



Review: Quality of life in lower limb peripheral vascular surgery

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Abstract

Purpose: Vascular intervention studies generally consider patency and limb salvage as primary outcomes. However, quality of life is increasingly considered an important patient-oriented outcome measurement of vascular interventions. Existing literature was analyzed to determine the effect of different treatments on quality of life for patients suffering from either claudication or critical limb ischemia.

Basic methods: A review of the literature was undertaken in the Medline library. A search was performed on quality of life in peripheral arterial disease. Results were stratified according to treatment groups.

Principal findings: Twenty-one articles described quality of life in approximately 4600 patients suffering from peripheral arterial disease. Invasive treatment generally results in better quality of life scores (at a maximum of 2 years of follow-up), compared with non-invasive treatment. In patients with critical limb ischemia, successful revascularization improves quality of life scores. Only one study reported long-term results.

Conclusions: Increase in quality of life scores can be found for any intervention performed for peripheral arterial disease. However, there is scarce information on long-term quality of life after vascular intervention.

Keywords

Quality of life, vascular, peripheral bypass surgery, peripheral arterial disease, peripheral vascular disease

Introduction

Peripheral arterial disease (PAD) is commonly caused by atherosclerosis of peripheral arteries. The prevalence of PAD is 3–10% in the current population and ranges up to 15–20% in the elderly population.^{1–4} PAD is categorized by the Rutherford classification.⁵ Rutherford classifications 1 to 3 are used for patients suffering from intermittent claudication. These patients can be treated either with exercise therapy or revascularization.¹

In patients with critical limb ischemia, Rutherford classifications 4 to 6, the need for intervention is inevitable, which can either be performed by a percutaneous transluminal angioplasty (PTA), peripheral bypass surgery or, when this is technically not possible, primary amputation or palliation.¹ Typically, reported outcomes of vascular interventions include walking distance, patency rates, limb salvage rates and operative mortality.⁵ However, these outcomes may reflect a physician-oriented view on results.

Quality of life (QoL) is increasingly considered an important outcome of vascular interventions.^{2,6} It is an

individual assessment of physical, psychological and social well-being that is based on the definition of health by the World Health Organization.⁷ QoL incorporates a patient's individual perception of his/her disease and functioning.⁸ Patients suffering from PAD frequently cope with a deprived health status and QoL due to the general effects of the disease and co-morbid conditions.⁸ In this perspective, QoL is a patient-oriented way of evaluating results and may

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provide a better-balanced estimate of the impact of a certain intervention for patients.

There are reviews available on different topics of QoL in vascular surgery. However, these are mostly outdated and they assess only a small spectrum of QoL in vascular surgery.

We decided to conduct a systematic literature review to analyze the effect of exercise therapy, endovascular procedures and surgical interventions on the QoL of patients suffering from lower limb ischemia.

Methods

This review is based on a search in the Medline library, which was accessed by the PubMed search engine on 31 December 2011. The search was based on both medical subject headings [MeSH] and normal search terms and was performed by the first author, aided by the institution's librarian.

Terms used were "Peripheral Vascular Diseases" [MeSH] and "quality of life" [MeSH] (215 results) and "Peripheral arterial disease" [MeSH] and "Quality of Life" (36 results). All titles and abstracts were read, and all articles which were not referring to QoL in peripheral vascular surgery were excluded ($n = 232$). Nineteen manuscripts were selected for thorough revision. Three manuscripts were excluded, and from all references read five manuscripts were included in the review. QoL was defined as outcome, either primary or secondary. All relevant articles were fully read, and possible references were included and read as well.

Inclusion criteria

All papers that reported QoL scores after the following interventions in PAD were included: exercise therapy, PTA procedures and surgical revascularization. QoL had to be assessed with a questionnaire. Only articles published in English were included. Papers had to be published before 1 January 2012.

QoL assessment

There are many different questionnaires used to assess patients' QoL. There are generic QoL questionnaires like the WHOQOL and the EQ-5D questionnaires, disease specific questionnaires like the VascuQoL questionnaire or health status questionnaires like the SF-36 and RAND-36 questionnaires.

Results

A total of 21 studies were included which analyzed approximately 4600 patients. These studies were

distributed by type of intervention as follows: QoL after exercise therapy ($N = 5$); QoL after endovascular procedures ($N = 11$); and QoL after open surgery ($N = 13$).

Many studies have analyzed and reported QoL results after all different types of vascular treatment, in either patients suffering from intermittent claudication⁹⁻¹⁶ or patients with critical limb ischemia,¹⁷⁻²¹ or studies with both groups of patients.²²⁻³² There are studies comparing endovascular treatment with bypass surgery,^{9,12,18,19,24,28} studies comparing endovascular therapy with exercise therapy,^{9,14} studies comparing autologous bypass surgery with Polytetrafluoroethylene (PTFE) bypass surgery²² and studies analyzing QoL after a single intervention.^{13,15-17,20,21,23,25,27,29-32}

QoL after exercise therapy

Five articles assessed QoL in patients after exercise therapy.^{9,13-16} All articles assessed QoL in patients suffering from intermittent claudication. Exercise therapy, both supervised and unsupervised, resulted in increment in QoL at a maximum of 24 months of follow-up. However, results of supervised exercise therapy were better compared to the unsupervised exercise therapy.¹³ Patients receiving invasive treatment (both endovascular and surgical reconstruction) showed more increment in QoL than patients who only received exercise therapy.¹⁴ For detailed information on studies analyzing QoL after exercise therapy, see Table 1.

QoL after endovascular procedures

Eleven articles assessed QoL in patients after endovascular procedures.^{9,12,14,18,19,23-25,28,31,32} For patients suffering from intermittent claudication, an increase in QoL could be expected up to 2 years of follow-up.¹⁴

Patients with critical limb ischemia also showed increased QoL up to 36 months of follow-up after endovascular treatment.¹⁸ The difference in QoL between patients suffering from critical limb ischemia and patients suffering from intermittent claudication remains unclear, as different papers report in contrast to each other.^{24,25} A study analyzing QoL in critical limb ischemia patients after endovascular procedures, bypass surgery and secondary amputations stated that achieving limb salvage was related to better QoL.¹⁹ One case-control study reported that both intermittent claudication patients and critical limb ischemia patients cope with a deprived QoL score compared to matched healthy control subjects.²⁸

Endovascular treatment can increase QoL, even for chronically occluded superficial femoral arteries.²³ For detailed information on studies analyzing QoL after PTA, see Table 2.

Table 1. Change from baseline in quality of life after exercise therapy.

Reference	N Start/ end	Questionnaires	Female (%)	Age ^a	Degree of ischemia	Follow-up months	Supervised?	Outcome	Mean change	P value
Currie et al. ⁹	78/78	SF-36	24	68	Claudicant	3	No	Physical function Physical role Pain Vitality	3 (95% CI: 0–6) 5 (95% CI: c3–12) 7 (95% CI: 2–11) 3 (95% CI: –1–7)	0.2 0.25 0.005 0.1
Nicolai et al. ¹³	102/83	SF-36	44	67	Claudicant	12	No	Physical function Physical role Pain Vitality	6.6 ± 18.5 4.8 ± 49.4 3.9 ± 26.6 –3.9 ± 18.7	<0.001 0.71 0.36 0.05
Nicolai et al. ¹³	202/169	SF-36	33	66	Claudicant	12	Yes	Physical function Physical role Pain Vitality	12.3 ± 18.3 16.6 ± 45.2 13.4 ± 24.5 –0.6 ± 17.5	<0.001 <0.001 <0.001 0.46
Nordanstig et al. ¹⁴	101/72	SF-36	36	68	Claudicant	24	Yes	Physical function Physical role Pain Vitality	0.46 ^b 0.17 ^b 0.44 ^b 0.07 ^b	<0.05 NS <0.05 NS
Fakhry et al. ¹⁵	142/95	SF-36/ VascuQoL	36	68	Claudicant	12	No	Physical function Physical role Pain VascuQoL total score	6.88 (95%CI: 2.85–10.91) 8.89 (95%CI: 0.57–17.21) 6.55 (95%CI: 1.54–11.56) 0.45 (95%CI: 0.21–0.69)	<0.05 <0.05 <0.05 <0.05
Fakhry et al. ¹⁵	75/75	SF-36/ VascuQoL	41	67	Claudicant	12	Yes	Physical function Physical role Pain VascuQoL total score	12.68 (95%CI: 7.33–18.03) 5.93 (95%CI: –4.7–416.61) 9.67 (95%CI: 3.85–15.49) 0.60 (95%CI: 0.28–0.91)	<0.05 NS <0.05 <0.05
Gardner et al. ¹⁶	31/28	SF-36	11	71	Claudicant	6	Yes	Physical score Mental score	0 +4	NS NS
Gardner et al. ¹⁶	30/24	SF-36	8	70	Claudicant	6	No	Physical score Mental score	–1 0	NS NS

NS: not significant.

Only articles reporting treatment specific before and after data are listed.

^aMean or median.^bEffect size (difference in mean values between baseline and 2 years per SD at baseline).

Table 2. Change from baseline in quality of life after endovascular treatment.

Article	N start/ end	Questionnaires	Female (%)	Age ^a	Degree of ischemia	Follow-up months	Outcome	Mean change	P value
Curie et al. ⁹	74/74	SF-36	28	73	Claudicant	3	Physical function Physical role Pain Vitality	18 (95% CI: 12–24) 19 (95% CI: 8–30) 17 (95% CI: 11–24) 8 (95% CI: 4–12)	<0.001 <0.005 <0.001 <0.05
Nordanstig et al. ^{14c}	100/86	SF-36	38	68	Claudicant	24	Physical function Physical role Pain Vitality	0.89 ^b 0.68 ^b 1.16 ^b 0.15 ^b	<0.05 <0.05 <0.05 NS
Johnson et al. ¹⁹	26/19	DomainQ	42	76	Critical	12	Pain Barthel ADL score Mobility	–3 0.14 1	<0.01 <0.05 <0.05
Dippel et al. ²³	44/44	Walking impairment Questionnaire	41	70.3	CL 88% CR 12%	12	WIQ score	7405 (95% CI: 6555–9245)	<0.0005
Kalbaugh et al. ²⁵	54/52	SF-36	NR	Pop: 64.5 Gr NR	Claudicant	12	Physical function Physical role Pain	9.2 7.0 7.2	<0.0001 0.0001 <0.0001
Kalbaugh et al. ²⁵	30/18	SF-36	NR	Pop: 64.5 Gr NR	Critical	12	Physical function Physical role	2.9 0.7	0.30 0.85
Egberg et al. ³¹	56/41	EQ-5D CLAUS	49	68	CL 85% CR 15%	12	Pain EQ-5D index CLAUS score total	11.2 0.19 18	0.0009 0.0019 <0.0001
Forbes et al. ¹⁸	224/132	SF-36 EQ-5D VascuQol	43	NR	Critical	12 ^d	EQ-5D index Physical function Physical role Pain	0.3 10.91 19.85 23.89	NR NR NR NR
Bosch et al. ^{32e} Gr I	143/143	EQ-5D Rand-36	29	59	Mostly claudicant	24	VascuQol score Physical function Physical role Pain EQ-5D index	1.74 35 75 33 0.24	NR NR NR NR NR

(continued)

Table 2. Continued

Article	N start/ end	Questionnaires	Female (%)	Age ^a	Degree of ischemia	Follow-up months	Outcome	Mean change	P value
Bosch et al. ^{32e}	136/136	EQ-5D	27	60	Mostly claudicant	24	Physical function	40	NR
Gr 2		Rand-36					Physical role Pain	100 45	NR NR
							EQ-5D index	0.20	NR

NS: not significant; NR: not reported.

Only articles reporting treatment specific before and after data are listed.

^aMean or median.

^bEffect size (difference in mean values between baseline and 2 years per SD at baseline).

^cData are for invasive treatment group (PTA + surgery).

^dTwelve-month follow-up was selected because of very little follow-up at 36 months (original study endpoint).

^eStudy consisted of two groups: first underwent PTA + Stent, second one underwent PTA only.

QoL after open surgical procedures

Thirteen articles assessed QoL in patients after surgical revascularization procedures.^{9,12,14,17–20,22,24,27–30} Surgical revascularization improved QoL in patients suffering from both intermittent claudication and critical limb ischemia, at least for two to three years after surgery. The increment in QoL achieved by a surgical revascularization intervention was significantly better compared to walking exercise.^{9,14}

Little is known about the long-term effect of endovascular or surgical reconstructive interventions on patients' QoL. Only one prospective study analyzed results after more than 2 years of follow-up, after both endovascular and surgical reconstructive procedures.¹⁸ They showed an increment in QoL for both procedures after 3 years of follow-up. A case-control study²⁸ showed that QoL scores of patients after both endovascular and surgical reconstructions (mean 3.5 years for surgery, 2.7 years for PTA) were lower compared to healthy subjects. One study analyzed long-term follow-up results (mean follow-up of 11 years) after reconstructive surgery,²⁹ and they reported decrement in QoL scores for patients treated with surgical reconstructions. Especially patients who experienced an adverse event during the follow-up period scored lower on QoL. For detailed information on studies analyzing QoL after surgical revascularization, see Table 3.

Discussion

Our systematic review involving approximately 4600 patients subjected to supervised walking therapy, endovascular or open revascularization revealed that for every performed intervention in PAD, some degree of increase in QoL scores was observed. However, this improvement varies significantly depending on the type of population (intermittent claudication vs. critical limb ischemia), the intervention performed and the type of QoL scoring method used. QoL scores also varied significantly with the duration of follow-up, which suggests that QoL in patients with PAD is very dynamic and multifactorial.

For patients suffering from intermittent claudication, walking advice itself can increase QoL scores as demonstrated by Nicolai et al.¹³ However, supervised walking exercise results in better QoL scores. Nordanstig et al.¹⁴ and Currie et al.⁹ reported increased QoL scores after walking exercise. They also stated that QoL could be further improved after invasive treatment with either endovascular intervention or surgical treatment.

In patients suffering from critical limb ischemia, endovascular treatment can result in improved QoL scores. A few studies analyzed the difference in QoL between endovascular and surgical intervention.

Table 3. Change from baseline in quality of life after surgical reconstructive treatment.

Article	N start/ end	Questionnaires	Female (%)	Age ^a	Degree of ischemia	Follow-up months	Outcome	Mean change	P value
Curie et al. ⁹	34/34	SF-36	32	67	Claudicant	3	Physical function Physical role Pain Vitality	18 (95% CI: 15–26) 16 (95% CI: 1–30) 17 (95% CI 6–27) 9 (95% CI: 2–17)	<0.002 <0.05 <0.01 <0.05
Engelhardt et al. ¹⁷	89/47	SF-36	28	71	Critical	24	Physical function Physical role Pain Vitality	20 11 21 10	<0.001 NS <0.001 NS
Johnson et al. ¹⁹	44/35	DomainQ	42	71	Critical	12	Pain Barthel ADL score	-3 0.05	<0.01 <0.01
v Hattum et al. ²⁹	482/53	EQ-5D Rand-36	29	73	Claudicant 72%	Mean 132	Mobility EQ-5D index Physical function	1 -0.16 (95% CI: -1.9--0.27) -20 (95% CI: -30--9)	<0.001 0.004 0.001
Ozturk et al. ²²	101/93	WHOQOL	26	69	Claudicant 34% Critical 66%	3	Physical role Pain Vitality Physical domain General QoL	-15 -1 -7 +10.0 0.14	NS NS NS <0.0005 0.078
Wohlgemuth et al. ³⁰	74/74	SF-36	NR	57.7	Claudicant 30 Critical 70%	18	Physical function Physical role Pain Vitality	17 38 57 22	<0.05 <0.05 <0.05 NS
Nguyen et al. ²⁰	1404/732	VascuQoL	36	69	Critical	12	VascuQoL score Pain EQ-5D index	2.27 2.7 0.34	<0.0001 <0.0001 NR
Forbes et al. ¹⁸	228/119	SF-36 EQ-5D VascuQoL	38	NR	Critical	12 ^b	Physical function Physical role Pain VascuQoL score	14.35 18.4 28.07 1.77	NR NR NR NR

NS: not significant; NR: not reported.

Only articles reporting treatment specific before and after data are listed.

^aMean or median.^bTwelve-month follow-up was selected because of very little follow-up at 36 months (original study endpoint).

They all showed increased QoL scores, but a significant difference between both treatments was not found. This suggests that the decision for treatment modality should not be based on QoL, which is similar after both types of intervention.

Surgical reconstructive intervention will increase patients' QoL scores, at least for short-term analyses. The long-term analysis reported by van Hattum et al.²⁹ showed that the increment in QoL scores may not be everlasting, and QoL scores may deteriorate at long-term follow-up.

Very little is known on QoL after major lower limb amputation. Only two studies were found which assessed QoL after this type of intervention. Johnson et al.¹⁹ stated that QoL of patients suffering from critical limb ischemia is higher in patients who underwent successful revascularization compared to patients who underwent primary or secondary amputations.

Remes et al.³³ stated that PAD patients who received lower extremity amputation have lower QoL scores compared to healthy control subjects. How PAD patients' QoL relates to other chronically illnesses is unclear. This study only analyzed QoL after amputation and compared these scores to a healthy control subject, not evaluating QoL change over time.

There are several problems we encountered while working on our study. First, in this review we used the term QoL even for studies that used health status questionnaires because they presented their results as QoL scores. For instance, the SF-36 (and the Rand-36) is a health status questionnaire. A study performed by Breek et al.,⁸ showed that there is a discrepancy between QoL scores and health status scores. Patients who scored relatively high on one scale could easily score lower on the other. Therefore, it is hard to compare studies with different questionnaires in a reliable way. Health status questionnaires should generally not be used for assessing patients' QoL. Best results can be achieved by using either a general QoL questionnaire or a disease specific QoL questionnaire. Also, the duration of follow-up in the included studies varied significantly, which makes it difficult to compare the results. Moreover, the number of included patients in many studies is small, which may lead to type-II errors. Finally, no studies were randomized and most were retrospective observational studies. There may be significant publication bias in the included studies, as positive results are more likely to be reported and published.

In conclusion, all types of interventions performed in patients with PAD may improve QoL or QoL-related aspects. However, the increment is not homogeneous and depends on the studied population, type of intervention, questionnaire used, scoring method and duration of follow-up. Little is known about the long-term

follow-up QoL after vascular intervention. Only a small number of studies analyzed QoL in patients who underwent lower limb amputation. These studies were not specifically designed to analyze the effect of lower limb amputation on QoL scores before and after surgery. Randomized studies are required to provide evidence of the true benefit of intervention in patients with PAD.

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