



Autologous saphenous vein and heparin-bonded expanded polytetrafluoroethylene as graft materials for below-the-knee femoro-popliteal bypass in patients with critical limb ischemia: A propensity score-matched analysis

Walter Dorigo ^{a,*}, Aaron Fargion ^a, Giulia Bassoli ^a, Rossella Di Domenico ^a, Elena Giacomelli ^a, Gabriele Piffaretti ^b, Alessandro Alessi Innocenti ^a, Carlo Pratesi ^a

^a Department of Vascular Surgery, University of Florence, Italy

^b Department of Vascular Surgery, University of Insubria, Italy

ARTICLE INFO

Article history:

Received 28 July 2020

Received in revised form

18 January 2021

Accepted 2 February 2021

Available online 6 March 2021

Keywords:

Critical limb ischemia

Infrainguinal bypass

Heparin bonded ePTFE

Autologous vein

Comparison

ABSTRACT

Objective: To compare the outcomes of heparin bonded expanded polytetrafluoroethylene (HePTFE) and autologous saphenous vein (ASV) in patients undergoing below-knee (BK) femoro-popliteal bypass for critical limb ischemia (CLI).

Design: Retrospective single-centre matched case–control study.

Methods: From 2003 to 2019, 275 consecutive BK bypasses for CLI were performed, 109 with the ASV and 166 with a HePTFE graft. All the baseline characteristics that were reliably measured and were potentially relevant in the decision-making process were included as confounders in a logistic regression model and the factors that were significantly different between the two groups then used to perform a propensity matching analysis. Propensity score-based matching was performed in a 1:1 ratio to compare outcomes. Arterial hypertension, hyperlipemia, the need for tibial anastomosis at the distal level and the run-off status were the covariates included in the matching. Follow-up outcomes were estimated by Kaplan–Meier methods and compared with log rank test.

Results: After propensity matching, 101 HePTFE bypasses were matched with 101 ASV bypasses. The median duration of follow-up was 37 months (range 1–192). The 5-year survival rate was 67.5% (standard error (SE) 0.05) in the HePTFE group and 64.5% (SE 0.06) in the ASV group ($p = 0.8$, log rank 0.04). Primary patency rates were 38% (SE 0.06) in the HePTFE group and 41% (SE 0.06) in the ASV group ($p = 0.7$, log rank 0.3). Also assisted primary patency and secondary patency rates did not differ in the two groups. Amputation-free survival was 53% (SE 0.05) in the HePTFE group and 58% (SE 0.06) in the ASF group ($p = 0.6$, log rank 0.2).

Conclusions: HePTFE provided 5-year similar results to those obtained with use of the ASV in equivalent patients with CLI undergoing below-knee or tibial bypass.

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* Corresponding author. Vascular Surgery, Department of Cardiothoracic and Vascular Surgery, Careggi University Teaching Hospital, University of Florence School of Medicine, Largo Brambilla 3, Florence, Firenze, 50134, Italy. Fax: +39 055 7947448.

E-mail address: walter.dorigo@unifi.it (W. Dorigo).

<https://doi.org/10.1016/j.surge.2021.02.001>

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Introduction

Femoro-popliteal bypass is still considered the treatment of choice in patients with critical limb ischemia (CLI), long and complex lesions of superficial femoral and popliteal arteries and low to mild/moderate surgical risk.¹ The preferred material for bypass is the autologous saphenous vein (ASV)²; however, good ipsilateral saphenous vein may be not available in up to 30% of the CLI patients,³ and the effectiveness of autologous alternative vein sources is still debatable.⁴ For this reason, in such circumstances the use of a prosthetic graft may be unavoidable. The most common used synthetic material is expanded polytetrafluorethylene (ePTFE), which however has not negligible rates of late failures, mainly in the below-knee setting.⁵ The use of heparin bonded to ePTFE surfaces seems to provide satisfactory outcomes in the mid and long-term period,^{6,7} with a clear superiority in comparison to standard ePTFE in CLI patients.⁸ The few studies directly comparing HePTFE and ASV report controversial results with significant selection bias.^{9–11} The aim of the present paper was to retrospectively compare HePTFE and ASV in patients undergoing below-knee (BK) femoro-popliteal bypass for CLI, in terms of perioperative and late outcomes, among a homogenous population. To this end, a single centre matched case–control study design was employed.

Materials and methods

Patients population, indications for surgery and surgical strategy

From January 2003 to December 2019, 554 consecutive femoro-popliteal bypasses were performed at the Department of Vascular Surgery of the University of Florence, Italy. Data on these interventions were collected in a dedicated multitasking database; data collection was retrospective until 2008, it was prospective thereafter.

A retrospective analysis of this database was performed and 275 BK bypasses performed for CLI were found, 109 with

ASV and 166 with HePTFE (Gore© Propaten, Vascular Graft, WL Gore and Associates, Newark, DE, USA; Fig. 1) Informed consent for the treatment of personal data was obtained for each patient at the moment of the hospital admission. The retrospective analysis of the data did not require approval of the Institutional Review Board. The interventions carried on until 2016 were object of the previous publications of the multi-center Italian Registry on heparin-bonded ePTFE graft for the part involving our centre (234 interventions).^{6,7,10,11} With respect to those publications, we updated our results by adding data on the interventions performed in the years following 2017 (41 interventions).

The indication for surgery was the presence of CLI, defined as ischemic rest pain and ankle-brachial index (ABI) < 0.4 or tissue loss (ulceration, gangrene) accompanied by objective evidence of significant peripheral arterial occlusive disease (PAOD),¹² in patients with low to moderate surgical risk (estimated perioperative mortality <5% and 2-year estimated survival >50%) and in the presence of complex infrainguinal lesions (long occlusions of the superficial femoral artery (SFA), involvement of the popliteal artery and of the popliteal trifurcation, severe and diffuse calcifications of the SFA, less complex lesions following a prior failed endovascular treatment).

All of the patients underwent both duplex scanning of the lower extremities and angio-computed tomography (CT) scans from the abdominal aorta to the tibial and foot vessels. During duplex examination, the status of ipsilateral ASV was assessed, and it was considered optimal in the presence of a >4 mm diameter, without varicosities and signs of previous thromboses. In selected cases, also suboptimal ASV (>3 mm) was considered for use. However, the choice to use a prosthetic graft was made not only in absence of a suitable vein but also in selected patients with good quality ASV, at the surgeon's discretion on the basis of clinical and anatomical considerations and of his habits and experience. The contralateral saphenous vein or alternative veins such were not considered as a source for venous materials.

The intervention was performed under general anesthesia; all the patients underwent intravenous systemic heparinization (30 international units/kg) followed with further doses

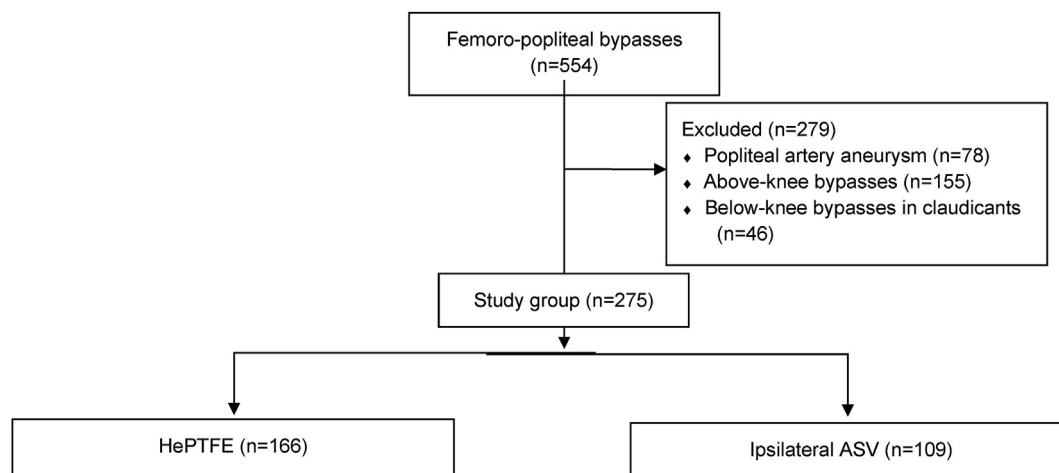


Fig. 1 – Flow diagram showing the study population.

on the basis of the activated clotting time (ACT) values. When ASV was used, both in situ and reversed techniques were used, at surgeon's discretion and following the standard technique of our school. In HePTFE group, adjunctive procedures for improving the inflow were selectively performed, while at the level of the outflow a policy of liberal use of techniques for run-off improvement was adopted. In the ASV group, the use of proximal and distal adjunctive procedures was selective, on the basis of the status of the femoral bifurcation and of the presence of concomitant significant lesions of the popliteal or tibial arteries. Completion angiography or intraoperative duplex ultrasound was routinely performed. In patients with extensive ulcers or dry gangrene of the foot, concomitant toes and/or forefoot amputation were performed. In both groups, patients were discharged with a prescribed double antiplatelet therapy for at least 3–6 months, followed by a single antiplatelet therapy indefinitely. Only patients who were on warfarin therapy prior to the lower extremity intervention, or patients supposed to be at increased risk of failure (redo surgery, concomitant severe disease of the tibial vessels) were prescribed to continue the treatment after the discharge, in selected cases in association with single antiplatelet therapy.

Follow-up and outcomes

Follow-up evaluations were performed at 1 month, 3 and 12 months, and then every 6–9 month. At follow-up controls we assessed the clinical status and we performed duplex ultrasound (DUS) which assessed the patency of the graft, the presence of progression of disease at the inflow and outflow levels, of flow-limiting stenosis, both at the anastomoses and in the graft course, and of saphenous collaterals causing a decreasing of flow velocity inside the bypass. The graft was defined as occluded when we were not able to detect blood flow inside, whereas significant stenosis was defined as an increase of the trans-stenotic peak systolic velocity (PSV) higher than 300 cm/s or a PSV ratio value higher than 3.5. Reintervention was proposed in the presence of significant stenosis, even asymptomatic, or in the case of occlusion leading to severe claudication, CLI or acute limb ischemia.

Additional data regarding long-term survival, major cardiovascular events and later hospitalizations were obtained from the Regional Health Care database.

Perioperative results were analyzed including mortality, graft thrombosis, major amputations (above-knee or below-knee level), severe local and systemic complications, defined as those requiring a surgical, medical, or endovascular intervention and including prolonged convalescence and durable disability.¹³ Follow-up outcomes were primary (the possibility to maintain a functioning graft without adjunctive interventions), assisted primary (the possibility to maintain a functioning graft with adjunctive interventions) and secondary (the possibility to restore graft patency when a thrombosis occurred) patency, freedom from amputation (the absence of amputation at above-knee or below-knee level), amputation-free survival (freedom from above the ankle amputation and from all-cause mortality) and overall survival. The analysis of follow-up results ceased in May 2020.

Statistics

Patients in the HePTFE group were matched to patients in the ASV group on the basis of a propensity score, which is defined as the probability of treatment assignment conditional on observed baseline characteristics.¹⁴ For its calculation, all the baseline characteristics that were reliably measured and were potentially relevant in the decision-making process (Supplemental content, SC; Table 1) were included as confounders in a logistic regression model (forward conditional; 0.05 for entry, 0.10 for removal); they included demographic data, cardiovascular risk factors and comorbidities, clinical status (presence or absence of ulcers) status of the run-off vessels, intended level of the distal anastomosis.

Logistic regression analysis revealed four baseline key factors that were significantly different between the two groups: the presence of hyperlipemia and arterial hypertension, the need for distal tibial anastomosis and less than two patent tibial vessels. Those factors were then used to perform a propensity matching analysis and to generate a score and a score-based matched control group. The two matched groups (HePTFE group, 101 interventions; ASV group, 101 patients) were compared in terms of perioperative results with χ^2 tests and Fisher's exact tests, when necessary. Follow-up data were analysed with Kaplan–Meier curves and compared with log-rank test. The follow-up index (FUI) for late survival up to May 2020 in the study group was assessed. A univariate analysis to identify potential significant predictors of primary patency in the matched groups was performed with Kaplan Meier survival estimates and log rank test for each covariate. Associations that yielded a p value ≤ 0.2 at 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 performed with dedicated Windows software (Statistical Package for the Social Sciences (SPSS) 26; SPSS Inc., Chicago, IL, USA). Statistical significance was defined as a p value less than 0.05.

Results

Demographic data, comorbidities, clinical and anatomical status

Baseline characteristics of the HePTFE and ASV patients in the original data set are reported in Table 1. After propensity matching, there were 101 interventions in the HePTFE group and 101 interventions in the ASV group, with correction of all differences in baseline characteristics (Table 1). The characteristics of the patients excluded from matching are shown in SC Table 2. In the HePTFE group, 44 patients had a Rutherford class 5 CLI and 10 patients a class 6; the corresponding values in the ASV group were 38 and 15 ($p = 0.2$). As far as the run-off status is concerned, among patients with more than one patent tibial vessel, 36 patients in the HePTFE group and 31 patients in the ASV group had two patent distal vessels, whereas only two patients per group had three patent tibial

Table 1 – Demographic data, comorbidities, risk factors, clinical and anatomical characteristics in the whole study group and in the two matched groups.

	HePTFE group (166 int.)	ASV group (109 int.)	<i>p</i>	Matched HePTFE group (101 int.)	Matched ASV group (101 int.)	<i>p</i>
Female gender	52 (31%)	30 (28%)	0.5	30 (30%)	29 (29%)	0.9
Mean age (years)	73.6 ± 8.2	72.1 ± 10.2	0.2	74.3 ± 8.2	72.2 ± 9.2	0.1
History of smoking	116 (70%)	78 (72%)	0.7	70 (69%)	72 (71%)	0.7
Hyperlipemia	130 (78%)	73 (67%)	0.01	69 (68%)	69 (68%)	1
Arterial hypertension	157 (95%)	95 (87%)	0.03	93 (92%)	93 (92%)	1
Diabetes mellitus	61 (37%)	43 (39%)	0.6	40 (40%)	42 (42%)	0.7
Coronary artery disease	74 (45%)	42 (38.5%)	0.3	46 (45.5%)	42 (42%)	0.6
Chronic renal failure	20 (12%)	13 (12%)	0.9	11 (11%)	13 (13%)	0.7
Primary intervention	108 (65%)	67 (62%)	0.5	70 (69%)	73 (72%)	0.2
Presence of ulcers/gangrene	79 (48%)	58 (53%)	0.3	53 (52.5%)	53 (52.5%)	1
Less than 2 outflow vessels	94 (57%)	74 (68%)	0.05	63 (62.5%)	66 (65%)	0.6
Planned tibial anastomosis	25 (15%)	31 (29%)	0.007	25 (25%)	25 (25%)	1
Preoperative ABI value	0.21 ± 0.2	0.19 ± 0.19	0.7	0.19 ± 0.19	0.21 ± 0.19	0.7

vessels. Preoperative ABI values were 0.19 ± 0.19 in the HePTFE group and 0.2 ± 0.19 in the ASV group ($p = 0.7$).

Intraoperative and postoperative details

The site of proximal and distal anastomosis in both groups are reported in Table 2, along with the target vessels. In the ASV group, 54 patients had an in situ vein bypass and 47 a reversed vein bypass. In 50 cases (31 in the HePTFE group and 19 in the ASV group, $p = 0.05$) adjunctive procedure to improve the run-in were performed. Adjunctive procedures at the run-off level were performed in 111 cases (83 in the HePTFE group and 29 in the ASV group, $p < 0.001$). The kind of adjunctive procedures are reported in Table 3. Four patients per group underwent intraoperative amputation of toes (one patient per groups) and of the forefoot (three patients per group). The mean duration of the intervention was 272.5 ± 103 min in the HePTFE group and 317.1 ± 118 min in the ASV group ($p = 0.04$). The mean hospital stay was 15 ± 11.7 days in the HePTFE group and 14.4 ± 10.1 days in the ASV group ($p = 0.7$). At discharging, ABI values significantly improved in both groups with respect to the preoperative assessment, without differences between the two groups. Patients were prescribed antiplatelet treatment in 72 cases in the HePTFE group and in 66 cases in the ASV group ($p = 0.3$), whereas the remaining patients were treated with oral anticoagulants.

Perioperative results

One patient of the ASV group suffered from fatal sepsis following bypass thrombosis, irreversible ischemia and above the knee amputation. Overall, perioperative thromboses occurred in 19 patients, 10 in the HePTFE group and 9 in the ASV group ($p = 0.8$). In the HePTFE group, five patients underwent reintervention (four open and one endovascular), one patient underwent a new bypass, three patients underwent immediate amputation and one patient refused the reintervention and he was medically treated. In the ASV group, three patients underwent open reintervention and six patients underwent immediate amputation. One adjunctive amputation occurred in a patient of the ASV group following the failure of the reintervention.

Overall, amputation rates were 3% in the HePTFE group and 6.9% in the ASV group ($p = 0.2$).

Major complications occurred in 8 patients in the HePTFE group (cardiac in 5 cases, respiratory in 2 cases and local in one case) and in 7 patients in the ASV group (cardiac in three cases and local in four cases; $p = 0.7$).

Follow-up results

In the whole study group, 264 patients (96.5%) had available follow-up data, with a median duration of 37 months (range

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

	HePTFE group (101 int.)	ASV group (101 int.)
Proximal anastomosis		
• Common femoral	98	86
• Superficial femoral	3	15
Distal anastomosis		
• Popliteal	55	62
• Tibioperoneal trunk	21	14
• Peroneal	13	14
• Posterior tibial	6	10
• Anterior tibial	6	1

Table 3 – Adjunctive intraoperative procedures in the matched groups.

	HePTFE group (101 int.)	ASV group (101 int.)	<i>p</i>
Proximal procedures	31 (30%)	19 (19%)	0.05
• Open femoral	27	15	
• Endo iliac	4	4	
Distal procedures	83 (82%)	29 (29%)	<0.001
• Vein cuff	42	15	
• Patching	31	9	
• Short vein segment	9	2	
• Tibial PTA	0	1	
• Tibial AVF	1	2	

1–192). With regard to the matched groups, 196 patients (97%) had follow-up data available, with a median duration of 37 months (range 1–192). The mean follow-up index was 0.69 (range 0.03–1) and it was similar between the two groups (0.67 and 0.69, respectively, $p = 0.7$).

During follow-up there were 57 deaths, 32 in the HePTFE group and 25 in the ASV group. The most frequent causes of death were cardiac disease and cancer in both groups; in 20 patients (10 per group) the cause of death was unknown.

Seventy-five thromboses were recorded, 43 in the HePTFE group and 32 in the ASV group. In Table 4 the adopted strategy following graft thrombosis is reported. Moreover, 11 flow-limiting lesions without graft thrombosis were identified, 1 in the HePTFE group and 10 in the ASV group. In the HePTFE group, one case of stenosis at the distal anastomosis was found. In the ASV group four anastomotic stenosis, two stenosis due to valve residual and four stealing collaterals occurred. All these patients underwent reintervention, which was endovascular in 2 cases and open surgical in 9 cases. In six patients, further reinterventions following the first reintervention were necessary.

Besides the 15 immediate amputations following graft thrombosis, other 22 amputations following the failure of the reintervention were necessary, 14 in the HePTFE group and 8 in the ASV group.

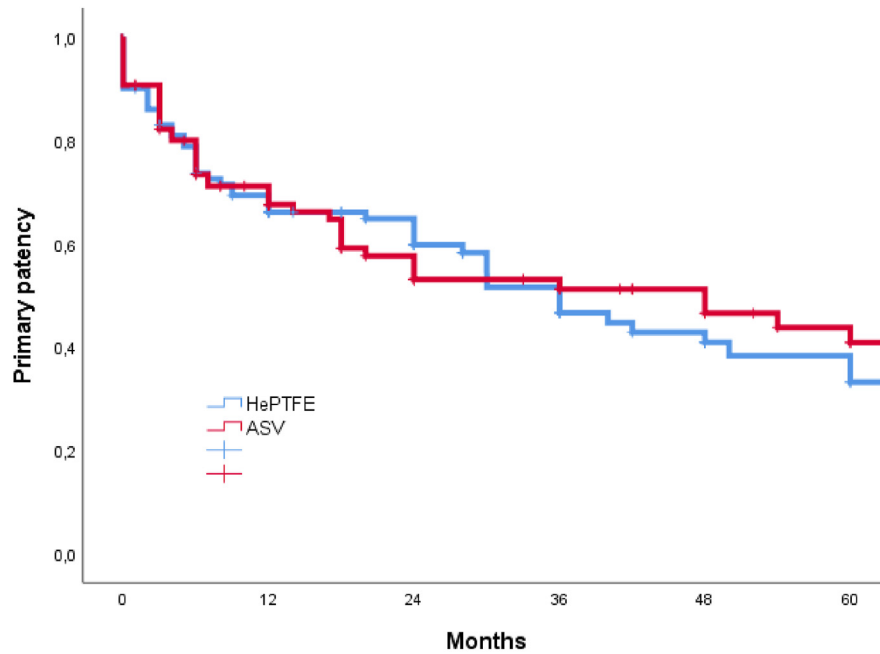
The estimated 5-year survival rate was 67.5% (standard error (SE) 0.05) in the HePTFE group and 64.5% (SE 0.06) in the ASV group ($p = 0.8$, log rank 0.04). Primary patency rates were 38% (SE 0.06) in the HePTFE group and 41% (SE 0.06) in the ASV group ($p = 0.7$, log rank 0.3; Fig. 2). Assisted primary patency was 39% (SE 0.06) in the HePTFE graft and 50.5% (SE 0.06) in the ASV group ($p = 0.1$, log rank 1.7), whereas secondary patency rates were 57.5% (SE 0.06) and 52% (SE 0.06), respectively ($p = 0.9$, log rank 0.01). Limb salvage rates were 74% (SE 0.05) in the HePTFE group and 73% (SE 0.05) in the ASV group ($p = 0.8$, log rank 0.03), whereas the corresponding values in terms of amputation-free survival were 53% (SE 0.05) and 58% (SE 0.06), respectively ($p = 0.6$, log rank 0.2, Fig. 3). In Table 5 the results in the matched groups are separately analysed on the basis of the level of distal anastomosis. Univariate analysis for primary patency in the matched groups is reported in Table 6: the presence of hyperlipemia and the need for tibial anastomosis were independent predictors of losing primary patency at the multivariate analysis (95% CI 1.1–1.9, HR 1.8 for hyperlipemia and 95% CI 1.8–4.2, HR 2.9 for tibial anastomosis).

Table 4 – Kind of reinterventions following graft thrombosis during follow-up.

	HePTFE group (43 thromb.)	ASV group (32 thromb.)
Open reintervention	5 (11.5%)	7 (22%)
Endovascular reintervention	1 (2.5%)	–
Isolated thrombolysis	12 (28%)	3 (10%)
Thrombolysis and endovascular	3 (7%)	–
New bypass	5 (11.5%)	3 (10%)
Immediate amputation	9 (21%)	6 (19%)
Medical treatment	8 (18.5%)	13 (39%)

Discussion

International guidelines and consensus indicate that the availability of a good quality autologous saphenous vein is a crucial issue in the indication to perform a below-knee surgical bypass in patients with critical limb ischemia.^{1,2, 12} Such recommendations derive mainly from more than four decades of good clinical practice and from the results of the meta-analyses performed during the years, but there is still a lack of robust scientific evidences in this field.^{5,15} In fact, there is only one prospective randomised trial comparing ASV and prosthetic grafts in the management of infrainguinal arterial occlusive disease¹⁶ and the most recent Cochrane review¹⁷ acknowledges that only very low-quality data exist on below-knee bypasses and there is uncertainty which graft type is best. Among prosthetic grafts, one of the most promising is heparin-bonded ePTFE; for over a decade, our institution has been the coordinating centre of an Italian multicentre registry on the use of that material in patients with peripheral arterial disease, whose results were the object of several papers confirming its safety and effectiveness.^{6,10,11} In the present study we analysed only the data from our centre, with particular interest to below-knee bypasses in patients with CLI, and we performed a propensity score matching in order to have similar baseline clinical and anatomical characteristics. We found similar 5-year patency rates between ASV and HePTFE, and this represents an uncommon finding in the literature. In fact, in the classical study from Veith et al.,¹⁶ 4-year patency rates were clearly better among patients treated with the ASV, and also in the following meta-analyses^{5,15} the results of both BK and tibial ASV bypasses were excellent and significantly better than those obtained with the ePTFE. The results of our multicentre registry had demonstrated less marked differences compared to the aforementioned studies, supporting the improvements of the results of the heparin-bonding to ePTFE^{10,111}, and Daenens et al. had even shown,⁹ in a retrospective comparative study, similar results between the two materials both at the popliteal and tibial levels, even if in non-equivalent populations. Our finding of non-inferior primary patency rates at 5 years for the HePTFE with respect to the ASV in similar subgroups of patients well compares with the results of the study from Uhl et al.¹⁸ and from a recent literature review,¹⁹ that reported similar outcomes in terms of graft patency between HePTFE and autologous vein. In our experience, however, we observed poorer primary patency rates both in the ASV and in the PTFE groups in comparison with the previous studies and meta-analyses. This finding may have different explanations: first, the progressive changes during the years of the surveillance protocols and of the definitions of failing grafts, once only clinical and angiographic, nowadays mainly hemodynamic and ultrasonographic. Second, the progressive changes in the medical management of patients with CLI, which improved their survival rates increasing the possibility of developing graft-related complications. Third, and in our opinion more important, the spreading of complex endovascular techniques, which allows to treat with endovascular means a higher proportion of difficult lesions, reserving the open



Months	0	24	48	60
HePTFe group				
• n. at risk	99	50	21	14
• S.E.	0.01	0.04	0.06	0.06
ASV group				
• n. at risk	97	45	22	14
• S.E.	0.01	0.05	0.06	0.065

Fig. 2 – Kaplan Meier curves for 5-year primary patency in matched groups with number of patients at risk at different time intervals.

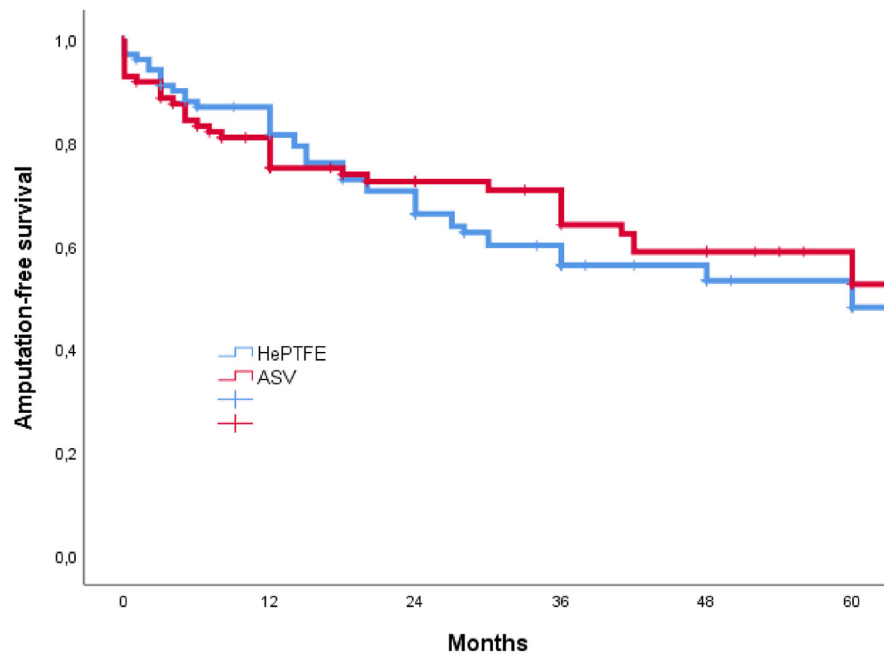
surgical intervention to patients with much more challenging anatomies than twenty or thirty years ago or to patients who had a failure of a previous endovascular attempt.

We found a trend towards better assisted primary patency rates among patients of the ASV group, where we observed several flow-limiting lesions which we were able to treat before the occurrence of the acute thrombosis, while in the HePTFE group only one flow-limiting anastomotic lesion was recorded. This finding confirms what observed by other authors, that only 10–15% of prosthetic graft thromboses occur in patients with flow-limiting lesions detected at duplex ultrasound.^{20,21}

Secondary patency rates were similar in the two groups, and we observed that, similarly to what reported in our previous papers, once thrombosis occurred, it was more difficult and complex to restore the patency in the ASV bypasses than

in the HePTFE ones. Limb salvage and amputation-free survival rates were not different between the two groups, too, with satisfactory values of more than 70% and 55% in both groups, respectively, in line with the literature data.

The present study has several limitations. It is a retrospective, non-randomised study, in which the choice of prosthetic material derived from multiple clinical and anatomical considerations, and not only from the absence of a satisfactory autologous saphenous vein. Moreover, we did not consider as a source for venous materials the contralateral saphenous vein or alternative veins such as the lesser saphenous vein, the contralateral greater saphenous vein or the arm veins, whose use in the literature has been reported with conflicting results in comparison with prosthetic graft.^{4,22} Finally, in the analysis of the results we did not



Months	0	24	48	60
HePTFe group				
• n. at risk	99	63	37	30
• S.E.	0.01	0.04	0.05	0.05
ASV group				
• n. at risk	97	52	33	27
• S.E.	0.01	0.05	0.06	0.06

Fig. 3 – Kaplan Meier curves for 5-year amputation-free survival in matched groups with number of patients at risk at different time intervals.

evaluate patients-centered outcomes such as the assessment of the quality of life. On the other hand, the propensity matching allowed us to reduce the selection bias in the choice of treatment; the follow-up was consistent, with a FUI of about

0.7 in both groups and with an accurate recording of the clinical events during the years.

Our results continue to support the change in the strategy we adopted in recent years, consisting in the use of the

Table 5 – Follow-up outcomes on the basis of the level of the distal anastomosis in the matched groups.

Outcome at 5 years	Survival	Primary patency	Assisted primary patency	Secondary patency	Limb salvage	AFS
BK bypass						
- HePTFE	71.5%	45%	45%	62%	77%	56%
- ASV	74%	50%	58%	59%	80%	66%
p	0.9	0.7	0.1	0.6	0.7	0.4
Tibial bypass						
- HePTFE	64%	18%	22%	35%	42%	36%
- ASV	70%	28%	28%	30%	56%	34%
p	0.6	0.7	0.9	0.3	0.8	0.6

Table 6 – Univariate analysis for primary patency at 5 years in the matched groups.

	PP at 5 years (%)	Log-rank	p
Gender			
Female	39		
Male	42	0.6	0.4
Kind of intervention			
Primary	44		
Secondary	30	5.4	0.02
Diabetes			
Yes	38		
No	42	1.9	0.1
Arterial hypertension			
Yes	41		
No	42	0.03	0.8
Hyperlipemia			
Yes	35		
No	51	10.9	0.001
Coronary artery disease			
Yes	30		
No	47	4.1	0.04
Chronic renal failure			
Yes	51		
No	40	0.6	0.5
Age			
≤80	51		
>80	38	0.4	0.6
Clinical status			
Rest pain	41		
Ulcers	36	0.1	0.7
Less than 2 patent tibial vessels			
Yes	45		
No	37	3.1	0.06
Distal anastomosis			
Popliteal	47		
Tibial	21	30.2	<0.001
Adjunctive distal procedures			
Yes	46		
No	38	0.4	0.5
Postoperative medical treatment			
Antiplatelet	38		
OAC	41	0.3	0.6
Graft material			
HePTFE	38		
ASV	41	0.1	0.7

ipsilateral ASV only when of excellent quality and in the preferential use of adjunctive procedures for the run-off improvement along with a well standardized intra and post-operative protocol when HePTFE is chosen.

Conclusions

In our retrospective matched comparison, HePTFE provided 5-year similar results to those obtained with use of the ASV in equivalent patients with CLI undergoing below-knee or tibial bypass. In our opinion, and following the suggestion of the recent Global Guidelines,¹¹ the time is ripe for new prospective comparison studies that reflect changes in daily clinical practice in terms of indications, materials, intraoperative strategies and postoperative medical therapy.

Declaration of competing interest

There are no conflicts of interest to be declared by any author, and the study is unfunded.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.surge.2021.02.001>.

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