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Overall Safety and Risks Associated with Blood Flow Restriction Therapy: A Literature Review

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ABSTRACT

Introduction:

Blood flow restriction therapy (BFRT) is used in scenarios ranging from muscle building in athletic performance to decreasing recovery time in postoperative orthopedic rehabilitation. The efficacy of BFRT for treating diseases has been increasingly researched; however, there has been less literature focused on establishing the safety of this therapy.

Materials and Methods:

An extensive literature review pertaining to BFRT and any deleterious events related to its usage was completed by searching multiple databases, including PubMed, EMBASE, and Cochrane Library using the terms "blood flow restriction therapy" or "KAATSU."

Results:

Ten case reports, five case series, two national surveys, two questionnaires, six randomized controlled studies, and one systematic review were included. A total of 1,672 individuals reported an adverse event following BFRT use out of 25,813 individuals. Commonly reported adverse events were numbness, dizziness, subcutaneous hemorrhage, and rhabdomyolysis. There were unique adverse effects of this therapy reported in individuals with comorbid conditions, such as hypertension and thoracic outlet syndrome, which included isolated cases of central retinal vein occlusion and Paget–Schroeder syndrome.

Conclusion:

Blood flow restriction provides tremendous opportunity with a potential for accelerated exercise rehabilitation and injury prevention. This modality could be used in the military setting to help injured active duty personnel expeditiously return to deployable status. Further prospective randomized controlled trials are warranted to further support BFRT safety; however, from this literature review, it can be concluded that BFRT can be utilized safely in the proper patient population when administered by qualified professionals who have undergone the appropriate training.

INTRODUCTION

Blood flow restriction therapy (BFRT) is a tool used in many scenarios, ranging from muscle building in athletic performance to decreasing recovery time in postoperative orthopedic rehabilitation. The efficacy of BFRT for treating diseases has been increasingly researched in recent years; however, there has been less literature specifically aimed at establishing the safety of this relatively novel therapy. The terms BFRT and KAATSU are often used interchangeably depending on geographic location, with the main principle of both being a partial occlusion of arterial inflow and complete obstruction of venous outflow from the muscle.[1]

Since the 1960s, when KAATSU training was first introduced by Sato in Japan, BFRT has been studied extensively in terms of physiologic impact and effects on multiple systems in the body.[2] In BFRT, post-capillary venous outflow from the muscle is obstructed, which induces blood consolidation within the capillary network. The most common method to achieve this targeted occlusion is through application of a pneumatic cuff to the extremity of interest.[3] As opposed to other techniques that specifically limit arterial blood flow to the muscle (i.e., tourniquet), BFRT allows limited arterial inflow with targeted distal obstruction of venous outflow. This, in combination with low-resistance exercise training, provides many metabolic, hormonal, cardiovascular, and cellular advantages to the exercising muscle.[3,4] Several studies have demonstrated promising results with regard to the effects of BFRT on cerebrovascular disease, neuromuscular diseases, respiratory disease, obesity, diabetes, and hypertension.[2,5] The aim of this paper was to review the available literature to elucidate the safety profile of BFRT.

MATERIALS AND METHODS

An extensive literature review pertaining to BFRT and any deleterious events related to its usage was completed by searching multiple databases, including PubMed, EMBASE,

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TABLE I. Adverse Events Associated with BFRT Use[*, a]

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Number of individuals with adverse outcome	$n = 1,662$	$n = 9$	$n = 1$	$n = 0$	$n = 0$
Percentage related to adverse outcome cohort	99.4	0.54	0.06	0.00	0.00
Percentage of adverse outcomes to total number of individuals	6.44	0.03	0.003	0.00	0.00

BFRT: blood flow restriction therapy; total number of individuals ($n = 25,813$).*

[a]Studies that did not report the specific number of individuals reporting adverse outcomes were excluded from this table.

and Cochrane Library. The target range for papers to be included was from January 2002 to July 2021. To ensure a broad scope was maintained for inclusion, any abstract title that included "blood flow restriction therapy" or "KAATSU" and discussed anything related to the safety profile or adverse events associated with this noninvasive therapeutic modality was reviewed. To objectively categorize the adverse events, the authors modified an already validated scoring method for characterizing complications. The Clavien–Dindo classification system, originally used to quantitatively rank postoperative complications, was modified in order to classify complications related to the non-surgical intervention, BFRT. Five categories (Grades 1-5) were modified to be defined as follows: (1) any deviation from the normal therapeutic course without the need for any pharmacologic, surgical, or radiographic intervention; (2) complication requiring pharmacologic intervention or supportive/noninvasive therapy i.e., Intravenous fluids/phototherapy; (3) complication requiring invasive intervention i.e., surgery/endoscopy/Interventional Radiology; (4) life-threatening complication requiring Intensive Care Unit care; and (5) complication resulting in death.

RESULTS

Ten case reports, five case series, two national surveys, two questionnaires, six randomized controlled studies, and one systematic review were included in this literature review. Of the studies from which exact results could be extracted, a total of 1,672 individuals reported an adverse event following BFRT use out of 25,813 people. Table I demonstrates the proportions of Grades 1-5 from the modified Clavien–Dindo classification. The most commonly reported adverse events were numbness, dizziness, subcutaneous hemorrhage, and rhabdomyolysis. There were unique adverse effects of this therapy reported in individuals with comorbid conditions, such as hypertension and thoracic outlet syndrome, which included isolated cases of central retinal vein occlusion (CRVO) and Paget–Schroeder syndrome (PSS).

Case Reports

There are 10 case reports that document adverse side effects with BFRT training.[6–15] Of these case studies, the majority discuss rhabdomyolysis as the main consequence of BFRT. To highlight a few, the first reported case of rhabdomyolysis as it pertained to the concurrent use of BFRT was seen in 2010.[6] A 31-year-old male ice hockey player who had failed to regain his quadriceps strength after arthroscopic knee articular cartilage debridement and microfracture initiated BFRT 11 months postoperatively. In his initial workout, he performed 90 repetitions of single leg extension with 12 kg of resistance using a 14-cm-wide cuff inflated to 100 mm Hg following a 10-minute warm-up on a stationary bike. Forty-eight hours following the exercise regimen, he reported to the emergency department (ED) with quadricep soreness and was found to have an elevated creatine kinase (CK) level of 12, 400 U/L. In another case report, a 30-year-old obese Japanese male performed BFRT on the first day of training and subsequently developed rhabdomyolysis. There was no information regarding exercise intensity or occlusion pressure.[7]

Interestingly, a 29-year-old female who worked as a KAATSU instructor came into the ED with PSS, also known as "effort thrombus," resulting from thoracic outlet syndrome and her occlusion training. She would occlude for up to an hour at times and had been utilizing BFR for 2 years before symptoms developed.[10] Paget–Schroeder syndrome is a very rare disease that causes vascular endothelial dysfunction from the retraction of the veins passing the thoracic outlet due to the development of upper limb musculature. Previous reports have shown PSS to be caused by weight-bearing exercises or push-ups.[16] Finally, in 2015, there was a case report detailing the development of CRVO in a 45-year-old man following his participation in KAATSU. This man, with a history of diabetic retinopathy and undiagnosed hypertension, had two incidents of CRVO that both occurred on the day following a KAATSU workout.[11]

Three additional studies involving participants with neurologic and pulmonary disease, to include Parkinson's disease, primary progressive multiple sclerosis, and chronic obstructive pulmonary disease, showed no adverse events.[12–14] Another study described pre-syncopal symptoms in eight individuals undergoing BFRT in spaceflight training.[15]

Case Series

A case series including 21 healthy young adults reported minor side effects in three of the participants. One male experienced a brief syncope, while two others experienced pre-syncopal symptoms.[17] One study focused on BFRT use on 13 people with polymyositis and dermatomyositis and included a 12-week, twice-per-week low repetition (30% of 1 max repetition) resistance exercise program.[18] Notably, no adverse events were found or reported, taking into account clinical signs and laboratory markers such as CK and aldolase. In a study looking at nine participants with incomplete spinal cord injury, BFRT was applied with knee extension exercise and 125% venous occlusion pressure. Parameters that included pain, lactate levels, hemodynamic changes, and D-dimer assessment were monitored, with no DVT formation occurring and no differences seen.[19] Another case series involving 17 healthy individuals undergoing two bouts of exercise 2 weeks apart from each session was reported, with the groups divided based on whether or not both sessions involved BFRT use. Creatine kinase levels peaked 4 days after exercise at a 13- and 36-fold increase from the baseline levels of 215 ±47 and 137 ±26, respectively, for each group. Two individuals experienced CK levels over 15,000 IU/L.[20] This study was not included in the statistical results because enzyme levels were not reported on for specific numbers of individuals. Finally, a study looking at 20 intensive care unit patients who were in a coma saw no adverse effects when blood flow restriction was applied to a lower extremity limb and passive motion was completed.[21]

National Surveys/Questionnaires

Although sparse, surveys provided the largest number of results reported for BFRT usage. In 2006, a national survey in Japan was conducted to study patient perceived outcomes and safety of KAATSU training.[22] Results were based on the 12,642 people that replied, with a distribution of 45.4% male and 54.6% female and 85.4% in their sixties or younger. Notable complications included 1,651 people with subcutaneous hemorrhage, seven people with venous thrombus, one person with pulmonary embolism, one person with cerebral infarction, and one with rhabdomyolysis. In 2016, Yasuda et al. conducted an internet questionnaire survey at the annual academic meeting for the Japan KAATSU Training Society as a follow-up to the national survey completed in 2006.[5] The 12,827 respondents (30.1% male and 69.9% female) had an age range between less than 19 years of age to greater than 80 years of age. Compared to the 2006 survey, no serious side effects such as rhabdomyolysis, pulmonary embolism, cerebral hemorrhage, or paralysis were reported. Minor side effects included cool feeling, numbness, subcutaneous hemorrhage, drowsiness, pain, nausea, itch, hypertension, anemia, headache, and others in a cohort amount that was not able to be determined.[5]

There were two questionnaire studies that did not report specific patient numbers and thus were not included in the statistical analysis but are mentioned as follows. In one study, 113 Brazilian physical rehabilitation and sports science professionals were surveyed and asked to report on side effects with the use of BFRT in their patients.[23] The incidence of rhabdomyolysis and fainting were reported to be 1.9% and 3.8%, respectively.[23] In the other study surveying 250 exercise/training practitioners, 115 stated they had prescribed blood flow restriction and 98 clinicians reported Grade 1 adverse events in their patients.[24]

Randomized Control Trials

A pilot randomized control study where BFRT was utilized in six patients with distal radius fractures treated with closed reduction and cast immobilization demonstrated that an 8-week course of BFRT was tolerated well with no complications.[25] Another randomized study performed on 21 individuals, 11 of which received BFRT, showed that there were no adverse events associated with its usage, taking into account clinical observation and comparison of baseline and 3-month post-usage creatine phosphokinase and D-dimer levels.[26] Bowman et al. compared high-load exercise alone versus low-load exercise with BFRT in 26 patients (16 BFRT vs. 10 control) with no reported adverse events.[27] Tennent et al. studied the utilization of BFRT after knee arthroscopy. Of the 10 patients who completed the trial using BFRT, none reported adverse events.[28] Fourteen patients who underwent rehabilitation following anterior cruciate ligament reconstruction reported no adverse events.[29] These individuals underwent eight biweekly sessions of unilateral leg press training at 30% of their one-repetition max. A prospective randomized control trial analyzing limb circumference and strength of the upper extremity with and without BFRT after a 6-week low weight training program reported no adverse events in the 14 people who had BFRT applied.[30]

Systematic Reviews

One systematic review reporting on BFRT use for lower extremity weakness due to knee pathology from 1974 to 2017 showed no complications in 165 individuals sequestered from the search.[31]

DISCUSSION

This study was developed to assess the frequency of adverse events associated with BFRT training reported in the literature. Of the studies that reported a specific number of individuals noting adverse events, a total of 1672 individuals ($n = 25{,}813$) or 6.47% indicated experiencing an adverse outcome. Based on the Clavien–Dindo classification system, 99.4% (1662/1672) of these were Grade 1 adverse outcomes defined as follows: Any deviation from the normal therapeutic course without the need for any pharmacologic, surgical, or radiographic intervention. It is notable that the bulk of these reported adverse events (1661/1672) were identified through a national survey in Japan aimed at investigating patient-perceived outcomes and safety of KAATSU training. Within this study, there was variability in the setting in which KAATSU training was performed, in the type of exercises used, and in which limb was used for partial occlusion. In studies with more controlled settings and patient selection, no adverse events were noted.[18,19,25–30]

Physiologic Effects of BFRT

In addition to increases in strength,[12,13,26,30] muscle hypertrophy,[27,30] and improved rehabilitation of musculoskeletal injury,[28,29] BFRT has been seen to reduce muscle wasting in elderly patients admitted to the intensive care unit,[21] and have systemic effects such as when implemented in pulmonary rehabilitation programs.[14] Further, there are several studies discussing the systemic physiologic effects of BFRT on the body and the theoretical risks on patients with cardiovascular disease.[32,33] The exercise-pressor reflex stimulated during muscle activation in exercise directly activates the sympathetic nervous system. In turn, cardiac output is increased to meet demand of the exercising muscle. Ultimately, this increases blood pressure, which if already elevated in hypertensive individuals, could have detrimental effects. Sympathetic activity has a heightened baseline in people with cardiovascular disease such as hypertension and heart failure.[32] Sugawara et al. demonstrated that several variables, including central blood pressure and aortic wave reflection, can have amplified increases even at walking.[33] These key factors, when increased in hypertensive patients and people with underlying vascular anomalies, could have a severe impact on a person's health when BFRT is combined with their exercise regimen.

Pope et al. hypothesized many potential effects of restricting the outflow of blood from the exercising muscle.[3] These include local metabolic acidosis, increased recruitment of fast twitch fibers from hypoxia, and muscle growth stimulation from reactive oxygen species. The muscle hypertrophy obtained after BFRT is thought to result from the lactic acidosis that occurs with the combination of blood flow restriction and low-intensity repetitions. This localized metabolic effect, along with systemic and hormonal actions, are not seen with BFRT used during no exercise or with walking.[4] Thus, effective BFRT must combine blood flow restriction with low-intensity exercise to be of clinical benefit. Another theorized risk of BFRT is its use in people with pre-existing diseases that affect the muscle itself. However, it has been shown that BFRT usage in this patient population can be administered safely with positive impacts on multiple health parameters, including increased muscle strength and quality of life.[18] Although there have been safety concerns raised, many papers have supported the safety and benefit of BFRT.[2,5,22,34]

Inter-user Variability

A key component in the safety of this modality lies within the experience of the user or trainer, as well as adherence to established guidelines and protocols. Patterson et al. demonstrated the inconsistencies seen in frequency, duration, cuff pressure, and cuff width parameters associated with BFRT, but provided general recommendations for people using BFRT in conjunction with resistance exercise.[1] They recommended 40-80% of arterial occlusion pressure, or the pressure needed to elicit complete occlusion of the supplying artery. One set pressure, or absolute pressure, should be watched carefully because the wide range of limb girth and cuff dimensions impacts this parameter.[35] Thus, a system that allows for variable pressure may be of use to ensure appropriate occlusion pressure throughout the cycle of exercise. Furthermore, BFRT should be used 2-3 times per week for training periods lasting longer than 3 weeks with 20-40% of a person's one maximal repetition.[1] Of note, one limitation to BFRT and adherence to specific protocols is the discomfort that can result from peripheral nerve compression.[36] Education on the proper techniques and how differing insufflation levels affect the individual should be maintained on an annual basis as more studies are completed on the safety of BFRT. All variables in the BFRT protocol, from duration and frequency to inter-set resting and cuff pressurization, can have an impact on the individual's health, and as such should be appropriately managed to avoid harm.[37]

Contraindications

Although no absolute contraindications have been established for BFRT as it is a relatively new treatment modality, there have been plausible contraindications noted. Potential increases in adverse outcomes can be associated with hematologic diseases such as sickle cell anemia, Factor V Leiden, estrogen use, past events with venous thromboembolism, liver disease, or any other entity that increases the risk for blood clotting.[38] Beyond the blood itself, the vasculature can be compromised by hyperlipidemia, diabetes, obesity, hypertension, and renal disease, and these patients should be appropriately counseled and monitored closely during therapy. Lastly, any event that decreases blood movement, such as extended immobility or in the immediate postoperative period, can increase the risk for thromboembolism. All of these factors that may increase an individual's risk for adverse events should be noted and discussed and informed consent should be obtained before starting BFRT.

Literature reviews are subject to the limitations of the given literature, and this review is no different. A primary limitation encountered in this study is the variability across the spectrum of BFRT protocols used in each study. There was variability in the set cuff pressures, duration of use, and frequency. Additionally, there was little transparency in regard to how often these protocols are routinely followed and how often deviations occur when protocols were used. Notably, in the randomized controlled trials, no adverse events were reported. This could be due to the fact that strict protocols are required, and deviations must be reported, again supporting the importance of an evidence-based program and training to safely administer BRFT.

CONCLUSION

From its beginning, BFRT in conjunction with low-resistance exercise has been progressively gaining ground in its effectiveness with assisting in a myriad of medical conditions. Blood flow restriction provides tremendous opportunity in the medical community with a potential for accelerated exercise rehabilitation and injury prevention. With its minimal side effect profile, it is a promising adjunct to helping in postoperative muscle recovery Furthermore, this modality could be used in the military setting to help injured active duty personnel expeditiously return to deployable status. As the use of BFRT continues to expand, it is imperative that a regimented protocol be implemented, to include monitoring for and recording of adverse outcomes. Caution is required for those with comorbid conditions, especially those that deal with cardiovascular disease. BFRT has effects on endovascular and muscular growth hormones, and as such, those with hypertension or other vascular disease should be warned about blood flow restriction exercises. Additional prospective randomized controlled trials are warranted to further support BFRT safety; however, from this literature review, it can be concluded that BFRT, in the hands of qualified professionals who have undergone the appropriate training and education, can be a useful and safe resource in the medical setting.

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