Comparison of long occlusive femoropopliteal de novo versus previous endovascularly treated lesions managed with in situ saphenous bypass

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ABSTRACT

Background: The aim of this study was to compare the 2-year outcomes of de novo versus postendovascular lesion treatment of femoropopliteal occlusions included in a national, multicenter, observational, prospective registry based on the treatment of critical Limb-threatening IschaeMia with infragenicular Bypass adopting in situ SAphenous VEin technique (LIMBSAVE) registry.

Methods: From January 2018 to December 2019, 541 patients from 43 centers have been enrolled in the LIMBSAVE registry. Of these patients, 460 were included in the present study: 341 (74.1%) with de novo lesions (DN group) and 119 (25.9%) with postendovascular treatment lesions (PE group). Initial outcome measures were assessed at 30 days after treatment. Furthermore, at the 2-year follow-up, the estimated outcomes of primary patency, primary-assisted patency, secondary patency, and limb salvage were analyzed with Kaplan-Meier curves and compared between groups with the log-rank test.

Results: Both groups were homogeneous in terms of demographic data, preoperative risk factors, and clinical presentation. However, compared with DN group, more patients in PE group had a great saphenous vein diameter of less than 3 mm (11.1% vs 21%; $P = .007$). Intraoperatively, both groups showed similar distal anastomosis sites: below-the-knee popliteal artery (63% DN group, 66.4% PE group) and tibial vessel (37% DN group, 33.6% PE group) ($P = .3$). The overall mean duration of follow-up was 11.6 months (range, 1-24 months). At the 2-year follow-up, there were no differences between the two groups in terms of primary patency (66.3% DN group vs 74.1% PE group; $P = .9$), primary-assisted patency (78.2% DN group vs 79.5% PE group; $P = .2$), secondary patency (85.1% DN group vs 91.4% PE group; $P = .2$), and limb salvage (95.2% DN group vs 95.1% PE group; $P = .9$).

Conclusions: The LIMBSAVE registry did not show a worsening of overall patency and limb salvages rates at the 2-year follow-up in patients undergoing in situ saphenous bypass after a failed endovascular approach for long femoropopliteal occlusive disease. This finding is in contrast with what has been published in literature. (J Vasc Surg 2022;■:1-9.)

Keywords: Critical limb-threatening ischemia; Limb salvage; In situ saphenous vein; Peripheral bypass

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The endovascular-first approach is a well-recognized strategy for the treatment of patients with critical limb-threatening ischemia (CLTI).[1-3] The latest European Society for Cardiology/European Society for Vascular Surgery guidelines[4] still recommended to offer open bypass surgery to patients with CLTI (who are fit for surgery) with an occlusive superficial femoral artery lesion longer than 250 mm (Class I, Level A). Additionally, a more recent, global vascular guideline on the management of patients with CLTI,[5] suggested the use of the autologous vein as the preferred conduit for infrainguinal bypass surgery (Class I, Level B). Among the autologous veins, the great saphenous vein (GSV) remains the conduit of choice for the femoropopliteal bypass.[6,7] The in situ saphenous vein bypass is a well standardized technique with satisfying long-term outcomes.[8]

Only one randomized controlled trial between endovascular therapy and bypass surgery has been published[9] to date, and a few trials are ongoing.[10,11] One of the debated topics in literature is the worsening of outcomes obtained with a surgical bypass performed after a failed endovascular approach. Some authors[12,13] reported that a previously failed endovascular approach could be predictive of poor outcomes in patients undergoing bypass surgery for CLTI.

The aim of this study was to compare the 2-year outcomes obtained in patients (de novo vs postendovascular treatment) with long femoropopliteal occlusions included in a national, multicenter, observational, prospective registry based on the treatment of critical Limb-threatening IschaeMia with infragenicular Bypass adopting in situ Saphenous Vein technique (LIMBSAVE).

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter, retrospective analysis of prospectively collected registry data (treatment of critical Limb-threatening IschaeMia with infragenicular Bypass adopting in situ SAphenous VEin technique [LIMBSAVE]), observational study
- **Key Findings:** We included 460 patients in this subanalysis of the LIMBSAVE registry: 341 (74.1%) with de novo lesions (DN group) and 119 (25.9%) with postendovascular treatment lesions (PE group). At 2 years, no differences in terms of primary patency, primary-assisted patency, secondary patency, and limb salvage were found.
- **Take Home Message:** The LIMBSAVE registry did not demonstrate worse 2-year outcomes in patients undergoing in situ saphenous bypass after a failed endovascular approach for long femoropopliteal occlusive disease.

METHODS

In Italy, the LIMBSAVE registry started enrollment in January 2018 and ended in December 2019. A total of 541 patients with CLTI treated with infragenicular in situ saphenous bypass (in 43 centers of vascular surgery) were enrolled in the registry. In all patients, a HYDRO LeMaitre Valvulotome (LeMaitre Vascular, Burlington, MA) was used to disrupt venous valves.[14] Patients with acute limb ischemia, aneurysmal disease of the lower limbs and/or with a GSV diameter of less than 1.6 mm were not enrolled into the registry.[15]

Institutional review board approval was waived, and all patients gave their written consent to the procedure approved by the ethics committee. The LIMBSAVE registry was an open registry: all centers applied their own protocols for preoperative and intraoperative diagnostic evaluation. Furthermore, no strict indications were established for postoperative medical care.

Study population. Of the 541 patients enrolled in the LIMBSAVE registry, 460 were included into the present study: 341 (74.1%) with de novo treated lesions (DN group), and 119 (25.9%) with postendovascular treated lesions (PE group). Fig 1 shows an overview of the selected study population. Patients were not included in the present subanalysis if one of the following criteria were true: vein bypass surgery after a failed prosthetic bypass graft, popliteal artery at the site of proximal anastomosis, and a femoropopliteal occlusive lesion length of less than 250 mm.

Timing of patient evaluations. Patient evaluations, at enrollment and on the day of the procedure, consisted of a clinical examination and Duplex scan. In all enrolled patients, a high-grade surveillance protocol with Duplex scan was established (30 days, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months). The preoperative Duplex scan was used to evaluate the diameter of the GSV in different segments of the index limb: the proximal part of the thigh, the distal part of the thigh, the proximal part of the leg, and the distal part of the leg. An accurate preoperative mapping of the GSV was made the day before the procedure and rechecked immediately before surgical cut-down in the operating room.

During all follow-up examinations, the diameter of the arterialized GSV was recorded.

Outcome measures and statistical analysis. All data concerning the procedures were prospectively collected in a dedicated database. The information included demographics, preoperative risk factors, clinical and diagnostic preoperative assessments, intraoperative features, and 30-day follow-up data.

Run-off status was defined on the basis of the patent tibial vessels. If all tibial vessels were occluded, the run-off was considered 0 and the distal anastomosis was performed on one of the foot arteries. A poor run-off status

was considered in patients with 0 or 1 patent tibial vessels.

A post hoc power calculation including alpha error was used to define the statistical power of the study based on two groups with a ratio of about 3:1.

Intraoperative and early (30-day) results in terms of technical success, major morbidity, and mortality were assessed. Demographic data, preoperative risk factors, anatomical features of the GSV, and intraoperative surgical strategies were analyzed and compared between the two groups with the χ^2 test, analysis of variance, or Fisher's exact test. A life-table analysis (Kaplan-Meier test) was used to evaluated the estimated 2-year outcomes: survival, primary patency (defined as no evidence of restenosis, peak systolic velocity ratio of ≥2.5 or occlusion based on color-coded duplex ultrasound examination), primary-assisted patency (defined as patency maintained by repeat intervention in an attempt to salvage the bypass before complete occlusion), secondary patency (defined as patency maintained by repeat intervention after complete occlusion of the bypass), and limb salvage (defined as absence of major amputation). The two groups were compared with the log-rank test.

Continuous data were expressed as the mean ± range. Follow-up data were also expressed as mean values. Categoric data were expressed as percentages. A multinomial logistic regression was used to predict single nominal dependent variables given one or more independent variables in order to identify factors affecting outcome measures of the study in the overall population. Wald test was used to calculate the odds ratio and 95% confidence intervals have been reported.

Statistical significance was defined when the *P* value was less than .05. Statistical analysis was performed using SPSS software (version 24.0 for Apple; IBM Corporation, Armonk, NY).

RESULTS

Demographic data. A post hoc power calculation demonstrated a 100% post hoc power of the study with an alpha error of 0.05. Demographic data of both groups are summarized in Table I. The two groups were homogeneous. In the PE group, there was a higher percentage (45.4% vs 25.7%) of patients with a history of coronary artery disease, but the difference did not reach statistical significance ($P = .2$).

Morphological data. In the PE group the overall mean number of previous endovascular procedures was 1.7 (range, 1-3), and the mean duration between last endovascular intervention and in situ bypass was 14.6 months (range, 1-63 months).

Regarding the type of last endovascular intervention, most patients received a stenting procedure (87/119 [73.1%]). In the remaining cases a balloon angioplasty with or without paclitaxel-coating was performed. In addition, in patients in the PE group the potential site of distal anastomosis was worsened in 7 of 119 cases (5.9%) after the last endovascular intervention (distalization of the re-entry site).

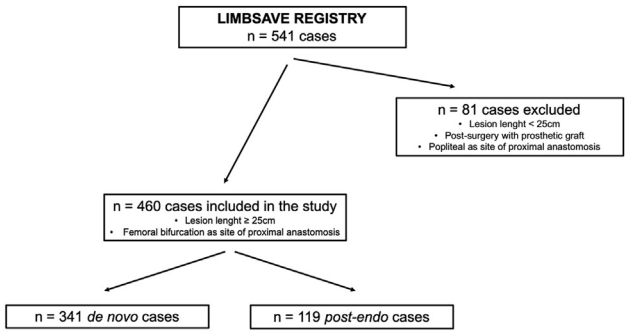

Fig 1. Study population.

The mean occlusive femoropopliteal lesion length was 405.1 mm (range, 250-800 mm) in the DN group and 411.5 mm (range, 250-600, mm) in the PE group, with no statistically significant difference ($P = .5$) between the two groups. The mean number of patent below-the-knee (BTK) run-off vessels was similar in both groups (1.6 DN group vs 1.6 PE group; $P = .5$). A poor run-off status was present in 154 patients (45.2%) in the DN group and in 51 patients (42.8%) in the PE group ($P = .4$).

Compared with the DN group, more patients in PE group had a mean preoperative GSV diameter of less than 3 mm (11.1% vs 21%; $P = .007$). The overall mean GSV diameter was similar in both groups (4 mm in the DN group vs 3.8 mm in the PE group; $P = .2$). The presence of a suprafascial tributary collateral was similar in both groups (5.6% in the DN group vs 9.2% in the PE group; $P = .1$).

Intraprocedural outcomes. The percentage of patients who received general anesthesia was similar for both groups (63.3% in the DN group vs 67.2% in the PE group; $P = .7$). The mean bypass length was 508 mm (range, 250-870 mm) in the DN group and 497.9 mm (range, 300-700 mm) in the PE group, with no statistically significant ($P = .3$) difference between the groups.

A proximal anastomosis was performed at the origin of the femoral superficial artery or on the profunda femoris in 90 cases in the DN group (26.4%) and in 41 cases (34.4%) in the PE group ($P = .2$). In the remaining cases, the proximal anastomosis was made on the common femoral artery. The site of distal anastomosis was similar in both groups: BTK popliteal artery (63% in the DN group vs 66.4% in the PE group), tibial artery (34.1% in the DN group vs 31.9% in the PE group), and pedal artery (2.9% in the DN group vs 1.7% in the PE group; $P = .3$). In all cases, technical success was obtained with a good pulsatility of the vein after the utilization of the valvulotome. Furthermore, ligation of GSV tributaries was performed in all cases.

Table I. Demographic data and comorbidities

	DN group (341 cases)	PE group (119 cases)	*P* value
Males	270 (79.2)	87 (73.1)	.1
Age, years	73.7	73.9	.8
Age >80 years	89 (26.1)	37 (31.1)	.2
Risk factors			
Smoking	106 (31.1)	50 (42)	.3
Former smoker	175 (51.3)	44 (37)	.1
Hypertension	304 (89.1)	103 (86.5)	.3
Hypercholesterolemia	193 (56.6)	73 (61.3)	.2
Diabetes mellitus	153 (44.9)	58 (48.7)	.3
Insulin treatment	92 (27)	33 (27.7)	.5
Coronary artery disease	139 (25.7)	54 (45.4)	.2
Chronic renal failure[a]	78 (22.9)	26 (21.8)	.5
Dialysis treatment	31 (9.1)	7 (5.9)	.2
Previous deep venous thrombosis	1 (0.3)	1 (0.8)	.4
Rutherford classification			.7
4 (rest pain)	112 (32.8)	35 (29.4)	
5 (minor tissue loss)	154 (45.2)	54 (45.4)	
6 (major tissue loss)	75 (22)	30 (25.2)	

DN, With de novo lesions; *PE*, postendovascular treatment lesions.
Continuous data are presented as the means; categorical data are given as the counts (percentage).
[a]Glomerular filtration rate of <30 mL/min.

Intraoperative diagnostic evaluation was equally performed for both groups (90.9% in the DN group vs 89.1% in the PE group; $P = .3$). In 11 cases, an intraoperative endovascular procedure was performed to improve the inflow/outflow of the surgical bypass (7 [2%] in the DN group vs 4 [3.4%] in the PE group; $P = .3$). Table II shows the postoperative medical therapy.

Early (30-day) outcomes. Table III summarizes the 30-day results. The mean hospital stay was similar ($P = .3$) for both groups: 10.9 days (range, 1-60 days) for the DN group and 10 days (range, 2-35 days) for the PE group. Overall, an early bypass occlusion was recorded in 13 cases. At discharge, the rate of overall bypass patency was 98.2% in the DN group and 99.1% in the PE group ($P = .4$).

At the 30-day follow-up, the overall mortality was 2.3% in the DN group and 4.2% in the PE group ($P = .4$). Furthermore, no differences were found in the 30-day major amputation rate (0.9% in DN group vs 0.8% in PE group; $P = .7$). Thirty-one patients underwent a minor amputation with no differences between the two groups (21 [6.1%] in the DN group vs 10 [8.4%] in the PE group; $P = .1$). The rate of early (30-day) redo surgery for failing bypass was higher in the PE group compared with the DN group (9.2% vs 5.0%, respectively; $P = .05$).

Two-year outcomes. Follow-up outcomes were available for 431 patients (93.7%). The overall mean and median duration of follow-up was 11.6 and 12.0 months (range, 1-24 months), respectively. During the follow-up examinations, the mean maximum GSV diameter was 5.3 mm (range, 2.3-8.2 mm) in the DN group and 4.8 mm (range, 2.8-8.0 mm) in the PE group with a statistically significant difference ($P = .02$). In addition, the mean positive increase (Δ) of the GSV diameter was better in the DN group (1.2 mm vs 0.9 mm; $P = .009$).

In both groups, there was an equal improvement of at least 1 Rutherford class during the follow-up (80.9% in the DN group vs 80.7% in the PE group; $P = .2$). At 2 years, there were no differences between the two groups in terms of survival (85.6% in the DN group vs 82.5% in the PE group; $P = .6$), primary patency (66.3% in the DN group vs 74.1% in the PE group; $P = .9$), primary-assisted patency (78.2% in the DN group vs 79.5% in the PE group; $P = .2$), secondary patency (85.1% in the DN group vs 91.4% in the PE group; $P = .2$), and limb salvage (95.2% in the DN group vs 95.1% in the PE group; $P = .9$) (Fig 2).

Multinomial logistic regression analysis. In the overall population, multinomial logistic regression analysis demonstrated that dialysis and a history of coronary artery disease strongly affected the overall survival rate. No other demographic or clinical factor affected outcomes measures of the study. Some morphological features could be considered independent variables of worse outcomes in terms of patencies and major amputation-free survival (Table IV).

Table II. Postoperative medical therapy

	DN group (341 cases)	PE group (119 cases)	*P* value
ASA	79 (23.2)	20 (16.8)	.1
ASA + ticagrelor + LMWH	1 (0.3)	0	.8
ASA + clopidogrel	26 (7.6)	7 (5.9)	.5
ASA + clopidogrel + LMWH	3 (0.9)	4 (3.4)	.1
ASA + LMWH	177 (52)	57 (48)	.3
ASA + DOAC	5 (1.5)	1 (0.8)	.8
ASA + warfarin	10 (2.9)	6 (5)	.5
ASA + warfarin + clopidogrel	1 (0.3)	0	.8
ASA + ticlopidine	2 (0.6)	0	.6
Clopidogrel	9 (2.6)	2 (1.7)	.6
Clopidogrel + LMWH	9 (2.6)	5 (4.2)	.4
Clopidogrel + DOAC	0	1 (0.8)	.8
LMWH	1 (0.3)	0	.8
DOAC	9 (2.6)	10 (8.4)	.1
Warfarin	8 (2.3)	5 (4.2)	.5
Ticagrelor	1 (0.3)	0	.8
Ticlopidine	0	1 (0.8)	.8

ASA, Acetylsalicylic acid; *DOAC*, direct oral anticoagulant; *DN*, With de novo lesions; *LMWH*, low-molecular-weight heparin *PE*, postendovascular treatment lesions.
Values are number (%).

Table III. Early results (30 days)

	DN group (341 cases)	PE group (119 cases)	*P* value
Overall mortality	8 (2.3%) - 3 acute myocardial infarction - 2 sepsis - 1 MOF - 1 pneumonia - 1 unknown	5 (4.2%) - 2 acute myocardial infarction - 1 acute heart failure - 1 sepsis - 1 unknown	.4
Systemic morbidity	15 (4.4%) - 6 acute myocardial infarction - 2 acute heart failure - 2 sepsis - 1 pneumonia - 2 acute renal failure - 1 MOF - 1 pneumonia	6 (5%) - 4 acute myocardial infarction - 1 deep venous thrombosis - 1 MOF	.7
Redo surgery for failing bypass	17 (5%) - 8 open - 5 endovascular - 4 hybrid	11 (9.2%) - 4 open - 6 endovascular - 1 hybrid	.05
Other surgical procedures	74 (14.4%) - 3 major amputation - 18 minor amputation - 6 ligation of patent tributaries - 3 bleeding - 16 surgical site dehiscence - 2 lymphocele - 1 surgical site infection	13 (10.9%) - 1 major amputation - 6 minor amputation - 1 ligation of patent tributaries - 2 bleeding - 3 surgical site dehiscence	.4

DN, With de novo lesions; *MOF*, multiorgan failure; *PE*, postendovascular treatment lesions.

DISCUSSION

In the TransAtlantic Intersociety Consensus (TASC) recommendations,[16-18] the length of occlusive femoropopliteal lesions has been considered a key factor in the recommendation of endovascular or open surgery in patients with CLTI. Particularly in TASC II,[17,18] an

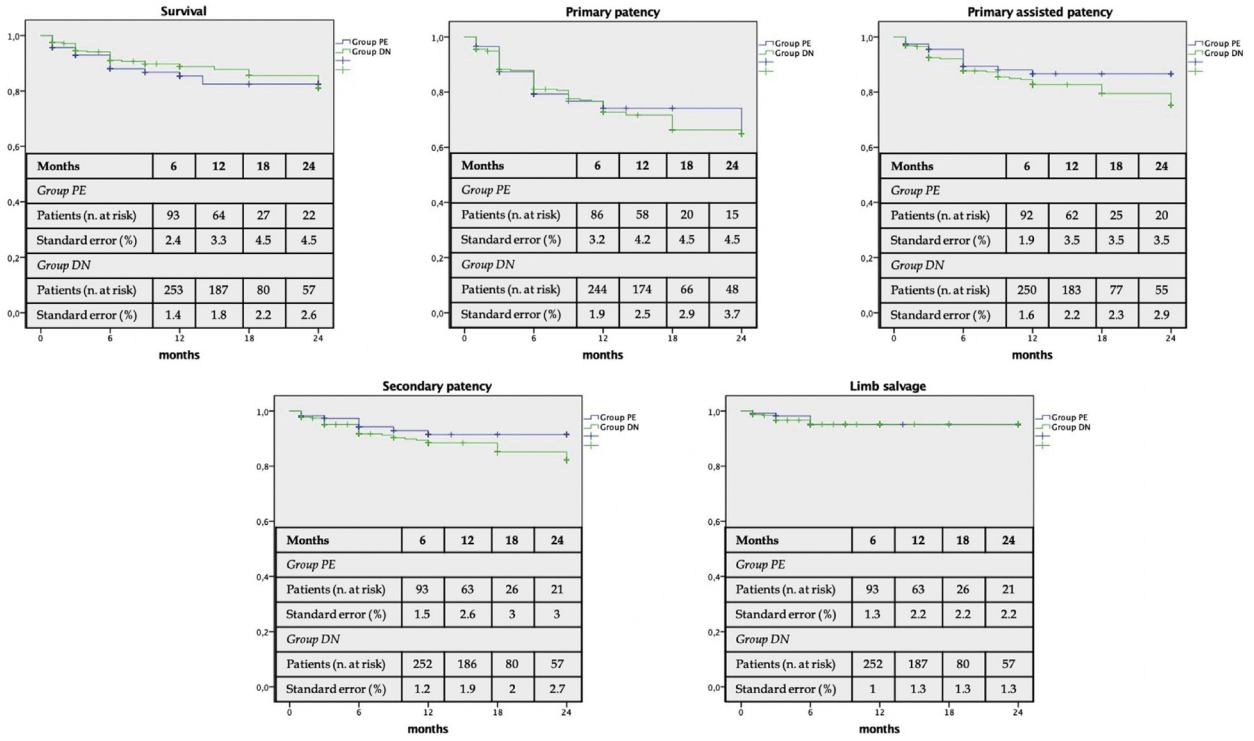

Fig 2. Estimated 2-year survival, primary patency, primary assisted patency, secondary patency, and limb salvage (Kaplan-Meyer curves with number of patients at risk and standard error values for each group).

occlusive femoropopliteal lesion threshold of 200 mm has been chosen to shift patients with CLTI toward an endovascular approach rather than open surgical bypass. However, some authors[19] demonstrated that there was poor interobserver agreement on the TASC II classification of femoropopliteal lesions. They cautioned against using TASC II as a basis for decision-making and reporting outcomes. Consequently, the literature remains inconclusive on which methods should be used for the treatment of long femoropopliteal occlusions in patients with CLTI.

In the Registry of First-line Treatments in Patients With Critical Limb Ischemia (CRITISCH),[1] the endovascular-first approach in patients with CLTI (even with long femoropopliteal occlusions) achieved a noninferior amputation-free survival rate compared with bypass surgery; a total of 423 patients (66%) in the endovascular group have been classified as TASC C or D. Moreover, in the Long Lesions of Superficial Femoral Artery Ischemic Vascular Disease (SFA-Long) study (105 symptomatic patients, mean occlusive lesion length of 251 mm), the authors demonstrated benefits (over 24 months) of primary angioplasty with paclitaxel-eluting balloons on primary patency and target vessel revascularization.[20] The endovascular approach with femoropopliteal stenting also demonstrated acceptable outcomes in long femoropopliteal occlusions.[21,22] Recently, The Cook Zilver PTX drug-eluting stent versus bypass surgery for the treatment of femoropopliteal TASC C & D lesions (ZILVERPASS) study[21] reported that paclitaxel-eluting stents had a noninferior 1-year primary patency rather than bypass surgery in symptomatic TASC C/D patients (mean occlusive length of approximately 247 mm). However, guidelines continue to be in contrast with this enthusiastic mini-invasive approach.

The latest 2017 European Society for Cardiology/European Society for Vascular Surgery guidelines[4] still recommended to perform open bypass surgery in patients with CLTI with an occlusive superficial femoral artery lesion of more than 250 mm and with a life expectancy of more than 2 years (Class I, Level A). Recently, global vascular guidelines on the management of patients with CLTI[5] have suggested open surgery in selected high-risk patients with advanced limb threat, significant perfusion deficits, and advanced complexity of disease (including length). Thus, open bypass surgery should still be considered successful in the treatment of patients with CLTI with long infrainguinal occlusions. In the present study, a history of coronary artery disease and dialysis were independent predictors of survival, but they did not affect the bypass patency rates. However, it is critical to understand when bypass surgery should be offered to patients with CLTI with long femoropopliteal occlusions: as primary treatment (bypass-first approach accordingly to guidelines[4,5]) or after a failed endovascular approach (endovascular-first approach according to several reports[1-3,20-22]).

Table IV. Multinomial logistic regression: Independent variables affecting outcome measures in the overall population

	Outcome measures				
	Survival	Primary patency	Primary assisted patency	Secondary patency	Limb salvage
CAD history	10.6 (8.3-12.1)	–	–	–	–
Dialysis	3.7 (3.0-4.2)	–	–	–	–
GSV <3 mm	–	17.7 (13.8-21.1)	15.1 (12.8-17.0)	13.8 (11.4-15.5)	13.4 (10.4-15.9)
Anastomosis on BTK/foot arteries	–	–	4.3 (3.5-4.9)	–	7.4 (6.2-8.7)
Bypass length >500 mm	–	–	–	5.3 (4.4-6.1)	–

BTK, Below-the-knee; *CAD*, coronary artery disease; *GSV*, great saphenous vein.
Values are odds ratio (95% confidence interval).

Some authors[12,13,15] reported that a previously failed endovascular approach is a predictor of poor outcomes in patients with CLTI undergoing bypass surgery. Nolan et al[12] demonstrated that a prior ipsilateral peripheral endovascular intervention, in patients (n = 603) undergoing infrainguinal surgical bypass, was highly predictive of poorer 1-year outcomes in terms of major amputation and graft occlusion.

In contrast, some authors[23-26] reported that the outcomes of lower extremity bypass were not necessarily affected by a prior ipsilateral endovascular procedure. Santo et al[23] reported that a prior endovascular procedure did not influence the 1- and 5-year outcomes in patients with CLTI who underwent autologous vein bypasses (n = 314). However, these authors regarded a prior endovascular procedure as a mixture of interventions, including inflow stenting and thrombolysis. In addition, some single-center experiences[24-26] with a limited study population reported that prior endovascular intervention is not disadvantageous for patients with CLTI undergoing tibiodistal or pedal bypasses. Also in this area, some authors[26] reported a mixture of endovascular procedures performed on the index limb.

In our study, anastomosis on a BTK/foot artery significantly affected primary assisted patency, and limb preservation independently from a prior endovascular procedure. Therefore, a femorotibial or femoropedal in situ vein bypass could be considered a predictor of poor outcomes. However, the present subanalysis of the LIMB-SAVE registry supports the hypothesis that there is no effect of prior endovascular intervention on overall patency and limb salvage rates in patients undergoing in situ saphenous bypass. In addition, our patient population was standardized to specifically reflect the femoropopliteal segment and a lesion length longer than 250 mm. As a prior endovascular intervention, we only considered procedures performed on the femoropopliteal arteries of the index limb. Nevertheless, the re-entry point was worsened in approximately 6% of the cases after the last endovascular intervention; the two groups did not globally differ about the length of the bypass and the site of distal anastomosis. Therefore, the prior endovascular interventions could be considered as procedures respective of the patients' anatomy.

In this study, both groups were very similar, with no differences in terms of age, preoperative risk factors, or morphological data regarding arterial lesions and GSV. Compared with the DN group, more patients in the PE group had a mean preoperative GSV diameter of less than 3 mm. This factor could be explained with the choice to postpone a surgical bypass in favor of a mini-invasive approach when a good autologous vein (diameter of <3 mm) is not available. According to recent global vascular guidelines,[5] physicians must perform ultrasound vein mapping (when available) in all patients with CLTI who are candidates for surgical bypass.[27] Furthermore, they must avoid using a nonautologous conduit for an infrainguinal bypass, unless there is no endovascular option and no adequate autologous vein.[7]

In the present subanalysis, the early surgery-redo rate for a failing bypass was not negligible. This rate was higher in patients with a prior endovascular intervention. This finding could be related to the smaller GSV diameter used (in this subgroup) to perform the in situ bypass, since vein diameter is a well-recognized risk factor for the early and long-term effectiveness of the technique.[28]

Compared with previous reports,[2,3] we found that a prior endovascular intervention was not predictive of poor outcomes in overall patency and limb salvage at 2-year follow-up. This finding could be related to a cautious endovascular approach in long femoropopliteal occlusions with respect to the re-entry points and the maintenance of an adequate run-off status. Some answers are present in the literature,[1,29] and greater clarity could arise from the ongoing randomized clinical trials[10,11] that are comparing endovascular-first and bypass-first approaches in patients with CLTI. The present study, however, suggests that a careful endovascular-first approach (in patients with CLTI with long femoropopliteal occlusions) does not worsen the 2-year clinical outcomes of a surgical vein bypass. In addition, our data demonstrated an inexplicable trend toward better patency outcomes in patients undergoing previous endovascular approaches (not statistically significant differences). Vein diameter

significantly affected the overall patency and limb salvage rates in accordance to what previously reported in the literature.[8,28]

Our study has some limitations. First, the LIMBSAVE registry is an open registry.[30] Thus, there is no homogeneity in the intraprocedural diagnostic evaluations and the postoperative medical care. Second, this study is restricted to surgical bypasses performed with autologous material (GSV) and a selected standardized technique (in situ). Finally, the follow-up period is short, but the study is ongoing and further data are expected.

CONCLUSIONS

In contrast with what has been published in some literature reports, the present (LIMBSAVE registry) subanalysis did not demonstrate inferior 2-year outcomes in overall patency and limb salvage rates in patients with CLTI undergoing in situ saphenous bypass after a failed endovascular approach for long femoropopliteal occlusive disease. This outcome was despite a small GSV diameter and a significant early redo rate for failing bypass procedures in PE group. Further examinations and continuous follow-up are needed to evaluate the long-term outcomes.

AUTHOR CONTRIBUTIONS

Conception and design: NT, SM, DA, RB
Analysis and interpretation: NT, SM, DA, RB
Data collection: NT, LIMBSAVE Collaborative
Writing the article: NT
Critical revision of the article: NT, SM, DA, RB, LIMBSAVE Collaborative
Final approval of the article: NT, SM, DA, RB, LIMBSAVE Collaborative
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