Safety of Blood Flow Restriction Training for Musculoskeletal Disorders: An Evidence-to-Practice Review

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ABSTRACT

Blood flow restriction training (BFRT) is low-level resistance training while partially occluding proximal blood flow. It is well documented that this style of training leads to increased muscle size as well as strength. It is theorized that these size and strength gains are due in part to the decreased oxygen environment. This results in increased muscular stress without the need for increased external load making this style of resistance training ideal for individuals who have restrictions due to musculoskeletal disorders. The guiding systematic review examined the safety of BFRT when used as a therapeutic intervention for patients with a variety of musculoskeletal disorders. Currently, there are no definitive set of parameters for clinicians to follow to ensure safe and effective use of BFRT. The purpose of the guiding review was to evaluate the safety and possible adverse events that may occur from different BFRT parameters in the rehabilitation or musculoskeletal disorders. There are many different types of devices used when implementing BFRT, but safety parameters suggest using a device that can measure the exact pressure so that occlusion can be personalized for each patient. Using a predetermined pressure for all patients could result in full occlusion, depriving the muscle of all oxygen and creating too much muscular stress. Conversely, not enough occlusion could result in a lack of muscular stress occurring to lead to muscular adaptations, ultimately rendering the treatment pointless. Additionally, timing of the exercises, which is work-to-rest ratios, as well as the frequency of training, is an important component for safe and effective use. Finally, the movement selection, load, and volume contribute to the parameters for safe and effective use of BFRT. Adverse reactions found in the guiding systematic review ranged from discomfort or dull pain to rhabdomyolysis. Following recommended safety guidelines decreased the risk of adverse reactions.

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ORIGINAL REFERENCE

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SUMMARY

CLINICAL PROBLEM AND QUESTION

Blood flow restriction therapy (BFRT) is a relatively new therapeutic technique that can be utilized in a variety of musculoskeletal injuries. The guiding systematic review examined 19 studies with eight randomized control trials, seven case report studies, three case series, and one prospective longitudinal quasi-experimental study. Of the eight randomized control studies, four studies diagnosed participants with knee osteoarthritis, three studies of post-surgical anterior cruciate ligament (ACL) reconstruction and non-reconstructive arthroscopy, and a final study on anterior knee pain. This evidence to practice review will discuss the safety and adverse effects associated with all 19 articles, however there will be particular focus placed on the

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randomized control trials of patients with post-surgical ACL reconstruction and non-reconstructive arthroscopy. This is due not only to randomized control trials offering higher levels of evidence than the other study designs, but also due to ACL rupture being a common injury seen in athletic populations.

The ACL prevents the tibia from moving anteriorly in relation to the femur. When the ACL is torn, the patient can feel instability with certain motions.[1] Surgical repair or reconstruction is sometimes needed to correct the instability. In an 18-month period, 2793 ACL surgeries in Norway were performed at an incidence rate of 85 per 100,000 of those in the main at-risk age group.[2] Due to this relatively high incidence rate, ACL rehabilitation is a commonly researched subject with an emphasis being placed on finding increasingly effective therapeutic techniques.[1,3] Even with the high incident rate for ACL rupture and reconstruction, there is no gold standard for a specific rehabilitation plan following surgical intervention.

Commonly examined factors include time and ability to return to preinjury functional levels. For traditional athletes, ACL rehabilitation can cause them to miss 6-9 months or longer due to rehabilitation needs which can equate to their entire season.[4,5] While most patients want a quick return-to-activity, it is the athletic trainer's responsibility to ensure the knee is able to handle the stresses of returning to high level activity without the risk of performance deficits or reinjury.[4] A major consequence of ACL injury and subsequent surgery is thigh muscle atrophy and subsequent strength deficits in the first 12 weeks post-surgery and can remain for over 2 years post operation.[6,7] Traditional resistance training requires increasing external load on a muscle resulting in increased muscular stress allowing for hypertrophy and strength adaptations to occur. However, heavy external load is unsafe for an extended period following ACL reconstruction due to graft weakness and overall knee instability. The use of BFRT would allow the patient to provide adequate muscular stress for training adaptations to occur while bypassing the need for heavy external loads.

Blood flow restriction therapy is the partial occlusion of blood vessels using a tourniquet or, more commonly, an inflatable cuff around a limb to train a distal muscle using low-level resistance exercises.[8] The cuff decreases the amount of oxygen supplied to the muscle which could have detrimental effects if not applied correctly. These detrimental effects can range from mild pain and discomfort to more rare but serious conditions such as rhabdomyolysis (0.008%) and deep vein thrombosis (0.055%).[9] Due to the possibility of serious detrimental effects resulting from improper application of BFRT, it is vital to examine the necessary parameters for BFRT that result in the safest application of this therapeutic device. Although use of BFRT does not seem to have adverse side effects when used correctly on adults with musculoskeletal knee conditions, the benefits of the intervention have not been fully examined.[10] Therefore, the purpose of this evidence to practice review was to examine the safety and possible adverse events that can occur from different BFRT parameters in order to help guide clinicians in the rehabilitation of patients with musculoskeletal disorders with an emphasis on post-surgical ACL reconstruction.[3]

SUMMARY OF LITERATURE

The authors of the guiding systematic review, Minniti et al., conducted a literature search for articles related to BFRT using MEDLINE, CINAHL, and Embase with a comprehensive list of keywords. The studies had to satisfy the following inclusion criteria: (1) BFRT was the clinical intervention, (2) participants were patients with musculoskeletal system disorders, (3) adverse events are discussed by the authors, (4) studies were published in English, (5) all subjects were human. Exclusion criteria included systematic or narrative reviews.

The literature search yielded 5,692 studies plus an 8 additional from hand searching. Duplicates, articles that did not meet the search criteria, and studies that did not include a qualitative synthesis were excluded which yielded 19 studies. Three reviewers were utilized, with two reviewing the articles for quality and the third was utilized to settle disputes. Of the 19 studies, the study design of 8 articles were randomized controlled trials (RCT), 1 article was a prospective longitudinal quasi-experimental study, 3 articles were case series, and the final 7 articles were case reports. Two independent reviewers evaluated the RCT studies and the prospective longitudinal quasi-experimental study for bias. Of these 9 studies, two studies met the Downs and Black rating of "excellent," and the remaining 7 met the rating of "good".[10]

SUMMARY OF INTERVENTION

Parameters of BFRT used in each study varied slightly based on application and musculoskeletal system disorder. In the RCTs and case reports, the frequency of BFRT ranged from 1 to 6 sessions per week and 1 to 4 times per week, respectively. The intensity during the RCTs was 20-30% of the subjects calculated 1 repetition maximum (1RM). In the case-control designs, intensity was based on 15RM, 25RM, 20% 1RM, and 30% 1RM. For RCTs, the intervention lasted between 1 and 16 weeks while for case control studies it lasted between 1 and 12 weeks. For RCTs and case-control studies, intervention sessions varied from 1 to 5 sets of 15 to 30 repetitions or until failure. Rest intervals ranged from 30 seconds to 1 minute between sets. There was 1 case control study that reported no rest and 2 reported occlusion for 30 minutes to 1 hour. The BFRT devices included Sports Rehab Tourniquet®, Delphi PTS ii portable tourniquet system®, KAATSU master®, Hokanson AG101 cc17 thigh cuff™, 180 x 80 mm cuff size, 150 mm cuff size, 34-inch tourniquet, and knee wraps.[10] Parameters for the BFRT device for the RCTs ranged from 160-200 mmHG or 70% to 80% occlusion. However, the case series and case report designs varied between 100-110 mmHG or 50% to 80% occlusion.

Exercise selection in the RCTs included leg press, leg extensions, reverse press, or a combination of the exercises. In the case series and case reports, exercise selection included leg press, knee extensions, reverse leg press, squats, half squats, leg curls, resisted ankle eversion, seated, and standing calf raises, and Romanian deadlifts. However, exercise progression was not mentioned in all studies. In the RCTs, training load, final exercise occlusion pressure, and volume were altered. In the case series and case reports, load was altered so that the patient could not perform >15 repetitions, increased 10% if patient could perform 1 set in >2 minutes, and increased by 5 kg if the patient could perform >15 repetitions in the second set.

SUMMARY OF OUTCOMES

To examine the safety of BFRT, the authors for the guiding systematic review divided the results of the studies based on the reported events. Reported events were defined here as what adverse effects occurred during treatment if any. The data were categorized into one of 3 categories: no adverse events, common adverse events, and rare adverse events. No adverse events were defined as a study that reported no adverse effects from the intervention.[11] Common adverse events were defined as effects that were no more than moderate severity, short term, had no impact on the patient's function, all effects are transient or reversible, and there was no alteration to therapy needed due to the short term nature of the effects. Rare adverse events were defined as being severe, long term, distressing to the subject, and/or those that required further treatment to correct.[12] To separate the data, the authors used a modified scale that included qualitative descriptions as well as incidence rates for each event. The modified scale was based off previous literature that investigated adverse effects for other therapeutic interventions.[13] Specifically related to BFRT no adverse events were defined, as having had no harmful effects and the patient was able to complete the intervention as prescribed. Common adverse effects were defined as temporary muscle soreness, acute

muscle pain, acute fatigue, intolerance to intervention, slight discomfort, or dull pain. Rare adverse events were those that had an incidence rate between 1 and 10 in 10,000 cases as well as those where a serious medical condition occurred.[10]

FINDINGS AND CLINICAL IMPLICATIONS

The guiding systematic review identified that BFRT was a safe intervention for adult patients based on predetermined safety recommendations.[10,14] **Table 1** provides the recommended safety guidelines. These recommendations specified cuff application, cuff type, occlusion pressure, exercise stimulus, type, and load, training volume, rest time, and training frequency.[14,15]

A RCT performed by Tennent et al. on postoperative non-reconstructive knee arthroscopy patients utilized single and multi-joint leg exercises at 30% of the subjects one rep max (1RM) at 80% limb occlusion pressure.[16] These subjects completed 4 sets of 30, 15, 15, 15 reps separated by 1 minute of rest in between sets twice a week for six weeks.[16] This study followed all 9 safety guidelines outlined below and no adverse events were reported.[16] Similarly, a RCT performed by Ferraz et al. studied patients with knee osteoarthritis followed similar protocols to the previous RCT, followed all 9 of the safety guidelines, and also found no adverse effects.[17] Another RCT performed by Hughes et al. compared BFRT with light exercise to high intensity resisted exercise alone on participants following ACL reconstruction and a non-injured control.[8] They followed 8 of the 9 recommended guidelines for BFRT as described in this review and had no adverse reactions.[8,10] Six RCT and four case series found no adverse effects from BFRT.[10] Eight of these studies followed 7 or more of the 9 guidelines. The studies performed by Bryk et al. and Gaunder et al. following 6 and 5 respectively.[18,19]

Participants in a total of 6 studies, 3 RCTs and 3 case studies, had common adverse effects. The RCT conducted by Ohta et al. in 2003 compared the use of BFRT with exercise to the same exercises without BFRT for participants with ACL reconstruction but only followed 6 of the 9 recommendations.[20] Discomfort and dull pain in the limb after 12 minutes of occlusion caused two participants to withdraw from the study.

Table 1. BFRT Recommended Guidelines[a]

Type	Guidelines
Cuff application	Around the limb proximal to the muscle(s) being trained
Cuff type	Wider for the leg (6-13.5 cm) and narrower for the arm (3-6 cm)
Occlusion Pressure	Upper Extremity: 40% to 50% of limb occlusion pressure[b] Lower Extremity: 50% to 80% of limb occlusion pressure[a,b]
Exercise stimulus	Aerobic: minor increase or maintenance of muscle mass and strength Low-load resistance: substantial increase in muscle mass and strength
Type of exercise	Single- and multi-joint exercises are beneficial
Exercise loads	~20-40% 1 rep max
Training volume	50-80 repetitions/exercise
Rest time	30-45 seconds; maintain occlusion
Training frequency	2-4 sessions/week with the addition of high-load resistance without BFRT for more active patients

Abbreviation: BFRT = Blood flow restriction training
[a]Guidelines adapted from Scott, Loenneke, Slattery, and Dascombe (2015).[14]
[b]Guideline adapted from Patterson, Hughes, Warmington, et al. (2019).[15]

They used a single pressure of 180 mmHg for all patients.[20] Likewise two studies, one with male subjects and one with female subjects, performed by Segal et al. examined the use of BFRT in patients with knee osteoarthritis. These studies used the same parameters outlined above by Tennent et al., however these studies used a standard 160-200 mmHG for all participants instead of a percentage of the individuals total limb occlusion pressure.[21,22] Each study had a single participant drop out due to inability to tolerate BFRT, but no other participants exhibited any adverse effect.[21,22] Utilizing a single pressure does not fall within the recommended guidelines of 50%-80% occlusion pressure.[10] The pressure applied to the limb must be calculated for each patient. Five of these studies followed 7 or more of the 9 guidelines, with the final study following 6 guidelines.

The final three case reports experienced rare adverse events. In two of the three cases with adverse events, it was stated that the individual had a preexisting condition. A case report by Noto et al. saw a patient develop Paget-Schroetter Syndrome when only 1 out of the 9 guidelines was followed.[23] However, the authors noted that this patient had a history of localized edema in the left clavicle.[10] The lack of guidelines followed, including occlusion of the upper extremity for long durations of 30 minutes to 1 hour, and preexisting condition are both factors that lead to the patient's development of Paget-Schroetter Syndrome.[10,23] A case report by Iverson et al. of a patient knee articular cartilage resection and microfracture and a case report by Krieger et al. of a patient with an ankle sprain, reported that the patient developed rhabdomyolysis after just a singular treatment.[24,25] In both cases, the authors concluded that this was a freak occurrence and both subjects made a full recovery and were able to continue BFRT training.[24,25] Additionally, the subject of the case report by Iversen et al. had a history of deep vein thrombosis after knee surgery.[10,24] Once this subject had been treated and recovered from rhabdomyolysis, they were able to return to the study and complete BFRT without any further complications. In the case by Krieger et al., the subject did not have any known preexisting conditions, but it should be noted that the exercise load is not specified.[25] Preexisting conditions should not be seen as an absolute contraindication for BFRT use and individuals with preexisting conditions are still able to experience the benefits of BFRT. To limit adverse events, future research should explore in depth safety precautions and guidelines, specifically for at-risk populations with specific factors or indicators, while continuing to explore mechanisms to improve clinician and patient adherence to the guidelines already outlined.[10]

This available research indicates that there is no greater risk for patients who use properly implemented BFRT than those who only use traditional therapeutic techniques. It is suggested that if the 9 guidelines are followed, the worst adverse effect that a patient would experience is mild discomfort and transient muscle pain. However, the use of BFRT is not completely devoid of risk and therefore only healthcare practitioners who wish to implement BFRT into their rehabilitation should be properly trained on the parameters and safety guidelines.[10]

CLINICAL BOTTOM LINE

Blood flow restriction therapy has been found to have little to no adverse effects on patients with knee related musculoskeletal disorders.[10] The risk of adverse effects is minimal when the 9 safety guidelines are followed as well as ensuring that the patient does not have a history of vascular disorders such as deep vein thrombosis.[10] In particular, BFRT can be particularly useful in rehabilitation of post-operative ACL reconstruction. Hughes and colleagues found that although muscle pain was higher for both the ACL reconstruction BFRT and the non-injured BFRT groups, knee pain was less than that of the ACL reconstruction without BFRT.[8] As discussed, BFRT can be a useful therapeutic intervention; however, certain parameters

should be followed during use. Most importantly, the athletic trainer must be trained by the accredited medical device manufacturer before using the BFRT device. The athletic trainer should choose the appropriately sized cuff for the patient to ensure that the BFRT device can function as intended. It is critical that cuff pressure be individualized to each patient as well as using cuffs that disperse the occlusion pressure around the circumference of the given extremity for not only safe, but effective implementation of BFRT. In addition to cuff size and cuff type, the guidelines of cuff application, limb occlusion pressure, exercise stimulus, type of exercise, exercise loads, training volume, rest, and training frequency should be followed in order to ensure safe implementation of BFRT.[10] Further research is needed to make definitive conclusions about the absolute safety in all patient populations and for other injuries such as upper extremities and low back pain.

Based on the findings in the guiding systematic review, athletic trainers should use caution when considering the use of cuffs for postoperative patients. First, they should be required to take the recommended training offered by the manufacturing company in order to be trained in cuff selection and application for the BFRT device. Next, clinical guidelines should be created for BFRT cuff use for low-load use during rehabilitation so that the proper protocols are followed including but not limited to individualized cuff pressure. Finally, athletic trainers should record observations and results for patient outcome analysis related to the efficiency of BFRT on a case-to-case basis to inform future clinical decision making.

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