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Review

Objective performance goals after open and endovascular intervention for critical limb ischaemia

A systematic review with a meta-analysis

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Summary: *Background:* Whether current real-world treatment of critical limb ischemia with lower extremity bypass (LEB) or infrainguinal endovascular intervention (IEI) meets the Society for Vascular Surgery objective performance goals (OPG) was investigated. *Materials and methods:* Literature search in PubMed, studies from 2010 to March 2021. A total of 35,981 endovascular interventions were reported in 82 publications and 26,707 open procedures in 49 publications. *Results:* Perioperative major adverse limb events was 8% (OPG) versus 9% for IEI and 10% for LEB (no significant differences). Perioperative major adverse cardiovascular events was significantly better with IEI (4%; $p < .001$) and LEB (6%; $p = .018$) than the OPG (8%). After 1 year, amputation-free survival (AFS) was 76.5% (OPG), compared to 71% with IEI ($p = .932$) and 77% with LEB ($p = .006$) and patient survival was 85.7% (OPG) compared to 84% (LEB; $p = .006$) and 78% (IEI; $p = .102$). 5-year survival was 51% with LEB and 45% with IEI ($p = .320$), and AFS was 44% with LEB and 46% with IEI ($p = .802$). 5-year OPGs were not reported. *Conclusions:* In the studies analysed, the results after IEI and LEB largely corresponded to the OPGs. 5-year outcomes after LEB and IEI did not differ significantly.

Keywords: objective performance goals (OPG), critical limb ischemia (CLI), infrainguinal endovascular intervention (IEI), lower extremity bypass surgery (LEB)

Introduction

Conte et al [1] developed a set of suggested objective performance goals (OPG) for evaluating new catheter-based treatments in critical limb ischemia (CLI), based on evidence from historical controls with lower extremity bypass surgery (LEB). The work was funded by the Society for Vascular Surgery (SVS). The OPGs provide benchmarks by which the performance of endovascular interventions and other treatment modalities can be measured. Goodney et al [2] could achieve these targets in everyday vascular surgery practice. In the meantime, the development of endovascular techniques has made significant progress, and it remains an open question to what extent these benchmarks are still valid today and whether they are better achieved with endovascular or open interventions and for which indications. Whether current real-world treatment of CLI meets the benchmarks recommended by the SVS OPGs was studied by Robinson et al [3] in a cohort of 11,043 revascularizations for CLI performed from 2011 to 2015 in the National Surgical Quality Improvement Program (NSQIP). In this study, LEB and infrainguinal endovascular intervention (IEI) for CLI failed to meet SVS OPG limb-related 30-day safety benchmarks for the entire CLI cohort as well as for the patients at high anatomical risk (infrapopliteal anatomy). The NSQIP database was also utilised by Latz, Wang et al [4] to evaluate whether IEI for CLI have improved in 2015–2018 compared to earlier years (2011–2014) regarding 30-day major adverse limb events (MALE), major adverse cardiovascular events (MACE) and major amputation, and to compare these outcomes to the OPG thresholds. In this study, outcomes following endovascular interventions for CLI continued to underperform when compared to OPG benchmarks for MALE and amputations. Given the uncertainties regarding the choice of treatment procedure (IEI or LEB) in patients with CLI or Chronic Limb-Threatening Ischaemia (CLTI) and infrainguinal lesions, despite recent randomised studies (Farber et al [5]; Bradbury et al [6]), this systematic review with a meta-analysis aims to examine which OPGs have been achieved with endovascular and open revascularization in CLI over the last 10 years. The aim was to go beyond the analysis by Conte et al [1],

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which only reported perioperative and 1-year results, and compare in addition the long-term outcomes after IEI and LEB.

Materials and methods

This paper is based on literature search in PubMed. We searched for studies from 2010 to the cut-off date 22 March 2021 under the keyword critical limb ischemia [Title] and endovascular intervention or lower extremity bypass. There were 1,113 papers whose eligibility was assessed for presentation of outcomes with endovascular and open revascularization in patients with CLI (Rutherford category 4 to 6; PRISMA flow chart, Figure 1). Only articles published in English language with an available abstract, full text and a minimum of 10 cases were included. Articles had to differentiate between IEI and LEB procedures in all follow up periods. Papers that reported on a composite patient population of CLI and intermittent claudication (IC) were excluded. Papers reporting on *CLTI* and hybrid procedures were excluded.

The included publications (n = 106) consisted of 21 prospective and 85 retrospective studies. The prospective studies included 4 randomised controlled studies and 14 uncontrolled studies. Of the 21 prospective studies, 18 focussed on endovascular interventions only and three on endovascular and open procedures. Of the 85 retrospective studies, 40 included only endovascular interventions, 21 endovascular and open procedures and 24 only open procedures.

Statistical analysis

The statistical analysis of the data was conducted using the software R (Version 2023.06.2+561). For the random effects meta-analysis, the R-packages 'meta' and 'metafor' were employed, using the inverse variance method for pooling the studies and the restricted maximum likelihood estimator for the between study variance. The results of the meta-analysis were visualised by creating forest plots to show the effect sizes and their confidence intervals. To visualise and test publication bias, funnel plots were created and tested for funnel-plot asymmetry using Egger's test. In the case of a significant result in the Eggers test, the trim-and-fill method of Duval & Tweedie [7] was applied. The corrected results of this method were compared with the previous results. The confidence intervals overlapped in all cases. The results using the trim and fill method were again tested for funnel-plot asymmetry. In all cases, the results were not significant, which largely rules out a publication bias.

To analyse the differences between the groups, t-tests were conducted. A two-sample t-test was used to compare the mean values of LEB and IEI. Additionally, a one-sample t-test was used to compare the mean values of

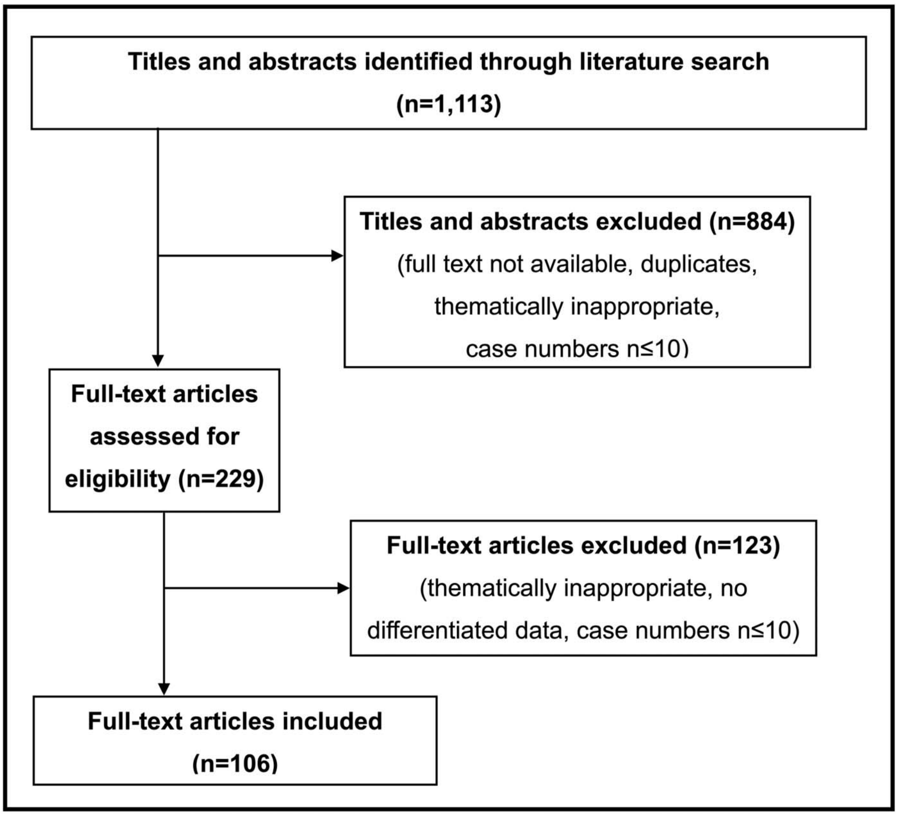

Figure 1. PRISMA flow chart for article selection.

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Table I. Number of procedures and studies for IEI (n = 35,981) and LEB (n = 26,707) depending on the location of the intervention

	IEI		LEB	
Location of the interventions	Procedures	Studies	Procedures	Studies
Procedures above the knee n = 21,958	n = 10,358	n = 29	n = 11,600	n = 20
Procedures below the knee n = 25,765	n = 17,090	n = 68	n = 8,675	n = 38
Combined procedures above and below the knee n = 9,689	n = 4,945	n = 16	n = 4,744	n = 10
Procedures at the level of the knee or infrainguinal without more detailed location information n = 5,276	n = 3,588	n = 12	n = 1,688	n = 9
Total amount: n = 62.688	**n = 35,981**	**n = 82**	**n = 26,707**	**n = 49**

Notes. IEI: infrainguinal endovascular intervention; LEB: lower extremity bypass surgery.

Table II. Number of procedures and studies on which the data of the outcome parameters (MALE, major amputation, MACE, survival) for the respective follow-up periods are based

	IEI		LEB	
Follow-up periods with associated outcome parameters	Procedures	Studies	Procedures	Studies
Perioperative (up to 30 days)				
MALE	n = 16,600	n = 17	n = 17,627	n = 14
Major amputation	n = 18,735	n = 23	n = 18,391	n = 17
MACE	n = 16,534	n = 17	n = 17,323	n = 12
Survival	n = 13,579	n = 27	n = 16,852	n = 20
Up to 1 year				
AFS	n = 10,813	n = 40	n = 5,623	n = 26
Survival	n = 16,875	n = 59	n = 7,064	n = 30
Up to 3 years				
AFS	n = 6,809	n = 21	n = 3,151	n = 21
Survival	n = 9,415	n = 27	n = 3,037	n = 22
Up to 5 years				
AFS	n = 5,964	n = 14	n = 3,389	n = 12
Survival	n = 6,706	n = 16	n = 2,921	n = 12

Notes. AFS: amputation-free survival; IEI: infrainguinal endovascular intervention; LEB: lower extremity bypass surgery; MACE: major adverse cardiovascular events; MALE: major adverse limb events.

LEB and IEI with those of the OPGs. P-values less than 5% were considered significant.

Performed procedures

A total of 35,981 endovascular procedures were reported in 82 publications and 26,707 open procedures in 49 publications. The localisation of the procedures and the number of reporting studies can be found in Table I.

Infrainguinal endovascular intervention (IEI)

A total of 14,321 procedures were performed using plain old balloon angioplasty, 1,938 procedures using percutaneous transluminal angioplasty (PTA) + stent, 1,045 procedures using stents alone and 1,009 procedures using atherectomy. Drug-coated balloons were used in 1,408 procedures and drug-eluting stents in 728 procedures. The mixed cohort, which contained no differentiated information regarding PTA + atherectomy, PTA ± stent, and/or atherectomy ± stent and/or no information on the numbers for the endovascular procedures, includes 16,184 interventions.

Lower extremity bypass (LEB)

A total of 19,298 procedures were performed using autologous vein graft bypasses, 4,321 procedures using bypasses with prosthetic grafts and 2,936 procedures using unspecified bypasses. Thromboendarterectomy (TEA) was performed in 152 procedures.

Follow-up periods and number of procedures for outcome parameters

The number of procedures and studies on which the data for the outcome parameters (MALE, major amputation, MACE, survival) and respective follow-up periods are based can be found in Table II. As can be seen, the number of interventions recorded decreased significantly with increasing duration of follow-up. While perioperative survival for endovascular interventions was reported for 13,579 interventions, this was the case for survival after 3 years for only 9,415 interventions. The same was observed for the open procedures, with data on perioperative survival for 16,852 interventions versus data on survival after 3 years for 3,037 procedures.

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Table III. Perioperative and 1-year results of the overall cohort of IEI and LEB (infrainguinal above and below the knee combined) compared to the results of Conte et al. (2009)

	IEI	LEB	Conte	OPG	*p* IEI versus OPG	*p* LEB versus OPG
MALE: perioperative in % (95%-CI)	9 (7–13)	10 (7–14)	6.1	8	.349	.336
Major amputation: perioperative in % (95%-CI)	5 (3–7)	4 (3–6)	1.9	3	.009	.107
MACE: perioperative in % (95%-CI)	4 (3–5)	6 (5–8)	6.2	8	<.001	.018
Survival: perioperative in % (95%-CI)	96 (95–97)	97 (95–98)	97.3	–	–	–
AFS: 1 year in % (95%-CI)	71 (67–75)	77 (73–81)	76.5	71	.932	.006
Survival: 1 year in % (95%-CI)	78 (74–80)	84 (81–87)	85.7	80	.102	.006

Notes. AFS: amputation-free survival; CI: confidence interval; IEI: infrainguinal endovascular intervention; LEB: lower extremity bypass surgery; MACE: major adverse cardiovascular event; MALE: major adverse limb event; OPG: objective performance goal.

Results

Perioperative and 1-year outcomes of the OPGs

The perioperative outcomes for MALE, major amputation, MACE and survival for IEI and LEB can be found in Table III. The perioperative period was defined as 30 days from index procedure. For comparison, the results from Conte et al [1] are also included. The OPGs represent the upper limit of the 95% confidence interval in the study of Conte et al.

The perioperative OPGs were significantly undercut for MACE (OPG: 8%) which applied to both IEI and LEB (IEI: 4% $p < .001$, LEB: 6% $p = .018$). In contrast, the OPG for MALE (8%) was slightly higher in LEB with 10% ($p = .336$) and 9% in IEI ($p = .349$). In IEI patients the OPG for major amputation (3%) was not met (IEI: 5%, $p = .009$). This was also the case for LEB patients (4%, $p = .107$) Survival after 1 year was 78% (IEI) and 84% (LEB), respectively. Survival in LEB was significantly better ($p = .006$) than the OPG of 80%. Table III also shows the amputation-free survival (AFS) after 1 year. The AFS was also significantly better for LEB (77%) than the OPG (71%) after 1 year ($p = .006$).

OPGs of the anatomical high-risk group

Table IV shows the perioperative and 1-year outcomes for the infrapopliteal revascularization described by Conte et al [1] as an anatomical high-risk group. The perioperative OPG for MALE (9%) was undercut by IEI with 5% ($p = .128$) while MALE in LEB (12%) was significantly higher than the OPG ($p = .033$). Major amputation (OPG 4%) was lower for both IEI (2%) and LEB (3%), with the difference being significant only for IEI ($p = .013$). In contrast, MACE was significantly lower than the OPG (10%) in both IEI (3%) and LEB (6%; IEI $p = .045$, LEB $p = .029$).

Regarding survival and AFS at 1 year, there were no differences between IEI or LEB and the OPG (Table IV).

Results for IEI versus LEB

LEB and IEI did not differ in perioperative mortality, MALE and major amputation (Table V). However, perioperative MACE was significantly ($p = .018$) higher in LEB (6%) than in IEI (4%). The results of the long-term follow-up can also be found in Table V. There were no significant differences in AFS between IEI and LEB. However, patient survival at 1 year was significantly better with LEB than with IEI at 84% versus 78% ($p < .001$) and at 3 years at 66% versus 58% ($p = .005$). Survival after three years is shown in forest plots (Electronic supplementary material 1, Figure E1 and Figure E2 [ESM 1]). In the anatomical high-risk group (Table V), perioperative MALE was significantly ($p = .026$) lower in IEI (5%) than in LEB (12%). In all other parameters, IEI and LEB did not differ significantly.

Discussion

In this systematic review with a meta-analysis, publications from 2010 to 2021 on the endovascular and open

Table IV. Perioperative and 1-year outcomes of IEI and LEB in below-the-knee procedures (anatomical high-risk group) compared to the results of Conte et al. (2009)

	IEI	LEB	Conte	OPG	*p* IEI versus OPG	*p* LEB versus OPG
MALE: perioperative in % (95%-CI)	5 (2–11)	12 (9–16)	6.1	9	.128	.033
Major amputation: perioperative in % (95%-CI)	2 (1–3)	3 (1–6)	2.2	4	.013	.280
MACE: perioperative in % (95%-CI)	3 (1–10)	6 (4–10)	7.3	10	.045	.029
Survival: perioperative in % (95%-CI)	97 (95–99)	96 (93–98)	97.2	–	–	–
AFS: 1 year in % (95%-CI)	68 (60–74)	75 (68–81)	74.4	68	.905	.054
Survival: 1 year in % (95%-CI)	82 (78–85)	84 (78–88)	85.9	80	.335	.155

Notes. AFS: amputation-free survival; CI: confidence interval; IEI: infrainguinal endovascular intervention; LEB: lower extremity bypass surgery; MALE: major adverse limb event; MACE: major adverse cardiovascular event; OPG: objective performance goal.

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Table V. Comparison between IEI and LEB

	IEI	LEB	p
Overall cohort (infrainguinal above and below the knee combined)			
MALE: perioperative in % (95%-CI)	9 (7–13)	10 (7–14)	.932
Major amputation: perioperative in % (95%-CI)	5 (3–7)	4 (3–6)	.558
MACE: perioperative in % (95%-CI)	4 (3–5)	6 (5–8)	.018
Survival: perioperative in % (95%-CI)	96 (95–97)	97 (95–98)	.744
AFS: 1 year in % (95%-CI)	71 (67–75)	77 (73–81)	.055
AFS: 3 years in % (95%-CI)	52 (45–60)	56 (50–62)	.499
AFS: 5 years in % (95%-CI)	46 (36–57)	44 (38–51)	.802
Survival: 1 year in % (95%-CI)	78 (74–80)	84 (81–87)	<.001
Survival: 3 years in % (95%-CI)	58 (54–61)	66 (61–70)	.005
Survival: 5 years in % (95%-CI)	45 (41–50)	51 (41–61)	.320
Patients with procedures below the knee (anatomical high-risk group)			
MALE: perioperative in % (95%-CI)	5 (2–11)	12 (9–16)	.026
Major amputation: perioperative in % (95%-CI)	2 (1–3)	3 (1–6)	.516
MACE: perioperative in % (95%-CI)	3 (1–10)	6 (4–10)	.291
Survival: perioperative in % (95%-CI)	97 (95–99)	96 (93–98)	.389
AFS: 1 year in % (95%-CI)	68 (60–74)	75 (68–81)	.134
Survival: 1 year in % (95%-CI)	82 (78–85)	84 (78–88)	.501

Notes. AFS: amputation-free survival; CI: confidence interval; IEI: infrainguinal endovascular intervention; LEB: lower extremity bypass surgery; MACE: major adverse cardiovascular event; MALE: major adverse limb event; OPG: objective performance goal.

treatment of patients with CLI were examined to determine whether the reported results were in line with the Objective Performance Goals of the Society for Vascular Surgery. The aim was to clarify whether these quality parameters have been met over the last 10 years or whether even better results have been achieved due to technical advances, especially in the endovascular treatment of this disease. It was shown that the perioperative results for both IEI and LEB largely corresponded to the OPGs or were even significantly better (MACE), meaning that the OPGs should continue to be used as quality targets. For MALE the OPG of 8% could not be achieved for LEB with 10% and for IEI with 9%, but this difference was not statistically significant. The OPG of 3% was also not met for perioperative major amputation, with 5% for IEI and 4% for LEB In addition, patient survival and amputation-free survival at 1 year for LEB were significantly better than the OPGs (Table III).

Perioperative results were also better than the OPGs in most parameters of the anatomical high-risk group (Table IV), again with the exception that MALE was significantly ($p = .033$) worse in LEB (12%) than the OPG (9%). MALE outcomes for LEB in the high-risk group is more than likely biased by patient selection. In this endovascular era, most patients with high-risk lesions are getting endovascular before LEB, which is usually left as a last resort. The ensuing high rate of MALE is therefore expected. The results for patient survival after 1 year and AFS after 1 year corresponded to the OPGs of this group in both IEI and LEB. Overall, the results allow the conclusion that the OPGs could be achieved in the reported case series.

Smaller monocentric studies have also confirmed that the OPGs can be achieved. Bloch et al [8] identified all patients who underwent LEB (n = 169) for CLTI over a 10-year period (2012–2021). Amputation-free survival at 1 year was 77.78%, which was like the overall SVS OPG cohort (76.5%). They concluded that suitable outcomes can be achieved after LEB for CLTI despite an increasing population of patients who would be considered high-risk. Varela et al [9] reported a retrospective study of 121 infrapopliteal endovascular procedures in patients with CLI. They found that infrapopliteal endovascular procedures performed in everyday vascular surgery practice could meet the main OPG end points proposed for catheter-based treatment of CLI. In the CRITISCH prospective multicentre registry with 1,200 consecutive CLI patients the AFS rates at 1 year exceeded the 71% OPG, both with endovascular revascularization (75%) and bypass surgery (72%; Stavroulakis et al [10]).

However, in large registries the OPGs are often not achieved. Latz et al [11] identified in the NSQIP database a total of 10,783 patients who underwent an infrainguinal intervention for CLI from 2015 to 2018. Overall, the MACE rates of 4.8% in the LEB and 3.4% in the IEI cohort met the SVS OPG safety threshold of < 8, but MALE rates in both cohorts failed to meet OPG safety thresholds of < 8% with IEI rates of 9.1% and LEB rates of 8.8%. In their analysis of the NSQIP-database, Robinson et al [3] analysed the results 30 days after the intervention. They found that in contemporary real-world practice, LEB and IEI for CLI failed to meet SVS OPG limb-related 30-day safety benchmarks for the entire CLI cohort as well as for the

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patients at high anatomical risk. The unadjusted rates of MALE after both LEB and IEI were significantly higher than those observed in the SVS OPG cohort. They concluded that there exist quality gaps in the treatment of CLI that deserve further investigation. However, interpretation of these findings must consider the inherent limitations of the NSQIP database, including the restriction to 30-day outcomes, the lack of detailed anatomic and lesion-specific information, and limited granularity regarding disease severity and procedural complexity, as previously highlighted by Geraghty and Conte [12]. Within these constraints, the study nonetheless suggested the presence of persisting quality gaps in the treatment of CLI that warrant further investigation.

The SVS OPGs were based on data from three prospective randomised trials that exclusively included patients with autologous venous conduits and without end-stage renal disease (ESRD). More broadly, the OPGs proposed by Conte et al. relied on a very limited evidence base, comprising only five heterogeneous randomised controlled trials conducted between 1990 and 2007. Due to substantial heterogeneity across study populations and interventions, no appropriate contemporaneous control groups for surgical treatment could be established. Instead, outcomes of autologous vein bypass grafting were pooled and suggested as a standard of care rather than being formally validated. Consequently, these OPGs represent pragmatic reference benchmarks, originally intended as historical controls for emerging catheter-based therapies. Despite this, they have since been widely adopted as outcome metrics for lower extremity revascularization. However, because a substantial proportion of routine vascular surgery patients, particularly those with ESRD or prosthetic conduits, were excluded from the original analyses, the generalisability of these results to everyday clinical practice remains debatable (Saraidaridis et al [13]). Saraidaridis et al. stratified patients of the Vascular Study Group of New England into OPG-eligible and non-OPG-eligible cohorts. The SVS OPG were attainable in New England for the population of patients who would have met SVS OPG study cohort inclusion criteria. However, 35% of the patients who underwent LEB for CLI fell outside of these criteria by having end-stage renal disease or requiring a prosthetic conduit. Therefore, Saraidaridis et al. suggested new benchmarks for these high-risk populations.

Zimmermann et al [14] came to a similar conclusion. They analysed OPGs of all patients with CLI treated by open revascularization techniques at a tertiary care facility in routine practice. 315 patients were included in this study. Of these, 128 patients (41%) fulfilled the adjusted SVS OPG criteria (OPG-group: femoral endarterectomies or vein graft and no ESRD), whereas the majority did not (non-OPG group: prosthetic grafts or ESRD). In this study, it was possible to reach the efficacy of OPGs set by SVS in a surgically treated all-comers cohort of CLI patients. Nevertheless, patients who did not fulfil the SVS OPG criteria showed significantly worse results for AFS and MALE + perioperative death.

In a systematic review with meta-analysis, Almasri et al [15] concluded that in patients with CLTI survival, major amputation, and amputation-free survival at 2 years were broadly similar between endovascular interventions and vein bypass, with prosthetic bypass having higher rates of limb loss.

In the randomised BEST-CLI study (Farber et al [5]) among patients with CLTI who had an adequate great saphenous vein for surgical revascularization, the incidence of a major adverse limb event or death was significantly lower in the surgical group than in the endovascular group. Among the patients who lacked an adequate saphenous vein conduit, the outcomes in the two groups were similar. Conversely, in the randomised BASIL-2 study the median amputation-free survival was 3.3 years in the vein bypass group and 4.4 years in the best endovascular group (Bradbury et al [6]). Taken together, the results of the recent randomised controlled trials indicate that contemporary outcomes in the treatment of chronic limb-threatening ischemia have substantially improved compared with the era in which the current OPGs were developed. While these findings argue for a redefinition of OPGs based on contemporary randomised evidence, updated benchmarks are currently lacking, and the existing OPGs therefore remain the only available reference for quality assessment in routine clinical practice.

The results of the present study do not match with these latter results, IEI and LEB did not differ in AFS even 5 years after intervention with 46% versus 44% ($p = .082$), but it should be noted that no distinction was made between venous bypass and synthetic bypass in the LEB group (Table V). However, patient survival was significantly better with open surgery compared to IEI both at 1year with rates of 84% versus 78% ($p < .001$) and at 3 years with 66% versus 58% ($p = .005$). The reasons for this remain unclear, but the results suggest that in clinical practice, for patients with higher risk and limited life expectancy, the endovascular approach is preferred when technically feasible, which would explain the lower long-term patient survival with IEI compared to open procedures due to a bias in patient selection.

This study has limitations. The literature research was restricted to studies in which the title had to include "critical limb ischemia". No distinction was made between prosthetic bypass and venous bypass in LEB. Patient age and gender were also not differentiated, as this was not possible for the subgroups (Table I). Furthermore, registry studies that contained a mixed patient population of patients with CLI and IC were excluded. In the presentation of results, primarily the OPGs were reviewed. In the long term only AFS and patient survival were analysed, but not MALE, MACE and major amputation rate, which was due

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to the limited number of study data. Also not the primary data from the studies were included in the analysis, but the aggregated, published data.

Despite this, to our knowledge, it is the largest study ever to comment on OPGs in the last 10 years. The main conclusion is that there are no significant perioperative outcome differences between LEB and IEI in routine clinical practice, apart from the significantly lower MACE rate with IEI. Short-term patient survival was better with LEB than with IEI, which can be explained by patient selection. Therefore, the choice of treatment must be based on the local findings and the patients risk factors. It is obvious that the current Objective Performance Goals (OPGs), published in 2009, are no longer well adapted to contemporary real-world practice in the treatment of chronic limb-threatening ischemia. Advances in perioperative care and treatment strategies, as well as recently published randomised trials, have substantially changed outcomes over time.

From a scientific perspective, these findings underscore the need to redefine OPGs based on contemporary evidence, ideally derived from randomised controlled trials. However, in the absence of updated benchmarks, the existing OPGs currently remain the only available reference for quality assessment in daily clinical practice.

Electronic supplementary material

The following electronic supplementary material is available with this article at https://doi.org/10.1024/0301-1526/a001285

ESM 1. 3-year survival of IEI (Figure E1), 3-year survival of LEB (Figure E2).

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