

Quality of life in perspective to treatment of postoperative edema after peripheral bypass surgery

| | |
|------------------|---|
| Authors | Oztürk,C.; Te Slaa,A.; Dolmans,D.E.; Ho,G.H. et al |
| Published in | Annals of Vascular Surgery |
| DOI | 10.1016/j.avsg.2011.07.012 |
| Publication Date | 2012 |
| Document Version | publishersversion |
| Link | https://research.tilburguniversity.edu/en/publications/58ee2e35-b4e7-4b1a-b380-0171a30ded1e |
| Citation | Oztürk, C, Te Slaa, A, Dolmans, D E, Ho, G H, de Vries, J, Mulder, P & van der Laan, L 2012, 'Quality of life in perspective to treatment of postoperative edema after peripheral bypass surgery', <i>Annals of Vascular Surgery</i> , vol. 26, no. 3, pp. 373-382. https://doi.org/10.1016/j.avsg.2011.07.012 |
| Download Date | 2026-03-12 23:05:45 |
| Rights | <p>General rights</p> <p>Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.</p> <ul style="list-style-type: none"> - Users may download and print one copy of any publication from the public portal for the purpose of private study or research. - You may not further distribute the material or use it for any profit-making activity or commercial gain - You may freely distribute the URL identifying the publication in the public portal" <p>Take down policy</p> <p>If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.</p> |

Quality of Life in Perspective to Treatment of Postoperative Edema After Peripheral Bypass Surgery

Çiğdem Öztürk,¹ Alexander te Slaa,¹ Dennis E.J.G.J. Dolmans,¹ G.H. Ho,¹ Jolanda de Vries,^{2,3} Paul G.H. Mulder,⁴ and Lyckle van der Laan,¹ Breda, Tilburg, and Rotterdam, The Netherlands

Background: To examine the effects of peripheral bypass surgery on patients' quality of life (QoL) as well as to compare two treatment modalities to reduce postoperative edema with regard to patients' QoL.

Methods: This was a randomized controlled trial set in the department of vascular surgery in a nonacademic teaching hospital. Ninety-three patients (mean age, 70 years; 33% Rutherford 5–6), enrolled between August 2006 and September 2009, who underwent peripheral bypass surgery (autologous 57, polytetrafluoroethylene 36). Patients were assigned to intermittent pneumatic compression (n = 46) or to compression stockings (n = 47). The main outcome measure was QoL, measured with the World Health Organization Quality of Life assessment instrument (short form: WHOQOL-BREF).

Results: QoL improved on the domain of Physical Health by 7.18 points ($P < 0.001$ [range, 0–100]) after 2 weeks and by 10.03 points ($P < 0.001$) after 3 months. Patients who received a polytetrafluoroethylene bypass scored 0.45 points ($P = 0.0008$ [range, 1–5]) lower at baseline on Global QoL than patients who received an autologous bypass. Type of bypass or edema treatment method did not affect the improvements. Edema did not correlate with QoL.

Conclusion: Improvement in QoL on the domain Physical Health following femoropopliteal bypass surgery was found as soon as 2 weeks after surgery. Improvement in QoL domains was not influenced by the type of bypass reconstruction. No specific effects of edema on QoL were detected.

INTRODUCTION

Quality of life (QoL) is increasingly considered a key outcome measure of vascular interventions,

next to traditional outcome measures including limb salvage, graft patency, and operative mortality.¹ Measures of health that include the impact of disease and impairment on daily activities and behavior, perceived health, and disability and functional status have been described as “the missing measurements in health.”² With the introduction of QoL measurements, health care has gained a humanistic and patient-oriented perspective.³

QoL is an individual assessment of physical, psychological, and social well-being that is in line with the definition of health by the World Health Organization (WHO)⁴ and incorporates a patient's individual perception of his/her disease and functioning.⁵ Many generic and disease-specific instruments measuring different constructs related to QoL are available. The World Health Organization Quality of Life assessment instrument (WHOQOL)

Trial registered in 2006 through “TWOR, Rotterdam, the Netherlands” under number 06.071.

¹Department of Surgery, Amphia Hospital, Breda, The Netherlands.

²Department of Medical Psychology, Tilburg University, Tilburg, The Netherlands.

³Department of Medical Psychology, St Elisabeth Hospital, Tilburg, The Netherlands.

⁴Erasmus University Medical Center, Department of Biostatistics, Rotterdam, The Netherlands.

Correspondence to: Lyckle van der Laan, PhD, MD, Department of Surgery, Amphia Hospital, PO Box 90158, 4800 RK Breda, The Netherlands, E-mail: lvanderlaan@amphia.nl

Ann Vasc Surg 2012; 26: 373–382

DOI: 10.1016/j.avsg.2011.07.012

© Annals of Vascular Surgery Inc.

Published online: November 7, 2011

is a generic QoL assessment instrument that has been satisfactorily used in patients suffering from cardiovascular diseases.^{3,4} The original WHOQOL-100 as well as an abbreviated version (WHOQOL-BREF) have good reliability and validity and are sensitive to treatment-related change and correlate highly with each other.^{6–8} These questionnaires, in which there is a recognition of the multidimensional nature of QoL, involve the patients' own criteria unlike other generic instruments that seem to measure objective QoL (i.e., perceived capabilities and functioning).⁹

Patients suffering from peripheral arterial disease (PAD) cope with a deprived health status and QoL owing to the effects of PAD and comorbid conditions.⁵ Improvements in both health status and QoL following peripheral bypass surgery have been observed between 3 months and 2 years.^{10–12}

Substantial postoperative edema occurs following peripheral bypass surgery,¹³ which can cause discomfort, hinders early mobilization, and has an inhibiting effect on wound healing because of the underlying hemodynamic disturbances.¹⁴ The effect of this postoperative edema on QoL is not clear.

The present study was a single-center randomized controlled trial to evaluate the efficacy of intermittent pneumatic compression (IPC), compared to compression stockings (CS), as a treatment method of edema following femoropopliteal bypass surgery. IPC was used successfully to treat edema following orthopedic and trauma surgery on a limb.^{15,16} However, failure of IPC to decrease edema formation following autologous and polytetrafluoroethylene (PTFE) femoropopliteal bypass surgery was reported recently.^{17,18} As part of this study, the effects of femoropopliteal bypass surgery on patients' QoL were prospectively assessed with the WHOQOL-BREF instrument, 1 day before surgery and 2 weeks and 3 months after surgery.

This study aims, first, to determine the effect of femoropopliteal bypass surgery on patients' QoL, and second, to explore whether improved QoL is associated with postoperative edema reduction in patients treated with IPC or CS.

MATERIALS AND METHODS

Trial Design

A single-center randomized controlled trial was performed to study the effects of IPC and CS on postoperative edema formation following femoropopliteal bypass surgery. The patients were enrolled between August 2006 and September 2009.

The inclusion criterion was severe peripheral vascular disease (Rutherford 3–6) that could not be treated with revascularization using endovascular techniques. Patients who suffered from pre-existing leg edema were excluded from the study. The key endpoints were edema reduction, changes in inflammatory parameters, and improvements in QoL. Further information on the trial design, the effects on the formation of postoperative edema, and changes in inflammatory parameters are reported elsewhere.^{17,18}

Approval was granted by both a nationally recognized medical ethical review committee and the hospital's medical ethical review committee. All patients who participated in this study gave written informed consent.

Surgical Procedure

All patients underwent supragenicular or infragenicular femoropopliteal bypass surgery. Whenever possible, autologous grafting (ipsilaterally or contralaterally) was performed.¹⁹ Alternatively, a PTFE graft (Dystaflo®; Bard Peripheral Vascular Inc., Tempe, AZ) was used. Thus, two types of grafts are considered: autologous and PTFE.

Treatment Groups

Patients in both surgery groups were allocated to either the CS group or the IPC group according to the randomization strategies.^{17,18} The patients in the CS group used an above-the-knee class I stocking (BREVET tx; Mölnlycke, Göteborg, Sweden), exerting up to 18 mm Hg pressure to the leg continuously during 1 week following surgery. IPC group patients received the A-V impulse technology (Orthofix Vascular Novamedix, Andover, UK) during 1 week at night, starting the night following the operation. The A-V impulse technology is an IPC device on the foot; it was developed to compress the venous plexus artificially and activate the physiological foot pump.^{15,16} Starting in the second week, all patients were discharged from hospital when possible and used the CS at day on the operated legs only for 8 weeks.

QoL Assessment

Patients were asked to complete the WHOQOL-BREF assessment questionnaire the day before surgery and 2 weeks and 3 months after surgery. The WHOQOL-BREF is an abbreviated version of the original WHOQOL-100.^{3,4} The WHOQOL-BREF has 26 questions of which 24 questions assess

the domains: Physical Health (7 questions), Psychological Health (6 questions), Social Relationships (3 questions), and Environment (8 questions). Each question has a five-point Likert scale. The remaining two questions assess overall QoL and the perceived health and make up the facet Global QoL. Scoring of the various QoL domains was based on instructions of the WHO.²⁰ The Likert scale data were converted into raw domain scores of the four distinct domains and transformed on a range from 0 to 100, with higher scores corresponding with a better QoL. The Global QoL facet was left untransformed.

The WHOQoL referred to the past two weeks at the moment assessment was taken. Studies concerning the psychometric properties of the WHOQOL-BREF have shown good internal consistency, validity,⁶ and good sensitivity to change.⁷

Detectable Effect Size Based on Cohen's *d*

The total number of patients with valid QoL data amount to almost 80, randomly 1:1 allocated to either IPC or CS across both surgical procedures. As the QoL scores are constructed dimensionless scores, Cohen's *d* was used as a measure for the effect size to be detected. Cohen's *d* is the mean difference in QoL scores between both treatment groups expressed in SD units, where SD is the within-surgical within-treatment group standard deviation of the QoL scores. With 2×40 patients and using a test size α of 0.05 (two-sided), an effect $d = 0.63$ ("medium") can be detected with 80% power. With 90% power, the detectable effect size equals 0.73 (in between "medium" and "large").

Statistical Analysis

The SPSS 16.0 (SPSS Inc., Chicago, IL) package was used for the statistical analysis.

All analyses were carried out while taking account of (stratifying by) the two surgery groups. To detect the effect of surgery on QoL domains having a Gaussian-shaped distribution, mixed model analysis of variance (ANOVA) for repeated measures was used to perform a pooled stratified analysis of the difference between the two edema treatment groups (IPC and CS) across the two surgery groups (autologous and PTFE). The independent variables were surgery group (autologous and PTFE), edema treatment group (IPC and CS), and measurement moment (2 weeks and 3 months). The baseline level at the preoperative day of the QoL domain at hand was entered as covariate. We tested whether the effect of this baseline level was modified by day and group and whether this baseline level modified

the treatment effect. We also tested whether the treatment effect was modified by measurement day or by surgery group. The baseline level of each QoL domain was related to both surgery and treatment by using multiple linear regression analysis.

Mixed model ANOVA was also used to test the correlation between leg circumference and domain scores, adjusted for bypass graft type (surgery group), edema treatment, and time.

The outcome variable Global QoL was analyzed using nonparametric methods because its distribution deviated strongly from a Gaussian-shaped distribution. The change from baseline of Global QoL was trichotomized into three ordered categories: change for worse, no change, and change for better. This ordered categorical change was compared between the two edema treatment groups (IPC and CS) by using a stratified chi-squared trend test, where the stratification was by bypass graft type (autologous and PTFE). This analysis was done for the two measurement moments (2 weeks and 3 months) separately. To detect changes from baseline in Global QoL, sign tests were used by bypass graft type, edema treatment, and measurement moment.

Binary categorical variables (complications) were compared between the two edema treatment groups by using Mantel-Haenszel chi-squared tests stratified by bypass graft type.

A *P* value < 0.05 was considered to denote statistical significance.

RESULTS

Baseline characteristics are summarized in Table I, subdivided by bypass graft type (autologous/PTFE) and edema treatment method (IPC/CS). Data of 93 patients (autologous 57/PTFE 36), who underwent femoropopliteal bypass surgery due to severe PAD was used. (Fig. 1) between August 2006 and September 2009. Of the 93 patients, 76 (82%) completed the QoL questionnaire preoperatively, 78 (84%) at 2 weeks postoperatively, and 69 (74%) at 3 months postoperatively.

Postoperative Course

Postoperative events are presented in Table II. No significant differences in the occurrence of postoperative events were found between the treatment groups.

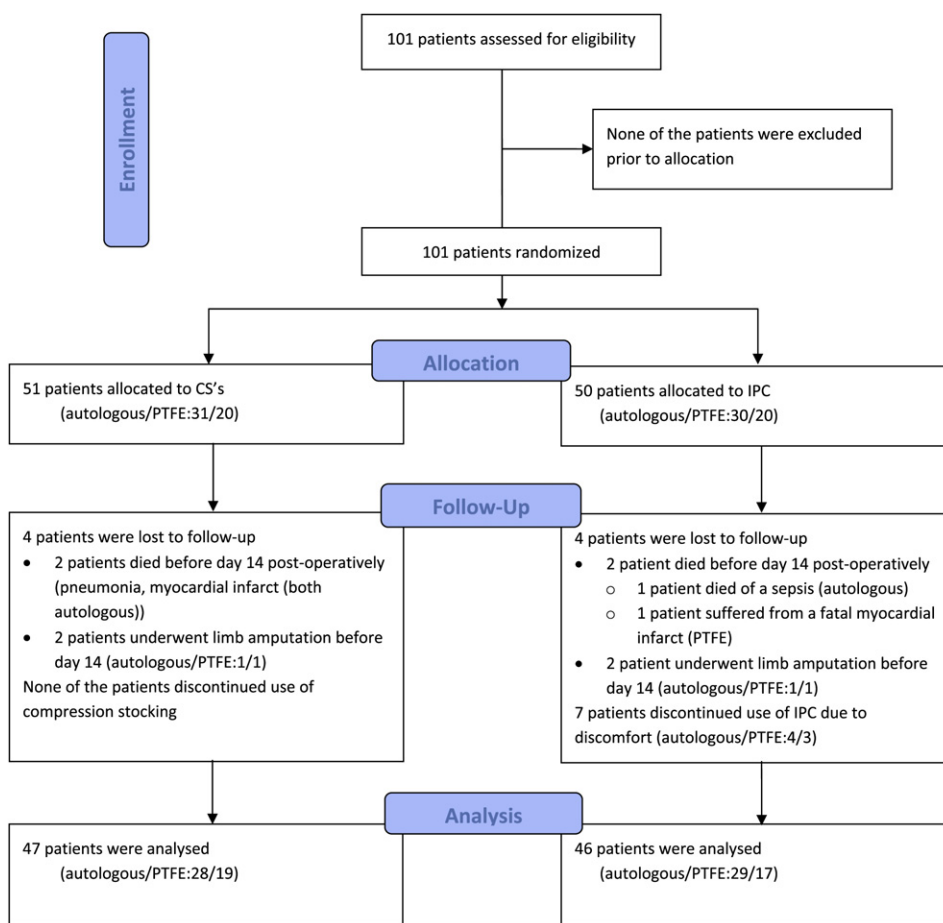
Effect of Surgery on QoL

Summary statistics of the raw domain scores are listed in Table III. Means of the QoL domains at

Table I. Baseline characteristics

| Parameter | Autologous | | PTFE | |
|----------------------------|------------|------------|------------|------------|
| | CS | IPC | CS | IPC |
| <i>N</i> | 28 | 29 | 19 | 17 |
| Age, mean (range) | 69 (57–84) | 67 (39–88) | 72 (46–84) | 71 (40–86) |
| Sex (M/F) | 23/5 | 22/7 | 13/6 | 11/6 |
| DM (%) | 10 (36) | 15 (52) | 5 (26) | 7 (41) |
| Smoke (%) | 13 (46) | 16 (55) | 11 (58) | 6 (35) |
| Rutherford 3/4/5–6 | 11/10/7 | 13/5/11 | 6/5/8 | 2/8/7 |
| Absent vein (re-operation) | NA | NA | 6 (6) | 5 (3) |
| Small caliber vein | NA | NA | 13 | 12 |

PTFE, polytetrafluoroethylene; CS, compression stockings; IPC, intermittent pneumatic compression; DM, diabetes mellitus; NA, not applicable.

**Fig. 1.** Trial design.

baseline adjusted for stratum and treatment group and adjusted mean differences between strata and treatment groups are presented in Table IV.

On the domain of Global QoL, a significant difference was detected at baseline between patients who were revascularized with an autologous graft versus

patients who were revascularized using a PTFE graft, in the disadvantage of the latter.

Mixed model ANOVA for the repeated assessments of the QoL domains showed that a simultaneous test of all interactions with the baseline measurement for each of the four QoL domains was not significant. Hence, the baseline level of

Table II. Incidence of complications compared between the two edema treatment groups (*p* values from Mantel–Haenszel chi-squared tests stratified by bypass graft type)

| Complication | CS (<i>N</i> = 47) | IPC (<i>N</i> = 46) | <i>P</i> value |
|---|---------------------|----------------------|----------------|
| Wound infection (autologous/PTFE) | 5 (2/3) | 9 (6/3) | 0.14 |
| Infection (origin other than wound) (autologous/PTFE) | 2 (1/1) | 2 (1/1) | 0.98 |
| Hematoma (autologous/PTFE) | 4 (3/1) | 4 (4/0) | 0.97 |
| Persisting seroma (>3 months) (autologous/PTFE) | 1 (0/1) | 2 (2/0) | 0.55 |
| Occlusion (autologous/PTFE) | 7 (2/5) | 5 (2/3) | 0.57 |
| Myocardial infarct (autologous/PTFE) | 1 (1/0) | 0 (0/0) | 0.33 |

a domain did not seem to modify the effects of the bypass graft type (autologous or PTFE), the edema treatment method (IPC or CS), and time on each domain. Also, none of the treatment-by-time interactions appeared to be significant. The test for heterogeneity of the treatment effect across the two treatment groups appeared to be significant only for the domain of Social Relationships ($P = 0.020$), so that for this domain, the estimated treatment results are listed separately for the two surgery groups (see Table V). For the other specific domains, a simple model with only the main effects of the baseline level, time, surgery group, and edema treatment group appeared to suffice. The only significant treatment effect ($P = 0.015$) was seen for Social Relationships in patients who received a PTFE bypass. None of the other edema treatment and bypass graft type effects reached significance. For significance of the changes from baseline detected using similar analyses as those yielding the results of Table V, see Table VI. Significant increases were seen consistently in the domain of Physical Health for either surgery group, for either edema treatment group, and for either measurement moment.

On the domain of Physical Health, a general improvement was found for all patients ($P < 0.001$) as shown in Figure 2. On the domains of Psychological Health ($P = 0.93$), Social Relationships ($P = 0.43$), Environment ($P = 0.35$), and Global QoL ($P = 0.35$) no significant differences were found. Item analysis on the domain Physical Health was performed. Significant improvement was found on three of the seven items: pain ($P < 0.001$), need for medical treatment in daily functioning ($P < 0.001$), and energy for daily functioning ($P < 0.05$).

In an efficacy test of the Global QoL domain, there was no significant difference in the changes between the two edema treatment groups, adjusted for surgery group. The *P* values are 0.17 and 0.81 for the respective measurements at 2 weeks and at 3 months. A significant change from baseline of the Global QoL could not be detected either.

Limb Edema and QoL

Patients who used IPC following autologous femoropopliteal bypass surgery developed significantly more edema than patients who used CS. This effect was only significant in the first week and slightly disappeared after patients in the IPC group switched to using CS after 1 week at discharge from hospital.¹⁸ This effect was not seen in patients who underwent PTFE femoropopliteal bypass surgery.¹⁷

The association between leg circumference and QoL was analyzed. Partial correlation analysis (adjusted for surgery group, edema treatment group, and time) on day 14 and 90 between leg circumference and QoL domains showed no significant correlations between leg circumference and the subsequent domains of QoL (*P* values ranging from 0.16 to 0.82).

DISCUSSION

The main research question of this study was to assess the effect of peripheral bypass surgery on patients' QoL. Furthermore, changes in QoL were examined in relation to postoperative edema reduction using two different edema treatment methods.

QoL increased significantly on the domain of Physical Health 2 weeks and 3 months following peripheral bypass surgery. This effect was seen regardless of the type of bypass graft or the edema treatment method. Before peripheral bypass surgery, patients suffering from severe PAD especially had a low QoL (mean, 50; range, 0–100) on the domain Physical Health. The facet of pain is incorporated in the domain of Physical Health. Improvements on this domain are understandable because a large portion of the participants (66%) suffered from chronic critical ischemia (Rutherford class 4–6) before surgery. Item analysis showed that patients suffered significantly less pain after surgery. Also, they experienced significantly more energy for daily functioning. Scores on the other domains were slightly higher than those on the domain of Physical Health, but still lower compared

Table III. Summary of raw QoL domain scores by bypass graft type, edema treatment, and measurement moment

| Day | Stratum | Domain treatment | Physical health ^a | | | Psychological health ^a | | | Social relationships ^a | | | Environment ^a | | | Global QoL ^b | | |
|-----------------|------------|------------------|------------------------------|-------|-------|-----------------------------------|-------|-------|-----------------------------------|-------|-------|--------------------------|-------|-------|-------------------------|------|------|
| | | | N | Mean | SD | N | Mean | SD | N | Mean | SD | N | Mean | SD | N | Mean | SD |
| -1 ^c | Autologous | CS | 23 | 49.69 | 15.61 | 23 | 68.48 | 14.26 | 23 | 64.49 | 16.33 | 23 | 64.81 | 11.70 | 23 | 3.37 | 0.66 |
| | | IPC | 25 | 54.31 | 11.34 | 25 | 75.67 | 17.33 | 25 | 69.33 | 22.66 | 25 | 70.45 | 16.81 | 25 | 3.88 | 0.58 |
| 14 | PTFE | CS | 15 | 49.44 | 8.90 | 15 | 66.33 | 12.55 | 15 | 66.67 | 17.82 | 14 | 65.47 | 14.28 | 15 | 3.37 | 0.83 |
| | | IPC | 13 | 44.09 | 14.53 | 13 | 63.14 | 14.62 | 12 | 66.32 | 15.94 | 13 | 65.87 | 11.59 | 13 | 2.96 | 0.52 |
| 90 | Autologous | CS | 23 | 54.81 | 15.31 | 23 | 67.39 | 14.84 | 23 | 63.95 | 18.95 | 23 | 69.37 | 14.46 | 23 | 3.54 | 0.66 |
| | | IPC | 24 | 59.67 | 16.20 | 24 | 71.70 | 17.80 | 24 | 69.44 | 21.23 | 24 | 71.52 | 17.26 | 24 | 3.79 | 0.67 |
| 90 | PTFE | CS | 17 | 57.88 | 14.16 | 17 | 66.52 | 13.07 | 16 | 69.79 | 19.45 | 17 | 68.93 | 15.84 | 17 | 3.50 | 0.61 |
| | | IPC | 14 | 52.55 | 17.91 | 14 | 63.39 | 17.69 | 14 | 66.37 | 16.38 | 14 | 62.85 | 17.42 | 14 | 3.32 | 0.91 |
| 90 | Autologous | CS | 21 | 60.71 | 17.53 | 21 | 67.30 | 15.75 | 21 | 63.10 | 19.47 | 21 | 68.90 | 12.90 | 21 | 3.57 | 0.95 |
| | | IPC | 26 | 65.68 | 15.65 | 26 | 73.40 | 14.53 | 25 | 71.67 | 23.69 | 26 | 71.19 | 16.44 | 26 | 3.83 | 0.65 |
| 90 | PTFE | CS | 12 | 58.28 | 13.61 | 13 | 65.64 | 11.68 | 13 | 62.82 | 18.82 | 13 | 66.35 | 16.04 | 13 | 3.46 | 0.75 |
| | | IPC | 9 | 50.40 | 13.88 | 9 | 55.56 | 15.02 | 9 | 49.54 | 13.89 | 9 | 61.11 | 11.60 | 9 | 3.11 | 0.60 |

QoL, quality of life; SD, standard deviation.

^aRange 0–100.

^bRange 1–5.

^c-1 implies 1 day before surgery.

with healthy elderly people. Healthy older people generally score approximately 75 on all domains.^{5,21}

A difference at baseline in Global QoL was detected between patients who were revascularized with an autologous graft versus patients who were revascularized with a PTFE graft, in the disadvantage of the latter. In our hospital, we prefer autologous grafting over PTFE grafting whenever possible.²² As a consequence, over the years, this policy resulted in a 25% reoperation rate in patients with a PTFE graft owing to failures of previous constructed autologous bypasses. It is not unlikely that progression of PAD and accompanying comorbid conditions are attributable to lower QoL scores. On the other domains, there were tendencies to lower scores in the PTFE stratum at baseline, although they did not reach significance.

In the PREVENT III study, a significant improvement in QoL after infragenicular femoropopliteal bypass reconstruction was found using the Vascular Quality of Life Questionnaire (VascuQoL).¹² The VascuQoL is a disease-specific questionnaire reflecting health status, comprising physical, social, and emotional facets.²³ Patients scored significantly higher in all domains at 3 months and at 12 months following revascularization compared to the situation before surgery. In the present study, such changes were not found with the WHOQOL-BREF, possibly due to the use of a generic instrument. Also, this study might deal with “too small numbers” in comparison to the PREVENT III trial (101 vs. 1,404 patients) to detect significant differences. However, the tendency of lower scores in the domain of Psychological Health must not be overlooked because recent studies revealed that depressive symptoms occur regularly in patients suffering from PAD.^{24,25}

In the present study, QoL was assessed in relation to postoperative edema reduction. A relationship between reduction in leg circumference indicating the amount of leg edema and QoL at 2 weeks was expected. However, by that time, the significant differences in leg circumference between the edema treatment groups had already vanished. A relation between QoL and postoperative edema was not found. Nonetheless, QoL improves more after successful revascularization than after failed revascularization.¹² It could therefore be hypothesized that the use of adequate edema reduction therapies could improve QoL after revascularization sooner than a passive regime.

Health status and QoL both are affected in patients with intermittent claudication.^{5,26} Breek

Table IV. Adjusted means of the QoL domains at baseline and adjusted mean differences between surgery groups (autologous/PTFE) and edema treatment groups (CS/IPC); results from multiple linear regression analyses

| Domain | Residual SD | Group | N | Adjusted mean | Difference | SE | P value | |
|-----------------------------------|-------------|------------|----|---------------|------------|------|---------|------|
| Physical health ^a | 13.10 | Autologous | 48 | 52.08 | -5.08 | 3.12 | 0.11 | |
| | | PTFE | 28 | 46.99 | | | | |
| | | CS | 38 | 49.73 | 0.95 | 3.01 | | 0.75 |
| | | IPC | 38 | 50.68 | | | | |
| Psychological health ^a | 15.23 | Autologous | 48 | 72.15 | -7.18 | 3.63 | 0.051 | |
| | | PTFE | 28 | 64.97 | | | | |
| | | CS | 38 | 67.82 | 3.37 | 3.50 | | 0.34 |
| | | IPC | 38 | 71.19 | | | | |
| Social relationships ^a | 18.83 | Autologous | 48 | 66.93 | -0.27 | 4.54 | 0.95 | |
| | | PTFE | 27 | 66.66 | | | | |
| | | CS | 38 | 65.36 | 2.99 | 4.36 | | 0.50 |
| | | IPC | 37 | 68.35 | | | | |
| Environment ^a | 14.03 | Autologous | 48 | 67.69 | -1.94 | 3.38 | 0.57 | |
| | | PTFE | 27 | 65.75 | | | | |
| | | CS | 37 | 65.09 | 3.75 | 3.24 | | 0.25 |
| | | IPC | 38 | 68.84 | | | | |
| Global QoL ^b | 0.69 | Autologous | 48 | 3.63 | -0.45 | 0.16 | 0.008 | |
| | | PTFE | 28 | 3.18 | | | | |
| | | CS | 38 | 3.38 | 0.17 | 0.16 | | 0.27 |
| | | IPC | 38 | 3.55 | | | | |

SE, standard error.

^aRange 0–100.^bRange 1–5.**Table V.** Estimated stratum and treatment effects on each of the four QoL domains, adjusted for one another, for the baseline level of the domain considered and for the time effect (results from mixed model analysis of variance)

| Domain | Contrast | Estimate | P value | 95% confidence interval | |
|-----------------------------------|---------------------|----------|---------|-------------------------|-------|
| | | | | Lower | Upper |
| Physical health ^a | Autologous–PTFE | 0.44 | 0.87 | -4.79 | 5.66 |
| | IPC–CS | -0.38 | 0.88 | -5.34 | 4.58 |
| Psychological health ^a | Autologous–PTFE | -1.15 | 0.60 | -5.55 | 3.25 |
| | IPC–CS | 0.16 | 0.94 | -3.95 | 4.26 |
| Social relationships ^a | Autologous–PTFE | 2.27 | 0.40 | -3.09 | 7.63 |
| | IPC–CS (autologous) | 2.03 | 0.53 | -4.44 | 8.51 |
| | IPC–CS (PTFE) | -10.74 | 0.015 | -19.33 | -2.16 |
| Environment ^a | Autologous–PTFE | 1.28 | 0.63 | -4.04 | 6.60 |
| | IPC–CS | -2.18 | 0.40 | -7.27 | 2.91 |

^aRange 0–100.

et al.⁵ showed that health status was affected in all domains, such as physical, social, emotional, and mental functioning, whereas QoL was mainly affected on the domain of Physical Health. They concluded that functioning (health status) and subjective appraisal of functioning (QoL) are different concepts and, therefore, instruments measuring health status may be misleading. A

functional limitation does not necessarily influence the patients' QoL. The results of the present study match this conclusion. QoL after surgery significantly improved, whereas significant results on other domains were lacking. This indicates that patients are relatively comfortable with their functioning in the different domains, even though health status seems to be affected.

Table VI. Adjusted mean changes from baseline of the four QoL domains as estimated from mixed model analysis of variance using a model similar to that used for the data shown in Table V

| Domain | Condition | Estimate | SE | P value | 95% confidence interval | |
|-----------------------------------|----------------|----------|------|---------|-------------------------|-------|
| | | | | | Lower | Upper |
| Physical health ^a | Autologous | 8.78 | 1.55 | <0.001 | 5.68 | 11.87 |
| | PTFE | 8.34 | 2.08 | <0.001 | 4.18 | 12.50 |
| | Day 14 | 7.18 | 1.46 | <0.001 | 4.27 | 10.10 |
| | Day 90 | 10.03 | 1.52 | <0.001 | 7.00 | 13.06 |
| | CS | 8.80 | 1.74 | <0.001 | 5.32 | 12.28 |
| | IPC | 8.42 | 1.76 | <0.001 | 4.89 | 11.94 |
| Psychological health ^a | Autologous | -1.42 | 1.29 | 0.27 | -4.00 | 1.15 |
| | PTFE | -0.28 | 1.74 | 0.88 | -3.75 | 3.20 |
| | Day 14 | -1.28 | 1.22 | 0.30 | -3.71 | 1.15 |
| | Day 90 | -0.68 | 1.14 | 0.55 | -2.96 | 1.60 |
| | CS | -1.06 | 1.44 | 0.47 | -3.93 | 1.82 |
| | IPC | -0.90 | 1.46 | 0.54 | -3.81 | 2.01 |
| Social relationships ^a | Autologous | -0.22 | 1.63 | 0.89 | -3.48 | 3.04 |
| | PTFE | -2.49 | 2.18 | 0.26 | -6.84 | 1.86 |
| | Day 14 | 0.04 | 1.47 | 0.98 | -2.90 | 2.97 |
| | Day 90 | -2.23 | 1.86 | 0.24 | -5.96 | 1.50 |
| | CS autologous | -1.23 | 2.36 | 0.60 | -5.95 | 3.49 |
| | CS PTFE | 2.88 | 2.83 | 0.31 | -2.76 | 8.53 |
| | IPC Autologous | 0.80 | 2.23 | 0.72 | -3.67 | 5.26 |
| Environment ^a | IPC PTFE | -7.86 | 3.28 | 0.019 | -14.41 | -1.31 |
| | Autologous | 3.04 | 1.57 | 0.057 | -0.10 | 6.17 |
| | PTFE | 1.76 | 2.14 | 0.41 | -2.52 | 6.03 |
| | Day 14 | 2.72 | 1.49 | 0.072 | -0.25 | 5.70 |
| | Day 90 | 2.36 | 1.50 | 0.12 | -0.65 | 5.37 |
| | CS | 3.63 | 1.80 | 0.047 | 0.05 | 7.21 |
| | IPC | 1.45 | 1.80 | 0.42 | -2.13 | 5.04 |

^aRange 0–100.

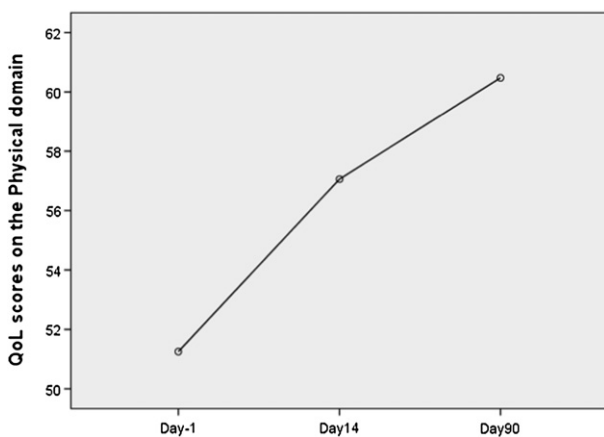


Fig. 2. Results of a multivariate analysis of variance of the domain of Physical Health regarding quality of life; $p < 0.001$.

The present study has a few limitations that could affect the generalizability of the results. Interpretation of QoL in clinical studies is hindered by several

factors, such as incompleteness of data. A bias mentioned regularly in QoL research in vascular surgery is that a large proportion of patients are lost to follow-up.^{12,27} In the present study, several questionnaires that were incompletely filled in were excluded: the WHOQOL-BREF instruction orders to include only those questionnaires in which the total number of items completed is greater than or equal to 80%.²⁰ Possibly, patients with the lowest QoL are overrepresented in the group of patients lost to follow-up. QoL reports may therefore very well hold out too beneficial an impression of improvement in QoL after revascularization.²⁷ Also, patients with very poor preoperative status benefit less from revascularizations.^{28,29}

Another factor we want to mention is called response shift.^{30,31} Response shift in QoL refers to a change in the meaning of a person's evaluation of his/her QoL as a result of factors such as changed internal standards and values and adaptation to illness. This factor makes this field of research extremely difficult because it affects the interpretation of QoL data. Ring et al.³⁰ mention

individualized measures of QoL where the patient selects the domains most important to their QoL.

Furthermore, other factors influencing QoL in the elderly population should not be overlooked. Patients' QoL is also influenced by comorbidity (i.e., joint symptoms of back, knee, and hip), and therefore, comorbidity should be taken into account.⁵

CONCLUSION

In this study, we have evaluated QoL before and after peripheral bypass surgery, and we have explored the relationship between QoL and revascularization-induced edema by using two treatment options.

This is, as far as we know, the first attempt to explore the effects of postrevascularization edema on patients' QoL. Differences in the amounts of edema between treatment groups were not significant at the time that QoL was measured. A correlation between the extent of postoperative edema and QoL was not detected. However, QoL improved as soon as 2 weeks after a peripheral bypass revascularization, regardless of type of bypass.

The vascular unit received an educational grant from Orthofix Vascular Novamedix, Andover, UK.

REFERENCES

- Rutherford RB, Baker JD, Ernst C, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg* 1997;26:517–38.
- Fallowfield L. *The Quality of Life: The Missing Measurement in Health Care*. Human Horizons Series. New York, NY: Souvenir Press, 1990. pp 234.
- The WHOQOL Group. Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychol Med* 1998;28:551–8.
- Saxena S, Orley J. Quality of life assessment: the world health organization perspective. *Eur Psychiatry* 1997;12(Suppl. 3): 263s–6.
- Breek JC, de Vries J, van Heck GL, et al. Assessment of disease impact in patients with intermittent claudication: discrepancy between health status and quality of life. *J Vasc Surg* 2005;41:443–50.
- Nelson CB, Lotfy M. The World Health Organization's WHOQOL-Bref Quality of life Assessment: Psychometric Qualities and Results of the International Field Trial. Geneva, Switzerland: World Health Organization, 1999. WHO (MNH/MHP/99.7).
- O'Carroll RE, Smith K, Couston M, et al. A comparison of the WHOQOL-100 and the WHOQOL-BREF in detecting change in quality of life following liver transplantation. *Qual Life Res* 2000;9:121–4.
- De Vries J, Van Heck GL. The World Health Organization Quality of Life assessment instrument (WHOQOL-100): validation of the Dutch version. *Eur J Physiol Assess* 1997;13:164–78.
- Huang IC, Wu AW, Frangakis C. Do the SF-36 and WHOQOL-BREF measure the same constructs? Evidence from the Taiwan population*. *Qual Life Res* 2006;15:15–24.
- Aquarius AE, Denollet J, Hamming JF, et al. Impaired health status and invasive treatment in peripheral arterial disease: a prospective 1-year follow-up study. *J Vasc Surg* 2005;41: 436–42.
- Engelhardt M, Bruijnen H, Scharmer C, et al. Prospective 2-years follow-up quality of life study after infrageniculate bypass surgery for limb salvage: lasting improvements only in nondiabetic patients. *Eur J Vasc Endovasc Surg* 2008;36:63–70.
- Nguyen LL, Moneta GL, Conte MS, et al. Prospective multi-center study of quality of life before and after lower extremity vein bypass in 1404 patients with critical limb ischemia. *J Vasc Surg* 2006;44:977–83. discussion 83–84.
- Porter JM, Lindell TD, Lakin PC. Leg edema following femoropopliteal autogenous vein bypass. *Arch Surg* 1972;105: 883–8.
- Cho S, Atwood JE. Peripheral edema. *Am J Med* 2002;113: 580–6.
- Stranks GJ, MacKenzie NA, Grover ML, et al. The A-V impulse system reduces deep-vein thrombosis and swelling after hemiarthroplasty for hip fracture. *J Bone Joint Surg Br* 1992;74:775–8.
- Gardner AM, Fox RH, Lawrence C, et al. Reduction of posttraumatic swelling and compartment pressure by impulse compression of the foot. *J Bone Joint Surg Br* 1990;72:810–5.
- te Slaa A, Dolmans DE, Ho GH, et al. Evaluation of A-V impulse technology as a treatment for oedema following polytetrafluoroethylene femoropopliteal surgery in a randomised controlled trial. *Eur J Vasc Endovasc Surg* 2010;40: 635–42.
- te Slaa A, Dolmans DE, Ho GH, et al. Prospective randomized controlled trial to analyze the effects of intermittent pneumatic compression on edema following autologous femoropopliteal bypass surgery. *World J Surg* 2010;35: 446–54.
- Mamode N, Scott RN. Graft type for femoro-popliteal bypass surgery. *Cochrane Database Syst Rev* 2000:CD001487.
- World Health Organization. WHOQOL-Bref: Introduction, Administration, Scoring and Assessment of the Generic Version—Field Trial Version. Geneva, Switzerland: World Health Organization, 1996.
- Hintenseher I, Saeger HD, Koch R, et al. Quality of life and long-term results after ruptured abdominal aortic aneurysm. *Eur J Vasc Endovasc Surg* 2004;28:262–9.
- Klinkert P, Post PN, Breslau PJ, et al. Saphenous vein versus PTFE for above-knee femoropopliteal bypass: a review of the literature. *Eur J Vasc Endovasc Surg* 2004;27:357–62.
- Morgan MB, Crayford T, Murrin B, et al. Developing the vascular quality of life questionnaire: a new disease-specific quality of life measure for use in lower limb ischemia. *J Vasc Surg* 2001;33:679–87.
- Aquarius AE, Denollet J, de Vries J, et al. Poor health-related quality of life in patients with peripheral arterial disease: type D personality and severity of peripheral arterial disease as independent predictors. *J Vasc Surg* 2007;46: 507–12.
- Aquarius AE, Denollet J, Hamming JF, et al. Type-D personality and ankle brachial index as predictors of impaired

- quality of life and depressive symptoms in peripheral arterial disease. *Arch Surg* 2007;142:662–7.
26. Hamming JF, De Vries J. Measuring quality of life. *Br J Surg* 2007;94:923–4.
 27. Chetter IC, Spark JI, Scott DJ, et al. Prospective analysis of quality of life in patients following infrainguinal reconstruction for chronic critical ischemia. *Br J Surg* 1998;85:951–5.
 28. Taylor SM, Kalbaugh CA, Blackhurst DW, et al. Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: an analysis of 553 consecutive patients. *J Vasc Surg* 2005;42:227–35.
 29. Taylor SM, Kalbaugh CA, Blackhurst DW, et al. Postoperative outcomes according to preoperative medical and functional status after infrainguinal revascularization for critical limb ischemia in patients 80 years and older. *Am Surg* 2005;71:640–5. discussion 5–6.
 30. Ring L, Hofer S, Heuston F, et al. Response shift masks the treatment impact on patient reported outcomes (PROs): the example of individual quality of life in edentulous patients. *Health Qual Life Outcomes* 2005;3:55.
 31. Postular D, Adang EM. Response shift and adaptation in chronically ill patients. *Med Decis Making* 2000;20:186–93.