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Original article

Long-term Results of a Randomized Trial of Stenting of the Superficial Femoral Artery for Intermittent Claudication.

Thordur Gunnarsson[1,2], Stefan Bergman[3,6], Håkan Pärsson[5], Anders Gottsäter[1,4], Hans Lindgren[1,2].

1. Faculty of Medicine, Lund University, 221 00 Lund, Sweden.
2. Department of Surgery, Helsingborg Hospital, 251 87 Helsingborg Sweden.
3. Primary Health Care Unit, Department of Public Health and Community Medicine, Institute of Medicine, The Sahlgrenska Academy, University of Gothenburg, Sweden.
4. Department of Medicine, Skåne University Hospital, 205 02 Malmö, Sweden.
5. Department of Biomedical and Clinical sciences, Faculty of Medicine, Linköping University, 581 83 Linköping Sweden.
6. Spenshult Research and Development Center, 302 74 Halmstad, Sweden.

Corresponding author: Thordur Gunnarsson, thordur.s.gunnarsson@gmail.com.

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Abstract:

Objectives: Primary stenting of the superficial femoral artery (SFA) in intermittent claudication (IC) increased health-related quality of life (HRQoL) after 12 and 24 months in this trial. We now present an extended follow-up of HRQoL 36 and 60 months after randomization.

Design: Multicenter randomized controlled trial conducted at seven vascular clinics in Sweden between 2010 and 2020. Registered at clinicaltrials.gov, ID: NCT01230229.

Materials: One hundred patients randomized to either primary stenting and best medical treatment (BMT) [n = 48] or BMT alone [n=52] followed for 60 months.

Methods: HRQoL assessed by the Short-Form 36 Health Survey (SF-36) and EuroQoL 5 dimensions (EQ5D) 36 and 60 months after randomization was the primary outcome. Walking Impairment Questionnaire (WIQ) score, reinterventions, progression to chronic limb threatening ischaemia (CLTI), amputation, and death were secondary outcomes.

Results: At 36 months follow-up the stent group (n = 32) had significantly better scores in the SF-36 domain Role Physical (RP, p = .023) and the Physical Component Summary (PCS, p = .032) compared to the control group (n = 30), however, there was no significant difference in EQ5D scores (p = .523). WIQ was significantly better in the stent group compared to the control group (p = .029) at 36 months. At 60 months follow-up no significant difference in HRQoL was seen between stent (n = 31) and control group (n = 32). Crossover from control to stent group was 25% at 60 months. There were no differences in progression to CLTI, amputation (2.1% vs 1.9%) or mortality (14.6% vs 15.4%) between groups.

5 year HRQoL after SFA stent treatment in IC patients.

Conclusions:

In patients with IC caused by isolated SFA lesions, primary stenting conferred benefits in HRQoL until 36 months from treatment compared with BMT alone, but these benefits were no longer detectable at 60 months where a high crossover rate affected the power of the final analysis.

Keywords:

Intermittent claudication

Superficial femoral artery

Stent treatment

Health-related quality of life

Long-term follow-up

What this paper adds:

This paper adds information regarding HRQoL 36 and 60 months after stent treatment of superficial femoral artery lesions in intermittent claudication patients. Long-term follow-up studies are rare in this patient group. The paper reports a remaining HRQoL benefit from primary stenting compared to patients receiving best medical treatment alone after 36 months, however there was no difference between groups after 60 months.

Introduction:

Intermittent claudication (IC) is a manifestation of peripheral arterial disease (PAD), presenting as muscle pain on mild exertion most commonly in the calf muscle during walking, with a prevalence of 6.5% in women and 7.2% men aged 60-90 years in Sweden(1). One important treatment goal in IC is to improve health-related quality of life (HRQoL), which is significantly lower in IC patients compared to healthy controls(2). Management of IC traditionally consists of risk factor modification and best medical treatment (BMT) with or without supervised exercise training (SET)(3) . Invasive treatment is recommended for patients with remaining severe IC after SET(4). Long-term patency of invasive treatment of suprainguinal lesions is excellent(5) and invasive treatment in these patients is commonly used. Invasive treatment of IC caused by infrainguinal lesions is more controversial, due to poor patency compared with invasive treatment of iliac artery disease(6). Several studies have reported improved patency with primary stenting compared to stenting bail-out strategy(6-8) with a primary patency of 90% and 69% at 1 and 5 year respectively(9). A Cochrane database meta-analysis(10) reported superior patency after 6 and 12 months for primary stenting compared to balloon angioplasty, however few trials included in the analysis had longer follow-up. Primary stenting is recommended for femoro-popliteal lesions in international guidelines(11). Limited evidence is present regarding long term results of HRQoL in IC patients treated invasively due to femoro-popliteal disease.

A randomized study in patients with stable IC due to superficial femoral artery (SFA) disease showed a significant increase in HRQoL measures and walking distance 12 and 24 months after randomization to SFA stenting in addition to BMT compared to BMT alone (12, 13). The aim of the present study was to assess HRQoL in these patients during continued follow-up until 36 and 60 months.

Materials and Methods:

The study was a multicenter randomized controlled trial conducted at seven vascular clinics in Sweden (Eskilstuna, Helsingborg, Kalmar, Kristianstad, Örebro University Hospital, Skåne University Hospital Malmö, and Växjö). Between 2010 and 2015, 310 patients were screened at the different clinics, out of which 100 patients were randomized on a 1:1 basis to either primary stenting or BMT alone. Enrolment and flow of patients in the trial are shown in Fig 1.

Inclusion criteria

Patients aged > 18 years with stable (i.e. > 6 months) IC (Fontaine IIb(14)) with absolute walking distance capacity < 500 meters measured by a standardized constant treadmill test (speed 3km/h, without incline), caused by de novo stenosis or restenosis of the SFA lesion (stenosis or occlusion) were included. The target segment was the full length of the SFA to the proximal limit of the popliteal artery not extending beyond 3 cm above the patella on magnetic resonance angiography (MRA) or computed tomography angiogram (CTA), TASC IIa-c(3). A patent popliteal and at least one patent non stenotic tibial runoff artery on the index side were required for inclusion in the study (12, 13).

Exclusion criteria

Patients with hemorrhagic stroke within the past 3 months, aneurysm of the SFA or popliteal artery, previously implanted stent(s) at the same site, or poor aorto-iliac or common femoral inflow were excluded. Patients with previous invasive correction of reduced proximal inflow 3 months prior to evaluation of eligibility were considered eligible for randomization. Patients with target artery diameter < 4.0 mm measured on MRA or CTA, chronic limb threatening ischemia

(CLTI) in the index leg, life expectancy of less than 24 months, or previous enrollment of the index or contralateral leg in this, or any other clinical trial were excluded.

Patient screening and randomization

Patients were screened and included in 2010-2015, 310 patients were screened out of whom 100 were randomized. Enrolment and flow of patients in the trial are shown in Fig 1. Randomization was carried out by Spenshult research and development center with sealed envelopes containing allocations to each study group. Treating physicians called an administrative officer at the research center after inclusion for the given study group allocation on a 1:1 basis. Medical professionals and study participants were not blinded to the group allocation. Stratification was performed with regard to short (≤90 mm) or long (> 90mm) lesions. Inclusion was stopped after 100 patients due to long inclusion time and the fact that minimum sample size had been reached.

Treatment procedures

Patients in both groups received instructions about regular exercise, antiplatelet (aspirin 75 mg/day or clopidogrel 75 mg/day) and lipid lowering drugs. Hypertensive patients were treated with antihypertensive drugs. Follow-up visits were performed at 1, 6, 12, and 24 months. In the absence of standardized program for SET in Sweden, patients received a pedometer and read-outs were recorded during each follow-up visit. Smokers were actively advised to quit smoking, with help from a smoking cessation unit if needed.

Stent treatment

Modern nitinol bare metal stents (BMS) designed for the SFA were selected by the treating physician from those available on the Swedish market. Stent diameter was chosen to be 1 mm larger than the reference vessel diameter. Stent length was chosen for complete coverage of the lesion with one stent if possible. If more than one stent was required, overlap (between 0.5 and 1 cm) was considered acceptable. Stents were placed to allow at least 5 mm of lesion free vessel at both ends. Post dilatation was performed with a standard angioplasty balloon shorter than the length and less than the diameter of the stent(s). A calibrated angiogram was made to compare pre- and post-implant minimum lumen diameters. The non-diseased artery diameters were measured, and the residual percent stenosis was calculated. Before crossing the lesion an intravenous heparin bolus of 5000 international units was administered. Stented patients were treated with either dual antiplatelet therapy (aspirin 75 mg and clopidogrel 75 mg daily) or in cases of ongoing anticoagulation treatment aspirin 75 mg was added daily during the first 12 weeks following stenting.

Follow-up

All patients were evaluated by a vascular surgeon, vascular physician, an interventional radiologist, or a research nurse at hospital outpatient visits 1, 6, 12, and 24 months after inclusion. At the visit, study related information and parameters were collected, including duplex assessment, measuring peak systolic velocity and peak velocity ratio (15), of stented lesions in patients randomized to stent treatment. Indications for reintervention were classified as clinical deterioration (IC or CLTI) or duplex finding. Follow-up HRQoL questionnaires were sent directly to patients by regular mail at 1, 6, 12, 24, 36, and 60 months after randomization.

Medical records were reviewed after 60 months, and all invasive vascular treatments, amputations, and other complications were recorded. Information regarding time and cause of death were retrieved from the Cause of Death Registry administered by the National Board of Health and Welfare in Sweden (http://socialstyrelsen.se/en).

Primary outcome measure

HRQoL assessment using the Short Form 36 Health Survey (SF-36, rating HRQoL 0-100 from worst to best in eight domains)(16) and EuroQol 5 dimensions (EQ5D, rating HRQoL 0 to 1 from worst to best)(17) were the primary outcome measures. SF-36 consists of eight domains (Physical Function [PF], Role Physical [RP], Bodily Pain [BP], General Health [GH], Vitality [VT], Social Function [SF], Role Emotional [RE], and Mental Health [MH]). From these eight domains, two linear combinations were computed: a Physical Component Summary (PCS), and a Mental Component Summary (MCS).

Secondary outcome measures

The Walking Impairment Questionnaire (WIQ, rating 0-100 from worst to best)(18) was used. Interventions or reinterventions on the included SFA lesion in the study patients were recorded and defined as target vessel (TV) interventions in the control group or either target lesion or TV reintervention in the stent group. Progression to CLTI, amputation, and mortality were also secondary outcomes.

Statistical analysis

The sample size was determined to study a clinically relevant difference between the two groups regarding the primary outcome variable, HRQoL. With significance level of 5% and with 50

patients in each group, a difference of 10 points in SF-36 domains PF and VT could be detected with a power of at least 80%, with a loss to follow-up of 10%, including crossovers, during a 24-month period. Comparison was performed at a 5% significance level based on two-sided test. Results are presented as 95% confidence intervals and p values. Differences in continuous variables between groups were analyzed using the intention to treat (ITT) principle. Intergroup comparisons were made using independent samples t test and paired t test for intragroup comparisons. Differences in binary outcomes were compared using the chi-squared test. Statistical analysis was performed with SPSS 26 software (IBM Corp, Armonk, NY, USA).

Ethical issues

The study was performed in accordance with the Declaration of Helsinki and the guidelines for conduct of clinical investigation as outlined in ISO 14-155. Written informed consent was obtained from all patients. The study was registered in the Clinical Trials database (NCT01230229) and approved by the Medical Ethics Committee of Lund University (Dnr 2009/478, 2013/822 and 2019-02641) and the Swedish Ethical Review Authority (Dnr 2021-01344).

Results:

Participant flow

Forty-eight patients were randomized to the stent group and 52 patients to the control group (Fig 1). HRQoL questionnaire answers were received from 63 patients at both 36 and 60 months. Twelve patients died during the study period and 25 did not return the questionnaires (Fig 1). All medical patient files were retrieved and reviewed.

Baseline data

Background variables such as age, sex, smoking habits, blood pressure, LDL-cholesterol, duration of IC (Table 1)(13), lesion characteristics (except lesion length which was longer in the stent group), and HRQoL at baseline did not differ between groups (Table 2).

Primary outcome measure at 36 and 60 months

In intergroup comparison at 36 months the stent group had significantly better SF-36 RP score ($p = .023$) and PCS ($p = .032$) compared with the control group (table 2). SF-36 scores in remaining domains were numerically higher in the stent group but the difference was not statistically significant. After 60 months, there were no longer any significant differences in SF-36 domain scores between groups. EQ5D scores were 0.63 and 0.58 in the stent and control groups respectively ($p = .523$) after 36 months, and 0.64 and 0.59 after 60 months ($p = .508$).

In intragroup comparisons, the scores in SF-36 domains PF ($p = .012$), RP ($p = .013$), BP ($p = .007$), and PCS ($p = .016$) 36 months from randomization, and BP ($p = .044$) after 60 months were significantly improved in the stent group, whereas no primary outcome measure had

improved in the control group after 36 and 60 months (Supplementary table 1). EQ5D scores were unchanged after 36 or 60 months in both groups (Supplementary table 1).

Secondary outcomes

WIQ was significantly better in the stent group compared to the control group (p = .029) after 36 months, whereas after 60 months this difference was no longer significant (p = .40) (Table 2). In intragroup comparisons, the WIQ scores at both 36 (p = .007) and 60 months (p = .025) had improved significantly in the stent group. In the control group, WIQ score was unchanged at 36 months, but had improved significantly at 60 months (p = .005) (Supplementary table 1).

Fourteen patients in the control group received stent treatment of the included SFA lesion during the study period due to progress to either disabling IC (10 patients) or CLTI (4 patients) with a median time from randomization to crossover of 19 (IQR 13 - 41) months. Six reinterventions on the included TV were subsequently performed in these 14 patients. Seventeen TV reinterventions were performed in the stent group, of which two were due to progression to CLTI, eight to worsening IC, and seven to significant in-stent restenosis on duplex ultrasound. Two patients underwent amputation, one in each group. Five-year mortality was 14.6% and 15.4% (p = .991) in the stent and control groups respectively. The most common cause of death was ischemic heart disease, no deaths were related to TV reinterventions.

Discussion:

In this randomized controlled study comparing patients with stable IC due to lesions in the SFA treated with either primary stenting in combination with BMT or BMT alone, patients in the stent group reported significant improvement in the primary outcome measure, HRQoL, compared to BMT alone after 12 and 24 months as previously reported (12, 13). This extended follow-up demonstrated improved HRQoL also at 36 months in the physical SF-36 measures RP and PCS, and WIQ. At 60 months no significant differences in HRQoL scores were detectable in intergroup comparison. However, in intragroup comparison among stented patients the SF-36 measures PF, RP, BP, and PCS were improved at 36 months after randomization and one SF-36 domain (BP) was improved at 60 months, whereas in the control group no primary outcome measure was improved at 36 and 60 months.

No difference was seen in terms of progression to CLTI, amputation rate, or mortality between the two treatment groups, whereas the need for reintervention was higher in the stent group. This might partly be due to study design; the stent group underwent duplex surveillance of stents for 24 months which might have caused reintervention bias.

Follow-up studies beyond 12 or 24 months on patients with IC are rare. Extended 5-year follow-up of the IRONIC trial(19) comparing BMT and revascularization and the ERASE study(20, 21) comparing SET versus SET combined with revascularization reported that the initial benefits of revascularization seen at 12 and 24 months in the IRONIC trial(19) and 12 months in the ERASE study(20-22) were no longer present after 5 years. However, these studies included both aortoiliac and femoropopliteal lesions whereas only patients with SFA lesions were included in our trial. These studies report similar rates of progression to CLTI, around 1 in 20 patients, 2-3

fold higher reintervention rates in the revascularized groups, and similar losses to follow-up at 5 years(19-22). Although these studies provide valuable information regarding long-term results after revascularization of lesions causing IC, it was unclear at what time the initial positive effect of revascularization disappeared. Our study showed positive effects of stent treatment of SFA lesions on HRQoL at 36 and 60 months, although not to the same extent as at 12 and 24 months(12, 13). Our findings in IC due to SFA lesions extend the results from the two previous RCT in IC due to both supra- and infrainguinal lesions (19, 20, 22): HRQoL and walking distance benefits for up to 3 years with no added risk of progression to CLTI, death, or amputation, whereas both the patient and physician need to be prepared for adjuvant interventions. Patients with IC are generally elderly and have a 40% mortality rate during 8 years after intervention(23), such increased HRQoL during three to five years might be valuable for patients even if it is transient and does not persist for the rest of their life(24).

The economic burden of IC and invasive procedures is increasing (25). A cost-effectiveness analysis of this RCT after 24 months (26) showed a mean benefit of 0.24-0.26 quality adjusted life years (QALY) in stented patients, at a cost of about € 24,000-34,000 per QALY. The national guidelines of the Swedish National Board of Health and Welfare have suggested a threshold of € 50,000 for medical technologies to be considered acceptable(27), whereas the UK´s National Institute for Health and Care Excellence (NICE) advices a lower cost-effectiveness threshold ranging between € 22,000 and € 33,900 (28). In a 5-year cost-effectiveness analysis from the IRONIC trial the treatment was not cost effective irrespective of the applied threshold (19). In our present study, no cost-effectiveness analysis has been performed after 36 or 60 months.

This study has some limitations. First, as it was originally designed to detect differences in the primary outcome at 24 months with an expected 10% loss to follow-up, both the prolonged follow-up and additional loss of patients at 36 and 60 months and the 25% crossover from the control group to stent at 60 months negatively affected the power of the analysis. In future trials of invasive treatment of IC, crossover and loss to follow-up need to be taken into account. As the study was analyzed with the intention to treat principle, the high crossover rate at 60 months renders the study unpowered to detect differences between the study groups at this time point, which could potentially explain the lack of difference between the groups. Most physical SF-36 domains as well as WIQ had increased numerically in the control group at 60 months compared to baseline, although only the WIQ increase was statistically significant. The lack of difference between groups at 60 months could therefore be due not only to a loss of effect of stent treatment but also to crossovers in the control group. Many other factors than walking capacity affect HRQoL, and other reasons for the increase in HRQoL in the control group at 60 months could be survival or response bias as participants with high morbidity and low HRQoL either passed away or did not answer the questionnaires. Another limitation during extended follow-up of this trial was the lack of objective measures like ABI, absolute walking distance by treadmill test, and duplex at 36 and 60 months. It is also worth acknowledging the large number of comparisons in our trial, which might have increased the risk of rejecting a true null hypothesis. However, we interpret the trial results in favor of stent treatment for at least 36 months for physical HRQoL measures for the intermittent claudication patient. The trial does not give robust evidence for a lasting effect of stenting until 60 months, but a transient period of improved HRQoL might be valuable for an elderly vascular patient. This trial provides information relevant when presenting treatment options for patients as well as for health authorities.

303 Conclusion:

304 In patients with IC caused by isolated SFA lesions, primary stenting conferred benefits in
305 HRQoL until 36 months from treatment compared with BMT alone, but these benefits were no
306 longer detectable at 60 months where a high crossover rate of 25% affected the power of the
307 final analysis.

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Conflict of interest:

Hans Lindgren has received compensation according to a proctoring and training agreement with ev3 Nordic AB and William Cook Europe ApS. These sponsors were not involved in any part of the study. The study was conducted without sponsoring from any medical device company.

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Consulting statistician Axel Ström, MSc, Clinical Studies Sweden.

5 year HRQoL after SFA stent treatment in IC patients.

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Table 1. Baseline demographic data and lesion characteristics in 100 patients with intermittent claudication randomized to primary stenting or best medical treatment only (control group). Mean (SD) or n (%). Table is adapted from previously published trial results, Lindgren et al (12)

	Stent (n=45)	Control (n=49)	P value
Age (years)	71.3 (5.3)	69.8 (5.8)	.184
Sex			
Male	22	28	.540
Female	23	21	
ABI	0.58 (.12)	0.63 (.17)	.129
Walking distance (m	178 (87.3)	210 (107.4)	.114
Duration of IC (months)	30 (29.3)	41 (48.3)	.179
Smoking			.125
Yes (n)	7	11	
Former (n)	26	32	
Never (n)	12	5	
LDL (mmol/l)	2.75 (1.1)	2.55 (0.9)	.374
B-glucose (mmol/l)	7.0 (2.8)	6.3 (2.1)	.207
Systolic BP (mmHg)	155 (21.7)	150 (20.7)	.282
Diastolic BP (mmHg)	80 (11.)	79 (8.8)	.831
S-creatinine (µmol/l)	84 (24.5)	82 (21.9)	.653
Lesion length (mm)	145 (91)	103 (97)	.021
Occlusion (n)	31	36	.654
Stenosis (n)	14	13	NS
Degree of stenosis (%)	81.7 (16.3)	91.5 (3.1)	.065
No crural vessels (n)	2.5 (0.6)	2.3 (0.7)	.219

B = blood, P = plasma, S = serum, BP = blood pressure, IC = intermittent claudication, LDL = low-density lipoprotein, ABI = ankle-brachial index.

Table 2. Baseline, 36- and 60-month levels of primary (SF-36 and EQ5D) and secondary (WIQ) outcome variables in 100 patients with intermittent claudication randomized to primary stenting or best medical treatment only. Mean (SD), p-values comparing groups.

	Baseline			36 mo			60 mo		
	Stent (n = 45)	Control (n = 49)	p	Stent (n = 33)	Control (n = 30*)	p	Stent (n = 31)	Control (n = 32**)	P
PF	43 (17)	43 (17)	.972	60 (23)	48 (24)	.065	52 (26)	54 (26)	.730
RP	41 (39)	43 (41)	.731	62 (40)	38 (38)	.023	38 (40)	44 (42)	.570
BP	40 (17)	38 (17)	.734	55 (26)	48 (23)	.258	51 (25)	49 (27)	.702
GH	54 (17)	52 (20)	.867	59 (22)	51 (20)	.166	55 (23)	50 (25)	.411
VT	49 (22)	50 (23)	.686	58 (25)	51 (25)	.253	56 (22)	51 (25)	.432
SF	74 (23)	72 (30)	.648	83 (23)	81 (26)	.859	76 (25)	73 (26)	.723
RE	54 (44)	58 (44)	.801	70 (36)	52 (47)	.096	52 (45)	58 (45)	.574
MH	72 (21)	72 (24)	.861	79 (20)	75 (25)	.503	78 (20)	73 (21)	.421
PCS	31 (8)	31 (7)	.912	38 (11)	33 (8)	.032	34 (11)	32 (11)	.961
MCS	48 (12)	49 (14)	.646	50 (10)	49 (13)	.691	48 (12)	47 (12)	.747
EQ5D	0.56 (0.27)	0.46 (0.31)	.121	0.63 (0.27)	0.58 (0.31)	.523	0.64 (0.23)	0.59 (0.32)	.508
WIQ	40 (18)	35 (18)	.175	62 (27)	46 (27)	.029	56 (27)	50 (24)	.404

Short Form 36 Health Survey (SF-36), rating HRQoL 0-100 from worst to best in eight domains (Physical Function [PF], Role Physical [RP], Bodily Pain [PB], General Health [GH], Vitality [VT], Social Function [SF], Role Emotional [RE], Mental Health [MH]), Physical Component Summary (PCS), Mental Component Summary (MCS), EuroQoL 5-dimensions (EQ5D, rating health-related quality of life states 0-1 from worst to best), and Walking Impairment Questionnaire (WIQ, rating 0-100 from worst to best). * At 36- and 60-month follow-up 6 and 8 patients respectively in the control group had undergone stenting of the included target vessel.

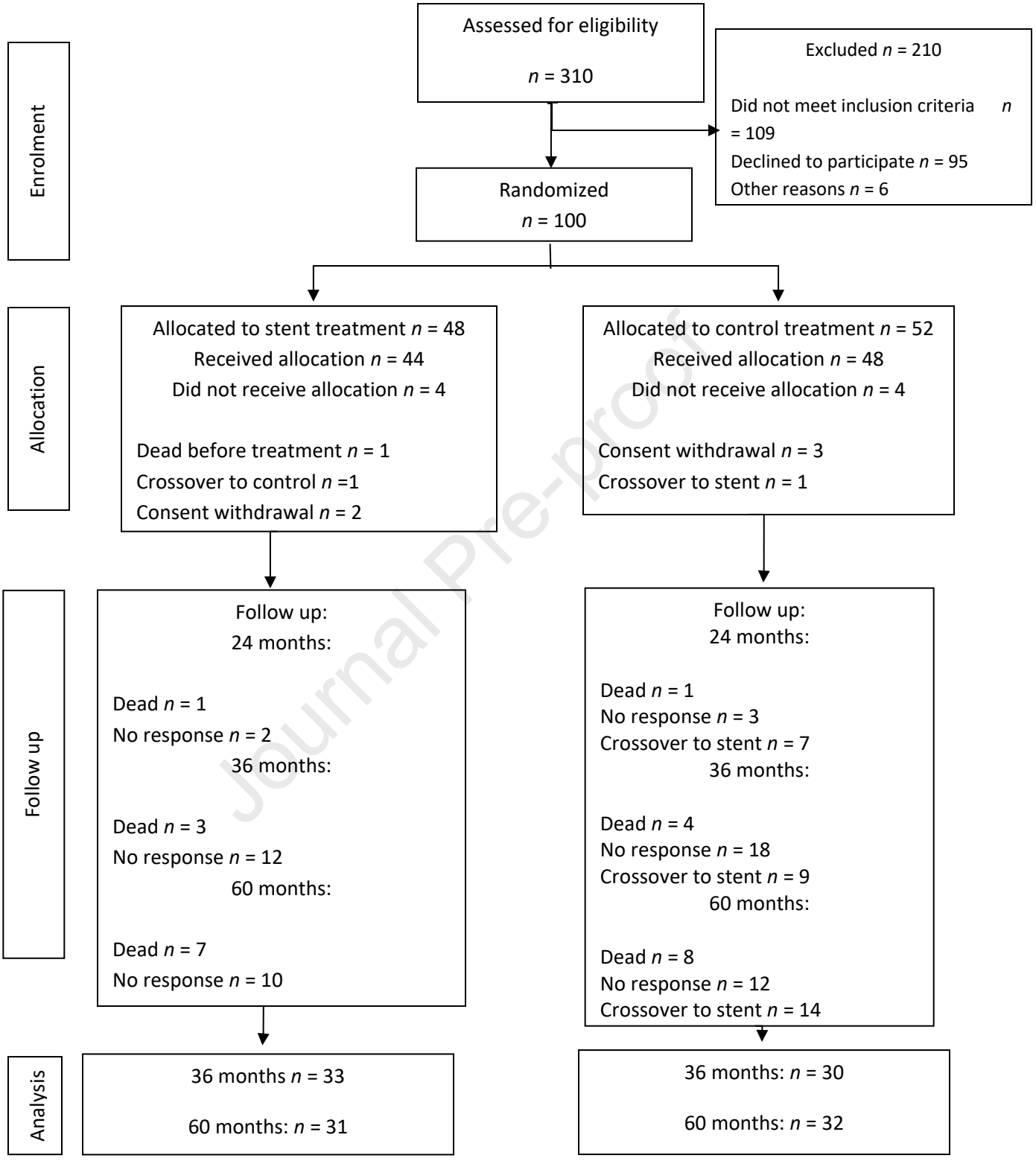
Supplement table.

Table S1. Mean change in primary (SF-36 and EQ5D) and secondary (WIQ) outcome variables in 100 patients with intermittent claudication randomized to primary stenting or best medical treatment only after 36- and 60-months. P-values compared to baseline. Intragroup comparisons.

	Stent group 0 vs 36 mo (n = 33)		Control group 0 vs 36 mo (n = 30*)		Stent group 0 vs 60 mo (n = 31)		Control group 0 vs 60 mo (n = 32*)	
	Mean change (95% CI)	P	Mean change (95% CI)	P	Mean change (95% CI)	P	Mean change (95% CI)	P
PF	11.1 (2.7- 19.5)	.012	1.6 (-7.1 - 10.4)	.704	6.9 (-1.7 – 15.4)	.112	7.3 (-1.7 – 16.3)	.110
RP	13.7 (3.2 - 24.3)	.013	-9.5 (-24.8 - 5.8)	.216	-4.6 (-18.6 – 9.3)	.503	1.1 (-12.4 – 14.7)	.868
BP	13.0 (3.7 - 22.3)	.007	6.6 (-2.4 - 15.6)	.145	10.2 (0.3 – 20.0)	.044	8.7 (-0.9 – 18.2)	.074
GH	1.8 (-4.9 - 8.4)	.594	-2.6 (-10.2 - 4.9)	.457	1.0 (-5.5 – 7.4)	.760	-0.2 (-7.2 – 6.7)	.950
VT	2.6 (-4.5 - 9.7)	.460	-0.2 (-7.9 - 7.4)	.951	5.2 (-1.4 – 11.8)	.120	-0.2 (-9.4 – 9.0)	.962
SF	2.7 (-5.0 - 10.5)	.477	5.2 (-4.0 - 14.4)	.260	1.3 (-7.4 – 10.0)	.771	-0.4 (-11.0 – 10.2)	.940
RE	9.7 (-8.0 - 27.3)	.271	-5.9 (-24.6 - 12.7)	.518	-4.8 (-26.0 – 16.6)	.650	0.0 (-15.0 – 15.0)	1.0
MH	2.56 (-4.2 - 9.3)	.444	-0.1 (-5.6 - 5.4)	.959	3.8 (-3.3 – 11.0)	.279	-2.9 (-10.0 – 4.2)	.411
PCS	4.1 (0.8 - 7.4)	.016	-0.7 (-3.7 - 2.3)	.654	1.0 (-3.0 – 5.1)	.609	2.3 (-1.6 – 6.2)	.236
MCS	1.2 (-3.5 - 5.9)	.604	0.36 (-4.2 - 4.9)	.871	0.1 (-5.6 – 5.8)	.977	-1.5 (-6.0 – 3.0)	.505
EQ5D	0.05 (-0.07 - 0.16)	.396	0.10 (-0.03 - 0.23)	.114	0.07 (-0.06 – 0.20)	.265	0.11 (-0.0.1 – 0.23)	.780
WIQ	15.2 (4.5 - 25.9)	.007	7.9 (-1.5 - 17.4)	.097	13.5 (1.9 – 25.2)	.025	13.3 (4.7 – 22.2)	.005

Short Form 36 Health Survey (SF-36), rating HRQoL 0-100 from worst to best in eight domains (Physical Function [PF], Role Physical [RP], Bodily Pain [PB], General Health [GH], Vitality [VT], Social Function [SF], Role Emotional [RE], Mental Health [MH]), Physical Component Summary (PCS), Mental Component Summary (MCS), EuroQoL 5-dimensions (EQ5D, rating health-related quality of life states 0-1 from worst to best), and Walking Impairment Questionnaire (WIQ, rating 0-100 from worst to best). * At 36- and 60-month follow-up 6 and 8 patients respectively in the control group had undergone stenting of the included target vessel.

Table 4 has been deleted as it is previously published, and we refer to this publication in the manuscript.



Short title:

Five Year HRQoL After SFA Stenting in Patients with IC

Figure:

Figure 1 is a CONSORT flowchart. Please follow the guidance on page D of the instructions document (similar to the PRISMA layout).

Supplementary material:

Supplementary Table S1