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Exercises with partial vascular occlusion in patients with knee osteoarthritis: a randomized clinical trial

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Abstract
Purpose The objective of this study was to evaluate whether women with knee osteoarthritis performing a rehabilitation programme consisting of low-load exercises combined with PVO exhibited the same results in changes in quadriceps strength, pain relief, and functional improvement when compared to women receiving a programme consisting of high-load exercises without PVO.
Methods Thirty-four women (mean age, 61 years) with a diagnosis of knee osteoarthritis were randomly assigned to a conventional or occlusion group. The women in the conventional group ($n = 17$) performed a 6-week quadriceps strengthening and stretching programme using a load around 70 % of the 1-repetition maximum (RM). The women in the occlusion group ($n = 17$) performed the same programme, however, only using a load around 30 % of the 1-RM, while PVO was induced. The PVO was achieved using a pressure cuff applied to the upper third of the thigh and inflated to 200 mmHg during the quadriceps exercise. An 11-point Numerical Pain Rating Scale (NPRS), the Lequesne questionnaire, the Timed-Up and Go (TUG) test, and muscle strength measurement using a hand-held dynamometer were used as outcome measures at baseline (pretreatment) and at the end of the 6-week of treatment. Pain, using the NPRS, was also assessed when performing the quadriceps exercises during the exercise sessions.
Results At baseline, demographic, strength, pain, and functional assessment data were similar between groups. Patients from both the conventional and occlusion groups had a higher level of function (Lequesne and TUG test), less pain (NPRS), and higher quadriceps strength at the 6-week evaluation when compared to baseline (all $P < 0.05$). However, the between-group analysis showed no differences for all outcomes variables at posttreatment (n.s.). Patients in the occlusion group experienced less anterior knee discomfort during the treatment sessions than those in the high-load exercise group ($P < 0.05$).
Conclusion A rehabilitation programme that combined PVO to low-load exercise resulted in similar benefits in pain, function, and quadriceps strength than a programme using high-load conventional exercise in patients with knee osteoarthritis. However, the use of PVO combined with low-load exercise resulted in less anterior knee pain during the training sessions.
Level of evidence I.

Keywords Resistance training · Muscle strength · Rehabilitation · Ischaemia · Occlusion

Introduction

The treatment recommendations for knee osteoarthritis (OA) have focused on symptom relief and functional status [11]. Many interventions have been used for lifestyle modification, including weight reduction, drugs, surgery, and specific physical therapy interventions such as strengthening exercises [11, 12]. In this scenario, the quadriceps strengthening can be considered one of the major

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challenges for clinicians in rehabilitation programmes for patients with knee injuries, because the strengthening principle is based on the muscle overload conferred by a progressive increase in resistance, which consequently leads to articular overload [7, 33]. The American College of Sports Medicine recommends that the required load for resisted exercise that focuses on muscle hypertrophy should be around 60–70 % of the 1-repetition maximum (1-RM) [1]. Furthermore, several studies have shown that quadriceps strengthening plays an important role in terms of pain relief and functional improvement in patients with knee injuries [3, 9]. However, many patients have knee discomfort when performing conventional high-load strengthening exercises [7, 27, 28, 33].

Recent studies in healthy people have shown that low-load exercises (20–50 % of the 1-RM) combined with partial vascular occlusion (PVO) present similar results in muscle strength to those achieved with high-load exercises [21, 32, 34], but with less anterior knee discomfort [29]. Partial occlusion has been achieved using a pressure cuff or tourniquet applied to the upper third of the thigh during exercises [5, 27]. Some authors have shown that the addition of PVO to low-load exercises can increase muscle strength by greater activation of fast-twitch (type II) fibres [15, 32]. This partial occlusion would generate an anaerobic environment in the muscle belly, thus anticipating activation of the type II fibres and thereby decreasing activation of the slow-twitch (type I) fibres [18, 32]. Other authors have hypothesized that the PVO effects are related to increased secretion of growth hormone and the activation of the protein synthesis mechanism [17, 30].

However, there is still a lack of clinical studies comparing different protocols for quadriceps strengthening in patients with degenerative knee injuries. Therefore, the purpose of this study was to evaluate whether women with knee OA performing a rehabilitation programme consisting of low-load exercises combined with partial vascular occlusion (PVO) exhibited the same results in changes in quadriceps strength, pain relief, and functional improvement when compared to women receiving a programme consisting of high-load exercises without PVO. It was hypothesized that both groups would present the same improvements during the rehabilitation programme, but with less anterior knee discomfort in the low-load group. The main clinical relevance of this study is based on validation of a less aggressive technique of muscular strengthening in this population.

Materials and methods

Thirty-four women with a diagnosis of knee osteoarthritis participated in the study and were randomly assigned to 1 of 2 groups: a conventional group ($n = 17$) or an occlusion group ($n = 17$) (Fig. 1). All volunteers were informed about the study procedures and signed informed consent forms in accordance with the National Health Council Resolution N° 196/96.

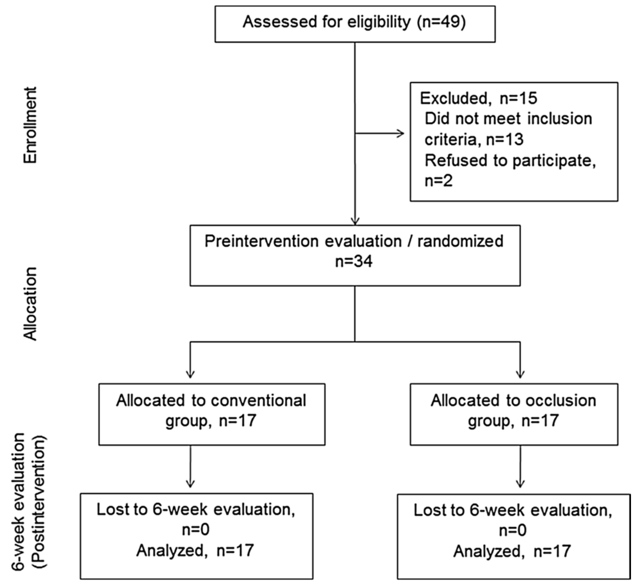

Fig. 1 CONSORT flow chart

All patients fulfilled the combined clinical and radiographic criteria of knee OA, as established by the American College of Rheumatology [1, 8]. Participants with scores of 2 or 3 in one of the knees based on the Kellgren and Lawrence scale [13] were included. We excluded patients with a history of surgery or any invasive procedure of the affected knee, physical therapy, or a strengthening programme for knee injuries, as well as the use of any medication that had changed in the last 3 months. Furthermore, patients were excluded that had any other diseases that affected function, or who presented any neurological disorder, heart, or vascular condition, including tumours. The participants were recruited from the rehabilitation service, by a single physical therapist with more than 12 years of clinical experience in knee rehabilitation.

All patients included in the study were submitted to a clinical assessment of femoral and tibial arterial pulses by a vascular surgeon in order to exclude potential vascular risks. Moreover, when the arterial pulse was not clearly palpable, a Doppler diagnostic ultrasound was performed. However, only two patients required this examination and they were released to participate in the study.

A single examiner was responsible for the administration of all clinical tests and questionnaires before the initiation of treatment (baseline) and at 6 weeks after intervention. The examiner was blind to the group assignment of the patients and did not participate in the intervention. The

Table 1 Treatment protocol performed by the conventional group and the occlusion group

Conventional group
Hamstrings stretching, 3 repetitions of 30 s
Bridge with isometric contraction of the transversus abdominis—CORE training, 3 repetitions of 30 s
Hip abduction with weights (side lying), 3 sets of 10 repetitions*
Hip abduction with weights (side lying), 3 sets of 10 repetitions*
Calf raises, 3 sets of 10 repetitions
Calm exercises (side lying) with elastic band, 3 sets of 10 repetitions^{+}
Sensori-motor training (standing) at mini-trampoline, 3 repetitions of 30 s
Seated knee extension (machine), 90°–0° of knee flexion, 3 sets of 10 repetitions*
Occlusion group
Hamstrings stretching, 3 repetitions of 30 s
Bridge with isometric contraction of the transversus abdominis—CORE training, 3 repetitions of 3 s
Hip abduction with weights (side lying), 3 sets of 10 repetitions*
Hip adduction with weights (side lying), 3 sets of 10 repetitions*
Calf raises, 3 sets of 10 repetitions
Clam exercises (side lying), 3 sets of 10 repetitions^{+}
Sensori-motor training (standing), 3 repetitions of 30 s
Seated knee extension with weights associated with partial occlusion, 90°–0° of knee flexion, 3 sets of 30 repetitions‡

* Load is 70 % of the 1-repetition maximum

$^{+}$ Maximum resistance that enables 10 repetitions

‡ Load is 30 % of the 1-repetition maximum

assignment of subjects to the two groups was performed randomly using opaque, sealed envelopes, each containing the name of one of the groups (conventional and occlusion). The envelopes were picked by an individual not involved in the study. Group assignment was performed following the initial evaluation but prior to the initial treatment session.

Interventions

The conventional and occlusion groups completed 18 treatment sessions, provided three times per week for 6 weeks. The treatment for the individuals in the conventional group emphasized stretching and strengthening of the inferior limb musculature, including high-load quadriceps exercises. Individuals in the occlusion group were treated using the same protocol, but with low-load quadriceps exercises combined with PVO (Table 1).

The load during quadriceps exercises in the conventional group was standardized to 70 % of the estimated 1-repetition maximum (1-RM), defined as the maximum load with which 1 repetition of the exercise could be completed without pain (using a knee extension amplitude between 90° and 0°). This non-weight-bearing exercise was initiated using ankle weights and progressed to a knee extension machine based on the patient's tolerance. These criteria were based on the protocol of a previous study [14]. The load in the occlusion group was standardized to 30 % of the 1-RM associated with PVO, which was achieved using a pressure cuff applied to the upper third of the thigh and inflated to 200 mmHg during the quadriceps exercises [5, 21]. The maximum load for all strengthening exercises (70 % of the 1-RM in the conventional group and 30 % of 1-RM in the occlusion group) was evaluated during the first treatment session and was reviewed weekly in order to make any necessary adjustments. The patients performed exercises solely during physical therapy and did not perform exercises at home.

Evaluation

An 11-point NPRS, in which 0 corresponded to no pain and 10 to the worst imaginable pain, was used to measure the maximum pain during the last week. The NPRS has been shown to be reliable and valid, with a minimal clinically important difference (MCID) of 2 points [4, 26]. The NPRS was also assessed when performing the quadriceps exercises during the exercise sessions. For this evaluation, we asked patients to describe the anterior knee pain and not the discomfort generated by the occlusion technique.

The Lequesne questionnaire [16, 20] is an evaluation tool composed of 10 questions regarding pain, discomfort, and function and has been used in clinical outcome studies. The sum of the scores is classified as little (1–4 points), moderate (5–7 points), severe (8–10 points), very severe (11–13 points), and extremely severe dysfunction (greater than or equal to 14 points). The Timed-Up and Go (TUG)

Table 2 Demographic data of the conventional and occlusion group

	Conventional ($n = 17$)	Occlusion ($n = 17$)	P value
Age, years	60.4 ± 6.7	62.3 ± 7.0	n.s.
Body mass, kg	75.5 ± 8.5	70.6 ± 7.3	n.s.
Height, m	1.57 ± 0.1	1.58 ± 0.1	n.s.
Body mass index, kg/m^2	30.8 ± 3.7	28.9 ± 3.7	n.s.

Values are mean ± SD. There were no differences between groups (n.s.)

test assesses physical mobility and balance among elderly people. The TUG measures the time that patients take to get up from a chair, cross a distance of 3 m, and come back and sit down on the same chair. The mean of 3 measurements was used for analysis [25].

Quadriceps maximum isometric voluntary contraction was evaluated using a hand-held dynamometer (Lafayette Instrument Co, Lafayette, Indiana) [31]. The patient was asked to sit on the table, with arms held against the body and hips and knees at 90° and 60° of flexion, respectively [6]. The dynamometer was positioned 2 inches proximal to the lateral malleolus on the anterior aspect of the tibia, and the leg was stabilized by an inelastic band. This band was placed to fix the dynamometer to the front face of the leg, being fixed on the base of the table. During strength testing, 2 submaximum trials to familiarize the patients with each test position were used. This was followed by 3 trials with maximum isometric effort. For data analysis, the average values of the 3 trials with maximum effort were used. Ten healthy volunteers (females; mean age, 34 years) were tested according to the protocol described above as a pilot study. The result indicated good reliability, with an intraclass correlation coefficient (ICC) of 0.89. The data were then normalized in relation to each patient's weight. The following formula was used for this normalization [24]: (Kg force/Kg weight) × 100.

The study was approved by the Research Ethics Committee of Santa Casa of São Paulo—BR, ID number 021/11.

Statistical analysis

Data were analysed with SPSS version 13.0 (SPSS Inc, Chicago, IL). Descriptive statistics for demographic data and all outcome measures were expressed as averages and standard deviations. Comparison between the groups was performed using independent *t* tests for age, body mass, height, body mass index, strength, functional scales, and pain score to determine homogeneity of the groups at baseline (pretreatment). The data for strength, the Lequesne functional scale, the TUG, and the NPRS were analysed using separate 2 by 2 (group-by-time) repeated measures of analysis of variance. The factor of group had 2 levels (conventional and occlusion), and the repeated factor of time had 2 levels (pretreatment and posttreatment). An intention-to-treat analysis was not used because there were no dropouts during the course of the study. Finally, independent t tests were used for NPRS during performing quadriceps exercises. Sample size was calculated assuming 80 % power to detect a 20 % improvement in pain (Numerical Pain Rating Scale—NPRS), with a standard deviation of 2 points and a significance level of 5 %. The required sample was 17 patients per group.

Results

Baseline and demographic data

There was no statistically significant difference (n.s.) for age, height, body mass, and body mass index between the participants in the conventional and occlusion groups (Table 2). There were also no statistically significant difference (n.s.) between groups for any of the outcome variables at baseline (pretreatment) (Table 3).

Strength, function, and pain

For the strength, the Lequesne scale, the TUG, and the NPRS, we found no statistically significant group-by-time interaction (Table 3). A significant time effect emerged for strength ($P = 0.001$), function in Lequesne ($P = 0.001$), TUG ($P = 0.006$), and NPRS ($P = 0.001$), with no significant group effect.

Knee discomfort during exercises

A significant between-group difference was found for NPRS while performing the quadriceps exercises. The patients of the occlusion group presented decreased anterior knee discomfort when compared to the conventional group ($P = 0.01$).

Discussion

The results of this randomized clinical trial demonstrated that the low-load strengthening associated with PVO presented the same improvements compared to conventional strengthening in terms of quadriceps strength, function, and pain relief in patients with knee OA. However, the patients of the occlusion group presented less anterior knee discomfort during exercises.

Table 3 Outcome measures preintervention and postintervention for the conventional ($n = 17$) and occlusion ($n = 17$) groups

Measure/group	Preintervention*	Postintervention*	Within-group change score	Between-group difference in change score‡
Quadriceps strength (normalized to weight), kg				
Conventional	24.1 ± 10.1	33.5 ± 12.9	9.4 ± 8.3 (1.3, 17.5)	7.4 (0.9, 13.9)
Occlusion	23.2 ± 8.4	40.0 ± 9.2	16.8 ± 10.3 (10.6, 22.9)	
Lequesne (0–20)#				
Conventional	13.0 ± 8.3	7.0 ± 3.6	(−) 6.0 ± 7.5 (−1.5, 10.5)	1.0 (−3.3, 5.3)
Occlusion	11.5 ± 2.9	6.5 ± 3.4	(−) 5.0 ± 4.5 (−2.8, 7.2)	
TUG(s)#				
Conventional	7.9 ± 2.7	6.3 ± 1.7	(−) 1.6 ± 3.5 (0, 3.2)	0.4 (−1.5, 2.3)
Occlusion	7.5 ± 1.2	6.3 ± 1.6	(−) 1.2 ± 1.8 (−2.9, −0.21)	
NPRS (0–10)#				
Conventional	6.0 ± 2.6	3.5 ± 2.3	(−) 2.5 ± 1.8 (4.2, −0.8)	(−) 0.8 (−2.2, 0.6)
Occlusion	6.5 ± 2.5	3.2 ± 1.9	(−) 3.3 ± 2.2 (−4.8, −1.7)	
NPRS—During performing exercises (0–10)#				
Conventional	6.2 ± 2.2			(−) 3.7 (−5.0, −2.4)
Occlusion	2.5 ± 1.5			

NPRS Numerical Pain Rating Scale (0–10 cm), *TUG* Timed Up and Go

* Values are mean ± SD

+ Values are mean ± SD (95 % confidence interval)

‡ Values are mean (95 % confidence interval)

Lower values represent better result

Patients with knee OA usually present pain, gradual loss of function and muscle strength, as well as a reduction in quality of life [22]. In this context, the European League Against Rheumatism (EULAR) recommends muscle strengthening, especially of the quadriceps, because it plays an important role during the rehabilitation process [8]. According to conventional concepts, the principle of muscular strengthening is based on the exercise with high-load and progressively increasing resistance [1]. Although these guidelines are optimal for healthy people, there are numerous circumstances in which it would be extremely difficult to achieve a high exercise intensity level in populations such as the frail elderly, in patients with degenerative disorders, or in patients undergoing the immediate rehabilitation phase following surgery [10].

Given the difficulty of adding high-load exercises for muscle strengthening without generating harmful effects on the knee joint, the PVO seems to be a good alternative for rehabilitation, especially in people with degenerative disorders [19]. Although it has been used in other injuries, we did not find any studies to date that assessed the efficacy of exercise associated with PVO in those with knee OA. Therefore, the exercise for quadriceps disinhibition has been a major challenge in patients with degenerative knee disorders due to anterior discomfort. We demonstrated in the present study that exercises with a low-load associated with PVO can be an important tool for treating patients with anterior knee pain. The fact of assessing specifically the anterior pain and not overall pain was based on the fact that most concern during quadriceps strengthening is the patellofemoral joint overload, which is explained by the great compression vector during high-load exercises [7, 27, 28, 33]. Another concern during the pain assessment was to instruct patients to report the anterior knee pain and not the discomfort caused by vascular occlusion in the proximal thigh. Still, the occlusion group presented decreased anterior knee discomfort when compared to the conventional group, showing that a possible discomfort in the thigh by partial occlusion did not influence in the results.

Authors have documented that a protocol utilizing low-load training with a blood flow restriction (30 % of 1-RM) presents the same results in terms of functional muscle adaptations when compared to high-load training (75 % of 1-RM) [32, 34]. Laurentino et al. [15] concluded that vascular occlusion in combination with high-load strength training does not augment muscle strength or hypertrophy when compared to high-intensity strength training alone. The present study showed similar effects between both treatment protocols, while Otha et al. [21] demonstrated that exercise associated with PVO was superior to exercise without PVO. In general, these authors concluded that resistance exercise with relatively low vascular occlusion pressure is potentially useful to increase muscle strength and endurance without discomfort [29].

Recent studies evaluated the results of similar quadriceps-strengthening programmes (ranging from 4 to 6 weeks), showing gains around 5–25 % [2, 5, 23]. Our results are similar, since the conventional group showed a gain of 30 % after treatment when compared to baseline. However, the occlusion group showed a gain of 42 % after treatment despite a lack of significant difference in between-group evaluation.

It is important to emphasize that all patients underwent a clinical or ultrasonographic assessment with a vascular surgeon to rule out concomitant pathologies. However, we believe that this is a safe method because previous studies have shown that pressure variations between 120 and 200 mmHg in the pressure cuff do not lead to a total arterial occlusion [5, 18, 21, 27]. This information corroborates previous studies [5, 18] which indicate that this protocol increases the strength without altering vascular function. Another study did not find difference between regular exercise and exercise with partial occlusion in terms of muscle damage, oxidative stress, and nerve conduction velocity responses [18]. Thus, the main clinical relevance of this study is based on validation of a less aggressive technique of muscular strengthening in this population.

While this study evaluated the effects of low-load quadriceps exercises associated with PVO in terms of clinical outcomes, we must caution that these findings are related to the elderly population with knee OA and cannot be extended to those in higher risks populations, such as postsurgical patients. Furthermore, this study has other limitations such as the lack of long-term follow-up, a small number of patients, as well as the lack of other variables such as different cuff pressures during exercise. Finally, only women were included, which may limit the generalizability of the results.

Conclusion

A rehabilitation programme that combined PVO to low-load exercise resulted in similar benefits in pain, function, and quadriceps strength when compared to a programme using high-load conventional exercise in women with knee OA. However, the use of PVO combined with low-load exercise resulted in less anterior knee pain during the training sessions.

Compliance with ethical standards

Conflict of interest The authors declared that they have no conflict of interest for this study.

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