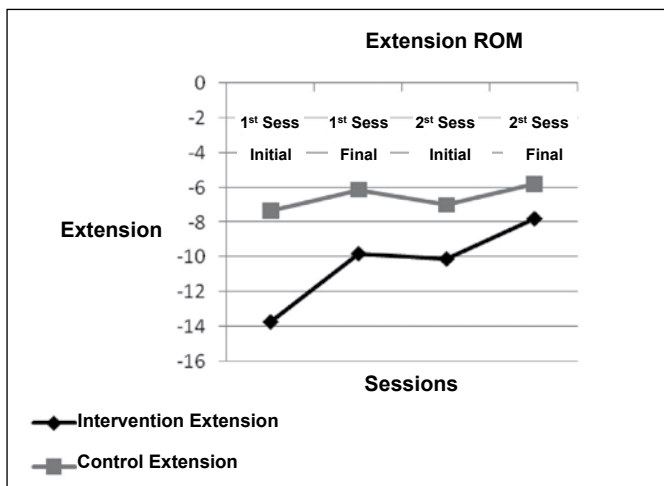


Figure 3. Mean range of motion of knee extension in the Intervention and Control groups.

Table 5. Mean and standard deviation of Pain in the Intervention and Control group.

Pain Intervention Group		Mean (SD)	
1 st IPs	2.8	±3.2	
1 st FPs	2.2	±2.0	
2 nd IPs	1.42	±1.5	
2 nd FPs	1.19	1.8	
Pain Control Group		Mean (SD)	
1 st IPs	2.8	±3.1	
1 st FPs	2.4	±2.4	
2 nd IPs	1.8	±2.0	
2 nd FPs	2.5	±2.0	

IPs: Initial physiotherapy session, FPs: Final physiotherapy session, SD: Standard Deviation.

ment for knee extension ROM was 5.9° in the Intervention group and 1.6° in the Control group. As regards pain, the absolute improvement was 1.6 cm in the Intervention group and 0.3 cm in the Control group. The percentual improvement is represented in Figure 6. In the Intervention group the percentual improvement of the knee flexion ROM was 46.07% and in the

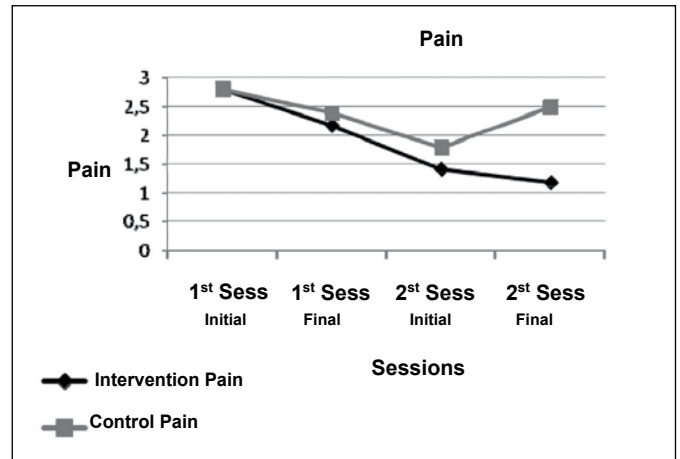


Figure 4. Mean pain at rest in knee in the Intervention and Control groups.

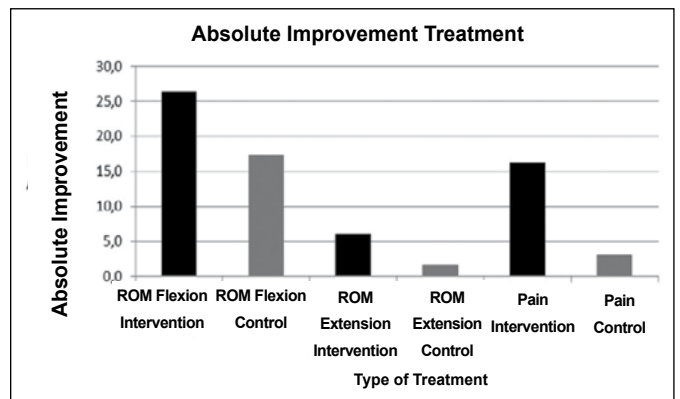


Figure 5. Absolute improvement of the physiotherapy treatment in the Intervention and Control groups in the range of motion of knee flexion and extension and in pain after anterior cruciate ligament reconstruction surgery.

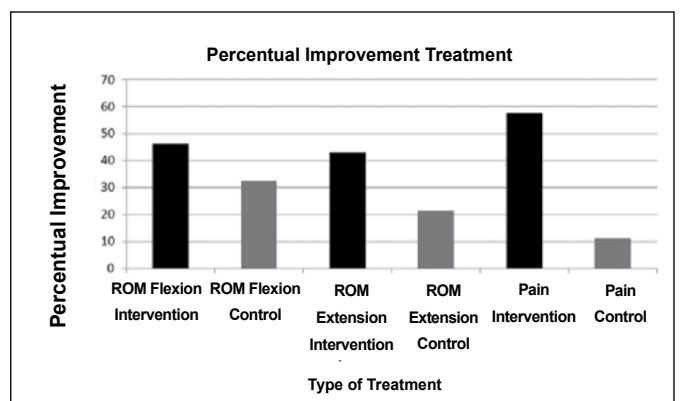


Figure 6. Percentual improvement of physiotherapy treatment in the Intervention and Control groups in the range of motion of knee flexion and extension and in pain after anterior cruciate ligament reconstruction surgery.

Control group it was 32.43%, while the percentual improvement of knee extension ROM was 43.07% in the Intervention group and 21.21% in the Control group. Finally, the percentual improvement of pain was 57.65% in the Intervention group, but only 11.07% in the Control group.

DISCUSSION

The objective of the present study was to evaluate the effect of cryotherapy after ACL reconstruction surgery, measured through knee ROM and VAS. As described in the literature, we observed that the application of the ice pack is an effective method for improving pain and knee ROM after ACL reconstruction surgery.^{12,15,16} Warren et al.¹⁷ demonstrated that in various injuries of soft tissues of the knee, the ice wrap presented better intra-articular temperature reduction in patients when compared to the external knee cooling device (*Cryocuff*®).

The association of cryotherapy with compression and elevation of the limb can be considered a factor of improvement for individuals as regards the analyzed outcomes. Bleakley et al.,¹² in a systematic review, presented several comparisons between ice application methods, demonstrating that associating cryotherapy with compression and elevation is effective when compared to cryotherapy alone, yet this study did not present an appropriate duration for application of the ice. On the other hand, Edwards et al.¹⁸ compared the use of ice and of compression with the non-application of cryotherapy and showed similar effects between the groups, yet this study was considered a high risk of methodological bias.

As regards the duration of cryotherapy application, differences of opinion are found in the literature, and it can range from 10 to 20 minutes to 30 to 45 minutes. In the systemic review mentioned previously concerning the application of ice, few studies evaluated the effectiveness of ice after injuries to the soft tissues and there was no evidence of the best method and duration of the treatment. As a conclusion, further studies need to be conducted with better standardization of this method in order to clarify which parameter is best for increasing the effectiveness of cryotherapy.¹²

It can also be emphasized that the effectiveness of an accelerated physiotherapy protocol in this study brought about an improvement in the outcomes analyzed in the two groups. The subject of physiotherapy treatment after ACL reconstruction has recently been researched in depth by various authors, consequently there is a focus on the accelerated physiotherapy protocol since in the immediate postoperative period, it promotes a decrease in hospitalization time besides an improvement of knee ROM and of function.¹⁹

As regards the characteristics of the sample, there were no major differences between the Intervention and Control groups in relation to age of the participants. They were all male, underwent surgery with the same type of graft from tendons of the knee flexor muscles and attended two physiotherapy sessions on the first postoperative day. These findings corroborate those of a review, showing that gender did not produce differences in relation to the results found, and it is hard to determine whether there is an effect of age in the groups or not.¹⁹ The Intervention and Control groups had some differences with regards to the surgery performed, relating only to whether surgery actually occurred or not, and to the type of meniscectomy; however, the patients were randomized before the surgery to one of the two groups and thus the surgical approach to be adopted was not known.

The procedures and assessment of the patients were not blind, which can be considered a bias in the results of the present

study, yet it is worth mentioning that the tools, such as the goniometry and the Visual Analog Scale of pain, are a routine practice for physiotherapists in the hospital environment. In this study there was a standardization of the evaluation, which consisted of only one evaluator, yet trained to perform the goniometric measurement through a correct positioning of the goniometer and of the individual, and we also standardized the method of application of the Visual Analog Scale of pain, particularly in relation to the verbal command and explanation of the extreme points of the scale: without pain and maximum pain.

VAS is the pain intensity scale most frequently found in clinical trials.^{8,9,13,14} As it is a subjective scale, differences can be found and questioned among individuals. Pain is considered an unpleasant sensory and emotional experience, presenting a threshold that can vary among people and the ability to tolerate pain varies according to personality, mood and the circumstances of each individual. VAS does not evaluate pain in an objective and direct manner - it only allows us to question the individual to obtain an estimate of the pain that they were feeling at a particular time. For this reason we cannot affirm that the results found among the participants are reliable, but we can correlate the effects at the beginning and at the end of the rehabilitation in the opinion of a single individual.

According to the results of the VAS, the Intervention group (A) had a decrease in mean pain when compared with the Control group (B), but we can observe that in the Control group the point of the second session (afterwards) presents a value that is inconsistent with the normal evolution of the treatment. This point may be due to the small number of participants of this study, but even if we disregard this value, the Intervention group (A) still presents an important improvement in the mean initial and final pain of the sessions when compared with the Control group. The findings of this study are in accordance with those found in literature, and the studies indicate reduction of knee pain intensity with the use of cryotherapy after the ACL reconstruction surgery⁸ and cryotherapy in the immediate postoperative period as it is an inexpensive measure of easy access and with a high level of satisfaction among individuals.¹⁶ When pain intensity is related to the different types of surgical approach, with regards to whether meniscectomy occurred or not, it is worth pointing out that in literature, a study that compared groups in which the individuals did not undergo meniscectomy, or had meniscal resection, or meniscal suturing, evaluating the evolution of pain intensity over the seven days of ACL reconstruction surgery postoperative period, showed that there were no significant differences in pain intensity, using VAS,²⁰ which corroborates the findings of our study.

The results found for knee flexion ROM showed that the mean goniometry had an important improvement in the Intervention group at the beginning and at the end of the second session, when compared to the Control group. Although the Control group had a better mean knee extension ROM value than the Intervention group at the end, it cannot be said that the treatment without ice was better, since on average the individuals of the Control group started the treatment in a better state than those of the Intervention group. It can also be perceived that in the Control group there was practically no improvement since the initial condition, while the Intervention group started with

greater extension deficit than the control group, but had an important improvement in the mean knee extension ROM.

According to similar studies, there is a difference of opinion in relation to the improvement of knee ROM with the use of cryotherapy after ACL reconstruction surgery. The studies indicate that there was no significant improvement of ROM in the group that made use of ice, when compared with the control group; however, these studies do not describe how and when the goniometry was performed, they just report that the two groups obtained an increase in the ROM of the knee in the postoperative period.^{14,16}

Finally, in relation to the absolute and percentual improvement of the treatment, with baseline in the initial condition and at the end of the physiotherapy treatment, the Intervention group achieved an important absolute and percentual improvement when compared with the Control group, for the parameters of pain intensity, flexion ROM and knee extension.

Thus, the use of cryotherapy is directly related to the immediate postoperative period and the prognosis of functionality after hospital discharge. After using ice, the patients, already in the hospital environment, manage to improve the parameters of pain and ROM, reducing the hospital stay time, the expenses of the health system with the hospitalization and the therapy of analgesic medications, therefore also improving the quality of life and satisfaction of the individuals. An important fact is that

cryotherapy is a rehabilitation method of easy application that can be guided and recommended for use at home, to assist in the progress of rehabilitation, avoiding the persistence of pain, edema, inflammation and complications in the postoperative period such as decreased range of movement in the joints, motor control and gait alterations.⁷ Therefore, the use of ice is geared towards functional improvement and the return of individuals to the level of activities of daily living prior to the injury. This study, as is the case of a pilot study, demonstrated good results with cryotherapy use after ACL reconstruction surgery in a reduced population. The authors intend to continue with this work to be able to conclude whether this type of therapy really is effective and safe, since it is a highly accessible, low-cost method, and future surveys with adequate methodological criteria would contribute to the scientific community, aiming to improve the satisfaction and quality of life of individuals after this surgical procedure.

CONCLUSION

Cryotherapy in the immediate postoperative period in association with an exercise protocol was effective in improving pain and range of knee joint motion in adults submitted to ACL reconstruction surgery, with application time of 20 minutes and carried out twice a day.

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