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Influence Of Blood Flow Restriction Training on Knee Pain After Anterior Cruciate Ligament Reconstruction: A Double Blinded Randamized Controlled Trial

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ABSTRACT

Background: Anterior cruciate ligament rupture thought to be one of the most popular injuries among adults. Knee pain is a common post-operative rehabilitation problem, which may disturb muscle physiological prosperities and hinder the fluence of post-operative rehabilitation milestones achievement and vise versa. Blood flow restriction is an innovative technique which positively affects postoperative knee function.

Purpose: To investigate the effect of adding Blood flow restriction to post-operative anterior cruciate ligament conventional rehabilitation protocol on knee pain.

Methods: Thirty six post-operative anterior cruciate ligament post-operative patients were randomized into two groups. Participants in group I received conventional rehabilitation protocol. Participants in group II received blood flow restriction training added to conventional rehabilitation protocol. Knee pain was evaluated using a visual analogue scale pre-operative and one and half months and three months post-operatively.

Results: There was significant improvement of knee pain on visual analogue scale post-operative at all measures in both groups (p-value<0.05), while there was no significant differences between both groups at post-operative measures (p-value>0.05).

Conclusions: Adding blood flow restriction technique to conventional rehabilitation protocol was not superior to conventional rehabilitation protocol alone on knee pain post anterior cruciate ligament reconstruction

Keywords: *Blood flow restriction technique; Anterior cruciate ligament reconstruction; Conventional rehabilitation; Knee pain ; Pain scale*

INTRODUCTION

Anterior cruciate ligament (ACL) rupture is among the most frequently occurring knee injuries among adult individuals aged 20 to 29, particularly in sports which make the player to pivot, jump, or strike with other players 1. Isolated ACL tear is still a common orthopaedic injury, with an annual incidence of 68.6 per 100,000 person-years2. Pain is a common post-operative rehabilitation problem, which may affect muscle quality and hinder the fluence of milestone achievement. Lower limb surgeries are frequently followed by a period of less loading, which leads to muscle mass loss. The quadriceps muscle is the most affected 3. Quadriceps weakness persists after anterior cruciate ligament reconstruction (ACLR) 4. The femoral nerve block (FNB) is one of the most common causes of quadriceps muscle atrophy in people who have had ACLR surgery 5, and arthrogenic muscle inhibition 6, As a result, patients who have ACLR do not totally regain quadriceps size 7. In addition quadriceps weakness has frequently been linked to knee pain in cross-sectional studies. 8,9.

Following ACLR, the rehabilitation protocol is regarded as a critical component of the recovery process, and it should include physical therapy modalities like neuromuscular electrical stimulation (NMES) and pneumatic ice compression that can be beneficial in the early stages of rehabilitation when pain, swelling, and other symptoms are present, as well as to allow for more pain-free exercise rehabilitation10. The post-operative rehabilitation programme includes a variety of exercises, such as isometric quadriceps strength, range of motion (ROM), weight bearing, balance, and proprioception training.

Blood flow restriction (BFR) is one of the new ways used to restore quadriceps muscular strength following ACLR, in which arterial flow is slightly limited but venous outflow in the working muscle is totally blocked during exercises. 11. Dr. Yoshiaki Sato pioneered it in Japan in 1966 as a form of training involving the restriction of arterial blood flow proximal to the working muscle via a pneumatic tourniquet system. It was known as BFR or KAATSU training, which means pressure added training 12. There is adequate evidence showing that BFR is a valuable method to increase muscle strength in athletes 13, normal persons 14, and in anterior knee pain syndrome patients 15. It clearly boosted the strength and muscular size as well as the functional performance of young adults 17,18 and active elderly people.16

The mechanisms of BFR that cause muscular adaptation are not well understood, according to a recent systematic review meta-analysis 19. Other studies have determined that BFR appears to be a risk free method 20 when used according to evidence-based guidelines in patients with knee-related musculoskeletal disorders 21 like post-ACLR operations at the early rehabilitation stage 22,23. According to Marissa 24, BFR with low load (LL) resistance training are effective methods for controlling the common side effects of ACLR surgeries while avoiding the hazards associated with high intensity load training. Systematic review by Koc et al., 25 suggested that LL-BFR training following ACLR may be superior to non-BFR training in terms of knee joint pain.

So, the objective of the study was to investigate the effect of adding BFR to post-operative ACLR

conventional rehabilitation protocol (CRP) on knee pain.

MATERIALS AND METHODS

Study Design

Double-Blinded Randomized controlled trial (P.T.REC/012/003141) in which participants scheduled to undergo ACLR were randomly assigned, using an online random number generator (www.graphpad.com), into one of two intervention groups: (I) CRP (II) CRP with BFR. The study intervention was provided 1 week post-surgically, until the end of the third month post-surgical. Both participants and the outcome assessors were blinded to treatment assignment. Participants completed study testing at 3 time points: (1) one week preoperative, (2) one and half months post operative, and (3) three months post operative. The outcome measure was change in knee pain using VAS scale.

Eligibility Criteria

Patients were eligible for inclusion in our study if they were aged between 18 to 35 years, were willing to take part in the intervention and follow-up, had a body mass index (BMI) less than 30 kg/m2, and their ACL grafts were semitendinosus autograft 23. Participants were excluded if they had insecure graft fixation (due to bone quality ,or suspension), postsurgical excess knee swelling which affect exercise performance, active infection, any lower limb trauma, any cardiovascular disease, and hip or ankle pathology. All participants were referred by orthopaedic surgeons, who were in charge of diagnosing ACL ruptures based on clinical and radiographic examinations as well as performing the ACLR semitendinosus autograft procedure.

Evaluation as well as treatment procedures were accomplished at a private physical therapy clinic after the approval of the Institutional Review Board of Cairo University's Faculty of Physical Therapy.

Participants

fifty five (males and females) participants were enrolled and scheduled to undergo ACLR (autograft of the semitendinosus muscle tendon) 23. following the surgical procedure, 18 participants were rejected from participation as they did not meet the inclusion criteria, and one participant refused to continue the study as illustrated in flow chart (Figure 1)

A total of 36 patients (males and females) assigned to one of each group; Group I (control group) (n=18): received the CRP (16 men, 2 women) with mean age of 25.22 ± 4.76 and mean BMI of 25.359 ± 2.1013 Group II (experimental group) (n=18): received CRP with BFR (15 men, 3 women) with a mean age of 23.78 ± 3.934 and mean BMI of 26.213 ± 3.9471 (Table 1)

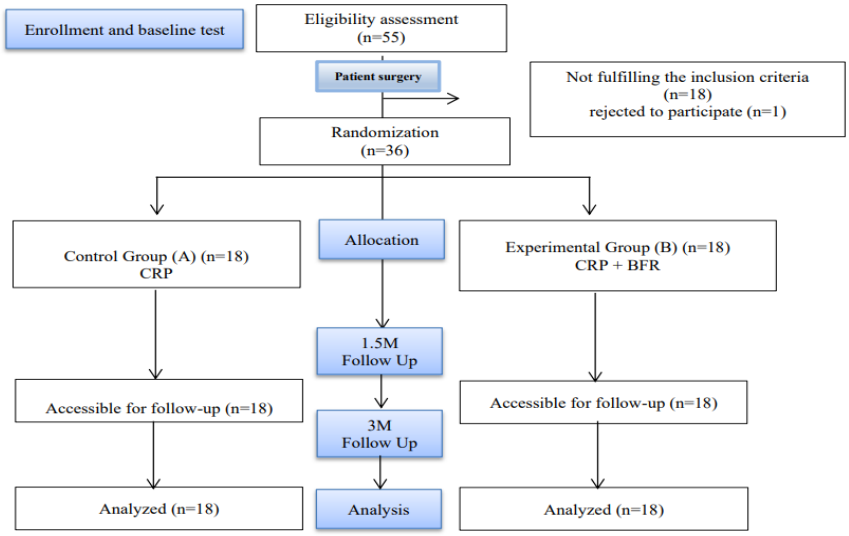

FIGURE 1: flow diagram illustrating the flow of participants throughout the trial.

Instrumentation

Portable Doppler ultrasound to evaluate limb occlusive pressure (LOP) 26.

A specially designed sphygmomanometer for BFR 12.

Resistant bands, a universal scale for height, weight, and BMI.

Visual analog scale (VAS):

Procedures For Assessment

We measured the outcomes three times, pre-operative, 1.5 and 3 months post-operatively at the end of the protocol of treatment to catch the results of the different treatment protocols.

Pain assessment

The VAS scale is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits. The patient draws a perpendicular line through the point that they believe represents their current state. The score is calculated by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark with a ruler, yielding a range of scores ranging from 0-100. A higher score indicates more intense pain27. Alghadir et al,28 reported that VAS scale was one of the most sensitive and reliable tools to evaluate the knee pain.

Procedures for treatment

After one week of post-operative ACLR, all individuals were randomised to one of two groups; all participants received standard immediate postoperative treatment until the end of the first week postoperative (3 sessions per week). The exercise protocol adopted from Patterson et al, 29

Standard immediate post-operative care included

Gentle active ROM, Passive joint and soft tissue mobilizations, Ice gel packs on the knee (cryotherapy), begin weight shifting ,flexibility training to calf muscle , Weight bearing with crutches as tolerated until quadriceps control is achieved.

A-Control group

post-operatively (2-6) weeks

Patients received: NMES, 10 minutes (min), passive joint (patellar mobilization), stretching exercise to calf muscle (15 seconds (s.) x 3 repetition (rep.)). Balance and proprioceptive training; weight shifting exercises (30 rep.) (supported to non-supported), single leg stance supported 30-60 s. and active joint reproduction (30 rep.), Ice packs (10 min.) (cryotherapy)

post-operatively (7-12) weeks

Patients continued NMES (10 min), begin stationary bike level 2 or 3 on bike (easy level) for 10-15 min., proprioceptive, neuromuscular, stability training; half swiss ball weight shifting (30 rep.) (supported to non-supported), single leg standing open and closed eyes for 30s to 60s. (supported to non-supported), static mini-squat with co-contraction (hold for 30s. x 3rep) of hamstring and quadriceps. Continue progression with active ROM and stretching exercise, leg press using elastic band (3x10 rep-3x15 rep), step-back lunge (3x10 rep), plantar flexion (3x10 rep.), and bike (10-15) minutes active work, increase intensity through higher resistance of

elastic band, bike resistance level or step height.

B- Experimental group (BFR group)

the same protocol was used with addition of BFR with NMES or during all mentioned strength exercises in CRP at the level of 80% of LOP.

Statistical Analysis

Data were statistically described in terms of mean ± standard deviation (± SD), median and range, or frequencies (number of cases) and percentages when appropriate. Numerical data were tested for normal assumptions using Shapiro Wilk test. Comparison of numerical variables between the study groups was done using Mann Whitney U test for independent samples. Within group comparison of numerical variables was done

using Freidman's test with Wilcoxon signed rank test for paired (matched) samples as post-hoc multiple 2-group comparisons after applying Bonferroni adjustment for multiple comparisons. For comparing categorical data, Chi-square ($\chi 2$) test was performed. Exact test was used instead when the expected frequency was less than 5. Two-sided p-values less than 0.05 were considered statistically significant. IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows was used for all statistical analyses.

RESULTS

Participants in both groups did not differ in terms of demographics. (Table 1) summarizes the demographics of patients in the two groups. The mean ± standard deviation (SD) of the age and the body mass index (BMI) for the two groups are shown. at baseline, there were no differences between groups (p>0.05).

TABLE 1: Patients' demographics, including age and BMI values, for the both tested groups at baseline (n= 36).

Variables	**Mean ± SD**		**P-value**
	CRP Group (n=18)	CRP+BFR Group (n=18)	
Age (years)	25.22 ± 4.76	23.78 ± 3.934	0.357
BMI (kg/m2)	25.359 ± 2.1013	26.213 ± 3.9471	0.527

SD, standard deviation, significance level put at P ≤ 0.05.

A- Within group Differences

Group A: As presented in (Table 2) the mean ± SD values in the pre-operative, post-operative 1.5m and 3m follow-up of VAS scale were 5.24 ± 1.48, 4.22 ± 1.26 and 1.39 ± 0.7 respectively, The test revealed that there was significant improvement of the VAS scale at 1.5 and 3 months post-operatively in comparison to pre-treatment (p-value<0.05).

Group B: As presented in (Table 2) the mean ± SD values in the pre-operative, 1.5 and 3 months post-operatively follow-up of VAS scale were (5.35 ± 1.64), (4.06 ± 1.43) and (1.00 ± 1.19) respectively, The test revealed that there was significant improvement of the VAS scale at 1.5 and 3 months post-operatively in comparison to pre-treatment (p-value<0.05).

TABLE 2: Descriptive and inferential statistics of VAS scale for both groups.

P-value: within & between groups comparison, CRP group: conventional rehabilitation protocol group, BFR group: Blood flow restriction group.

VAS scale	**Group A (CRP)**	**Group B (CRP+ BFR)**	**P. value**
Pre-operative	5.24 ± 1.48	5.35 ± 1.64	0.949
1.5m post-operative	4.22 ± 1.26	4.06 ± 1.43	0.636
3m post-operative	1.39 ± 0.70	1.00 ± 1.19	0.148
P. value	0.000	0.000	

B. Between Group Differences

As presented in Table 2, there were no significant differences (p-value 0.05) between both groups (A) CRP and (B) BFR added to CRP when the knee pain VAS scale was measured.

DISCUSSION

This study investigated the effectiveness of adding BFR to CRP post ACLR on knee joint pain.

Results revealed that knee pain improved over time in both groups, but there was no significant difference between both groups at follow-up periods (1.5 and 3 months postoperatively).

Hughes et al.,30 conducted a randomized controlled trial (RCT)to examine the pain with BFR resistance training compared to standard care heavy load resistance training during ACLR rehabilitation. Twenty-eight patients were recruited following unilateral ACLR surgery with hamstring autograft. Following surgery, participants were randomly assigned to either high load training at 70% repetition maximum (1RM) or BFR at 30% 1RM, and they completed 8 weeks of twice weekly unilateral leg press training on both limbs. Main outcome measures were muscle pain, perceived knee pain, and rating of perceived exertion (RPE) were assessed using Borg's RPE and pain scales during training. They concluded that BFR when compared to typical high load training, ACLR patients experienced less knee joint pain and reported nearly equal rates of perceived exertion during and after leg press activity.

That study came into agreement with our finding as the BFR cuff was not an exaggerative tool to knee pain when it was added to the conventional exercise, the addition of the cuff with its tactile stimulation in the thigh may alter knee joint pain and cause it to fade away from the knee.

Giles et al, 31 evaluated the effect of BFR training which conducted both before and after ACLR on early quadriceps strength and patient reported outcomes. A total of 79 participants were randomly assigned to either a standardised quadriceps strengthening or BFR. Both groups did 8 weeks of leg press and leg extension, the conventional group at 70% of 1RM and the BFR group at 30% of 1RM. The VAS scale for 'worst pain' and 'pain with daily activities was measured. At 8 weeks, a LL with BFR resulted in a larger reduction in pain with daily life.

Quadriceps weakness has frequently been linked to knee pain in cross-sectional studies 8,9 , so BFR training documented as tool which improve quadriceps muscle strength and in parallel reduction of knee joint pain happened. This study didn't come into agreement with our finding, as

both groups didn't receive the same intensity of exercise as one group was 30% of 1RM and other one was 70% of 1RM.

Curley et al.,32 conducted an RCT to evaluate whether early BFR exercises, combined with LL exercises, could improve quadriceps strength and functional outcomes after ACLR compared to a CRP without BFR. A total of 26 patients undergoing ACLR were randomized in to either BFR or CRP only. Knee ROM, thigh circumference, terminal knee extension (TKE) strength, knee pain VAS scale and IKDC scores were assessed. At both 6 and 12 weeks, the BFR exercise group reported significant reductions in knee pain VAS scale.

That study did not come into agreement with our results because both groups did not receive the same CRP. The intensity of post-operative ACL exercise was LL in one group and CRP in the other. As a result, the change in pain score between groups could be due to a difference in load.

To the authors' knowledge there was no study evaluating the effect of adding BFR to CRP after ACLR on knee pain using VAS scale. So, our results will be explained as follow; regarding the post-operative period, time is considered a key factor in knee pain control, over time, the natural tissue healing process takes place along with pain relief, which might contribute to the knee pain reduction within groups. The CRP in both study groups which contains a list of exercises like (balance33, proprioceptive34 and neuromuscular training) has been reported to decrease knee joint pain. The tactile stimulation provided by the cuff used in BFR might help to reduce discomfort by deflecting it away from its source at the knee throughout the recovery phase, according to the widely accepted theory of gait control.

Our results revealed that there was no superiority of the BFR training when added to CRP over the CRP alone in reducing knee pain, suggesting that the adding of BFR training in a non-operative rehabilitation situation might have a better chance for pain reduction.

CONCLUSION

Adding BFR technique to CRP was not superior to CRP alone on knee pain post ACLR.

RECOMMENDATIONS

- More researches are needed to determine the effectiveness of BFR when combined with other types of therapeutic exercise.
- More researches are needed to determine the effectiveness of BFR on pain in other musculoskeletal problems.
- More research should be done with of longer follow-up period.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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