ORIGINAL ARTICLE

The use of a single resistance exercise with or without blood flow restriction in the treatment of pain in knee osteoarthritis: a randomized clinical trial

A utilização de um único exercício resistido com ou sem restrição do fluxo sanguíneo no tratamento da dor na osteoartrite de joelho: um ensaio clínico randomizado

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ABSTRACT

BACKGROUND AND OBJECTIVES: Physical exercise is an efficient non-pharmacological strategy for the treatment of knee osteoarthritis (KOA). Blood flow restriction (BFR) is a technique known to enhance strength and hypertrophy gains when combined with low-intensity resistance exercise. This study aimed to analyze the effects of 12 weeks of low-intensity resistance training with and without blood flow restriction (BFR) on pain control and strength improvement in patients with KOA.
METHODS: Two intervention groups performed low-intensity resistance exercise (knee joint extension on the leg extension chair at 30% of one repetition maximum) with (LI+BFR, n=13) or without blood flow restriction (LI, n=13), twice a week for 12 weeks. Pre- and post-test of one repetition maximum, functional strength (Chair-test), peak torque for unilateral knee extension exercise and pain (Visual Analogue Scale) were evaluated.
RESULTS: No statistically significant differences were observed between treatments in pain reduction (p>0.05). Both interventions increased muscle strength and functional strength after 12 weeks of intervention (p<0.05). The peak torque for knee joint extension increased only in the LI+BFR group (p<0.05). Has no difference in reducing pain in patients with KOA among the groups (p< 0.05), both in the LI+BFR and the LI group.
CONCLUSION: The results of the present study showed that BFR associated with low-intensity resistance exercise does not produce additional effects in terms of pain reduction and strength gain in patients with knee osteoarthritis, when compared to resistance exercise alone.
Keywords: Chronic pain, Exercise therapy, Muscle strength, Pain Management.

RESUMO

JUSTIFICATIVA E OBJETIVOS: O exercício físico é uma estratégia não farmacológica eficiente para o tratamento da osteoartrite de joelho (OAJ). A restrição do fluxo sanguíneo (RFS) é uma técnica conhecida por potencializar o ganho de força e hipertrofia quando combinada com exercícios de resistência de baixa intensidade. Este estudo teve como objetivo analisar os efeitos de 12 semanas de treinamento de resistência de baixa intensidade com e sem restrição de fluxo sanguíneo (RFS) no controle da dor e melhora da força em pacientes com OAJ.
MÉTODOS: Dois grupos de intervenção realizaram exercício resistido de baixa intensidade (extensão da articulação do joelho na cadeira extensora a 30% de uma repetição máxima) com (ER+RFS, n=13) ou sem restrição do fluxo sanguíneo (ER, n=13), duas vezes por semana durante 12 semanas. Foram avaliados pré e pós-teste de uma repetição máxima, força funcional (Chair-test), pico de torque para exercício de extensão de joelho unilateral e dor (Escala Analógica Visual).
RESULTADOS: Não foram observadas diferenças estatisticamente significativas entre os tratamentos na redução da dor (p>0,05). Ambas as intervenções aumentaram a força muscular e a força funcional após 12 semanas de intervenção (p<0,05). O pico de torque para extensão da articulação do joelho aumentou apenas no grupo ER+RFS (p<0,05). A dor crônica relacionada à OAJ não apresentou diferença estatisticamente significativa na redução da dor (p> 0,05) em resposta a ambas as intervenções.
CONCLUSÃO: Os resultados do presente estudo evidenciaram que a RFS associada ao exercício de resistência de baixa intensidade não prouduz efeitos adicinais na redução da dor e no ganho

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HIGHLIGHTS
• There is no difference in pain improvement whether the exercise is performed with or without blood flow restriction.
• A single exercise can be used as an option to the early phases of rehabilitation.
• Low-intensity resistance exercise with or without blood flow restriction, can be applied as an alternative in cases of knee osteoarthritis.

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de força em pacientes com osteoartrite de joelho, quando comparada apenas ao exercício de resistência.
Descritores: Dor crônica, Força muscular, Manejo da dor, Terapia por exercício.

INTRODUCTION

Osteoarthritis (OA) is a painful condition that affects the joints, leading to an inflammatory condition that, over time, results in joint stiffness, compromising the performance of activities of daily living or sports because of the painful condition in 80% of patients[1]. In about 25% of cases, these limitations are associated with worsening quality of life, especially in relation to pain and the psychological dimension[2].
The major risk factors are advanced age, previous knee injury, obesity, female gender, family history of the disease, and occupational demand. In the United States, more than 22.7 million people have symptoms of OA, with concomitant impairment in the level of physical activity practice[3]. In Brazil, according to Brazilian Society of Rheumatology (*Sociedade Brasileira de Reumatologia*)[4], OA is the most common rheumatologic disease, especially knee osteoarthritis (KOA).
Pain is a condition that compromises the practice of physical activities in patients with OA, enhancing the reduction of muscle strength. This condition, in a cyclical way, potentiates the loss of strength and pain[5]. In KOA, non-drug treatment includes weight loss and low-impact exercises such as cycling, rowing, swimming, walking, strength training, and Tai-Chi-Chuan, which have positive effects in reducing pain and improving functionality[1]. Moderate to high intensity resistance training is among the main interventions indicated to improve conditions that may be associated with chronic pain in patients with KOA, such as muscle weakness[6]. A study[7] provided evidence that strengthening the knee extensor muscles plays an important role, both in the prevention and in the treatment of KOA.
Interventions based on resistance exercises focused on increasing muscle strength are associated with important improvements in quality of life, especially in more vulnerable population groups, such as the elderly and patients with chronic pain[8,9]. Considering that high-intensity resistance exercise is more effective for reduction of pain and improvement of strength and functionality in patients with KOA and that this type of exercise (high-intensity) is not always well tolerated, lower-intensity exercise alternatives should be explored with a view to greater adherence to intervention protocols[10]. Therefore, blood flow restriction (BFR) techniques associated with low-intensity exercise have potential as a non-pharmacological intervention in the treatment of pain in patients with KOA[10].
In addition, interest in the technique of blood flow restriction associated with low-intensity exercise is growing, due to its effects on the musculature are comparable to high-intensity exercise and the potential to generate less pain and discomfort during exercise in patients with KOA[10,11]. Therefore, the present study aimed to analyze the effects of low-intensity resistance training with and without blood flow restriction for pain management and improvement of strength and functional capacity in patients with KOA.
The hypothesis of this study was that blood flow restriction associated with low-intensity exercise (knee extension on the extension chair) would be more effective than low-intensity exercise alone in reducing pain intensity, increasing muscle strength, and functional strength in patients with KOA.

METHODS

The present study was characterized as a randomized clinical trial, followed the protocol registered at ensaiosclinicos.gov.br and was reported according to Consolidated Standards of Reporting Trails (CONSORT)[12].

Study design
As shown in figure 1, 35 subjects with a clinical diagnosis of KOA of both genres, aged 45 to 70 years were recruited. Twenty-six men (n=10) and women (n=16) met the eligibility criteria, underwent the pretest, and were randomly assigned to two experimental groups: low-intensity resistance exercise with blood flow restriction (LI+BFR: n=13), and low-intensity resistance exercise without blood flow restriction (LI: n=13). All subjects, regardless of the protocol, performed two sessions per week for 12 weeks and were reassessed (post-test).

Participants
The sample of the present study consisted of 26 participants distributed in the two intervention groups. To calculate the sample size, an online calculator was used (http://hedwig.mgh.harvard.edu/sample_size/). The sample size was estimated considering a statistical power of 0.85; significance level of 0.05 (two-tailed), mean standard deviation of the main outcome variable (pain) of two units[13] and a minimum detectable difference between the treatment of 2.5 units. Considering a sample loss of 10%, the sample in the present study consisted of 26 participants (LI+BFR = 13 and LI = 13).

Eligibility
This study included men and women aged between 45 and 70 years, with a diagnosis of KOA (assessed by a specialized physician), with no clinical restrictions for performing exercises, recruited in a Basic Health Unit (*Unidade Básica de Saúde* - UBS). For the classification of osteoarthritis, the criteria established by the American College of Rheumatology[14] were used. Patients who underwent a recent surgical procedure (last three months), which compromised their participation in the study, with a diagnosis of vascular problems, and those who had functional limitations to perform the exercise proposed in the intervention protocols were excluded from the sample.

Randomization
The entire randomization process was designed and carried out by an administrative technician who was not part of the research team. Participants were randomly assigned to one of two intervention groups, with opaque sealed envelopes containing the description of the interventions inside.

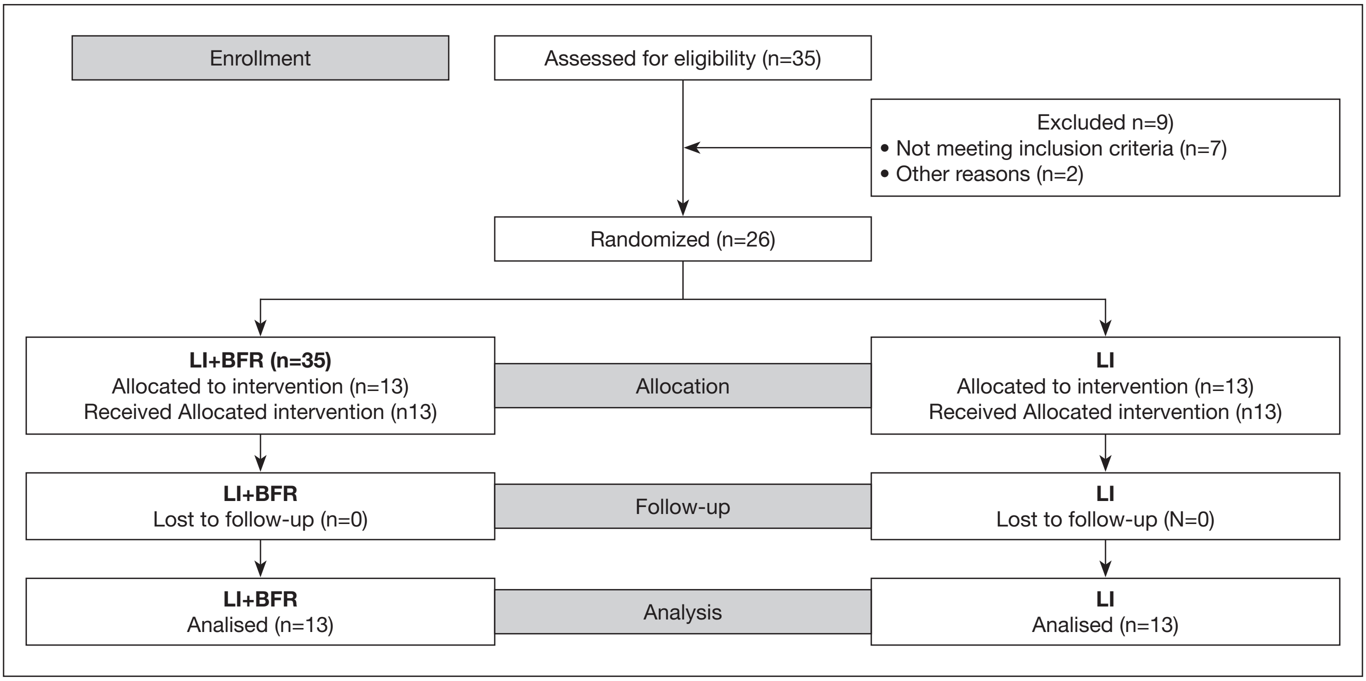

Figure 1. Study design.

LI+BFR = Low-intensity resistance exercise with blood flow restriction; LI = Low-intensity resistance exercise.

Interventions

Low-intensity resistance exercise with blood flow restriction (LI+BFR)

The protocol consisted of performing two weekly sessions of bilateral knee joint extension exercise on the extension chair (TRG Fitness™, Blumenau-SC, Brazil), for 12 weeks. In the first two sessions, one set of 15 repetitions was performed, followed by two sets of 15 repetitions in the two subsequent sessions and three sets of 15 repetitions until the end of the 12 weeks of intervention. All participants performed the number of sets and repetitions prescribed in the intervention protocols. The progression of the number of sets and repetitions was chosen based on clinical practice to minimize pain during the physical exercise adaptation phase and improve adherence to the intervention protocol. The load used was equivalent to 30% of a maximum repetition (1-RM), assessed in the pretest and at the beginning of the 3^{rd}, 5^{th}, 8^{th}, and 10^{th} weeks of intervention.

The exercise execution speed was three seconds for each repetition (1.5 seconds for the concentric phase and 1.5 seconds for the eccentric phase) monitored by a digital metronome (Sanny Personal Counter™, São Bernardo do Campo-SP, Brazil) and the recovery interval between sets in all phases of the intervention protocol was one minute. To restrict blood flow, pneumatic tourniquets 7.5 x 90 cm (Clinic Leg WCS, Tecnologia/Cardiomed™, Curitiba-PR, Brazil) were attached to the proximal portion of both thighs at a height equivalent to the gluteal line. The pressure used in the tourniquets corresponded to 70% of the posterior tibial artery occlusion pressure measured by Portable Vascular Doppler (MEDPEJ™ DV-2001, Ribeirão Preto-SP, Brazil) with the subject in the standing position. The Visual Analog Scale (VAS) was used for pain monitoring, before, during, and immediately after each training session.

Low-intensity resistance exercise (LI)

The same strength exercise was used as indicated in the low intensity protocol, but without the use of pneumatic tourniquets.

Outcome measures

Primary outcome

The evaluation of maximum dynamic of muscle strength in knee extension exercise (TRG Fitness™, Blumenau, Santa Catarina, Brazil) followed the recommendations of the American Society of Exercise Physiologists.[14] The exercise consisted of the full extension of the knee joint (180º), starting from the initial position (90º), and returning to the initial position. To assess pain intensity, the VAS, as proposed by a study[15], was used in pre- and post-test and immediately after each training session. The instrument consisted of a scale with a score ranging from zero (no pain) to 10 (worst pain possible).

Secondary outcomes

The evaluation of the mean peak torque for unilateral knee joint extension[16,17] was performed using an isokinetic dynamometer (Biodex System 4 Pro™, Biodex Medical Systems INC., Shirley, NY, USA). The quadriceps strength of both legs was evaluated, although for the present study only the peak torque of the limb with OA was considered. Briefly, one minute after the end of the warm-up (cycle ergometer for five minutes), the participants performed six maximum concentric extensions on each limb at a speed of 60º/s. Peak torque is defined as the highest output force exerted at any time during a repetition. To assess the functional strength of the lower limbs, the chair test was used, which consists of getting up from a chair without an armrest, performing a full extension of the knee and hip joints, maintaining the torso upright and returning to the starting position as often as possible within 30 seconds[18].

Data collection and blinding

All participants selected for the study attended the physical therapy clinic one week before the start of data collection, to familiarize themselves with the data collection procedures that were used in the pre- and post-test. In the following week, on previously established days and times, each subject attended the clinic to assess anthropometric parameters (body mass and height) and assess functional strength and maximum dynamic strength. The isokinetic evaluation was performed as previously scheduled at the physiotherapy clinic. In the week following the pretest, 12 weeks of intervention were started, followed by post-test evaluations.

The intervention protocols were performed at different times, so that subjects from different groups did not use the intervention site at the same time. To minimize the risk of bias, additional measures were taken. All data collection procedures were performed by professionals who were blinded to the treatments.

Ethical procedures

All procedures, objectives, risks, and benefits of the study were explained to the volunteers, who signed the Free and Informed Consent Term (FICT), consenting to their participation in the research. This study was approved by the Ethics Committee for Research Involving Human Beings (*Comitê de Ética em Pesquisa Envolvendo Seres Humanos* - Protocol 3.061.166) and registered in the Brazilian Registry of Clinical Trials (*Registro Brasileiro de Ensaios Clínicos* - ReBEC).

Statistical analysis

Shapiro-wilk, Levene, and Mauchly tests were used to analyze the distribution and data characteristics (normality, homoscedasticity, and sphericity, respectively). Logarithmic adjustments and Greenhouse-Geisser correction were made when the distribution did not meet the normality assumptions of the data distribution. A two-way analysis of variance (ANOVA 2x2) was used for comparisons between time (pre- and post-intervention) and between groups (LI+BFR and LI) and for the evaluation of the "time x group" interaction, followed by Bonferroni multiple comparison test. For all analyzes, the Statistical Package for Social Sciences (SPSS™) version 24.0 was used, and the significance level adopted for all analyzes was 5%.

The effect sizes were calculated for the outcome variables as suggested by an author[19]. Effect sizes were classified as very small (< 0.19), small (0.20 to 0.49), medium (0.50 to 0.79), large (0.80 to 1.19), very large (1.20 – 1.99), and huge (> 2.0)[20] The calculation of confidence intervals for effect sizes was performed as proposed by a study[21].

RESULTS

Figure 1 shows the flow diagram of the study. Of 35 individuals invited to participate in the study, seven did not meet inclusion criteria and two had another reason for exclusion. Of the 26 remaining individuals, 26 were randomized to the exercise program with and without blood flow restriction groups. The final analysis included all randomized individuals (13 in the low-intensity resistance exercise with blood flow restriction LI+BFR and 13 low-intensity resistance exercise LI).

Table 1 presents the sociodemographic and clinical characteristics of the participants (pre-test).

Table 1. Characterization of study participants.

Variables	LI+BFR		LI		p-value
	Mean	SD	Mean	SD	
Age (years)	65.54	± 8.15	63.31	± 8.91	0.512[a]
BMI (kg/m^2)	30.70	± 4.48	30.69	± 5.37	0.889[a]
Strength 1-RM (kgf)	28.85	± 15.43	22.69	± 16.02	0.223[b]
Relative strength (kgf/kg)	0.37	± 0.17	0.30	± 0.23	0.139[b]
Pain (VAS)	6.08	± 1.66	6.08	± 1.66	0.997[a]

LI+BFR: low-intensity resistance exercise with blood flow restriction; LI: low-intensity resistance exercise; SD = standard deviation; VAS = Visual Analog Scale.
No statistically significant differences were found between the groups (LI+BFR and LI) for the variables age; BMI = body mass index; strength for 1-RM, relative strength, and pain (p ≥ 0.05).

The analysis of data related to the effects of interventions on chronic pain is presented in table 2. There were no statistically significant differences (p>0.05) between treatments in pain reduction. In both protocols, the effect size was evaluated as large (LI+BFR: ES = -2.44; LI: ES = -2.04). The analysis of pain data showed that both protocols (LI+BFR and LI) significantly reduced pain from pre to post-test (p<0.05).

Table 2. Effects of low-intensity resistance exercise with blood flow restriction (LI+BFR) and low-intensity resistance exercise (LI) on pain in patients with knee osteoarthritis.

	Pre-test Mean (±SD)	Post-test Mean (±SD)	ES	ES - CI 95%	
LI+BFR	6.08[a] (1.89)	1.47[b] (1.71)	-2.44	-3.45	-1.23
LI	6.08[a] (1.66)	2.69[b] (1.70)	-2.04	-2.99	-0.92

SD = Standard Deviation; ES-CI 95% = Confidence Interval for Effect Size. Different letters indicate statistically significant differences between pre- and post-test or between groups (p < 0.05).

Data relating to strength for 1-RM, functional strength (chair-test) and peak torque are shown in Figure 2. No statistically significant difference (p>0.05) between treatments was found for the variables strength for 1-RM and functional strength. Both the strength for 1-RM and the functional strength increased significantly (p < 0.05) from pre- to post-test in both intervention protocols (LI+BFR and LI). Peak torque, expressed as a function of body mass, showed a significant increase from pre- to post-test only in the LI+BFR group ($p < 0.05$). No statistically significant differences between groups ($p \geq 0.05$) were found, both pre- and post-test for the variables, strength for 1-RM, functional strength, and peak torque (Figure 2).

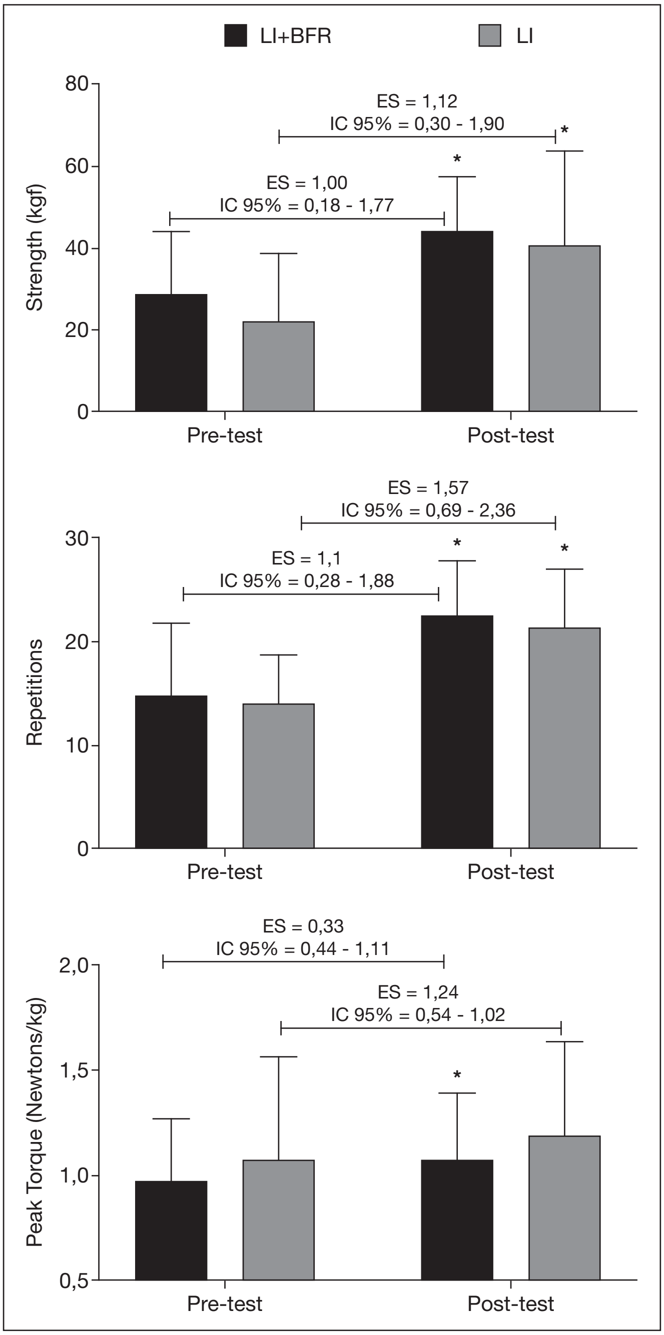

Figure 2. Effects of 12 weeks of strength exercise (knee joint extension on extensor chair) on maximal dynamic strength (1-RM) and functional strength (chair-test) in patients with knee osteoarthritis (KOA)

LI+BFR: Low-intensity resistance exercise with blood flow restriction; LI: Low-intensity resistance exercise; ES: Intragroup effect size. *Statistically significant difference from the pretest (p<0.001).

Effect sizes related to interventions (Figure 2) were evaluated as large and very large for functional strength (LI+BFR: ES = 1.10; LI: ES = 1.57, respectively), large for strength for 1-RM (LI+BFR: ES = 1.00, LI: ES = 1.12), and small for the peak torque (LI+BFR: ES = 0.33, LI: ES = 0.24). It should be noted that the magnitude of effect of the interventions was quite similar between treatments for the variable's strength for 1-RM, functional strength (chair-test) and peak torque.

DISCUSSION

The main finding of this study was the fact that blood flow restriction added to resistance exercise does not produce additional effects on strength gain and pain reduction in patients with KOA. The magnitudes of the effects of the analyzed outcomes were similar between interventions. Although no differences were demonstrated between the interventions in the analyzed outcomes, both analyzed protocols increased muscle strength for 1-RM, functional strength and reduced pain in patients with KOA.

In KOA, muscle strength is usually reduced and accompanied by pain. For this reason, the American College of Rheumatology recommends muscle strengthening as the first therapeutic strategy for the treatment of this condition[14]. The strengthening of the femoral quadriceps is commonly indicated in the treatment of KOA, considering that this condition has a static and dynamic chondroprotective effect on the knee joint.

In the present study, both interventions were effective to improve strength and reduce pain in patients with KOA. Low-intensity exercise may have been a factor that contributed to the high adherence of participants, with a consequent improvement in the evaluated outcomes[22]. Another aspect that can be considered to explain the results of this study was suggested by a study[23], who reported that the effects of interventions for KOA may be mainly related to the placebo effect, natural history of the disease, and the long duration of intervention that may increase the placebo response to subjective findings such as pain.

To some extent, data from the present study on the potential effects of low-intensity physical exercise, with or without blood flow restriction, on pain reduction may be associated with increased strength and muscle hypertrophy, as proposed by a study[24], who also observed that ischemic conditions potentiate the signaling network that increases the gene expression of substances involved in the preservation of the nervous system and neuronal apoptosis in patients with orthopedic injuries.

Although a study[24] have shown that exercise with blood flow restriction potentiates gains in strength and muscle mass, the same study[24] strongly advocate the inclusion of BFR to gain strength and muscle mass in the early stages of rehabilitation, when high-intensity exercises would not be tolerated by patients, and another study[5] demonstrated that high-intensity exercises do not reduce more knee pain and knee joint compression forces than low-intensity exercises, in the present study, BFR was not efficient to promote additional increases in dynamic strength or functional strength, which is why pain improvement was similar between the experimental protocols used.

Other studies on KOA patients have also shown that exercise with BFR was effective in promoting strength gain and pain improvement[7,8,11,14]. However, in these studies, the authors used different protocols such as isometric contraction of the abdomen, hip abduction, sensorimotor training, and knee extension in the extension chair associated with leg press exercise. None of the protocols studied in the literature showed similar characteristics to the present study. A study[11], was the closest methodologically closer to the present study, however, the protocol used in that study included two exercises (bilateral leg press and knee extension exercise) and was performed in a hospital environment.

Unlike the study[11,26] who did not find increases in muscle strength associated with low intensity exercise despite performing a protocol with two exercises over 12 weeks, the present study demonstrated that only one knee extension exercise was sufficient to increase muscle strength in response to the same training period. Although the results of this present study are encouraging, they need to be interpreted with carefully. More important than the increase in muscle mass for the patient with KOA is the increase in strength, especially in the initial phase of the intervention, and different muscle components of sarcopenia and therapeutic interventions to increase muscle strength have important impacts on reducing pain and improving performance in activities of daily living, with consequent improvement in quality of life[27].

Pain associated with physical dysfunction is one of the main factors that compromise the daily activities of people with KOA[7,27-30]. A systematic review with meta-analysis[31], showed that quadriceps strengthening improves pain in patients with KOA, although there is no consensus on the most appropriate protocol to be used, especially in relation to exercise dosages[30,31]. The results of the present study point to the importance of muscle strengthening, especially of the quadriceps, in the treatment of pain in patients with KOA. Despite being a study with limitations, the results of this study represent a positive perspective for future analyzes on this protocol for subjects with knee osteoarthritis.

In this research, the gain in strength, regardless of the intervention, occurred concomitantly with the improvement in muscle function and with the reduction in pain. Thus, this research hypothesized that these associated factors may also result in an increase in self-confidence to perform activities of daily living (not assessed), alleviating fear and the expectation of pain[27,32,33]. It should be noted that the main advantage attributed at the blood flow restriction (BFR) is to be an effective clinical intervention used to increase strength in healthy individuals. However, its effects on pain and function in individuals with knee pain are unknown[34]. In this study, blood flow restriction did not produce additional effects regarding the parameters used when compared to exercise without blood flow restriction. The findings of this study showed that in the initial phase of an intervention (first 12 weeks), a single low-intensity resistance exercise twice a week is sufficient to significantly reduce pain in a patient with KOA and that blood flow restriction it was not a condition that potentiated this effect.

Improvements in peak torque in isokinetic knee extension exercise (LI+BFR) were consistent with other studies in which strength gain was similar between low-intensity exercise protocols with BFR[11,26,34,35], reinforcing the hypothesis that pain improvement can be attributed to strength gain. The data from this study corroborate the findings by a research[7], which also showed improvements in peak torque from pre- to post-test for the LI+BFR group. It should also be noted that increases in functional strength are associated with the improved performance of activities of daily living, and this factor can be contributed indirectly to reducing pain in knee OA[27].

Regarding the frequency of sessions[36], was demonstrated that a high frequency of low-intensity training associated with BFR over a period of three weeks can produce significant increases in the cross-sectional area of all quadriceps muscles without edema-induced muscle swelling. A study suggested that low intensity, short duration, and high-frequency BFR may be a better training approach than high intensity to achieve hypertrophy without noticeable influence of muscle edema[36]. This hypothesis corroborates the findings of the present study, which in the short term, reported significant improvement in pain only with low-intensity exercise, regardless of blood flow restriction.

One limitation of the present study was the low sample size. A second limitation was the absence of a high-intensity resistance exercise and a control exercise group as well as missing to include an evaluation of biomarkers that allow identification of the mechanisms involved in response to BFR exercise. However, to date, few studies have demonstrated new alternatives for KOA patients[7,24,27]. In this sense, the protocols analyzed in this study are a possible effective alternative to increase maximum dynamic strength, functional strength, and reduce pain, especially because they use a single exercise, easy to apply and perform, which facilitates treatment adherence. Clearly, further studies are needed to examine whether the present results are representative of the general population with KOA.

CONCLUSION

The results of this study showed that blood flow restriction associated with low-intensity resistance exercise does not produce additional effects on muscle strength gain and pain reduction in patients with knee osteoarthritis, compared to strength exercise alone. In this sense, the hypothesis of the study was rejected.

AUTHORS' CONTRIBUTIONS

Fernando Schorr Grossl
Statistical Analysis, Project Management, Research, Methodology, Writing - Preparation of the Original, Writing - Review and Editing, Validation

Clodoaldo Antônio De-Sá
Statistical Analysis, Methodology, Writing - Review and Editing, Supervision, Validation
Marzo Edir Da-Sila-Grigoletto
Statistical Analysis, Methodology, Validation, Visualization
Fátima Ferretti
Writing - Review and Editing, Supervision, Validation
Sedinei Lopes Copatti
Statistical Analysis, Project Management, Writing - Preparation of the Original
Vanessa da Silva Corralo
Methodology, Writing - Review and Editing, Supervision, Visualization

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