



## Percutaneous Transluminal Angioplasty for Intermittent Claudication: Evidence on Which to Base the Medicine

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**Objectives:** this study aims to assess the impact of PTA on the quality of life (QoL) of claudicants and to analyse which patients and which arterial lesions derive the most benefit.

**Design:** a prospective observational study

**Materials:** one hundred and seventeen claudicants undergoing PTA were studied, 35 patients had bilateral disease, whilst 82 had unilateral disease and underwent PTA to a solitary iliac lesion, solitary superficial femoral or a iliac lesion above a diseased superficial femoral artery in 24, 39 and 19 cases, respectively.

**Methods:** patients completed the Short Form 36 (SF36) and EuroQol (EQ) QoL assessment instruments prior to and at 1, 3, 6, and 12 months following intervention. The SF36 produces a QoL profile, whilst the EQ produces two QoL indices.

**Results:** claudication has a deleterious effect on QoL, especially in patients with multi-segment disease. PTA results in an immediate and lasting improvement in the QoL of claudicants. Unilateral claudicants undergoing PTA to a solitary iliac lesion demonstrate the most marked QoL benefits and 12 months post PTA report a QoL approaching that of an age-matched population. Patients with bilateral claudication undergoing unilateral PTA and unilateral claudicants undergoing PTA to a solitary SFA lesion demonstrate some QoL benefits, but at 12 months post PTA do not approach the QoL scores of an age-matched population. Unilateral claudicants undergoing iliac PTA above a diseased SFA demonstrate minimal QoL changes.

**Conclusions:** these results should influence decision making in the management of claudication and it may be possible to prioritise PTA waiting lists to ensure patients with greatest potential benefit are treated with most urgency.

**Key Words:** Intermittent claudication; Percutaneous transluminal angioplasty; Quality of life.

### Introduction

Intermittent claudication is a relatively benign but common problem which has been demonstrated to seriously impair quality of life (QoL).<sup>1-3</sup> Over recent years there has been a dramatic increase in the use of percutaneous transluminal angioplasty (PTA) in the management of claudication.<sup>4,5</sup> This has been based on the solid foundations of good technical success rates, low complication rates and acceptable patency rates.<sup>6-8</sup> However, greater proof of efficacy for the procedure has been requested<sup>9,10</sup> as the current evidence regarding QoL following PTA for claudication is equivocal.<sup>11-13</sup> This study aims to assess the impact of PTA on the QoL of claudicants in the early and medium follow-up periods and to identify which patient and arterial lesion subgroups derive the most benefit from PTA.

### Materials and Methods

This study was approved by the ethical committee of St. James's and Seacroft University Hospitals. In the 18-month period between September 1994 and February 1996, all patients undergoing PTA for claudication consented to participate in the study. Patients were assessed in the Vascular Laboratory prior to treatment and at 1, 3, 6 and 12 months post-treatment.

#### Clinical assessment

Prior to PTA a history was taken using a proforma specifically designed to assess patient reported maximum walking distance (PRWD) on the flat under normal conditions, duration of symptoms, affected limb(s), and factors predisposing to peripheral vascular disease in accordance with ISCVS suggested

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reporting standards.<sup>15</sup> A physical examination was then performed including the measurement of right brachial and right and left ankle systolic pressures using a Doppler probe and sphygmomanometer. From these measurements resting right and left ankle brachial pressure indices (ABPI-R) were calculated. A standardised treadmill test was performed (2.5 km/h at 10° incline) measuring the time to cessation of walking due to claudication, up to 5 min. This time was then converted to a maximum treadmill walking distance (MTWD). Immediately following treadmill testing, right and left ABPIs were reassessed (ABPI-PE). PRWD, right and left ABPI-R and ABPI-PE, and MTWD were all reassessed at 1, 3, 6 and 12 months following PTA. A duplex scan was performed to assess the patency of the angioplastied segment if there was no improvement in ABPI-R (i.e. a change of  $\geq 0.1$ ) at any follow-up appointment.

#### *QoL assessment*

QoL was assessed using the Medical Outcomes Study Short Form 36 (SF36) and EuroQol (EQ) health status questionnaires.

The SF36, developed from the Medical Outcomes Study General Health Survey Instrument, is a standardised generic questionnaire designed for interview or self completion. It contains 36 questions covering eight health domains: physical functioning (PF), role limitation due to physical problems (RP), social functioning (SF), role limitations due to emotional problems (RE), mental health (MH), vitality (Vit), bodily pain (BP), and general health (GH). For each dimension, question scores are coded, summed and transformed onto a scale from 0 (worst possible score) to 100 (best possible score). In this study the anglicised or U.K. version of the SF36 was used. The attraction of the SF36 is that it is the product of a vast amount of developmental work and psychometric testing in the U.S.A.<sup>16,17</sup> It is short and covers a wide range of areas which may be affected by illness. Response rates have been shown to be high and British population norms are available.<sup>18</sup> It has been shown to be valid and reliable in both population samples and in this specific group of patients.<sup>19,20</sup> It is also more sensitive to change in this group of patients than other commonly utilised generic instruments.<sup>20</sup> It produces a profile of health related quality of life but unfortunately no single index.

The EQ, developed by a multi-disciplinary group of European researchers, is also a standardised generic questionnaire designed for interview or self-completion in conjunction with other instruments.<sup>21</sup> It

measures five dimensions of health each on three levels: mobility; self care; usual activities; pain/discomfort and anxiety/depression. Thus the EQ generates 243 theoretically possible health states, from which a global QoL index can be derived using a matrix generated from time trade off (TTO) data.<sup>22</sup> This TTO index is scored from 1 (the best possible health state) to  $-0.594$  (the worst possible health state). The EQ also incorporates a visual analogue scale (VAS) on which patients are requested to rate their health on a scale 0 (worst imaginable health) to 100 (best imaginable health). Thus the EQ produces a QoL profile and two global indices of QoL, one derived from a VAS, the other from TTO data. The EQ has been found to be acceptable, valid and reliable in population studies, other patient groups, and in patients with claudication.<sup>20,23,24</sup> However, the responsiveness of the EQ derived health profile has been shown to be poor in claudicants, and thus in this study only the EQ derived TTO and VAS derived single indices of health were used.<sup>20</sup>

SF36 and EQ questionnaires were sent by post with the patient's vascular laboratory appointment letter and a request to complete the questionnaires themselves at a quiet time of the day, taking time to answer honestly. Appointment letters were sent 1–2 weeks prior to the appointment date. On arrival at the vascular laboratory, questionnaires were examined and patients were prompted to complete any omissions. Patients attending without questionnaires were supplied with further copies for completion in the vascular laboratory. Thus, fully completed questionnaires were presented by all attending patients to the researcher performing the assessment (ICC), rather than to the surgeons directly responsible for the patients' care.

#### *Data analysis*

Data was collected using a specifically designed Microsoft Access database and analysed on a Microsoft Excel spreadsheet (Microsoft Ltd., Wharfedale Road, Winnerish Triangle, Wokingham, Berks, U.K.) using Astute statistical software (DDU software, The University of Leeds, Old Medical School, Leeds, U.K.). The clinical indicators of lower limb ischaemia are presented as median values. QoL results are presented as effect sizes, calculated by dividing the difference between the pre-treatment and post-treatment median values by the interquartile range of the pre-treatment values. Effect sizes have been strongly recommended for interpretation of QoL changes in health care in order to demonstrate the relative importance of a

treatment effect within a study.<sup>25</sup> Kruskal–Wallis Analysis of variance test was used to assess the significance of change over time. SF36 scores prior to and at 12 months following PTA are presented as standard scores, calculated by dividing the differences between the median scores of each subgroup and those of the general population by the interquartile range of the general population.<sup>26</sup> Standard scores have been recommended to facilitate simple comparisons between patient groups and the general population across the entire SF36 profile.<sup>27</sup>

## Results

One hundred and seventeen patients undergoing PTA for claudication were studied, 78 men and 39 women, with a median age 67 years, range 40–87 years. Thirty-five patients, 23 men and 12 women, median age 68 years (range 42–84 years) reported bilateral symptoms and had angiographic evidence of bilateral disease. These patients underwent PTA to the most symptomatic limb. Eighty-two patients, 56 men and 28 women, median age 67 years (range 40–87 years) reported unilateral symptoms. Of these unilateral claudicants, 19 underwent PTA of an iliac lesion above a significantly (>70%) stenosed or occluded superficial femoral artery (SFA), 24 underwent PTA of a solitary iliac lesion and 39 of a solitary SFA lesion. Of the 117 patients, 16 (14%) were diabetic, 43 (37%) were being treated for hypertension, 68 (58%) were current smokers, 35 (30%) gave a history of ischaemic heart disease, 15 (13%) of cerebrovascular disease, 23 (20%) of chronic obstructive pulmonary disease, and 23 (20%) of hyperlipidaemia.

In eleven (9%) cases the PTA was technically unsuccessful due to inability to cross the lesion with the guide wire. Cumulative patency rates for all PTA sites were 83% 78% and 71% at 3, 6 and 12 months, respectively.

### *Clinical outcome indicators (Table 1)*

Significant improvement in PRWD, ABPI R and ABPI PE in the angioplastied limb, and in MTWD were observed in the PTA group as a whole, and all PTA subgroups ( $p < 0.05$ ) except unilateral claudicants undergoing iliac PTA above a diseased SFA who failed to demonstrate an improvement in MTWD ( $p = 0.31$ ).

### *QoL results*

Intermittent claudication causes severe QoL limitations, with standard scores in virtually all QoL domains being  $\leq -0.5$ . Pre-intervention QoL seems particularly impaired in patients with multi-segment disease (i.e. bilateral claudicants and unilateral claudicants undergoing iliac PTA above a diseased SFA) whose standard scores are in general lower than those patients with single segment disease (Fig. 1).

### *All patients*

QoL analysis following PTA in all 117 patients (Fig. 2) reveals an immediate and prolonged improvement in both global QoL, as indicated by the EQ VAS and TTO indices, and the individual SF36 domains of physical functioning, physical role, bodily pain, vitality and social functioning. However, many of these domains demonstrate a downward trend with effect sizes falling below 0.5 at 6 and 12 months. PTA has no significant impact on the psychological domains of Role Emotional or Mental Health in the group as a whole or in any PTA subgroup, suggesting PTA has a negligible placebo effect. The largely negative effect size of the SF36 domain general health perception following PTA, despite obvious improvements in global QoL and the majority of SF36 domains, detracts from the validity of this specific domain.

### *Subgroup analysis*

Bilateral claudicants undergoing unilateral PTA demonstrate immediate and sustained significant improvements in global TTO QoL, physical functioning, bodily pain, vitality and social functioning (Fig. 3). However, despite these improvements, 12 months following PTA, bilateral claudicants demonstrate persistent QoL impairments compared to an age-matched population (Fig. 1). Unilateral claudicants undergoing iliac PTA above a diseased SFA demonstrate minimal QoL benefits, with improvement only seen in the SF36 domain social functioning (Fig. 4). With the exception of this domain, standard scores at 12 months post-PTA are similar to pre-intervention scores, both of which are substantially lower than those of an age-matched population (Fig. 1).

Unilateral claudicants undergoing PTA to a solitary iliac lesion demonstrate an immediate and sustained improvement in both EQ global QoL indices and in

Table 1. Clinical indicators of lower limb ischaemia (median values); outcome following PTA.

Clinical indicator	PTA group	Pre-PTA	1 month post-PTA	3 months post-PTA	6 months post-PTA	12 months post-PTA	KW ANOVA (p =)
PRWD (m)	All	100	600	450	450	500	<0.01
	Bilateral claudicants	60	300	400	200	300	<0.01
	UC (PTA to a solitary iliac lesion)	100	1200	1200	1200	1200	<0.01
	UC (PTA to a solitary SFA lesion)	100	600	400	500	600	<0.01
MTWD (m)	UC (iliac PTA above a diseased SFA)	30	300	85	85	110	0.02
	All	56	95	111	101	125	<0.01
	Bilateral claudicants	38	95	80	83	125	<0.01
	UC (PTA to a solitary iliac lesion)	63	208	208	208	200	<0.01
ABPI (resting)	UC (PTA to a solitary SFA lesion)	63	167	153	141	208	<0.01
	UC (iliac PTA above a diseased SFA)	42	73	49	83	69	0.31
	All	0.65	0.93	0.88	0.89	0.87	<0.01
	Bilateral claudicants	0.67	0.86	0.81	0.88	0.81	<0.01
ABPI (post-exercise)	UC (PTA to a solitary iliac lesion)	0.65	1.00	1.00	1.10	0.97	<0.01
	UC (PTA to a solitary SFA lesion)	0.67	1.00	0.89	0.89	0.90	<0.01
	UC (iliac PTA above a diseased SFA)	0.63	0.82	0.69	0.73	0.77	<0.01
	All	0.56	0.95	0.88	0.84	0.85	<0.01
UC = unilateral claudicant, PRWD = patient reported walking distance, ABPI = ankle-brachial pressure index; MTWD = maximum treadmill walking distance	Bilateral claudicants	0.58	0.85	0.83	0.77	0.82	<0.01
	UC (PTA to a solitary iliac lesion)	0.65	1.00	1.00	1.00	0.99	<0.01
	UC (PTA to a solitary SFA lesion)	0.56	1.00	0.94	0.88	0.84	<0.01
	UC (iliac PTA above a diseased SFA)	0.50	0.89	0.74	0.65	0.65	0.03

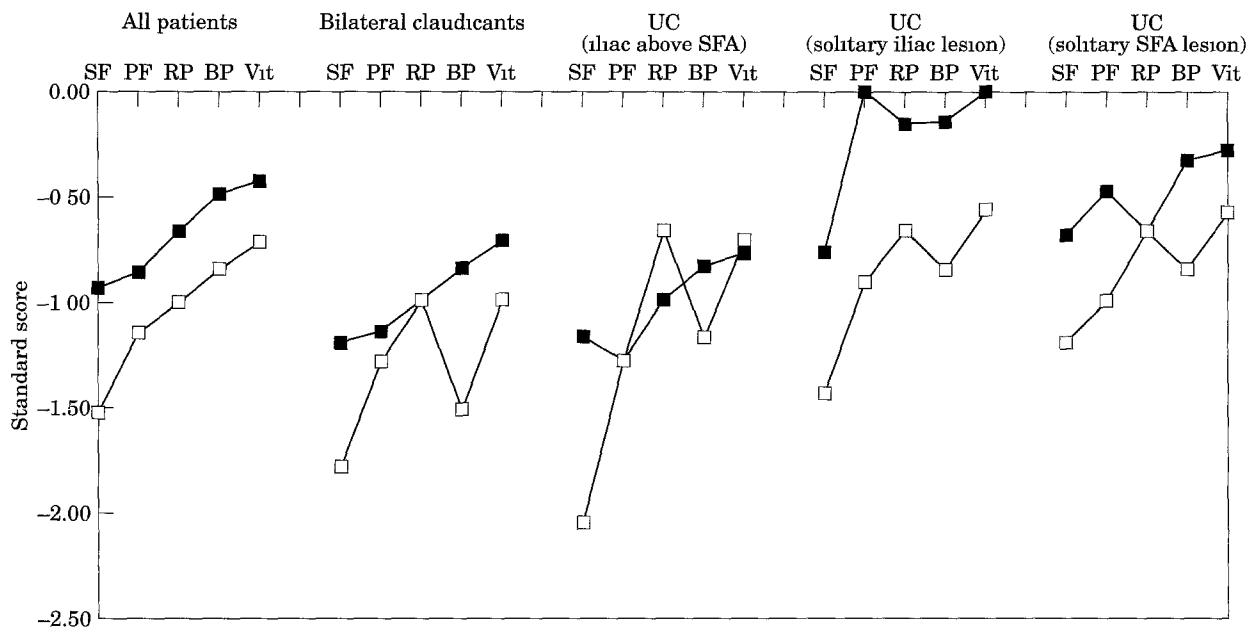


Fig. 1. Standard scores prior to and at 12 months following PTA (■) 12 months post PTA; (□) prior to PTA UC=Unilateral claudicant, SF=social functioning, PF=physical functioning, RP=role physical, BP=bodily pain, Vit=vitality

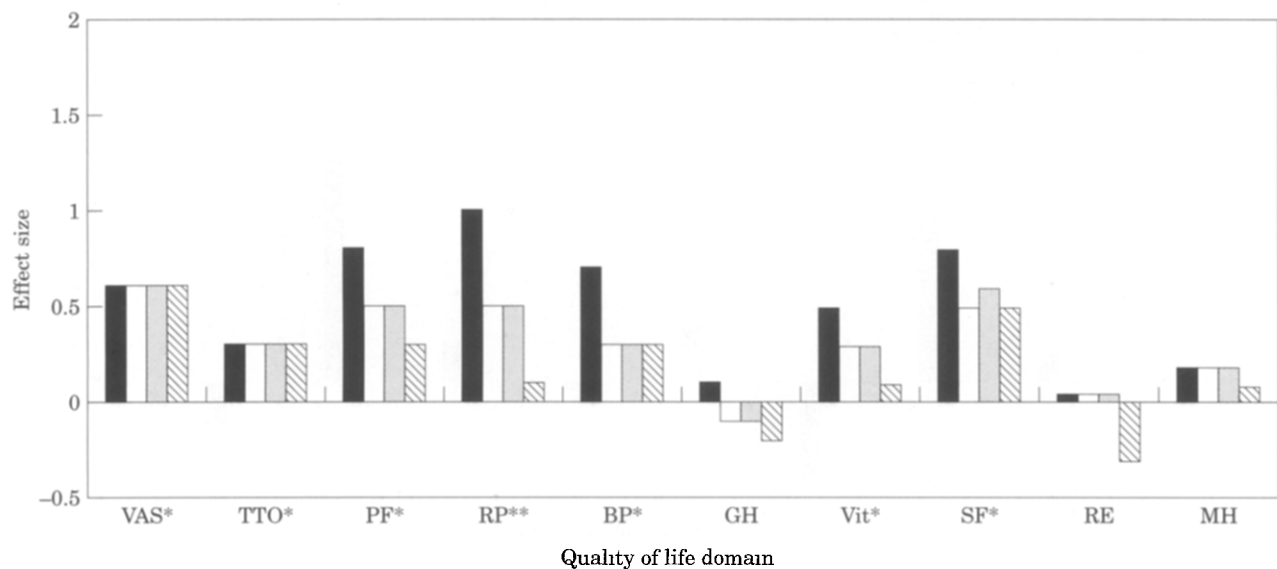
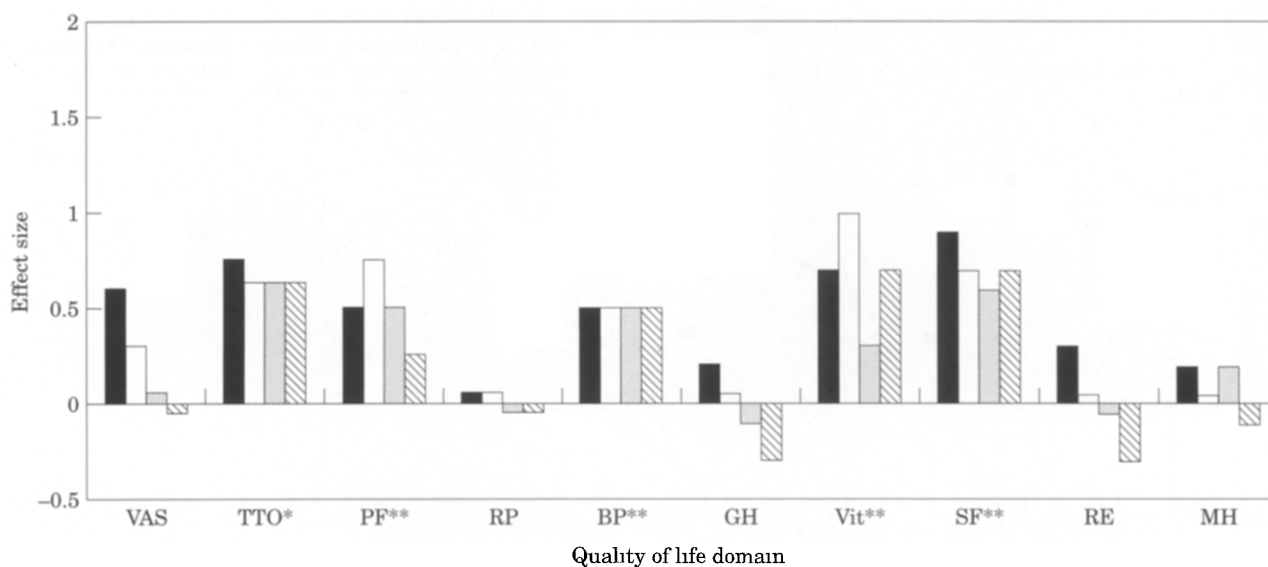


Fig. 2. Quality of life changes following PTA all patients (■) One month, (□) 3 months, (▨) 6 months, (▩) 12 months VAS=EuroQol visual analogue scale, TTO=EuroQol time trade off index, PF=physical functioning, RP=role physical, BP=bodily pain, GH=general health, Vit=vitality, SF=social functioning, RE=role emotional, MH=mental health  
 \*= $p < 0.01$ ,  
 \*\*= $p < 0.05$  Kruskal-Wallis analysis of variance

the majority of SF36 QoL domains (Fig. 5). This is the only subgroup whose QoL 12 months following PTA approaches that of a age-matched population (Fig. 1).

The only QoL domain to demonstrate significant improvement in unilateral claudicants following PTA to a solitary SFA lesion is the EQ VAS global QoL index. This on initial examination may seem slightly

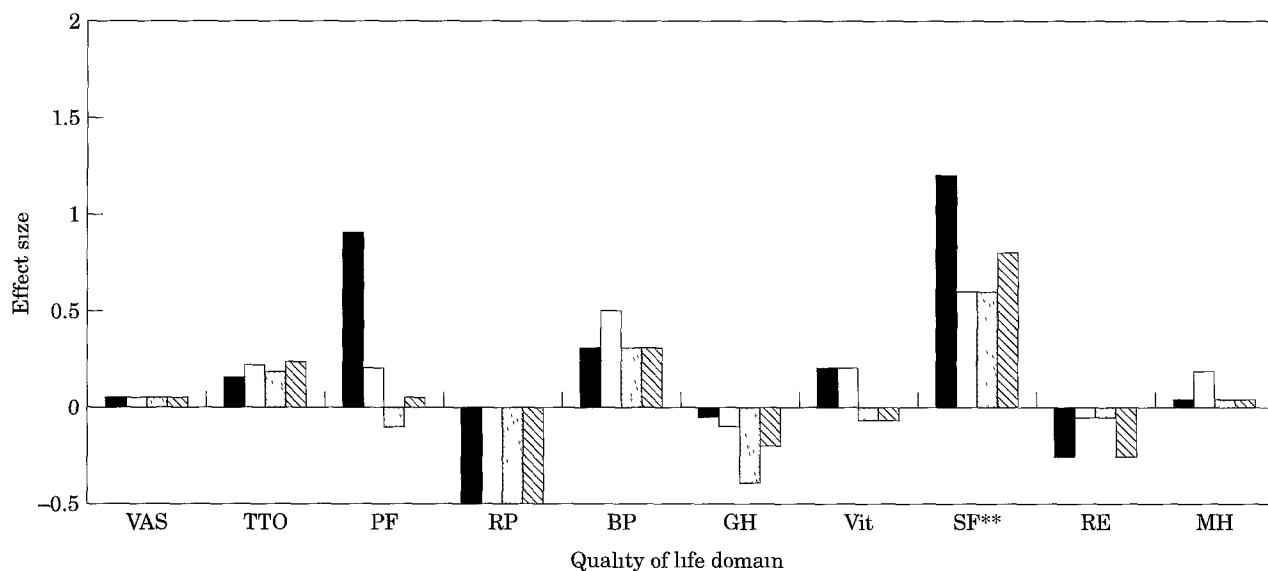
surprising; however, closer inspection reveals that the majority of the other domains do demonstrate a tendency to improvement, as indicated by the largely positive effect sizes, but this fails to reach statistical significance (Fig. 6). However, at 12 months, QoL scores in these patients do begin to approach those of an age-matched population (Fig. 1).



**Fig. 3.** Quality of life changes following PTA bilateral claudicants (■) One month, (□) 3 months, (▨) 6 months, (▩) 12 months. VAS = EuroQol visual analogue scale, TTO = EuroQol time trade off index, PF = physical functioning, RP = role physical, BP = bodily pain, GH = general health, Vit = vitality, SF = social functioning, RE = role emotional, MH = mental health.

\* =  $p < 0.01$ ,

\*\* =  $p < 0.05$  Kruskal-Wallis analysis of variance



**Fig. 4.** Quality of life following PTA unilateral claudicants (iliac lesion above diseased SFA) (■) One month, (□) 3 months, (▨) 6 months, (▩) 12 months. VAS = EuroQol visual analogue scale, TTO = EuroQol time trade off index, PF = physical functioning, RP = role physical, BP = bodily pain, GH = general health, Vit = vitality, SF = social functioning, RE = role emotional, MH = mental health.

\* =  $p < 0.01$ ,

\*\* =  $p < 0.05$  Kruskal-Wallis analysis of variance.

## Discussion

Intermittent claudication is essentially a benign disease, with the majority of patients remaining stable,<sup>28</sup> thus a conservative approach to its management is generally recommended.<sup>29</sup> However, we have demonstrated here that claudication causes QoL impairments, and conservative management inevitably

means that patients must resign themselves to these limitations. If these QoL limitations are unacceptable, it has been suggested that in all claudicants with an amenable arterial lesion, PTA should be considered amongst the primary treatment options.<sup>30</sup> The clinical indicator outcomes in this study would certainly appear to support this suggestion. The QoL outcome indicators would also suggest that all

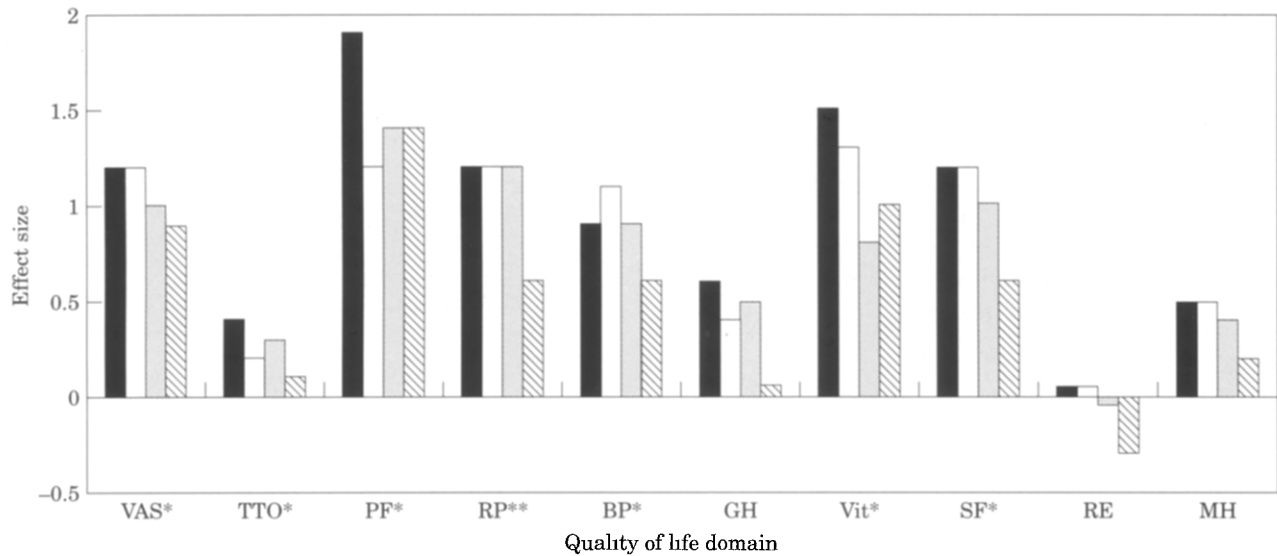


Fig. 5. Quality of life changes following PTA. unilateral claudicants (solitary iliac lesion) (■) One month, (□) 3 months, (▨) 6 months, (▩) 12 months VAS=EuroQol visual analogue scale, TTO=EuroQol time trade off index, PF=physical functioning, RP=role physical, BP=bodily pain, GH=general health, Vit=vitality, SF=social functioning, RE=role emotional, MH=mental health  
 \*= $p < 0.01$ ,  
 \*\*= $p < 0.05$  Kruskal-Wallis analysis of variance

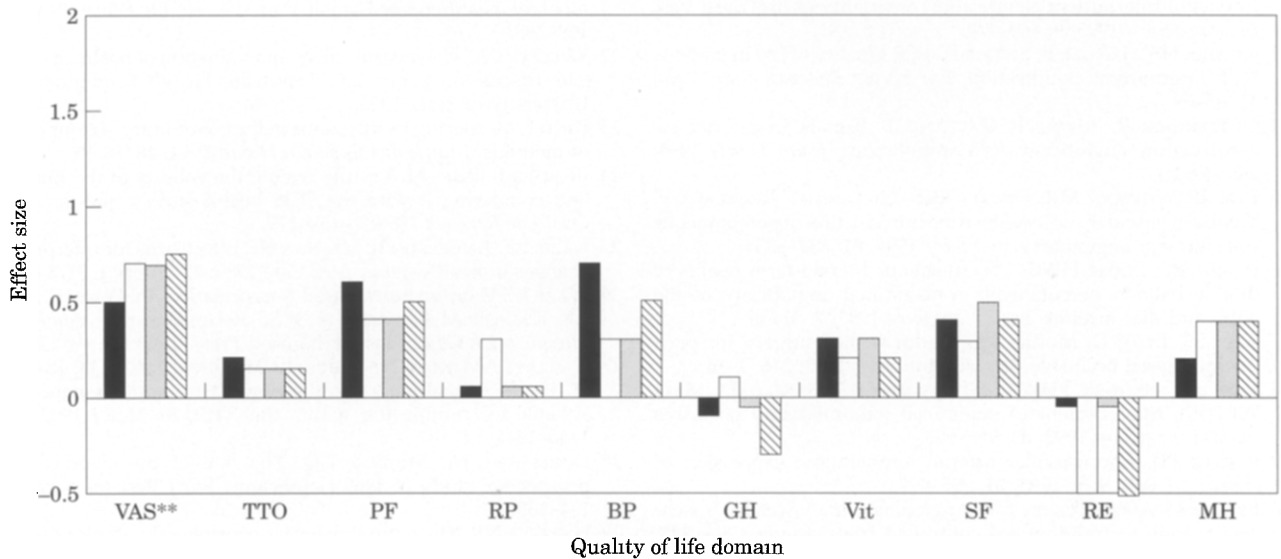


Fig. 6. Quality of life following PTA unilateral claudicants (solitary SFA lesion). (■) One month, (□) 3 months, (▨) 6 months, (▩) 12 months. VAS=EuroQol visual analogue scale, TTO=EuroQol time trade off index, PF=physical functioning, RP=role physical, BP=bodily pain, GH=general health, Vit=vitality, SF=social functioning, RE=role emotional, MH=mental health  
 \*= $p < 0.01$ ,  
 \*\*= $p < 0.05$  Kruskal-Wallis analysis of variance

unilateral claudicants with a solitary iliac lesion amenable to PTA should undergo the procedure as a primary treatment option, as PTA in these patients results in a return to a "normal" QoL. Bilateral claudicants or unilateral claudicants with a solitary SFA lesion, can also expect some QoL improvements following PTA, but residual QoL impairments are

to be expected. Iliac PTA above a significantly diseased SFA would appear to be an inadequate sole treatment for claudication. Potential explanations for residual QoL limitations following PTA in these latter groups of claudicants include age variations, comorbid conditions, and residual or recurrent claudication.

## Conclusion

Only approximately 10% of claudicants will have a lesion amenable to PTA.<sup>13</sup> The evidence presented here should assist both doctors and patients in deciding whether PTA is appropriate in the management of an individual's claudication, thus ensuring judicious use of resources. It may also be possible to prioritise PTA waiting lists to ensure patients with greatest potential benefit are treated with most urgency.

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