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ORIGINAL ARTICLE
SECTION

Secondary endovascular procedures improve overall patency and limb salvage in patients undergoing *in situ* saphenous vein infragenicular bypass

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ABSTRACT

BACKGROUND: Secondary interventions strongly improves patency and limb salvage rates in patients undergoing infrainguinal vein bypass. The aim of this study was to evaluate the influence of secondary endovascular procedures performed during the follow-up on patency and limb salvage in patients with critical limb-threatening ischemia (CLTI) undergoing in situ saphenous vein infragenicular bypass.

METHODS: From January 2018 to December 2019 541 patients in 43 centers have been enrolled into the LIMBSAVE registry (treatment of critical Limb IschaeMia with infragenicular Bypass adopting in situ SAphenous VEin technique). In all patients a strict surveillance program with Duplex scan was established (1, 3, 6, 9, 12, 18, 24 months). During the follow-up indications for endovascular procedures were anastomotic stenoses, improvement of run-in (iliac stenosis) or run-off (tibial vessels' stenoses or occlusions). Two-year estimated outcomes in terms of overall patency, and limb salvage were analyzed by life-table analysis (Kaplan-Meier test). Outcomes obtained in patients undergoing endovascular procedure (Group-endo) were compared by means of Gehan-Breslow-Wilcoxon Test with those obtained in patients with no secondary endovascular procedure during the follow-up (Group-no endo).

RESULTS: Two groups were homogeneous in terms of demographics and intraprocedural details. Overall mean duration of follow-up was 12.1 months (range 1-24). During the follow-up period (>30 days) 55 endovascular procedures were performed in 49 patients (9.1%) (Group-endo). Most of endovascular procedures (37/55, 67.3%) was performed to treat stenoses at proximal or distal anastomosis. Secondary endovascular procedures (40/55, 72.7%) were predominantly performed within 6 months from the index procedure. Estimated 2-year overall patency (97.9% *vs.* 85.2%, P=0.05), and limb salvage (100% *vs.* 93.9%, P=0.05) rates were significantly better in Group-endo.

CONCLUSIONS: Secondary endovascular procedures in patients with CLTI undergoing in situ saphenous infragenicular bypass significantly improve the rates of overall patency and limb salvage in the mid-term period.

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KEY WORDS: Ischemia; Limb salvage; Saphenous vein; Endovascular procedures.

Recent guidelines recommended open surgical revascularization for long infrainguinal arterial occlusions.[1] Great saphenous vein still remains the conduit of choice to perform an open surgical infrainguinal bypass.[2]

Regardless the surgical technique adopted (*in situ*, *ex situ*, inverted, spliced, bifurcated), several authors[3-8] reported the importance of an adequate management of a vein bypass during the follow-up in order to maintain the graft patency and to improve the amputation-free survival rate.

Recently Jongsma *et al.*[9] demonstrated that secondary interventions could strongly improve the secondary paten-

cy and limb salvage rates in patients undergoing infrainguinal vein bypass.

Therefore, in the last decades several reports[10-13] described the use of endovascular techniques to improve the overall patencies of infrainguinal vein bypasses.

In situ saphenous vein bypass is an old and standardized technique to treat patients with long occlusions of infrainguinal arteries.[14] In 1990's Shah *et al.*[15] reported the long-term outcomes of this technique applied in more than 2,000 people with satisfying overall 10-year estimated rates of secondary patency (70%), and limb salvage (90%). Even with this surgical technique a routine surveillance is mandatory in order to perform graft preserving interventions.[8]

Recently a national, multicenter, observational, prospective registry based on the examination of treatment of critical Limb IschaeMia with infragenicular Bypass adopting in situ SAphenous VEin technique (LIMBSAVE registry) started the enrollment.[16-18]

The aim of this study was to evaluate the influence of secondary endovascular procedures performed during the follow-up on overall patency and limb salvage rates in patients with critical limb-threatening ischemia (CLTI) undergoing in situ saphenous vein infragenicular bypass.

Materials and methods

Population study

Between January 2018 and December 2019 541 patients in 43 centers of vascular surgery have been enrolled into the LIMBSAVE registry. In all patients a HYDRO LeMaitre® Valvulotome (LeMaitre Vascular, Burlington, MA, USA) was used to obtain the pulsatility of the vein.

The registry has been elaborated on the concept of "all-comers."

Main inclusion criteria were: patients suffering from CLTI in presence of rest pain and/or ischemic lesions (Rutherford classes 4-5-6), and availability of ipsilateral autologous saphenous vein in the limb to be operated on with a minimum diameter of not less than 1.6 mm (detected at Duplex scan in standing position).

The main exclusion criterion was the presence of aneurysmal disease of the lower limbs.

All centers were free to apply their own protocols in terms of pre- and intraoperative diagnostic evaluations. Furthermore, no strict indications have been established in terms of postoperative medical therapy.

A strict surveillance protocol was established for each patient including a clinical examination and Duplex scan in the following steps of the study: enrollment, procedure, 30 days, 3 months, 6 months, 9 months, 12 months, 18 months and 24 months. During all follow-up examinations the Duplex criteria to define the presence of a stenosis was a peak systolic velocity (PSV) ratio ≥2.5; anastomoses and all vein segments were accurately evaluated. Retained flow-limiting valves were searched. During the follow-up period (>30 days) in 49 patients (9.1%) an endovascular procedure was performed to maintain the graft patency (Group-endo).

Outcome measures

All data related to the procedure were prospectively collected in a dedicated database. This included demographics, preoperative risk factors, clinical and diagnostic preoperative assessments, intraoperative features, and 30-day follow-up data. Follow-up assessment included patients' survival, graft patency, and major amputations. The analysis of the cohort study was retrospectively performed.

Statistical analysis

Estimated 2-year outcomes were evaluated in terms of overall patency (defined as patency maintained during the follow-up nevertheless repeat interventions performed after incomplete or complete occlusion of the bypass), and limb salvage (defined as absence of major amputation) by life-table analysis (Kaplan-Meier test). Estimates were given with the 95% confidence intervals (CI). A comparative analysis between the two groups (endo vs. no endo) was performed by means of Gehan-Breslow-Wilcoxon Test. Continuous data were expressed as the mean±range or median with interquartile range (IQR) values when necessary. Categoric data were expressed as percentages. The nonparametric Pearson chi-square test and mean T test were used when necessary to compare variables.

Statistical significance was defined at the $P<0.05$ level. Statistical analysis was performed using SPSS software (version 24.0 for Apple; IBM Corporation, Armonk, NY, USA).

Results

Demographic and morphological data

Table I shows demographic data and preoperative risk factors of the overall population study comparing patients in both groups. Two groups were homogeneous.

The femoro-popliteal lesion was classified as "*de novo*" in 35 cases (71.4%) Group-endo *vs.* 360 cases (73.2%)

TABLE I.—*Demographic data.*

	Group endo N.=49	Group no-endo N.=492	Total N.=541	P
Males	39 (79.6%)	377 (76.6%)	416 (76.9%)	0.39
Age, y (range)	72.8 (53-88)	71.6 (39-95)	73.1 (39-95)	-
>80 years	11 (22.4%)	131 (26.6%)	142 (26.2%)	0.33
Risk factors				
Smoking	11 (22.4%)	181 (36.8%)	192 (35.5%)	0.07
Former smoking	24 (49%)	223 (45.3%)	247 (45.7%)	0.36
Hypertension	40 (81.6%)	435 (88.4%)	475 (87.8%)	0.13
Hypercholesterolemia	23 (46.9%)	285 (57.9%)	308 (56.9%)	0.09
Diabetes mellitus	26 (53.1%)	232 (47.1%)	258 (47.7%)	0.26
Insulin treatment	14 (28.6%)	134 (27.2%)	148 (27.4%)	0.48
Coronary artery disease	22 (44.9%)	198 (40.2%)	220 (40.7%)	0.31
Chronic renal failure*	9 (18.4%)	114 (23.2%)	123 (22.7%)	0.28
Dialysis treatment	3 (6.1%)	38 (7.7%)	41 (7.6%)	0.48
Rutherford classification				
4 (rest pain)	12 (24.5%)	164 (33.3%)	176 (32.5%)	0.39
5 (minor tissue loss)	25 (51%)	209 (42.5%)	234 (43.3%)	
6 (major tissue loss)	12 (24.5%)	119 (24.2%)	131 (24.2%)	

Continuous data are presented as the means; categorical data are given as the counts (percentage).
*Glomerular filtration rate <30 mL/min.

Group no-endo (P=0.68). The mean occlusive lesion length (406.7 mm Group-endo *vs.* 375.2 mm Group-no endo, P=0.07), and the mean number of below-the-knee run-off vessels (1.5 Group-endo *vs.* 1.6 Group-no endo, P=0.24) were similar between the two groups.

Periprocedural outcomes

Table II shows intraprocedural "surgical" technical data. There were no differences between the two groups in terms of anastomotic sites. The mean bypass length was similar in both groups (522.4 mm Group-endo *vs.* 509.1 mm Group-no *endo*, P=0.01). During the intra-operative period 4 patients in *Group-endo* needed an adjunctive procedure to maintain the graft patency (1 femoral patch, 1 popliteal patch, 2 removals of retained flow-limiting valves).

The median hospital stay was similar in both groups (8±6-13 days Group-endo *vs.* 9±6-13 days Group no-endo, P=.62). At 30 days 6 patients (12.2%) in Group-endo, and 39 patients (7.9%) in Group-no endo (P=.21) required an early intervention to preserve vein graft patency. Overall bypass patency was 100% in Group-endo

TABLE II.—*Intraprocedural data about the index procedure.*

	Group endo N.=49	Group no-endo N.=492	Total N.=541	P
Anesthesia				
General	35 (71.4%)	302 (61.4%)	337 (62.3%)	0.35
Locoregional	11 (22.4%)	156 (31.7%)	167 (30.9%)	
Peripheral nerve block	3 (6.1%)	34 (6.9%)	37 (6.8%)	
Proximal anastomosis				
Common femoral artery	31 (63.3%)	338 (68.7%)	369 (68.2%)	0.88
Superficial femoral artery	15 (30.6%)	132 (26.8%)	147 (27.2%)	
Deep femoral artery	1 (2%)	8 (1.6%)	9 (1.7%)	
Popliteal artery (P3 segment)	2 (4.1%)	14 (2.9%)	16 (3%)	
Distal anastomosis				
Popliteal artery (P3 segment)	31 (63.3%)	304 (61.8%)	335 (61.9%)	0.95
Tibioperoneal trunk	4 (8.2%)	63 (12.8%)	67 (12.4%)	
Posterior tibial artery (proximal)	3 (6.1%)	27 (5.5%)	30 (5.5%)	
Posterior tibial artery (distal)	3 (6.1%)	23 (4.7%)	26 (4.8%)	
Peroneal artery	3 (6.1%)	29 (5.9%)	32 (5.9%)	
Anterior tibial artery (proximal)	3 (6.1%)	26 (5.3%)	29 (5.4%)	
Foot artery	2 (4.1%)	20 (4%)	22 (4.1%)	

Categorical data are given as the counts (percentage).

TABLE III.—*Secondary endovascular procedures in Group-endo.*

	Procedure	N. (%)
Target lesion location		
External iliac artery (N.=2 cases)	Stenting	2 (3.6%)
Proximal anastomosis		
(N.=10 cases)	POBA	6 (10.9%)
CFA=5 cases	DCB	1 (1.8%)
SFA=3 cases	DES	1 (1.8%)
DFA=1 case	Stenting	1 (1.8%)
POP P3=1 case	Covered stent	1 (1.8%)
Vein graft	POBA	4 (7.3%)
(N.=6 cases)	DCB	1 (1.8%)
	Covered stent	1 (1.8%)
Distal anastomosis	POBA	17 (31%)
(N.=27 cases)	DCB	5 (9.1%)
POP P3=15 cases	Stenting	2 (3.6%)
TPT=2 cases	Covered stent	3 (5.4%)
PTA=5 cases		
PA=2 cases		
ATA=2 cases		
FA=1 case		
Tibial vessels	POBA	10 (18.3%)
(N.=10 cases)		

POBA: plain old balloon angioplasty; DCB: drug-coated balloon; DES: drug-eluting stent; CFA: common femoral artery; SFA: superficial femoral artery; DFA: deep femoral artery; POP: popliteal artery; TPT: tibioperoneal trunk; PTA: posterior tibial artery; PA: peroneal artery; ATA: anterior tibial artery; FA: foot artery.

vs. 98.6% in Group-no endo (P=.51), whilst limb salvage rates were 100% in Group-endo *vs.* 99.2% in Group-no endo (P=0.73).

Two-year outcomes

Follow-up was available in all patients. Median duration of follow-up was similar in both groups (12±8-15 months Group-endo *vs.* 13±9-16 months Group-no endo; P=0.44).

During the follow-up period (>30 days) 4 patients in Group-no endo underwent surgical revision of the vein graft in order to avoid the occlusion. In addition, 55 endovascular procedures were performed in Group-endo. Most of endovascular procedures (37/55, 67.3%) was performed to treat stenoses at proximal or distal anastomosis (Table III). Procedures (40/55, 72.7%) were predominantly performed within 6 months from the index procedure.

Estimated 2-year overall patency (97.9% [95% CI 97.1% to 98.3%] *vs.* 85.2% [95% CI 83.7% to 87.1%]; log-rank 3.8, P=0.05), and limb salvage (100% *vs.* 93.9% [95% CI 91.7% to 95.2%]; log-rank 3.5, P=0.05) rates were significantly better in Group-endo (Figure 1).

Discussion

Vein bypass graft is still recommended as "first choice" in patients with CLTI, concomitant long infrainguinal arterial occlusions, and life expectancy more than 2 years.[1] The choice of surgical technique to be adopted should be tailored on each patient according to surgeon's and center's experiences.[19] In 1991 Bergmark *et al.*[20] reported a comparative analysis between in situ and reversed technique; patency after 6 months was significantly higher for the *in situ* grafts (84% *vs.* 49%). More recently, Davidovic *et al.*[21] demonstrated that *in situ* bypass showed better outcomes even in the long-term period (better 10-year patency over the reversed bypass technique in 290 patients analyzed and compared).

LIMBSAVE Registry collected the contemporary outcomes of this surgical technique. In a recently published report[18] the early outcomes are very satisfying.

In addition, early and long-term outcomes of a periph-

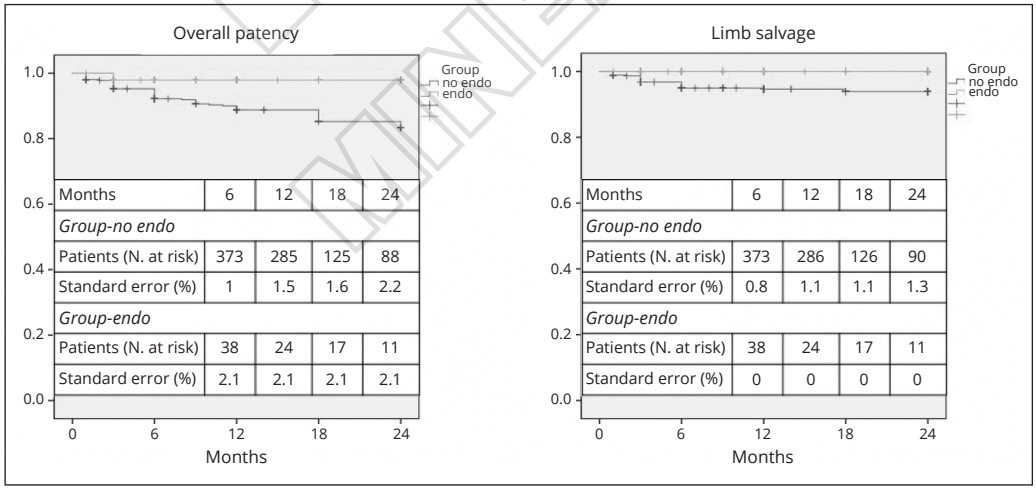

Figure 1.—Estimated 2-year overall patency and limb salvage (Kaplan-Meyer curves with numbers of patients at risk and standard error values for each group).

eral vein bypass could be affected by many factors, including the quality of the vein graft, the vein diameter, and the inflow/outflow status.[21]

Several authors[3-8] demonstrated the importance to establish an accurate surveillance protocol for patients undergoing peripheral vein grafts in order to perform graft preserving reinterventions whenever necessary. In 1996 Golledge *et al.*[4] analyzed 6,649 infrainguinal vein grafts and demonstrated that the overall patency would appear to be improved as a result of Duplex surveillance. Follow-up surveillance for patients enrolled in LIMBSAVE registry included a Duplex scan at 30 days, 3 months, 6 months, 9 months, 12 months, 18 months and 24 months.[22]

The aim of a high-grade surveillance protocol is to perform surgical reinterventions not only on the vein bypass but also on the inflow/outflow vessels in order to avoid the graft occlusion. In the current Literature there is a debate about open or endo surgical revisions of vein grafts. Mofidi *et al.*[23] suggested balloon angioplasty as the primary treatment or failing infrainguinal vein grafts, albeit with a significant risk of re-stenosis potentially managed by repeat endovascular interventions during the follow-up (99 endovascular procedures on 76 grafts). On the other hand, Simosa *et al.*[24] demonstrated that early graft stenosis, long, and multiple stenoses are markers for procedural endo failure. In addition, McCallum *et al.*[25] underlined the superiority of open surgical reinterventions on vein grafts for unfavorable lesions (multiple lesions, lesions >2 cm in length, lesions in grafts <3 months old, lesions in grafts <3 mm in diameter).

Therefore, endovascular treatment seems to be effective and safe for fibrous, short, focal lesions placed at proximal/distal anastomosis or inside the vein bypass.[26, 27] In the present study, the majority of endovascular procedures have been performed to treat this kind of lesions. The surgeons clearly preferred an endovascular approach to manage the anastomotic complications of the vein grafts. Only in 4 cases an open surgical approach was performed (Group-no endo).

However, endovascular tools could be also useful to improve the inflow/outflow status. Patel *et al.*[28] demonstrated the usefulness of endovascular improvement of inflow/outflow even in distal bypass grafts. In the present study, an iliac stenting was performed in 2 cases in order to improve the inflow to the vein bypass, whilst a recanalization of below-the-knee (BTK) vessels was performed in 10 cases.

Endovascular treatment of BTK vessels could be obtained with different techniques.[29] However, the need to repeat endovascular revascularizations of tibial vessels over the time is well-known.[30] About this topic it is mandatory to have a well-established modern multidisciplinary team approach in order to early detect decrease of run-off status or graft failures.[31]

During the years different endovascular techniques and materials have been proposed to treat vein bypass lesions.[10-13, 23, 26, 27, 32-36] Cutting balloons seemed to not offer advantages over standard balloon angioplasty[33] with a not irrelevant rate of pseudoaneurysms/ruptures.[31] Furthermore, Linni *et al.*[36] demonstrated paclitaxel-coated and plain angioplasty of significant infrainguinal vein bypass stenoses performed equally well in clinical and hemodynamic improvement and in primary and assisted primary bypass patency rates.

In the present study follow-up endovascular procedures to treat stenoses or to improve inflow/outflow were able to obtain 100% of limb salvage at 2 years in patients with CLTI undergoing in situ saphenous infragenicular bypass. Furthermore, this "aggressive" approach guaranteed a 2-year overall patency rate of 97.9% in a subgroup of patients with a lot of potential risk factors.

These outcomes appeared significantly better when compared with those obtained in patients not endovascularly treated. Both groups were homogeneous in terms of demographics and intraoperative details. Maybe in the group of patients not undergone endovascular management there was an underestimation of such stenotic lesions nevertheless the patients had the same strict follow-up surveillance with Duplex scan. In addition, during the follow-up most of endovascular procedures was performed within 6 months from the index procedure underlying the importance to establish a strict surveillance program.[4, 6]

Limitations of the study

Finally, this study has some limitations. First, the registry is based on the concept of "all-comers"; therefore, there is no homogeneity about the intraprocedural diagnostic evaluation, and the endovascular treatment performed. Second, the follow-up is quite short; further investigations are needed to obtain long-term outcomes.

Conclusions

Secondary endovascular procedures during the follow-up in patients with CLTI undergoing in situ saphenous infragenicular bypass significantly improve the rates of overall

patency and limb salvage in the mid-term period. Majority of endovascular procedures was related to the treatment of restenotic lesions at proximal/distal anastomosis or improvement of the inflow/outflow. Endovascular procedures predominantly occurred within 6 months from the index procedure.

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