A novel exercise approach to improve exercise performance and quality of life in intermittent claudicants [abstract only]

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TITLE

A novel exercise approach to improve exercise performance and quality of life in patients with intermittent claudication: Safety and feasibility study

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ABSTRACT

INTRODUCTION

Intermittent claudication (IC) is a common and debilitating symptom of peripheral arterial disease, resulting in poor exercise performance and quality of life (QoL). Supervised exercise programmes are effective rehabilitation for patients with IC, but they are poorly adhered to partly due to high pain and effort associated with walking, aerobic and resistance exercise. Therefore, alternative exercise methods that improve clinical outcomes and are well tolerated and adhered to by patients with IC are warranted and important.

Low-intensity resistance exercise with blood flow restriction (BFR) is becoming popular as a rehabilitation tool for clinical populations as it has shown to enhance muscle function and size comparable to high-intensity resistance exercise despite using low workloads. The BFR technique involves a pneumatic cuff on the proximal aspect of the exercise limb to apply a pressure sufficient to occlude venous flow during exercise. The primary mechanisms explaining the effectiveness of BFR is sustained low muscle oxygenation, enhanced anaerobic metabolism, and accumulation of metabolic by-products by muscular tension causing high metabolic stress.

BFR represents an alternative exercise method for individuals who are intolerant to high-intensity protocols. To date, no study has investigated a BFR regime in patients with IC. The study aim was to evaluate the safety and feasibility of BFR in patients with IC.

METHODS

Thirty patients with stable IC were recruited through the Sheffield Vascular Institute of Sheffield Teaching Hospitals NHS Foundation Trust. Patients were randomly assigned into the two exercise groups (1) BFR (n=15) or (2) a control of matched exercise without BFR (CON, n=15).

Both groups completed 8-weeks of twice weekly resistance exercise sessions (16 sessions total). Sessions involved 4 sets (30, 15, 15 and 15 repetitions) of horizontal leg press and 3 sets (15, 15 and 15 repetitions) of knee extension performed at 20% of one repetition maximum (1RM). Patients in the BFR group completed the resistance exercises with the addition of a pneumatic cuff placed around the proximal aspect of the legs. The pneumatic cuff was inflated during the start of each resistance exercise to 50% arterial occlusion pressure (149.6 ± 35.4 mmHg) and was deflated immediately at completion.

Safety of the protocols was defined by the number, type, and severity of adverse events. Completion rate was defined as the number of patients attending the baseline and follow-up assessments. Walking performance was assessed by the six-minute walk test (6MWT), QoL was assessed using the EQ-5D-5L, and vastus lateralis muscle thickness was measured via B-mode ultrasonography.

Given this is a feasibility study, no formal sample calculation was required. Thirty patients were recruited as this is sufficient to provide precise estimates of feasibility outcomes and not cause undue burden on patients. All data is presented as means ± standard deviations unless stated otherwise. As

this study was not powered to detect statistical differences in outcomes (e.g., *p*-value < 0.05), estimated mean differences are presented with 95% confidence intervals.

RESULTS

Patients' characteristics were similar between the two groups at baseline (TABLE 1). There were no adverse events and both groups observed high completion rates (BFR = 93%, C = 87%). Both groups observed an overall improvement in 6MWT distance (BFR = 55.2 m [42.4, 67.9], CON = 36.3 m [10.8, 61.8]) (TABLE 2). However, at an individual level, 86% of patients in BFR improved their 6MWT distance by >35.5 m (which represents a large clinically important difference) at follow-up compared with 33% of patients in CON. Additionally, time to claudication during 6MWT was prolonged at follow-up for BFR (44.7 s [20.8, 68.6]) but not CON (2.6 s [-23.2, 28.4]), and ratings of pain at the end of the 6MWT may have been reduced for BFR (1.1 CR-10^{+} [-0.1, 2.4]) but not CON (-0.3 CR-10^{+} [-1.4, 0.8]). QoL improved for BFR with score reductions in 4 out of 5 dimensions and increased self-rated overall health but did not improve for CON with only 1 dimension score reduction (FIGURE 1).

CONCLUSION

BFR is safe and feasible in patients with IC and has potential to increase exercise performance, reduce pain, and improve QoL. We next plan to compare BFR with standard supervised walking exercise.

TABLE 1: Patients' baseline characteristics.

	BFR (n = 15)	**CON (n = 15)**	**Total (n = 30)**
Age (years)	66.8 ± 8.6	71.6 ± 9.1	69.0 ± 9.0
Sex, Female	3 (20%)	3 (20%)	6 (20%)
Ethnicity (%white)	100	100	100
Stature (cm)	168.6 ± 11.7	171.1 ± 10.2	169.8 ± 10.9
Body Mass (kg)	79.4 ± 12.3	77.6 ± 12.1	78.6 ± 12.0
BMI ($kg \cdot m^2$)	27.9 ± 3.1	26.5 ± 3.5	27.3 ± 3.3
Bilateral Claudication	7 (47%)	5 (33%)	12 (40%)
ABPI	0.62 ± 0.16	0.69 ± 0.11	0.65 ± 0.14
Current Smoker	4 (27%)	3 (20%)	7 (23%)
Previous Smoker	14 (93%)	11 (73%)	25 (83%)

TABLE 2: Change in exercise performance and muscle thickness.

Variable	**Baseline**	**Follow-up**	**% Difference**
6MWT			
Distance (m)			
BFR	371.3 ± 91.9	426.5 ± 102.2	15%
CON	372.4 ± 98.4	408.7 ± 104.1	10%
Time to claudication (s)			
BFR	127.5 ± 68.5	172.2 ± 59.8	35%
CON	113.6 ± 65.5	111.0 ± 55.0	-2%
Pain (CR-10^{+})			
BFR	4.3 ± 2.6	3.1 ± 1.8	-28%
CON	4.3 ± 1.4	4.5 ± 2.2	6%
Leg Press 1RM (kg)			
BFR	124.0 ± 63.2	196.6 ± 97.9	59%
CON	101.5 ± 60.6	153.9 ± 89.6	52%
Knee Extension 1RM (kg)			
BFR	45.5 ± 20.4	70.0 ± 27.4	54%
CON	34.8 ± 23.3	53.4 ± 37.3	53%
Muscle Thickness			
(mm)			
BFR	21.9 ± 2.7	21.8 ± 3.3	0%
CON	21.7 ± 4.1	22.1 ± 4.2	2%

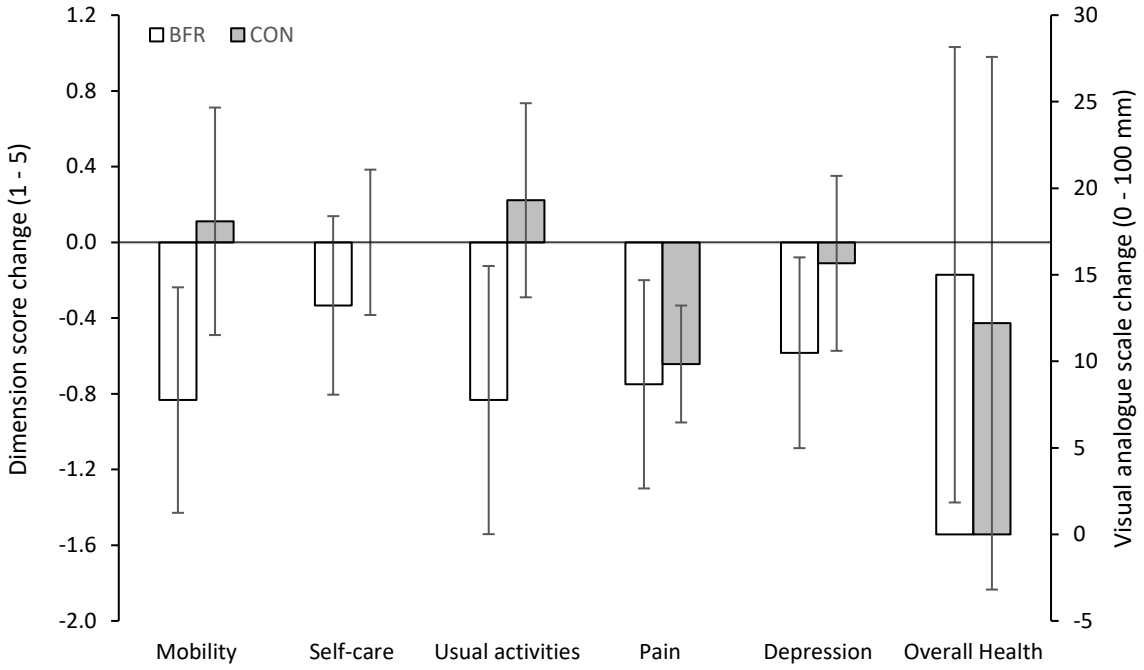

FIGURE 1: Change in QoL assessed using the EQ-5D-5L at baseline and follow-up. Data are presented as mean difference with 95% confidence intervals.