SHORT COMMUNICATION

A comparison of continuous cold flow and compression device and traditional icing regimen and no icing following anterior cruciate ligament reconstruction: A pilot study

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Abstract

The aim of this study was to investigate the effectiveness of continuous cold flow and compression device as against traditional icing regimen and without icing after anterior cruciate ligament (ACL) reconstruction. All patients undergoing ACL reconstruction from June 2021 to August 2021 were enrolled in this study. Patients were randomly allocated to three groups: A control group (n=10) with no ice regimen post-operatively, a second control group (n=10) with ice bag, and a third group (n=10) with continuous cold flow and compression device (physiolab). All patients who had isolated ACL tear evident on magnetic resonance imaging were included. Pain intensity, limb girth, Oxford Knee Score, and 12-item survey form were measured pre- and post-operatively. Significant difference was noted between pain scores in all groups at two- and six-week follow-ups with p-value of 0.004 and 0.01. The test for "between subject effects" showed significant difference (p=0.007) in limb girth between the two groups. Cold and compression device can be used to reduce swelling immediately after ACL reconstruction.

Keyword: Cryotherapy, ACL tear, Arthroscopy, Sports injury, Rehabilitation.

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Introduction

Anterior cruciate ligament (ACL) ruptures are the most prevalent musculoskeletal sports related injury. In case of young and active patients, arthroscopic ACL reconstruction is the gold standard for such injuries.[1] However, the short- and long-term outcomes depend on proper rehabilitation after reconstruction.[2] Although inflammation, pain, and oedema are part of the healing process, they also interfere with early rehabilitation and mobility after surgery. Therefore, limiting these problems is necessary for better functional outcomes. For early mobilisation, it is imperative to reduce swelling and pain immediately after ACL reconstruction. In early postoperative phase, pain and oedema can interfere in the rehabilitation process, hampering the patients' return to their routine activities and their functionality.[2,3] The use of ice compression therapy immediately after surgery can be a cost-effective and easily available option to decrease swelling and pain.[4] Temperature-controlled continuous cold flow device is thought to accelerate rehabilitation after ACL reconstruction by reducing acute symptoms like pain and swelling.[5] It has been reported in literature that cold and compression reduces cellular metabolism, nerve conduction, oedema formation, and pain, thus contributing to early recovery.[6] Many clinical studies only investigated the effect of cold compression therapy on swelling, pain, range of motion, and hospital stay.[7] However, it has also been reported previously that the cryotherapy alone relieves pain and increases the range of motion after ACL reconstruction.[8] To the best of our knowledge, only a few prospective studies have dealt with the effects of temperature-controlled continuous cold flow device, cryotherapy, and no ice therapy after ACL reconstruction.[9]

None of the previous studies compared temperature-controlled continuous cold flow device, cryotherapy, and no ice therapy after ACL reconstruction. It is also beneficial to measure the long-term outcomes of temperature-controlled continuous cold flow device, cryotherapy, and no ice therapy on analgesics, cellular parameters, rehabilitation, and quality of life. The aim of the present study is to investigate the effectiveness of temperature-controlled continuous cold flow device (Physiolab) following anterior cruciate ligament reconstruction and to compare it with traditional icing method without compression and no icing regimen.

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Patients/ Methods and Results

This pilot study was approved by the institutional review board (IRB) of United Medical and Dental College, Karachi, (Ref no: UMDC/Ethics/2020/27/08/394). Informed consent was obtained from patients prior to data collection. A total of 30 patients undergoing ACL reconstruction from June 2021 to August 2021 were enrolled in this study. All patients who had symptomatic, isolated ACL tear (grade 1 and 2 meniscal tear and small osteochondral lesions that do not require surgery) evident on magnetic resonance imaging (MRI) that required ACL reconstruction were included in this study. Exclusion criteria were any vascular disease of the injured leg (e.g. Raynaud's syndrome, diabetic vasculopathy), active phlebitis, hypersensitivity to cold and superficial wound or infection. In the pre-operative settings, all patients were randomly allocated to three groups: a control group (n=10) in which no ice therapy was given post-operatively; a second control group (n=10) in which cryotherapy was applied in all patients after ACL reconstruction; and the third group which was the study group (n=10) in which temperature-controlled continuous cold flow device (Physiolab) was administered after surgery. A computer-generated algorithm was used for randomisation. Patients were enrolled by algorithm generated numbers.

Physiolab is a temperature-controlled, continuous cold and compression device that works as a coolant and compressor. It consists of thermoplastic polyurethane cuffs that compress the body part and cooling device control unit. The temperature setting is adjustable and set from 10 to 300^{o}C. Physiolab was applied to all patients in the study group from first post-operative day till they were discharged from the hospital (at least for one day) after every two hours. Similarly, in the control group cryotherapy cuff was applied after every two hours from the first post-operative day. For all patients, arthroscopy was performed by the same surgeon, in supine position under spinal anaesthesia. Tourniquet was applied during arthroscopy and two standard portals: anterolateral and anteromedial were used.

General demographic details like age, gender, mechanism of injury, duration of surgery, and number of physiotherapy sessions are mentioned in Table 1. Pain intensity was a primary outcome measured by using visual analogue score (VAS).[10] The pain intensity was measured at pre-operative, 24 hours after surgery, and 2, 6 and 12 weeks post-operatively. The secondary outcomes were limb girth to evaluate post-operative oedema. It was measured pre-operative, postoperative after 24 hours, 2, 6 and 12 weeks. The limb girth measurement was taken at the level of the patella. Oxford Knee Score[11] (OKS) and 12-item short survey form (SF-12)[12] were also measured pre-operatively and three months after surgery. The OKS is a reliable and valid tool to assess knee joint function[11] and SF-12 was used to evaluate overall quality of life in all patients12 after arthroscopy. The SF-12 has two components: physical component score (PC score) and mental component score (MC score).

After surgery, compressive thin bandage was applied to protect the stitches. All patients were allowed full weight-bearing or weight-bearing as tolerated after 24 hours of surgery. The rehabilitation protocol included isometric exercise for Quadriceps, hamstring and gluteal muscles, knee range of motion exercises, and icing as per enrolled group. Two weeks after the surgery, open chain isotonic exercises and strengthening exercises were commenced.

The statistical analysis was done by using SPSS software version 26 and Stata. Descriptive statistics was used for general demographics. The mean, standard deviation, frequencies and percentages were estimated for descriptive analysis. The normality of the data was checked by using Shapiro–Wilk test (p=<0.05) and normality plot. Since data was not normally distributed we used non-parametric tests for analysis. The limb girth measurement was compared between three groups at pre-operative, 24 hours, two, six and 12 weeks after surgery by using non-parametric repeated measure ANOVA (Friedman test). The non-parametric Kruskal Wallis test was used to compare Oxford and SF-12 scores. The p-value< 0.05 was considered as level of significance. The sample size for pilot and feasibility studies remains unclear. However, recommendation varies from 10 to 12 participants in each group as reported previously.[13] Therefore, 10 participants were included in each group.

The mean age of the study population for cryotherapy, no ice therapy and temperature-controlled continuous cold flow device was 26.60±3.40 years, 27.40±3.59 years and 27.30±3.23 years, respectively. All other demographics are mentioned in Table 1.

The pain intensity in all groups reduced at every follow-up with p<0.001. At six weeks, there was a significant difference in pain intensity between groups (p=0.01). At 12 weeks, no statistically significant difference was noted among groups (p=0.06) with mean VAS of 0.40±0.51, 0.20±0.63 and 0±0 for cryotherapy, no ice therapy, and temperature-controlled continuous cold flow device group, respectively.

The limb girth at each follow-up in all groups are mentioned in Table 2. The test of between subject effect showed significant difference ($F_{2,27}$= 6.06, p= 0.007). The

pair wise comparison between groups showed significant difference between temperature-controlled continuous cold flow device group with cryotherapy and temperature-controlled continuous cold flow device group with no ice therapy group (p=0.002, 0.04). According to the profile plot, temperature-controlled continuous cold flow device group reduced immediate swelling after 24 hours of surgery with decreased limb girth of operated limb as illustrated by profile plot (Figure 1).

Table-1: Inter-Group Analysis of Neck Range of Motion.

Pre-operative parameters	Icing (n=10)	No- icing (n=10)	Physiolab (n=10)
Mean Age (years)	26.60±3.40	27.40±3.59	27.30±3.23
Mechanism of injury	RTA=6, fall=4	RTA=7, fall=3	RTA=4, fall=6
Time from injury to surgery	5.5 months	6 months	5 months
Pre- operative CRP	10.95±9.45	4.71±4.42	0.17±0.26
Duration of surgery	30 minutes	30 minutes	30 minutes
Menisectomy (%)	20%	35%	25%
Minor chondral damage (I-II ICRS) (%)	35%	42%	40%

RTA: Road traffic accident; CRP: C- reactive protein; ICRS: International cartilage repair society

Table-2: Limb girth measurement at pre-operative and post-operative after 24 hours, 2, 6 and 12 weeks.

Measurement level	Physiolab	No-icing	icing
Pre-operative	36.80±3.76	41.60±4.14	44.35±6.94
24- hours post-operative	36.80±4.28	42.75±4.87	45.80±7.03
2 weeks post-operative	36.10±5.23	40.65±3.48	40±6.04
6 weeks post-operative	35.90±5.10	40.30±3.63	43.20±6.42
12 weeks post-operative	35.40±5.27	39.90±3.45	42.80±6.57

Table-3: Comparison of pre-operative and three months SF 12 (physical and mental component) and Oxford score between groups.

SCORES	Icing	No icing	Physiolab	p-value
Pre-operative SF-12 PC score	36.62 (5.50)	39.43 (3.78)	42.16 (4.66)	0.01
Pre-operative SF-12 MC score	44.16 (1.41)	35.27 (3.90)	34.19 (8.71)	0.03
3 months post-operative SF-12 PC score	56.57 (9.56)	56.57 (1.55)	56.57 (0.23)	0.20
3 months post-operative MC score	60.75 (28.08)	60.75 (3.64)	60.75 (2.06)	0.16
Pre-operative oxford	30 (13.5)	33 (6.25)	35.5 (4.25)	0.05
3 months Post-operative oxford	48 (3)	48 (0)	48 (2.50)	0.25

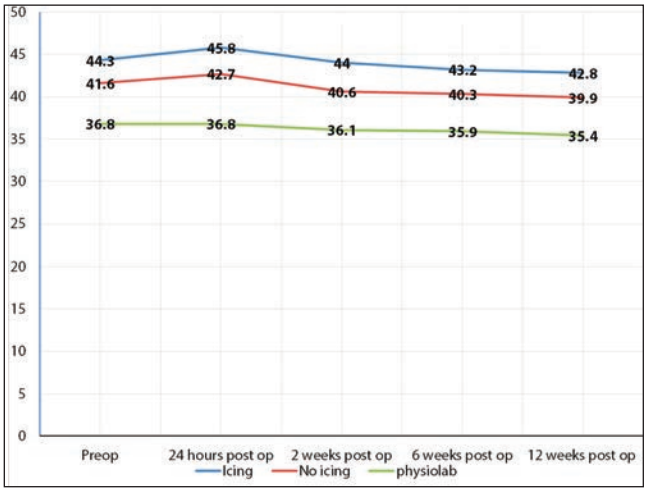

Figure: Mean limb girth values for all groups at pre-operative, 24 hours, 2, 6 and 12 weeks after reconstruction.

The median (IQ) scores for SF-12 and Oxford score are mentioned in Table 3, showing insignificant difference between groups after 12 weeks of reconstruction. No statistical difference was noted between frequency of analgesic used and icing regimen. The average analgesic used in all groups was a dose of Acetaminophen thrice a day for two weeks. Twenty-seven (90%) patients did not require additional pain relief after two weeks. However, 3(10%) still use Acetaminophen occasionally.

Conclusion

In early postoperative phase pain and oedema govern the rehabilitation process, interfering with the patients' return to their routine activities and their functionality. In this prospective study, results proved the synergistic effect of compression and cold on early oedema formation. Future studies in this direction could possibly provide more insight in the potential effect of continuous cold flow and compression device on hospitalisation, further rehabilitation protocol, and overall patient satisfaction.

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ZAK: Data analysis, interpretation, drafting, literature review.
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