Original article

Effect of supervised exercise on physical function and balance in patients with intermittent claudication

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Background: **The aim of the study was to identify whether a standard supervised exercise programme (SEP) for patients with intermittent claudication improved specific measures of functional performance including balance.**

Methods: **A prospective observational study was performed at a single tertiary vascular centre. Patients with symptomatic intermittent claudication (Rutherford grades 1–3) were recruited to the study. Participants were assessed at baseline (before SEP) and 3, 6 and 12 months afterwards for markers of lower-limb ischaemia (treadmill walking distance and ankle : brachial pressure index), physical function (6-min walk, Timed Up and Go test, and Short Physical Performance Battery (SPPB) score), balance impairment using computerized dynamic posturography with the Sensory Organization Test (SOT), and quality of life (VascuQoL and Short Form 36).**

Results: **Fifty-one participants underwent SEP, which significantly improved initial treadmill walking distance ($P = 0{\cdot}001$). Enrolment in a SEP also resulted in improvements in physical function as determined by 6-min maximum walking distance ($P = 0{\cdot}006$), SPPB score ($P < 0{\cdot}001$), and some domains of both generic (bodily pain, $P = 0{\cdot}025$) and disease-specific (social domain, $P = 0{\cdot}039$) quality of life. Significant improvements were also noted in balance, as determined by the SOT ($P < 0{\cdot}001$).**

Conclusion: **Supervised exercise improves both physical function and balance impairment.**

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Introduction

Intermittent claudication is a chronic debilitating condition predominantly affecting older patients, in which the main symptom is reduced walking ability. Other impairments include poorer overall physical function[1–3], quality of life (QoL) and balance[4]. Recent guidance on peripheral arterial disease issued by the National Institute of Health and Care Excellence (NICE)[5] states that all patients with intermittent claudication should be offered participation in an exercise programme. This is supported by a number of studies[6–9] that show exercise improves walking distances and QoL, raises levels of daily activity, reducing functional decline and associated morbidity and mortality in the mid to long term[10,11]. There is increasing evidence that patients with claudication have associated balance impairment[12], predisposing to an increased risk of falls with associated physical and socioeconomic consequences[4,13]. The effect of a supervised exercise programme (SEP) on such outcomes has not yet been investigated. The present study investigated the role of a standard SEP on measures of overall physical function, including balance, for up to 12 months after enrolment.

Methods

This prospective longitudinal study was performed at a single academic surgical vascular unit of a university hospital. All participants provided written informed consent and were recruited in accordance with the Declaration of Helsinki. Ethical approval for the study was gained from the local research ethics committee (07/Q1105/12, 07/Q1105/13, 07/H1305/83).

Patients with claudication were identified at outpatient clinics by a consultant vascular surgeon, and those suitable for SEP were subsequently invited to participate in the study. Data were collected prospectively at baseline and at 3, 6 and 12 months after SEP enrolment.

Inclusion and exclusion criteria

Claudication was determined by documented current symptoms of intermittent claudication with either an ankle : brachial pressure index (ABPI) of 0·9 or less, or drop in ankle pressure of more than 20 mmHg after exercise testing, or documented haemodynamically significant atherosclerosis on radiological imaging (angiography or Duplex ultrasonography). Other inclusion criteria included: living independently in the local community; no assistance required for general activities of daily living, including shopping, cleaning and self-care; age over 50 years; English speaking; and able to comply with simple study protocol instructions.

Patients were excluded if they: were unable to perform balance testing safely and to comply with the study protocol as determined by the referring consultant or study doctor; had significant peripheral neuropathy (Toronto clinical neuropathy score[14] of 8 or more); had a life-limiting condition (such as active cancer); had mobility problems (such as leg amputation, wheelchair use or hemiplegia); or suffered dementia.

Assessments

On enrolment into the study, each patient underwent the following assessments, which were repeated 3, 6 and 12 months after SEP enrolment.

Clinical indicators of lower-limb ischaemia

A constant-load treadmill test (2·5 km/h) with a 10° incline was performed for a maximum of 5 min. ABPI was calculated before and after exercise using a hand-held ultrasonic Doppler flow detector (model 811-B; Parks Medical Electronics, Aloha, Oregon, USA). Initial claudication distance (ICD; the distance at which symptoms of ischaemic lower-limb muscle pain began) and maximum walking distance (MWD; the distance at which the patient could not walk any further) were calculated, and disease severity was determined using the Rutherford claudication grade[15].

The 6-min walk test was performed. Patients were asked to walk at their usual pace continually over a 20-m path. They were instructed to cover as much ground as possible during 6 min at a self-selected comfortable pace. MWD was recorded to the nearest 5 m[1,16].

Assessment of physical ability

Data were collected from the usual paced 4-m walk, the chair stand test and semi-tandem/tandem balance tests to derive scores for the Short Physical Performance Battery (SPPB), a global measure of lower-limb physical function[17]. Patients were assigned a score of zero for each task they were unable to complete and scores of 1–4 for the remaining tasks, based upon quartiles of performance for over 6000 patients in the Established Populations for the Epidemiologic Study of the Elderly. Patients' scores were then added to obtain an overall score of between 0 and 12[18].

For the 4-m walk test, the time taken to walk in a straight line for 4 m was measured in seconds, and walking velocity in metres per second was calculated. Patients were asked to walk at their 'usual' and then their 'fastest' pace. Each walk was performed twice, and the faster times were used for analysis.

For the chair stand test, patients were asked to sit in a straight-backed chair (approximate seat height 42 cm) with their arms folded across their chest, and were requested to stand up and sit down five times, as quickly as possible. The total time taken to complete five chair stands was measured in seconds. This test was repeated after 3 min and the mean score calculated.

For semi-tandem and full-tandem stance, the ability to maintain a tandem or semi-tandem stance for 10 s was documented. The semi-tandem position required the feet to be parallel, with the toes of one foot adjacent to and touching the heel of the opposite foot. The full-tandem stance position requires one foot to be completely in front of the other but touching heel to toe.

In addition, each patient underwent the Timed Up and Go (TUG) test and a hand-grip strength test. The TUG test is a simple assessment of the risk of falls[19]. During the TUG test the patient was observed and timed as they rose from a standard chair (seat height 46 cm, arm height 65 cm), walked 3 m, turned around, walked back to the chair and resumed a seated position.

The hand-grip strength test was performed on the dominant arm using a digital hand-grip dynamometer (T.K.K.5401 Grip-D; Takei Scientific Instruments, Tokyo, Japan). Whilst sitting, individuals were asked to extend their elbow and grip the dynamometer as hard as they could for 5 s. The test was repeated three times and the mean score calculated for the dominant arm[20].

Balance

Computerized dynamic posturography was used to assess balance objectively. The Sensory Organization Test (SOT) was performed using the EquiTest® system (NeuroCom® International, Clackamas, Oregon, USA). This system comprises a standing platform with dual force plates, which can undergo angular rotation in the anterior–posterior direction (toes up *versus* toes down), termed 'sway-referenced support'. Movement of the brightly coloured visual surround, equally capable of movement in the anterior–posterior direction, was termed 'sway-referenced surround'. The SOT has been described previously[13,21]; briefly, it assesses the ability to cope with six different conditions to test balance during static, dynamic and sensory conflicting conditions. Each condition was repeated three times, and the mean data were used. Sensory conflicting situations were created by movement of the visual surround or standing platform in response to the patient's sway (calibrated sway-referencing) either with, or without visual input (eyes open or closed).

Data were collected and analysed using NeuroCom® International software (NeuroCom® system version 8·1.0, 1996–2006) and compared with values for healthy controls (who had no symptoms or history of disequilibrium or motor problems) from the NeuroCom® normative database. Data were stratified into three age groups: 20–59, 60–69 and 70–79 years. The scores for patients aged over 79 years were compared with those of the 70–79 years age group controls owing to lack of older age data. Scores for SOT that fell outside those obtained by 95 per cent of controls (below the fifth percentile) were described as abnormal.

Assessment of patient-reported quality of life

All patients completed a generic Short Form 36 (SF-36®; QualityMetric, Lincoln, Rhode Island, USA) QoL questionnaire[22] and the disease-specific King's College Hospital Vascular Quality of Life Questionnaire (VascuQoL)[23,24]. The generic SF-36® has been used extensively in vascular patients[25–27]. The VascuQoL is a validated QoL tool that measures disease-specific QoL for patients with Rutherford grade 1–5 peripheral vascular disease.

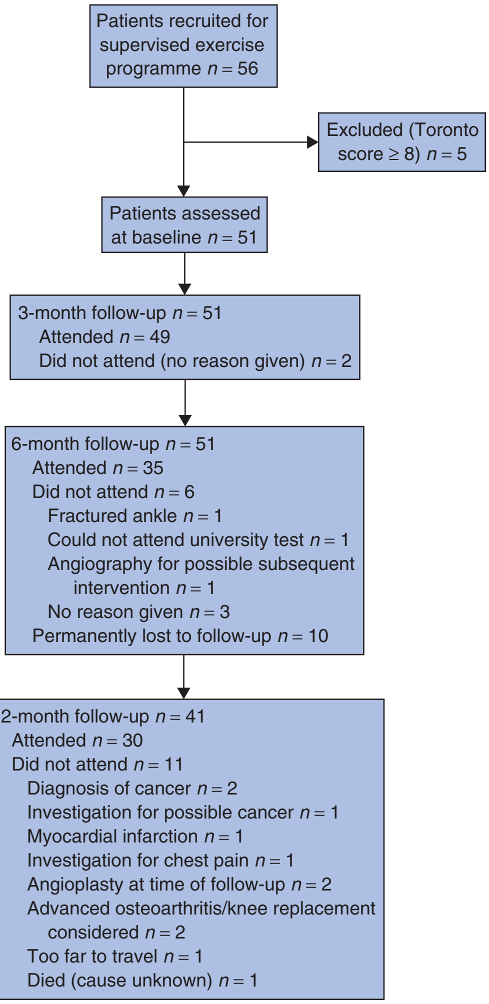

Fig. 1 Flow chart demonstrating follow-up in the study. Patients who did not attend missed only one of the follow-up appointments

Supervised exercise programme

The SEP took place on three afternoons per week for 12 weeks (total course 36 sessions per patient) from the baseline to 3-month visit. If patients missed a session due to illness or holiday they were allowed to make up the sessions at the end of the course. Each session lasted for a minimum of 30 min. SEP was conducted in groups of up to 12 patients and attendance was recorded. The SEP is described in *Fig. S1* (supporting information); all exercises were performed at low intensity. The SEP was originally designed according to level 1 recommendations regarding exercise rehabilitation programmes for the treatment of claudication[28]. This circuit training format focused specifically on increasing lower-limb strength and endurance, and has been clearly demonstrated to be clinically and cost effective in the treatment of claudication[29,30]. There are some similarities with balance-focused rehabilitation programmes, but no specific adaptations were made to the original SEP.

Statistical analysis

Data sets were analysed using SPSS® version 19 (IBM, Armonk, New York, USA). $P \leq 0{\cdot}050$ was used to determine significant differences in the data set. Data were analysed on an intention-to-treat basis. Intragroup analysis was performed using Friedman analysis of variance (ANOVA) for continuous data and the χ^2 test for categorical data. Where the χ^2 test had inadequate

Table 1 Demographics at baseline for patients who attended the supervised exercise programme and follow-up, and for those who did not attend the 12-month follow-up

	Attended follow-up (*n* = 30)	Failed to attend 12-month follow-up (*n* = 21)	*P*†
Age (years)*	71 (65–74)	68 (64–75)	0·666
Sex ratio (M : F)	24 : 6	10 : 11	0·016‡
Rutherford claudication grade			0·044§
1 (mild)	0	1	
2 (moderate)	19	7	
3 (severe)	10	13	
Medical history			
Ischaemic heart disease	13	8	0·708‡
Hypertension	22	18	0·383§
On statin therapy	26	18	0·923§
Stroke or TIA	4	4	0·302§
Diabetes	9	5	0·626‡
Smoker			0·275§
Current	8	6	
Ex-smoker	14	13	
Height (cm)*	167·3 (165·0–173·5)	166·0 (161·0–173·0)	0·363
Weight (kg)*	80·0 (74·5–86·3)	76·5 (67·5–85·5)	0·518
Body mass index (kg/m^2)	28·2 (26·0–32·2)	27·1 (25·4–29·3)	0·724
ABPI (worse leg)*			
Before exercise	0·64 (0·53–0·86)	0·58 (0·49–0·77)	0·329
After exercise	0·34 (0·22–0·51)	0·26 (0·20–0·43)	0·360
Treadmill ICD*	50·0 (28·9–72·5)	46·5 (31·5–62·7)	0·983
Treadmill MWD*	107·3 (59·0–150·0)	90·1 (53·0–107·0)	0·146

*Values are median (i.q.r.). TIA, transient ischaemic attack; ABPI, ankle : brachial pressure index; ICD, initial claudication distance; MWD, maximum walking distance. †Mann–Whitney *U* test, except ‡χ^2 test and §likelihood ratio.

numbers within each category (1 cell contained less than 20 per cent of the total), a likelihood ratio was used instead.

Sample size was calculated based on the composite equilibrium score from the SOT of the EquiTest® system. Owing to a lack of data on which to base a power calculation, initial pilot data from 19 patients with a mean(s.d.) baseline SOT score of 65·3(12·5) per cent was used. The minimum expected clinically significant improvement chosen was a score of 72·9(5·4) per cent, which represented the lowest normal mean score for NeuroCom® healthy controls in the 70–79 years age category. The calculated sample size was 29 subjects, based on 90 per cent power to detect this difference in the SOT means (difference of 7·5) using a paired *t* test with a 0·05 two-tailed significance level. Assuming a 25 per cent drop-out rate, the target group size was 40.

The initial estimate was a 25 per cent drop-out rate, but it became evident early in the study that the drop-out rate was significantly higher (40 per cent). The sample size was therefore increased to 50.

Results

Fifty-six patients were recruited for SEP, of whom five had a Toronto (neuropathy) score of 8 or above and were excluded from further analysis. The 51 eligible patients had a median age of 69 (i.q.r. 64–75) years, and 34 (67 per cent) were men. Their median height was 167 cm; median weight was 78 kg and median body mass index 27·5 kg/m^2. Twenty-one patients who underwent SEP were lost during follow-up (10 lost permanently at 6 months and 11 who did not attend at 12 months) (*Fig. 1*). Patient co-morbidities are shown in *Table 1*; there were no differences between patients who attended all follow-up assessments and those who withdrew from the study.

Markers of claudication

ABPI before and after exercise did not change significantly following the SEP. Significant improvements were seen for ICD (baseline 49·0 m *versus* 64·0 m at 12 months; $P = 0·001$) but not for MWD (baseline 100·6 m *versus* 113·5 m at 12 months; $P = 0·411$) (*Table 2*).

Markers of physical function

Six-minute MWD improved following the SEP: baseline 320·0 m, which improved and then returned to 320 m at 12 months ($P = 0·006$). The median SPPB score had improved from 7·5 to 10 by 12 months ($P < 0·001$). The

Table 2 Changes in markers of lower-limb ischaemia and physical function over 12 months after supervised exercise

	No. of patients	Baseline	3 months	6 months	12 months	P*
Pre-exercise ABPI	24	0·64 (0·53–0·86)	0·69 (0·47–0·85)	0·64 (0·54–0·80)	0·66 (0·51–0·82)	0·731
Postexercise ABPI	23	0·38 (0·26–0·53)	0·30 (0·21–0·46)	0·33 (0·20–0·48)	0·43 (0·25–0·57)	0·040
Treadmill ICD (m)	21	49·0 (26·4–66·9)	58·0 (47·0–74·0)	59·0 (42·5–106·0)	64·0 (43·2–92·5)	0·001
Treadmill MWD (m)	24	100·6 (54·8–145·0)	108·0 (71·2–193·8)	123·5 (70·5–205·0)	113·5 (67·5–154·5)	0·411
6-min MWD (m)	23	320·0 (240·0–420·0)	420·0 (360·0–460·0)	385·0 (280·0–480·0)	320·0 (240·0–420·0)	0·006
Dominant hand-grip strength (kg)	18	30·9 (24·5–38·8)	30·8 (26·6–38·0)	30·4 (24·2–39·4)	31·3 (26·3–37·8)	0·413
Short Physical Performance Battery score	25	7·5 (9–10)	11 (10–12)	11 (10–12)	10 (9–12)	< 0·001
Timed Up and Go test (s)	24	8·68 (7·52–9·73)	7·97 (7·17–9·53)	7·75 (6·67–9·66)	7·58 (6·11–10·03)	0·199

Values are median (i.q.r.). ABPI, ankle : brachial pressure index; ICD, initial claudication distance; MWD, maximum walking distance. *Friedman's ANOVA.

Table 3 Changes in markers of balance over 12 months after supervised exercise

	Baseline	3 months	6 months	12 months	P*
Passed SOT	22 of 50 (44)	34 of 49 (69)	26 of 35 (74)	26 of 30 (87)	
Composite SOT (*n* = 22)	63·5 (52·8–74·0)	72·0 (62·0–79·3)	73·0 (65·5–78·0)	74·5 (69·0–78·5)	< 0·001
Tandem stance time (s) (*n* = 24)	30·0 (21·9–30·0)	30·0 (30·0–30·0)	30·0 (30·0–30·0)	30·0 (21·2–30·0)	0·126

Values are median (i.q.r.). SOT, Sensory Organization Test. *Friedman's ANOVA.

time taken to complete the TUG test (baseline 8·68 s *versus* 7·58 s at 12 months; $P = 0·199$) and hand-grip strength (baseline 30·9 kg *versus* 31·3 kg at 12 months; $P = 0·413$) remained unaltered over the study interval (*Table 2*).

Quality-of-life analysis

Generic QoL improved in only one domain on the SF-36® over the 12 months of the study. Bodily pain (baseline value 41·0) increased after 3 months and then gradually declined back to baseline at 12 months ($P = 0·025$). The improvement in disease-specific QoL was evident only in the social domain ($P = 0·039$) (*Table S2*, supporting information).

Balance

The tandem stance time did not improve over the 12 months of the study ($P = 0·126$) (*Table 3*). The composite SOT score improved significantly from 63·5 to 74·5 over the 12 months ($P < 0·001$) and was associated with an increasing proportion of patients passing the SOT (44 per cent at baseline *versus* 87 per cent at 12 months) when compared with normalized data (likelihood ratio = 4·49, 2 d.f., $P = 0·034$).

Discussion

This study shows that enrolment in a SEP improves walking distance and overall markers of physical function. Furthermore, it suggests that a SEP can improve balance in patients with claudication. A parallel study[31] assessing the role of percutaneous transluminal angioplasty for claudication showed no effect on balance. This suggests that exercise training delivers added benefits not seen after revascularization alone.

The positive effect of exercise training on balance has been noted previously, and similar exercises are included in falls rehabilitation programmes. Current recommendations for balance training and falls prevention include tai chi, gait training and strength building[32]. Supervised exercise includes predominantly leg-strengthening exercises. Only one station in the present SEP focused specifically on balance (standing knee bends).

It is not clear which aspect of the SEP improved balance in the present cohort of patients. Balance improvement was maintained 1 year after supervised exercise; this was not mirrored by improvements in walking ability. The present observation remains unsupported by other data on balance or falls in patients with claudication. Previous work from the authors' unit suggested that abnormal balance is associated with central sensorineural disturbance that may be corrected by exercise. A further possibility is that of local improvement in lower-limb function, including muscle strength. Hand-grip strength and TUG did not improve over time here, yet there were improvements in the SPPB, which is in part a surrogate marker of lower-limb strength. It is likely that sedentary behaviour is associated with leg muscle atrophy[11]. Although the nature of this study did not provide control subjects, all balance test results were compared with normal population data.

The improvements in walking distance and QoL were less marked than in other studies of supervised exercise[33–36]. The majority of patients included in this study had Rutherford grade 2 or 3 claudication, and were thus more severely affected than those normally seen in a SEP. Other studies may have focused on patients with unilateral claudication who were amenable for angioplasty[37], had less severe claudication and could complete a 5-min treadmill test[33,34], or were able to walk at a faster speed of 3·2 km/h[35,36] compared with the 2·5 km/h in the present study. These are potential confounding factors that may have influenced the high drop-out rate of 41 per cent associated with SEP in the present study.

Enrolment in a SEP is now recommended as first-line treatment for suitable patients with claudication in the UK[5,38]. There is still debate as to the optimal method of delivering a SEP. This study suggests that exercise also improves overall physical ability and balance, which is also likely to reduce the subsequent risk of falls.

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Supporting information

Additional supporting information may be found in the online version of this article:

Table S1 Changes in generic (Short Form 36) quality of life for 12 months after supervised exercise (Word document)

Table S2 Changes in disease-specific (VascuQol) quality of life for 12 months after supervised exercise (Word document)

Fig. S1 Structured exercise programme (Word document)