Percutaneous Transluminal Angioplasty results in Improved Physical Function but Not Balance in Patients With Intermittent Claudication

RA Gohil MBChB, MRCS[1], KA Mockford MBChB, MRCS[1], FA Mazari MBChB, MRCS[1], JA Khan MBChB, MRCS[1], N Vanicek PhD[2], IC Chetter MBChB, FRCS[1], PA Coughlin MBChB, FRCS[1]

[1] Hull York Medical School, University of Hull, Hull And East Yorkshire Hospitals NHS Trust

[2] Discipline of Exercise and Sport Science, Faculty of Health Sciences, University of Sydney, NSW 2141 Australia

Corresponding Author & Address:

Miss Risha Gohil; Academic Vascular Department, First Floor, Hull Royal Infirmary, Anlaby Road, Hull, HU3 2JZ UK

Telephone no: +441482 675523, Fax: +441482 674765

Email address: risha@doctors.net.uk

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Abstract

Objectives: The aim of this study was to identify whether revascularisation by percutaneous transluminal angioplasty (PTA) for patients with intermittent claudication improved measures of functional performance including balance.

Design: A prospective observational study was performed at a single tertiary vascular centre. Methods: Patients with symptomatic intermittent claudication (Rutherford grades 1-3) were recruited to the study. Participants were assessed at baseline (pre-PTA) and then 3, 6 and 12 months post-PTA for markers of (a) lower limb ischaemia (treadmill walking distances and ABPI), (b) physical function (6-minute walk, Timed Up and Go and chair stand time), (c) balance impairment using computerised dynamic posturography with the Sensory Organisation Test (SOT) (d) quality of life (VascuQoL and SF36).

Results: 43 participants underwent PTA. Over 12 months a significant improvement was demonstrated in; initial ($p=.04$) and maximum treadmill walking distance ($p=.019$). Physical functional ability improved across all outcome measures ($p<.02$), and some domains of both generic ($p<.03$) and disease specific quality of life ($p<.01$). No significant improvement in balance was demonstrated by the SOT ($p=.24$).

Conclusion: Balance impairment is common in claudicants and does not improve with revascularisation. Further research regarding effective treatment of balance impairment is required in this specific group of patients.

Key Words: PTA / Angioplasty, Intermittent Claudication, Balance, Physical Function

Word Count 3118

Introduction

Intermittent claudication is a common condition affecting over 5% of the population over the age of 65 years. Patients exhibit limited walking ability, but over recent years a number of studies have identified that claudication is also associated with significant impairments in overall physical function(1), including walking speed(2,3), lower limb strength(4) and balance(5).

There is strong evidence that higher levels of daily activity in claudicants reduces functional decline and associated morbidity/ mortality in the mid to long term(6,7). Furthermore, there is increasing evidence that claudicants have associated balance impairments that may predispose to an increased risk of falling and its' associated physical and socio-economic consequences(5,8).

Percutaneous transluminal angioplasty (PTA) is now a well recognised treatment option for claudicants with appropriate disease distribution(9) with acceptable early and mid-term results with regards to both walking distances(10) and patient reported quality of life(11,12). Little data is available on the effect of revascularisation as a whole and PTA specifically on more global measures of functional ability including balance.

This study assessed whether patients undergoing PTA would demonstrate improved measures of physical function including balance up to 12 months post-intervention.

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 of the study was gained from the Local Research Ethical Committee (LREC) (07/Q1105/12, 07/Q1105/13, 07/H1305/83).

Patients were identified at outpatient clinics by their consultant vascular surgeon, and patients deemed suitable for PTA (as decided at the departmental multi-disciplinary team meeting) were subsequently invited to participate in the study. Data were collected prospectively at baseline and at 3, 6 and 12 months post-PTA.

Inclusion / Exclusion Criteria

Claudication was determined by documented current symptoms of intermittent claudication with either (a) an Ankle Brachial Pressure Index (ABPI) of ≤0.9 or (b) >20 mmHg drop in ankle pressure post-exercise testing or (c) documented haemo-dynamically significant atherosclerosis on radiological imaging (angiogram or Duplex ultrasound). Further patient specific inclusion criteria included: 1) living independently in the local community; 2) not requiring assistance for general activities of daily living including shopping, cleaning and self-care; 3) over 50 years of age; 4) English speaking, and; 5) able to comply with simple study protocol instructions. Patients were excluded if they: 1) were unable to safely perform balance testing and to comply with the study protocol as determined by the referring consultant or study doctor (for example, coexisting neurological or limiting cardio-respiratory or other significant medical problems); 2) had significant peripheral neuropathy (Toronto clinical neuropathy score of >8(13)); 3) had life-limiting conditions (such as active cancer); 4) had mobility problems (such as major limb amputations, wheelchair use and hemiplegia), and; 5) suffered with dementia.

Assessments

On enrolment into the study, each patient underwent the following assessments, which were repeated at 3, 6 and 12 months post-PTA:

1. Clinical Indicators of Lower Limb Ischaemia

A constant load treadmill test (1.6 mph) with a 10-degree incline was performed for a maximum of 5 minutes. A pre- and post-exercise ABPI was calculated using a hand held Doppler (Parks Medical Electronics, Inc. Oregon, USA). Initial claudication distance (ICD: the distance at which symptoms of ischaemic lower limb muscle pain began) and maximal walking distance (MWD: the distance at which the patient could not walk any further) were calculated and disease severity determined using the Rutherford grade(14).

The 6-minute walk test was performed. Patients were asked to walk at their usual walking pace continually over a 20-metre path. They were instructed to cover as much ground as possible during the 6-minute time period at a self selected comfortable pace. The maximum walking distance was recorded to the nearest 5 metres(1,15).

2. Assessment of Physical Ability.

Data were collected from the usual paced 4-metre 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(16). Patients were assigned a score of 0 for each task they were unable to complete and scores of 1-4 were assigned 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 between 0 and 12(17).

Furthermore, each patient underwent the Timed Up and Go (TUG) test. The TUG test is a simple assessment of falls risk**(18)**. During the TUG test the patient was observed and timed as they rose from a standard chair (seat height 46cm, and arm height of 65cm), walked 3 meters, turned around, walked back to the chair and resumed a seated position. An abnormal result was recorded when the time to complete the test was greater than age-matched healthy controls, specifically if they exceeded 9.0 seconds for 60-69 year olds, 10.2 seconds for 70-79 year olds and 12.7 seconds for 80-99 year olds**(19)**.

3. Balance

Computerised Dynamic Posturography (CDP) was used to objectively assess a patient's balance. The Sensory Organisation Test (SOT) was performed using the EquiTest system (NeuroCom International Inc., Clackamas, OR, USA). This system is comprised of a standing platform with dual force plates which can undergo angular rotation in the anterior-posterior direction (toes up vs. toes down), termed "sway-referenced support". Movement of the brightly coloured visual surround, equally capable of movement in the anterior-posterior directions was termed "sway-referenced surround". The SOT has been described previously(8,20) but briefly it assesses the patient's ability to cope with 6 different conditions to test balance during static, dynamic and sensory conflicting conditions. Each condition was repeated 3 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 patients' 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, NeuroCom International Inc.) and compared to healthy controls (who had no symptoms or history of disequilibrium or motor problems) from the NeuroCom normative database (Clackamas, OR, USA). The data were stratified into three age groups: 20-59 years, 60-69 years and 70-79 years. For any patient over the age of 79 years, their scores were compared to the 70-79 years age group controls due to the absence of older age data. Scores for SOT which fell outside of those obtained by 95% of controls were described as abnormal (i.e. those falling below the 5th percentile).

4. Assessment of Patient Reported Quality of Life

All patients completed the generic SF-36 QOL questionnaire(21) and the disease specific QOL the Kings' VascuQol questionnaire.(22,23) The generic Short Form 36 has been extensively used within vascular disease. (24-26) The Kings College VascuQoL is a well validated QOL tool that measures disease specific quality of life for patients with Rutherford grade 1-5 disease.

Percutaneous Transluminal Angioplasty (PTA)

All angioplasties were performed or supervised by one of four consultant interventional radiologists in a dedicated suite under local anaesthesia with a single post-intervention overnight stay. PTA was performed in all patients and arterial stents were used where clinically indicated (either in lesions thought to be at high risk of primary failure or distal embolisation). Each procedure was performed within a month of the baseline visit.

Statistical Analysis

Data sets were analysed using SPSS (IBM SPSS version 19). An alpha value of $p \leq .05$ 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 for continuous data and Chi-squared test for categorical data.

Sample Size Calculation

Sample size was calculated based on the composite equilibrium score from the SOT of the EquiTest System. Due to a lack of data on which to base a power calculation, initial pilot data from 19 patients with a mean baseline SOT score of 60% (SD 24.8) was used. The minimum expected clinically significant improvement chosen was a score of 73% (SD 5.4), which represented the lowest normal mean score for NeuroCom healthy controls in the 70-79 years age category. The calculated sample size was n=29 based on 80% power to detect this difference in the SOT means (difference of 13) using a paired t-test with a .05 two-tailed significance level. Assuming a 25% drop out rate, the target group size was 37.

Results

47 patients underwent PTA, with a median age of 69 (IQR 63-76), and 70% (n=33) were men. Median height was 169 cm; median weight was 80 kg resulting in a median body mass index of 28. 43 patients had a Toronto score between 0-7, whilst 4 patients had a score of ≥8; these 4 were excluded from further analysis. Of those that underwent PTA, 15 were lost to follow-up and one died over the 12-month follow-up period (Figure 1). Patient comorbidities are shown in Table 1.

Clinical Indicators of Lower Limb Ischaemia

Pre-exercise ABPI improved significantly over the 12 month time course (p<.01) however post exercise ABPI did not (p=.12). All walking distance measures, by either treadmill (MWD p=.02, ICD =.04) or the 6-minute walk (MWD p=.01, ICD p=.01) on the flat showed a significant improvement over time (Table 2).

Outcomes of the Assessment of Physical Ability

Improved significantly over time as measured by the short physical performance battery score (SPPB, p<.01), TUG test (p<.01) and mean chair stand time (p=.02) in addition to the short 4m normal (p=.03) and fast pace (p=.04) walks (Table 2).

Quality of Life

Generic quality of life as measured by the SF-36 (Table 3a), showed an improvement in four of the domains; physical functioning (p<.01), role physical (p=.03), vitality (p=.03) and physical summary score (p=.01). Disease-specific quality of life improved significantly in all domains (p<.01) except social (p=.11) over the 12-month period (Table 3b).

Balance

a) Tandem stance time

Both semi- and full-tandem stance did not alter over the course of the 12-month period, p=.05 and .41 respectively (Table 4).

b) Sensory Organisation Test (SOT)

At baseline, 27 (63%) of the participants passed the SOT test when compared to healthy age-matched controls. The median SOT composite scores improved significantly between baseline and 3 months, but this was not observed over the 12-month duration (p=.24) (Table 4).

There was no significant difference between those who had unilateral or bilateral disease (Table 5a) or the distribution of disease (Table 5b) when looking at any time point and the likelihood of passing the SOT test at any time point.

Discussion

Impaired walking ability is the principal symptom reported by claudicants. Detailed analysis however reveals that impairment in walking ability is only a single factor contributing to overall physical disability in these patients. A number of other factors including lower limb strength and balance are also important factors contributing to impaired physical function and generic quality of life in claudicants. Simple assessments of balance, such as the single leg stance time, show postural impairments in individuals with PAD, and are associated with a higher prevalence of stumbling, unsteadiness on walking and history of previous falls. Poor balance may be due to reduced physical function secondary to ischaemic muscle changes (27) or central cerebral ischaemia causing vestibular related symptoms associated with systemic atherosclerosis (8). Poor balance, with an incidence approaching 40% in the claudicant population, is recognised to play an important role in poor overall physical ability. It is well recognised that poor balance is a significant risk factor for subsequent falls risk with its associated physical and socioeconomic consequences. Assessment of routine balance impairment is not routinely undertaken either in primary care or within the vascular surgical clinic.

There is a strong association between daily physical activity and longer term outcomes in both the older population in general and in claudicants specifically (6,7,28). Our study shows that over the one-year follow up period, angioplasty significantly improves the clinical indicators of lower limb ischaemia, overall physical ability, and quality of life in claudicants with one year follow up. No lasting improvements in balance (either static or dynamic) were observed, despite the improvement seen in other markers of physical ability. Given the observed improvements in pre-exercise ABPI and physical ability, the aetiology of balance impairment and its full impact on claudication remains as yet unknown. The lack of improvement in balance when physical ability does improve following PTA justifies our use of balance specific investigations. The CPD is a relatively new method of assessing balance, having been used predominantly in patients with vestibular related conditions and latterly in amputees. As such there is still little data available on patients with other chronic disease states but given the increasing age of the overall population we feel that CPD will continue to deliver further high quality data on the causes of poor balance.

The observational nature of this study reflects contemporary, pragmatic vascular practice, recruiting all patients with claudication undergoing PTA. This is also reflected by the fact that we didn't routinely undertake post angioplasty duplex scanning to confirm patency but relied on both symptoms and ankle pressure measurement. Disease distribution (supra / infra-inguinal disease or uni / bilateral disease) did not appear to impart a confounding influence on the SOT results although the study was not powered to specifically look at these factors. Lastly, the slight diversity between treadmill and 6 minute walking distances at 12 months is difficult to fully explain. It is likely to be multifactorial and requires further investigation.

One criticism of the study may be the slightly high drop out rate (15 of 43 patients) Indeed, this is higher than previous claudicant based trials from our unit, but may reflect the slightly older population examined (12). Drop out is an inherent problem with longer-term prospective studies. Despite the drop out rate, this was factored into our recruitment so as to meet the requirements of the power calculation.

Supervised exercise is currently recommended as the first line treatment in the UK for claudicants(29), and given the strong evidence that exercise improves balance in elderly patients, it is likely to be specifically beneficial for claudicants with balance impairment, but further studies are required. For patients with impaired balance, we would advocate that the same advice that is recommended for people with previous falls is employed(30); a balance and strength exercise training regimen that has been evidenced(31). The use of Tai Chi (32) has also been advocated although we still await level one evidence for this form of intervention(33) . Interestingly this study is using CPD as an outcome measure.

Intermittent claudication is a relatively stable disease and as such treatment is presently prescribed only if the walking impairment affects the patient's day-to-day quality of life. This is reflected in the large numbers of claudicants with moderate or severe disease in our patient cohort. Our study confirms the success in enhancing walking distances with improvements in both treadmill and corridor walking tests seen up to up to 12 months. This is mirrored in the physical ability results, where there was at least a one point improvement in the median SPPB score at all time points when compared to baseline. This improvement may be considered as not "clinically significant", however the associated QOL domain improvements suggest that this is a meaningful change.

In summary, balance impairment is common in patients with claudication and shows no significant sustained improvement following PTA. Specific exercise routines are beneficial in elderly populations with balance impairment, and merit further investigation in the claudicant population. Routine balance assessment may be worthwhile in claudicants prior to any intervention as this may contribute to treatment selection.

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Conflict of Interest: Nil

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