Comparison Between Autogenous Saphenous Vein and Heparin-Bonded Expanded Polytetrafluoroethylene for Below-the-Knee Popliteal and Tibial Bypasses in Patients With Critical Limb Ischemia

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Abstract

Objective: To retrospectively compare the outcomes of heparin-bonded expanded polytetrafluoroethylene (HePTFE) and autogenous saphenous vein (ASV) in patients undergoing below-the-knee (BTK) femoropopliteal bypass for critical limb ischemia (CLI). **Methods:** From January 2002 to December 2022, 337 BTK bypasses were performed in patients with CLI: 145 with ASV and 192 with a HePTFE graft. Perioperative outcomes were analyzed in terms of mortality, thrombosis, reinterventions, and early amputation, and compared with an $\chi 2$ test. Follow-up outcomes were analyzed in terms of survival, primary patency, secondary patency, limb salvage, and amputation-free survival with Kaplan-Meier curves and a log-rank test. **Results:** There were no differences in terms of perioperative outcomes. The median duration of follow-up was 37 months. The estimated 10-year survival rate was 46% in the HePTFE group and 49.7% in the ASV group (P = .8, log-rank 0.07). Primary patency rates at 10 years were 26% in the HePTFE group and 36% in the ASV group (P = .1, log-rank 2.2). Secondary patency rates were 29% (standard error [SE] 0.06) and 36.6% (SE 0.08), respectively (P = .7, log-rank 0.08). Amputation-free survival rates were 38% (SE 0.06) and 40.5% (SE 0.05), respectively (P = .9, log-rank 0.09). The presence of coronary artery disease, ulcers or gangrene, and the need for tibial anastomosis were independent predictors of death and/or amputation during follow-up. **Conclusions:** HePTFE demonstrated comparable 10-year outcomes to those achieved with ASV in patients with CLI undergoing BTK or tibial bypass, particularly in the BTK setting, whereas, in the tibial artery, the performance of both materials was extremely poor.

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Key words: critical limb ischemia, femoropopliteal bypass, HePTFE, autogenous saphenous vein, below the knee

Femoropopliteal bypass remains the preferred treatment for individuals with critical limb ischemia (CLI), particularly those presenting with long and complex lesions in the superficial femoral and popliteal arteries and who have a low-to-mild/moderate surgical risk.[1,2]

The preferred choice for bypass material is the autogenous saphenous vein (ASV)[3]; however, up to 30% of patients with CLI may lack a suitable ipsilateral saphenous vein.[4] The efficacy of alternative autogenous vein sources is still a matter of debate.[5] Consequently, in such situations, the use of a prosthetic graft may be necessary. The most commonly utilized synthetic material is expanded polytetrafluoroethylene (ePTFE), which exhibits non-negligible rates of late failures, particularly in below-the-knee (BTK) applications.[6] Heparin bonded to ePTFE surfaces appears to yield satisfactory outcomes in the medium to long term,[7,8] demonstrating a clear advantage over standard ePTFE in patients with CLI.[9] Studies directly comparing heparin-bonded ePTFE (HePTFE) and ASV present conflicting results, often influenced by significant selection bias.[10-12] Moreover, in the recent CLI-BEST trial,[2] the autogenous vein had the same

rate of late failure of prosthetic grafts, raising further doubts on this issue.[13] The objective of this paper is to conduct a retrospective comparison between HePTFE and ASV in patients undergoing BTK femoropopliteal bypass for CLI. The study aimed to assess both perioperative and late outcomes within a single-center cohort.

Materials and Methods

Patient population, indications for surgery, and surgical strategy

From January 2002 to December 2022, 625 consecutive femoropopliteal bypasses were performed at our institution. Data on these interventions were collected in a dedicated multitasking database; data collection was retrospective until 2008 and was prospective thereafter.

A retrospective analysis of this database was performed, and 337 BTK bypass procedures performed for CLI were found. Among these, 145 used ASV and 192 utilized HePTFE (Propaten vascular graft [Gore]). This graft has been available for use in Italy since the end of 2001. Thirty-nine above-the-knee (ATK) HePTFE bypasses in patients with CLI were performed in the same period, which were excluded from the analysis. Informed consent for the treatment of personal data was obtained from each patient upon hospital admission. The Institutional Review Board did not require approval for the retrospective analysis of the data. The interventions conducted prior to 2019 had been previously documented in publications from the multicenter Italian Registry on the HePTFE graft, which encompasses our center's involvement in 234 procedures.[7,8,11,12] Results from these interventions were also part of a single-center publication.[14] The current study updates these findings by incorporating data from procedures performed after 2019.

The surgery was recommended for individuals experiencing CLI, characterized by ischemic rest pain and an ankle-brachial index (ABI) below 0.4 or tissue loss (ulceration, gangrene).[15] This recommendation applied to patients with a low-to-moderate surgical risk (with an estimated perioperative mortality < 5% and a 2-year estimated survival rate exceeding 50%). Additionally, surgery was advised in the presence of challenging infrainguinal lesions, such as long occlusions of the superficial femoral artery (SFA), involvement of the popliteal artery and popliteal trifurcation, severe and widespread calcifications of the SFA, and less complex lesions following an unsuccessful prior endovascular treatment.

All patients underwent both duplex scanning of the lower extremities and computed tomography angiography (CTA) scans from the abdominal aorta to the tibial and foot vessels. The duplex examination included an assessment of the ipsilateral great saphenous vein (GSV), which was deemed optimal if it had a diameter greater than 4 mm, was devoid of varicosities, and showed no signs of previous thromboses. The decision to employ a prosthetic graft was not solely based on the absence of a suitable vein; in selected cases, patients with a good-quality ASV (as determined by the surgeon's clinical and anatomical considerations, habits, and experience) were also considered. The contralateral saphenous vein or alternative veins were not considered as potential sources for venous materials.

The intervention was conducted under general anesthesia, with all patients receiving intravenous systemic heparinization at a dose of 30 IU/kg, followed by additional doses based on activated clotting time (ACT) values. When utilizing the GSV, both in situ and reversed techniques were employed at the surgeon's discretion, following the standard technique of our institution. In the HePTFE group, adjunctive procedures to enhance inflow were selectively performed, and a liberal approach to techniques for improving runoff was adopted at the outflow level. For the ASV group, the use of proximal and distal adjunctive procedures was selective, considering the status of the femoral bifurcation and the presence of significant concurrent lesions in the popliteal or tibial arteries. Patients who had a distal anastomosis at the tibioperoneal trunk were included among those with a BTK popliteal and not a tibial bypass. Completion angiography or intraoperative duplex ultrasound was routinely conducted. Patients with extensive ulcers or dry gangrene of the foot underwent concomitant toe and/or forefoot amputation. In both groups, patients were discharged with prescribed double antiplatelet therapy for a minimum of 3 to 6 months, followed by a single antiplatelet therapy indefinitely. Warfarin therapy was continued after discharge for patients who were on it prior to the lower extremity intervention or those deemed at increased risk of failure (eg, redo surgery, concurrent severe disease of the tibial vessels), sometimes in combination with single antiplatelet therapy. In selected cases, low-dose rivaroxaban plus aspirin was prescribed, particularly following the publication of the Voyager trial.[16]

Follow-up program

Follow-up assessments were conducted at 1, 3, and 12 months with subsequent evaluations every 6 to 9 months. During follow-up examinations, the clinical status was evaluated and duplex ultrasound (DUS) performed to assess graft patency. The examination also checked for disease progression at the inflow and outflow levels, the presence of flow-limiting stenosis at anastomoses and along the graft course, and saphenous collaterals causing a reduction in flow velocity within the bypass. Graft occlusion was defined when blood flow was not detectable, while significant stenosis was characterized by an increase in trans-stenotic peak systolic velocity (PSV) exceeding 300 cm/sec or a PSV ratio value exceeding 3.5. Reintervention was recommended in the presence of significant stenosis, whether symptomatic or asymptomatic, or in cases of occlusion leading to severe claudication, CLI, or acute limb ischemia. Additional data concerning long-term survival, major cardiovascular events, and subsequent hospitalizations were obtained from the Regional Health Care database.

Outcomes and statistics

Perioperative outcomes were scrutinized, encompassing mortality, graft thrombosis, major amputations (ATK or BTK), and severe local and systemic complications. The latter were defined as complications necessitating surgical, medical, or endovascular interventions, and included instances involving prolonged convalescence and lasting disability.[17] Follow-up outcomes were primary and secondary patency, freedom from major amputation, amputation-free survival (AFS), and overall survival. The analysis of follow-up results concluded in September 2023.

To compare the 2 groups (HePTFE and ASV), perioperative results were analyzed using $\chi 2$ tests and Fisher's exact tests when necessary. Follow-up data were assessed using Kaplan-Meier curves and compared with the log-rank test. The follow-up index (FUI) for late survival was determined in the study group, which was defined as the ratio between the investigated follow-up period and the theoretically possible follow-up period up to September 2023. Univariate analysis, employing Kaplan-Meier survival estimates and log-rank tests for each covariate, was performed to identify potential significant predictors of AFS. Covariates showing a *P* value less than or equal to 0.2 in univariate analysis were included in a forward Cox regression analysis for primary patency, with measurement of hazard ratio (HR) and confidence intervals (CI; significance criteria: 0.25 for entry, 0.05 for removal). Statistical analysis was carried out using dedicated Windows software (Statistical Package for the Social Sciences [SPSS] 26), with statistical significance defined as a *P* value of less than 0.05.

Table 1. Demographic data, comorbidities, risk factors, and clinical and anatomical characteristics in the 2 groups

	HePTFE group (192)	ASV group (145)	*P* value
Female gender	54 (28%)	35 (24%)	0.4
Mean age (years)	73.3 ± 8.1	72.1 ± 9.9	0.1
History of smoking	135 (70%)	107 (74%)	0.7
Hyperlipidemia	148 (77%)	105 (72%)	0.3
Arterial hypertension	180 (94%)	129 (90%)	0.1
Diabetes mellitus	69 (36%)	63 (43%)	0.3
Coronary artery disease	80 (42%)	54 (37%)	0.3
Chronic renal failure	22 (11%)	22 (15%)	0.4
Primary intervention	129 (67%)	88 (61%)	0.2
Presence of ulcers/gangrene	90 (47%)	77 (53%)	0.3
Less than 2 outflow vessels	105 (55%)	94 (65%)	0.06
Preoperative ABI value	0.21 ± 0.2	0.2 ± 0.19	0.3

Abbreviations: HePTFE, heparin-bonded expanded polytetrafluoroethylene; ASV, autogenous saphenous vein; ABI, ankle-brachial index.

Table 2. Site of distal and proximal anastomosis with the involved vessels in the 2 groups

	HePTFE group (192)	ASV group (145)	*P* value
Proximal anastomosis			
Common femoral	174 (90.5%)	124 (86%)	0.09
Superficial femoral	18 (9.5%)	21 (14%)	
Distal anastomosis			
Popliteal	130 (68.5%)	88 (60.5%)	
Tibioperoneal trunk	35 (18%)	18 (12.5%)	
Peroneal	14 (7%)	21 (14.5%)	0.01
Posterior tibial	6 (3%)	13 (9%)	
Anterior tibial	7 (3.5%)	5 (3.5%)	

Abbreviations: HePTFE, heparin-bonded expanded polytetrafluoroethylene; ASV, autogenous saphenous vein

Results

Baseline data, intraoperative and postoperative details

The baseline characteristics of patients in the HePTFE and ASV groups were comparable (**Table 1**). In the HePTFE group, 73 patients were classified as Rutherford class 5 CLI, and 17 patients were classed as Rutherford class 6. In the ASV group, the corresponding numbers were 59 and 18, respectively ($P = .4$). Regarding the runoff status, among patients with more than 1 patent tibial vessel, 76 patients in the HePTFE group and 35 patients in the ASV group had 2 patent distal vessels. Additionally, 8 patients in the HePTFE group and 13 patients in the ASV group had 3 patent tibial vessels ($P = .008$).

Table 2 provides details on the site of proximal and distal anastomosis in both groups, along with the target vessels. A distal tibial anastomosis was necessary in 27 patients in the HePTFE group (14%) and in 39 cases in the ASV group (27%, $P = .003$). In the ASV group, 78 patients underwent an in-situ vein bypass, while 67 underwent a reversed vein bypass. In 80 cases (51 in the HePTFE group and 29 in the ASV group, $P = .1$), adjunctive procedures to enhance the run-in were performed. Adjunctive procedures at the runoff level were conducted in 190 cases (149 in the HePTFE group and 41 in the ASV group, $P < .001$). The types of adjunctive procedures are detailed in **Table 3**. The mean duration of the intervention was 268.2 ± 114.8 minutes in the HePTFE group and 332.4 ± 116.3 minutes in the ASV group ($P = .001$). The mean hospital stay was 13.5 ±

TABLE 3. ADJUNCTIVE INTRAOPERATIVE PROCEDURES IN THE 2 GROUPS

	HePTFE group (192)	ASV group (145)	*P* value
Proximal procedures	51 (26.5%)	29 (20%)	
Open femoral	27	15	0.1
Endo iliac	4	4	
Distal procedures	149 (78%)	41 (28%)	
Vein cuff	66	21	
Patching	65	14	
Short vein segment	13	2	< 0.001
Tibial PTA	5	2	
Tibial AVF	-	2	

Abbreviations: HePTFE, heparin-bonded expanded polytetrafluoroethylene; ASV, autogenous saphenous vein; PTA, percutaneous transluminal angioplasty; AVF, arteriovenous fistula.

10.7 days in the HePTFE group and 14.5 ± 11.5 days in the ASV group (*P* = .2).

Upon discharge, ABI values significantly improved in both groups compared with preoperative assessments, with no significant differences between the 2 groups. Double antiplatelet treatment was prescribed for 112 cases in the HePTFE group and 72 cases in the ASV group. Single antiplatelet treatment was prescribed for 33 patients in the HePTFE group and 21 patients in the ASV group, while the remaining patients were on oral anticoagulant therapy with or without additional antiplatelet drugs. In 15 cases, the Voyager protocol was adopted, while, in 1 patient, dual antiplatelet therapy and low-dose rivaroxaban was used for the first postoperative month and then shifted to aspirin and rivaroxaban. The overall rate of patients treated with oral anticoagulants was 25% in the HePTFE group and 37% in the ASV group (*P*= .05) (**Table 4**).

Perioperative results

There were 4 perioperative deaths: 1 in the HePTFE group and 2 in the ASV group, resulting in a mortality rate of 0.5% in the HePTFE group and 2% in the ASV group (*P* = .2). In total, perioperative thromboses occurred in 29 patients, with 15 in the HePTFE group and 14 in the ASV group (*P* = .5). There were 13 perioperative amputations, leading to an overall amputation rate of 3.8% (6 in the HePTFE group [3.1%] and 7 in the ASV group [4.8%], *P* = .4).

Major complications were observed in 8 patients in the HePTFE group (5 cardiac cases, 2 respiratory cases, and 1 local case) and in 7 patients in the ASV group (3 cardiac cases and 4 local cases, *P* = .7).

Long-term results

In the entire study group, 310 patients (92%) had available

TABLE 4. UNIVARIATE ANALYSIS FOR AMPUTATION-FREE SURVIVAL AT 10 YEARS IN THE 2 GROUPS

	AFS at 10 years (%)	Log-rank	*P* value
Gender			
Female	32	2.4	0.1
Male	41		
Kind of intervention			
Primary	40	2.9	0.08
Secondary	29		
Diabetes			
Yes	23	17.8	< 0.001
No	48		
Arterial hypertension			
Yes	43	0.6	0.5
No	38		
Hyperlipemia			
Yes	31	5.3	0.02
No	53		
Coronary artery disease			
Yes	31	6.6	0.01
No	43		
Chronic renal failure			
Yes	20	3.5	0.05
No	39		
Clinical status			
Rest pain	49.5	30.2	< 0.001
Ulcers	24		
Less than 2 patent tibial vessels			
Yes	44	6.1	0.01
No	34		
Distal anastomosis			
Popliteal	42	16.8	< 0.001
Tibial	14		
Adjunctive distal procedures			
Yes	35	0.03	0.8
No	39		
Postoperative medical treatment			
Single antiplatelet	34	1.3	0.5
Double antiplatelet	34		
Oral anticoagulant	29		
Graft material			
HePTFE	38	0.09	0.9
ASV	40.5		

Abbreviations: AFS, amputation-free survival; HePTFE, heparin-bonded expanded polytetrafluoroethylene; ASV, autogenous saphenous vein.

follow-up data, with a median duration of 37 months (range 1-168). The mean follow-up index was 0.7 (range 0.03-1), which was similar between the 2 groups (0.68 and 0.71, respectively; *P* = .5).

During follow-up, there were 83 deaths (24.5%), with 54 (28%) in the HePTFE group and 29 (20%) in the ASV group. The most common causes of death were cardiac disease and cancer in both groups.

A total of 127 (37.5%) thromboses were recorded, with 88 (45.8%) in the HePTFE group and 39 (27%) in the ASV group. Additionally, 18 flow-limiting lesions without graft thrombosis were identified: 6 in the HePTFE group and 12 in the ASV group. In the entire study group, 16 flow-limiting lesions were found during follow-up: in the HePTFE group, 4 cases of stenosis at the distal anastomosis were found and all underwent reintervention, which was open in 3 cases (patching at the distal anastomosis) and endovascular in 1 case (percutaneous transluminal angioplasty [PTA] of the anastomosis). In the ASV group, 7 anastomotic stenoses, 2 stenoses due to valve residuals, and 3 stealing collaterals occurred; 11 of these underwent reintervention, which was endovascular in 4 cases (PTA of the valve residuals in 2 cases and of the anastomotic stenosis in 2 cases) and open surgical in 7 cases (patching of the anastomosis in 4 cases and ligature of the collaterals in 3 cases). One patient with anastomotic stenosis refused the reintervention.

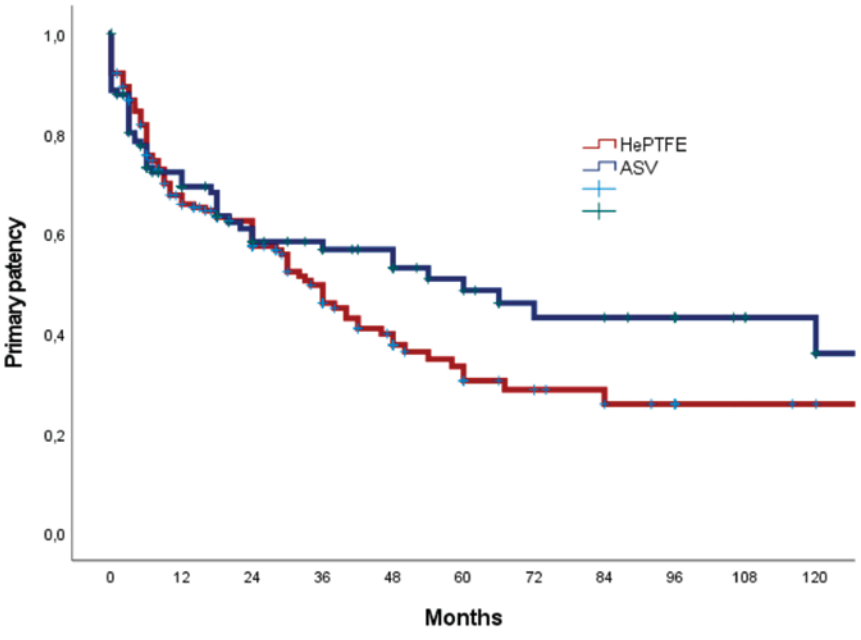
In addition to the 13 perioperative amputations, another 56 (16.6%) amputations were necessary during follow-up, with 36 (18.7%) in the HePTFE group and 20 (13.7%) in the ASV group.

The estimated 10-year survival rate was 46% (SE 0.06) in the HePTFE group and 49.7% (SE 0.08) in the ASV group (*P* = .8, log-rank 0.07). Primary patency rates at 10 years were 26% (SE 0.05) in the HePTFE group and 36% (SE 0.08) in the ASV group (*P* = .1, log-rank 2.2) (**Figure 1**). Secondary patency rates at 10 years were 29% (SE 0.06) and 36.6% (SE 0.08), respectively (*P* = .7, log-rank 0.08). Limb salvage rates were 69% (SE 0.04) in the HePTFE group

TABLE 5. TEN-YEAR OUTCOMES BASED ON THE DISTAL ANASTOMOTIC SITE

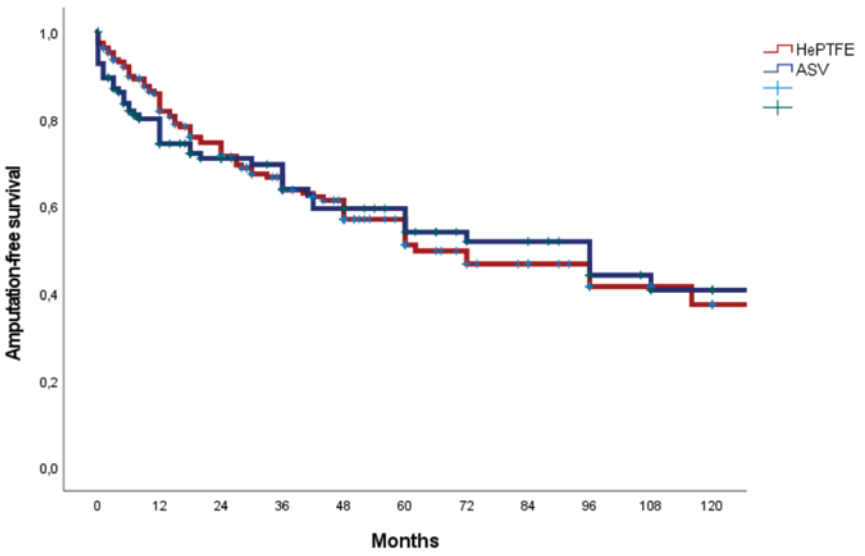
Outcome at 10 years	Survival	Primary patency	Secondary patency	Limb salvage	AFS
BTK bypass					
HePTFE	53%	27%	33%	74%	42%
ASV	50%	43%	44%	80%	45%
P value	0.8	0.01	0.1	0.6	0.5
Tibial bypass					
HePTFE	18.5%	19%	33%	44%	17%
ASV	31.5%	21%	21%	54%	27%
P value	0.8	0.9	0.4	0.9	0.8

Abbreviations: AFS, amputation-free survival; BTK, below-the-knee; HePTFE, heparin-bonded expanded polytetrafluoroethylene; ASV, autogenous saphenous vein.



Months	0	48	60	120
HePTFE group				
• n at risk	187	94	23	2
• SE	0.01	0.04	0.05	0.05
ASV group				
• n at risk	122	30	21	5
• SE	0.01	0.05	0.06	0.08

FIGURE 1. Kaplan-Meier curves for 10-year primary patency in the 2 groups with the number of patients at risk at different time intervals. Abbreviations: HePTFE, heparin-bonded expanded polytetrafluoroethylene; SE, standard error; ASV, autogenous saphenous vein.



Months	0	48	60	120
HePTFE group				
• n at risk	187	70	47	8
• SE	0.01	0.04	0.05	0.06
ASV group				
• n at risk	122	58	32	9
• SE	0.01	0.04	0.05	0.07

FIGURE 2. Kaplan-Meier curves for 10-year amputation-free survival in the 2 groups with the number of patients at risk at different time intervals. Abbreviations: HePTFE, heparin-bonded expanded polytetrafluoroethylene; SE, standard error; ASV, autogenous saphenous vein.

and 73% (SE 0.05) in the ASV group (P = .6, log-rank 0.1), whereas the corresponding values in terms of AFS at 10 years were 38% (SE 0.06) and 40.5% (SE 0.05), respectively (P = .9, log-rank 0.09) (**Figure 2**). Univariate analysis for AFS in the entire study group is reported in **Table 4**. The presence of coronary artery disease, ulcers or gangrene, and the need for tibial anastomosis were independent predictors of death and/or amputation at the multivariate analysis (95% CI, 1.1-3.1; HR 1.9 for coronary artery disease; 95% CI, 1.7-3.9; HR 2.6 for ulcers or gangrene; and 95% CI, 1.4-4.2; HR 2.7 for tibial anastomosis). In patients operated on with ASV, the method of handling the vein (in situ or reversed) did not affect 10-year AFS. The outcomes are reported based on the distal anastomotic site (BTK or tibial) in **Table 5**.

Discussion

International recommendations and consensus emphasize the significance of having access to a high-quality ASV when considering the decision to undergo a BTK surgical bypass in individuals with CLI.[1,3,15,18] These recommendations primarily stem from over 4 decades of clinical practice and the findings of meta-analyses conducted over the years. However, the field still lacks strong scientific evidence to substantiate these guidelines.[6,19] Indeed, there is only 1 prospective randomized trial that compares ASV and prosthetic grafts in addressing infrainguinal arterial occlusive disease.[20] Additionally, the most recent Cochrane Review recognizes the presence of only very low-quality data concerning BTK bypasses, creating uncertainty regarding the optimal graft type for this purpose.[21]

Within the category of prosthetic grafts, HePTFE stands out as particularly promising. For more than a decade, our institution has served as the coordinating center for an Italian multicenter registry focused on the application of this material in patients with peripheral arterial disease. The outcomes of this registry have been documented in several papers, affirming the safety and efficacy of HePTFE.[7,10-12,14] In this current investigation, we specifically examined data from our center, focusing on BTK bypass procedures in patients with CLI. Surprisingly, we observed comparable 10-year patency rates between ASV and HePTFE, which is an uncommon finding in the existing literature. Notably, in the seminal study by Veith et al,[20] 4-year patency rates favored ASV, and subsequent meta-analyses consistently demonstrated excellent results for both BTK and tibial ASV bypasses, surpassing the outcomes achieved with ePTFE.[6,19] The outcomes from our multicenter registry revealed fewer pronounced differences compared with the studies mentioned earlier, providing further support for the enhancements in results associated with HePTFE.[11,12,14] In a retrospective comparative study,[10] Daenens et al have demonstrated comparable outcomes between the 2 materials at both the popliteal and tibial levels, despite differences in the populations being nonequivalent. Our finding of noninferior performance at 10 years for HePTFE with respect to ASV in similar subgroups of patients compares well with the results of a recent literature review[22] that reported similar outcomes in terms of graft patency and limb salvage between HePTFE and autogenous vein.

The secondary patency rates were comparable between the 2 groups and we observed, consistent with our previous publications, that once thrombosis occurred, restoring patency in ASV bypasses was more challenging and intricate compared with HePTFE bypasses. AFS rates did not exhibit significant differences between the 2 groups, with both showing satisfactory values of around 40%. This finding is particularly noteworthy consider-

ing the unfavorable natural course of CLI in untreated patients. However, the 10-year results of tibial bypasses were notably poor in both HePTFE and ASV patients, underscoring the pivotal role of an endovascular approach in the infrapopliteal segment, as recently emphasized in the BASIL-2 trial.[23]

The present study has several limitations. It is a retrospective, nonrandomized investigation in which the selection of prosthetic material was influenced by various clinical and anatomical factors, not solely the absence of a satisfactory ASV. Additionally, alternative venous sources such as the contralateral saphenous vein, lesser saphenous vein, contralateral GSV, or arm veins, which have been reported in the literature with conflicting results compared with prosthetic grafts, were not considered as sources for venous material.[5,15] Moreover, patient-centered outcomes such as the assessment of quality of life were not included in the results analysis. We also had a limited number of patients at risk at 10 years, even with SE values lower than 0.10, which probably reflects the poor natural history of CLI, particularly when long-term mortality is analyzed.

However, it is worth noting that the 2 groups were relatively homogeneous from both clinical and anatomical perspectives. The follow-up was consistent, with a FUI of about 0.7 in both groups, and there was meticulous documentation of clinical events over the years.

Despite these limitations, our findings continue to support the shift in our recent strategy, which involves using ipsilateral ASV only when of excellent quality. In cases in which prosthetic grafts are chosen, we preferentially employ adjunctive procedures for runoff improvement, coupled with a well-standardized intra- and postoperative protocol.

Conclusions

In our retrospective analysis, HePTFE demonstrated comparable 10-year outcomes to those achieved with ASV in patients with CLI undergoing BTK or tibial bypass. Satisfactory results were observed in both groups in the BTK setting. In the context of infrapopliteal and tibial revascularization, the significantly high failure rates observed at the 10-year follow-up with both materials underscore the predominance of the endovascular approach as the primary intervention method.

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