A multicenter comparison between autologous saphenous vein and heparin-bonded expanded polytetrafluoroethylene (ePTFE) graft in the treatment of critical limb ischemia in diabetics

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Objectives: **The aim of this study was to evaluate early and follow-up results of below-knee bypasses performed using a bioactive heparin-treated expanded polytetrafluoroethylene (ePTFE) graft in diabetic patients with critical limb ischemia (CLI) in a multicenter retrospective registry involving seven Italian vascular centers and to compare them with those obtained in patients operated on with autologous saphenous vein (ASV) in the same centers in the same period of time.**

Methods: **Over an 8-year period, ending in 2009, a heparin-bonded prosthetic graft (Propaten Gore-Tex; W. L. Gore & Associates Inc, Flagstaff, Ariz) was implanted in 180 diabetic patients undergoing below-knee revascularization for CLI in seven Italian hospitals (group 1). In the same period in these seven centers, 133 below-knee bypasses with ipsilateral ASV in diabetics with CLI were performed (group 2). Data concerning these interventions were retrospectively collected in a multicenter registry with a dedicated database. Early (<30 days) results were analyzed in terms of graft patency, major amputation rates, and mortality. Follow-up results were analyzed in terms of primary and secondary graft patency, limb salvage, and survival.**

Results: **The interventions consisted of below-knee bypasses in 132 cases in group 1 (73%) and in 45 cases in group 2 (33%; $P <$ .001); 48 patients in group 1 (27%) and 88 patients in group 2 (67%; $P <$ .001) had distal tibial anastomosis. Patients in group 1 had more frequently adjunctive procedures performed at distal anastomotic sites to improve run-off status. Postoperative and long-term medical treatment consisted of single antiplatelet therapy in 93 cases (52%) in group 1 and in 64 cases (48%, $P =$ ns) in group 2, of double antiplatelet therapy in 18 cases (10%) in group 1 and in four cases (3%; $P = .05$) in group 2 and of oral anticoagulants in 69 patients in group 1 (38%) and in 65 (49%; $P = .02$) in group 2. Mean duration of follow-up was 28.3 ± 21.4 months; 308 patients (98%) had at least one postoperative clinical and ultrasonographic examination and 228 (72%) reached at least a 1-year follow-up. Estimated 48-month survival rates were 76.6% in group 1 and 72.7% in group 2 ($P =$ > .9, log-rank 0.08). Primary patency rate at 48 months was significantly better in group 2 (63.5%) than in group 1 (46.3%; $P = .03$, log-rank 4.1). Assisted primary patency rates at 48 months were 47.3% (SE 0.05) in group 1 and 69% (SE 0.05) in group 2 ($P = .01$, log-rank 6.3). The rates of secondary patency at 48 months were 57.5% in group 1 and 69.6% in group 2 ($P = .1$, log-rank 2.3); the corresponding values in terms of limb salvage and amputation free-survival rates were 75.4% and 82.4% ($P = .3$, log-rank 1), and 59.9% and 64.4% ($P = .3$, log-rank 0.9), respectively.**

Conclusions: **Data from this large, retrospective registry confirmed that the indexed heparin-bonded ePTFE graft provides satisfactory early and midterm results in diabetic patients undergoing surgical treatment of CLI. While autologous saphenous vein maintains its superiority in terms of primary patency, secondary patency rates are not statistically different, even in the presence of a trend for improved secondary patency with vein graft; and also limb salvage rates are comparable. (J Vasc Surg 2011;54:1332-8.)**

Diabetes mellitus has been reported to significantly affect long-term patency and limb salvage rates in surgical lower limb revascularizations in patients with peripheral arterial disease.[1,2] Multiple studies and an international consensus[3] have concluded that autologous vein conduit offers better long-term patency than prosthetic grafts in below-knee revascularizations in patients with critical limb ischemia (CLI), and this was also in diabetics.[4] In recent years, the use of heparin-bonded grafts has been proposed as an alternative to autologous vein to reduce both early thrombotic risk and late myointimal hyperplasia development, and we reported satisfactory early and midterm results in patients undergoing surgical treatment of CLI using a bioactive polytetrafluoroethylene (PTFE) graft with a covalent end point attachment of heparin.[5]

The aim of this study was to evaluate early and follow-up results of below-knee bypasses performed with

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this bioactive heparin-treated expanded polytetrafluoroethylene (ePTFE) graft in diabetic patients with CLI in a multicenter retrospective registry involving seven Italian vascular centers and to compare them with those obtained in patients operated on with autologous saphenous vein (ASV) in the same centers in the same period of time.

METHODS

Over an 8-year period, ending in 2009, a heparin-bonded prosthetic graft (Propaten Gore-Tex; W. L. Gore & Associates Inc, Flagstaff, Ariz) was implanted in 503 patients undergoing below-knee revascularization for CLI in seven Italian hospitals. Data concerning these interventions were collected in a multicenter registry with a dedicated database. The modalities of the choice of the type of graft and of data collection and insertion have been already described.[5] The choice to use a prosthetic graft was made on the basis of surgeons' discretion and not only in the absence of a suitable vein.

The reliability of the data contained in the registry was certified by an external validation (Castalia Group, ICT and Quality Management, Aosta, Italy).

A retrospective analysis of the database was performed and 180 diabetics were found (group 1). In the same period in the same seven centers, 133 diabetic patients with CLI had a below-knee bypass with ipsilateral ASV (group 2). In these patients, the diameter of the vein was at least 3 mm on duplex ultrasonography scan, and this finding was confirmed at operation.

The presence of diabetes mellitus was defined as the need for specific drugs. Early (<30 days) results were analyzed in terms of graft patency, major amputation rates, and mortality. Graft patency was defined as the possibility to maintain a functioning graft without adjunctive interventions. Major amputation was defined as the occurrence of amputation at above-knee or below-knee level. The results in the two groups were compared with χ^2 test and Fisher exact test, when necessary.

Follow-up was performed within the third postoperative month, at 12 months, and then yearly, and consisted of clinical examination, ankle-brachial index (ABI) measurements, and graft duplex examination. Graft failure was diagnosed when ABI deterioration was associated with duplex evidence of graft thrombosis. Angiography and reintervention were indicated when recurrence of CLI or acute limb ischemia occurred.

Follow-up results were analyzed in terms of 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) graft patency, limb salvage (the absence of amputation at above-knee or below-knee level), and survival with Kaplan-Meier curves. The results in the two groups were compared by means of log-rank test. Univariate and multivariate analysis (Cox's regression) of the factors affecting primary and secondary patency in the whole group were performed. In Cox regression analysis, the factors with statistical significance at univariate analysis were included. Pre- and postoperative ABI values were compared with the *t* test for independent samples. Statistical significance was defined as a *P* value less than .05.

Table I. Demographic data, comorbidities, and main risk factors for atherosclerosis in the two groups

	Group 1 (180 int.)	*Group 2 (133 int.)*	P
Female sex	39 (22%)	51 (39%)	<.001
Median age (years)	72.5	72.9	.6
History of smoking	137 (76%)	70 (52.5%)	<.001
Hyperlipemia	114 (63%)	69 (52%)	.04
Arterial hypertension	163 (90%)	112 (84%)	.09
Coronary artery disease	99 (55%)	51 (38%)	.004
Chronic renal failure	32 (18%)	20 (15%)	.5

RESULTS

Demographic data, clinical and anatomical status. There were no differences between the two groups in terms of median age; there was a higher frequency of female patients in group 2, whereas patients in group 1 had, more frequently, a history of smoking, hyperlipemia, and coronary artery disease than patients in group 2. Demographic data, comorbidities, and main risk factors for atherosclerosis in the two groups are summarized in Table I.

Indication for surgical intervention was the presence of CLI in all patients; 115 patients in group 1 (64%) and 73 in group 2 (55%; $P = .1$) had Rutherford's class[6] 5 and 6 clinical status. Secondary interventions, defined as a reintervention for the late occlusion of a prior open or endovascular femoropopliteal revascularization, accounted for 60 cases in group 1 (33%) and for 18 cases in group 2 (13.5%, $P < .001$).

Patients in group 2 had, more frequently, only one patent tibial vessel than patients in group 1 (67% and 47%, respectively; $P < .001$).

Mean preoperative ABI in the affected limb was 0.22 (standard deviation [SD] 0.20), without differences between the two groups (0.31 in group 1 and 0.25 in group 2, $P = .09$).

Surgical interventions and drug therapy. Intervention consisted of a below-knee bypass in all the cases. Surgical technical details in the two groups are reported in Table II; patients in group 2 had a higher percentage of distal tibial anastomosis than patients in group 1 (67% and 27%, respectively, $P < .001$), whereas patients in group 1 had more frequently, adjunctive procedures performed at distal anastomotic sites to improve run-off status. In group 2, in situ vein bypass was used in 63 patients, whereas the remaining had an inverted vein bypass.

Postoperative and long-term medical treatment consisted of single antiplatelet therapy in 93 cases (52%) in group 1 and in 64 cases (48%, P = ns) in group 2, of double antiplatelet therapy in 18 cases (10%) in group 1 and in four

Table II. Surgical technical details in the two groups

	Group 1 (180 int.)	*Group 2 (133 int.)*	P
Inflow vessels			
• External iliac	4 (2%)	2 (1.5%)	n.s.
• Common femoral	172 (95%)	116 (87%)	n.s.
• Superficial femoral	4 (3%)	15 (11.5%)	.004
Distal tibial anastomosis	48 (27%)	88 (66%)	<.001
Outflow vessels			
• BK popliteal artery	132 (73%)	45 (33%)	<.001
• Tibioperoneal trunk	23 (12.5%)	11 (8%)	.06
• Peroneal artery	5 (2.5%)	15 (11%)	.004
• Anterior tibial artery	10 (6%)	33 (25%)	<.001
• Posterior tibial artery	10 (6%)	29 (23%)	<.001
Adjunctive distal procedures	42 (23%)	12 (9%)	.001
• Vein cuff	34	4	
• Patching	8	7	
• Tibial PTA	–	1	

BK, Below knee; *PTA,* percutaneous transluminal angioplasty.

cases (3%; $P = .05$) in group 2, and of oral anticoagulants in 69 patients in group 1 (38%) and in 65 (49%; $P = .02$) in group 2, the regimen for anticoagulation or antiplatelet being determined just on the basis of the surgeon's preference.

Early results. There were four perioperative deaths, all in group 1 (mortality rate 2.2%; $P = .08$ with respect to group 2). The cause of death was acute myocardial infarction in three cases and pulmonary embolism in the remaining one.

One case of perioperative severe bleeding (requiring surgical revision at the distal anastomosis) occurred in a patient in group 1. No case of postoperative heparin-induced thrombocytopenia was recorded in both groups. Mean postoperative hospital stay was 13.3 days in group 1 and 16.2 days in group 2 ($P = .8$; 95% CI -10.7/4.9).

Early graft thrombosis occurred in 23 patients (14 in group 1 and nine in group 2), with cumulative 30-day graft patency rates of 92.2% and 93.2%, respectively ($P = .7$). There were 13 early major amputations (nine in group 1 and four in group 2), with 30-day major amputation rates of 5% and 4%, respectively ($P = .3$).

Follow-up results. Mean duration of follow-up was 28.3 ± 21.4 months; 308 patients (98%) had at least one postoperative clinical and ultrasonographic examination and 228 (72%) reached at least a 1-year follow-up.

Mean ABI value during follow-up was 0.59 (compared with 0.22 preoperatively; $P < .001$), with a significant increase in both groups.

During follow-up, 43 deaths (23 in group 1 and 20 in group 2), 85 new graft thomboses (58 in group 1 and 27 in group 2), and 41 major amputations (25 in group 1 and 16 in group 2) occurred. In seven cases (one in group 1 and six in group 2), significant stenoses at anastomotic sites without graft thrombosis were detected; in five cases, percutaneous transluminal angioplasty of the distal anastomosis was performed; while in the remaining patients, endarterectomy of the common femoral artery with patching of the proximal anastomosis was required.

Estimated 48-month survival rates were 76.6% in group 1 (standard error [SE] 0.05) and 72.7% in group 2 (SE 0.06; $P = .9$, log-rank 0.08). Primary patency rate at 48 months was significantly better in group 2 (63.5%, SE 0.05) than in group 1 (46.3%, SE 0.05; $P = .03$, log-rank 4.1; Fig 1). In below-knee bypasses, the corresponding figures were 46.5% in group 1 (SE 0.06) and 76% in group 2 (SE 0.07; $P = .02$, log-rank 5.1); in tibial bypasses, they were 45.8% (SE 0.1) and 58% (SE 0.06; $P = .4$, log-rank 0.6).

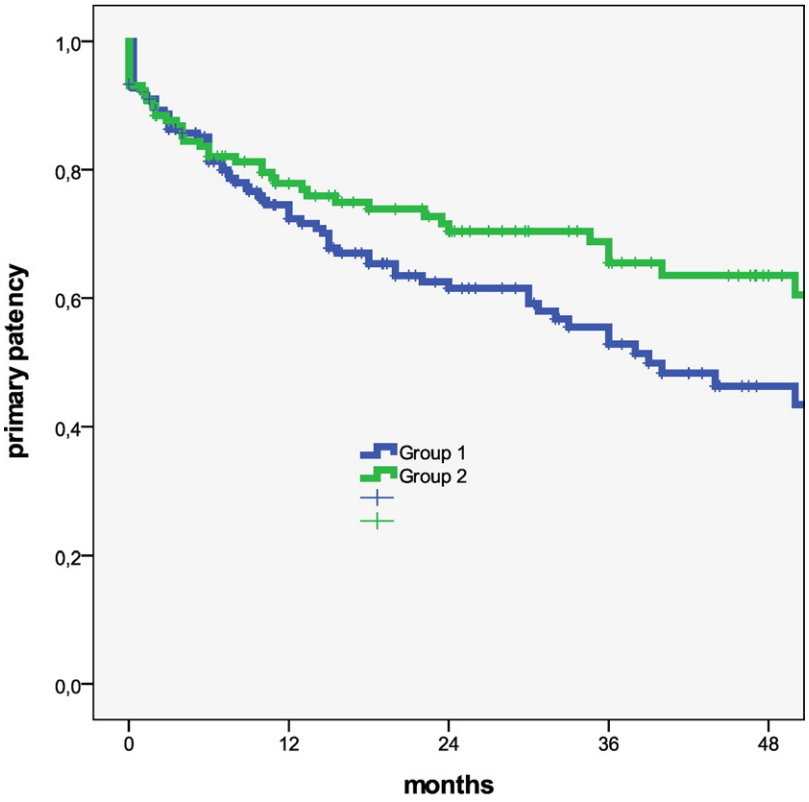
Assisted primary patency rates at 48 months were 47.3% (SE 0.05) in group 1 and 69% (SE 0.05) in group 2 ($P = .01$, log-rank 6.3).

In group 1, among patients with graft thrombosis, 15 underwent successful reintervention, 24 underwent major amputation despite the attempts of further revascularization, whereas in the remaining 24 patients, graft thrombosis caused intermittent claudication without critical or acute limb ischemia and nonoperative management was decided; and one patient had below-knee amputation despite the presence of patent bypass for severe foot infection. In group 2, only four out of the 27 patients presenting with vein thrombosis had successful reintervention; 16 patients underwent major amputation despite the attempts of further revascularization, and seven patients with vein thrombosis without critical ischemia underwent nonoperative management. All the patients with graft thrombosis undergoing nonoperative management for the absence of critical or acute ischemia had their limb salvaged. The rates of secondary patency at 48 months were 57.5% in group 1 (SE 0.05) and 69.6% in group 2 (SE 0.05), without significant differences between the two groups ($P = .1$, log-rank 2.3; Fig 2); the corresponding values in terms of limb salvage and amputation free-survival rates were 75.4% (SE 0.04) and 82.4% (SE 0.04; $P = .3$, log-rank 1), and 59.9% (SE 0.05) and 64.4% (SE 0.05; $P = .3$, log-rank 0.9), respectively.

At univariate analysis, secondary intervention, poor run-off score and type of graft were found to significantly affect long-term primary patency and this was also at multivariate analysis (Table III); as far as secondary patency is concerned, secondary intervention, the presence of ulcers and a poor round-off score were found to significantly affect it at univariate analysis, while at multivariate analysis, only the presence of ulcers and of a poor run-off status maintained their significance (Table IV).

DISCUSSION

The ideal material for below-knee revascularizations is an autogenous vein conduit that has been demonstrated to provide significantly better results than prosthetic grafts.[4] However, the availability of such a conduit is a relevant limitation of lower extremity bypass surgery: good ipsilateral greater saphenous vein may be lacking in up to 40% of the patients,[7] and the strong relationship



Months	0	12	24	48
Group 1 (n. at risk)	178	100	62	16
SE	0.02	0.03	0.04	0.05
Group 2 (n. at risk)	129	89	61	23
SE	0.02	0.03	0.04	0.05

Fig 1. Kaplan-Meier curves for primary patency rates during follow-up with number of patients at risk and standard error (*SE*) values.

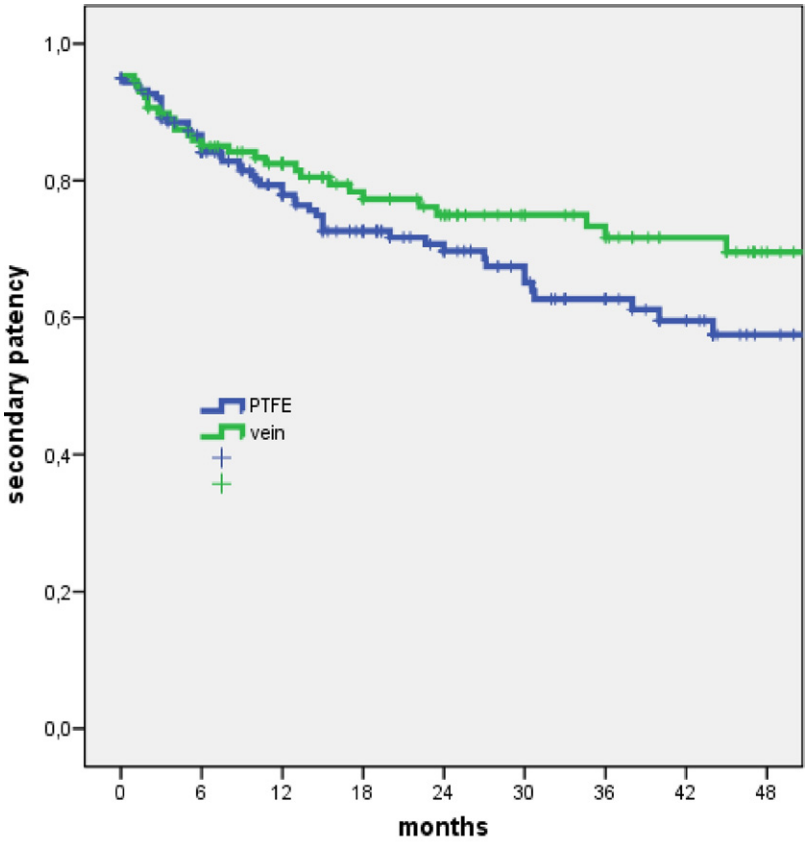
between vein diameter and graft failure makes autologous saphenous vein unsuitable in some 25% of the patients with CLI.[8]

In these situations, the use of a prosthetic graft may be unavoidable: the most common used synthetic material is ePTFE, which has provided results similar to those achieved with autologous vein in above-knee revascularizations in the first 24 postoperative months,[9] but poorer results in below-knee interventions.[10]

In the last years, several attempts have been made to develop prosthetic materials with intrinsic thrombosis resistance given by modifications of chemical and physical graft properties. In particular, the use of heparin bonded to biomaterial surfaces has been suggested.[11,12] Researchers have proposed the immobilization of the heparin on the graft with covalent end point linkages to maintain a prolonged bioactivity on the antithrombin sites of the bound heparin,[13] and several studies reported promising results with this graft.[14-16]

We reported satisfactory results also in our multicenter registry[5] at an intermediate follow-up period, with a primary patency rate of 61% and a limb salvage of 83% after 3 years in patients with CLI undergoing below-knee revascularizations. In this study, diabetics accounted for more than 40% of the patients and no influence of diabetes on early and follow-up results was found.

Whereas the presence of diabetes mellitus in patients undergoing lower limb revascularization has been reported by some authors[2] to significantly impair graft patency rates, other studies have demonstrated that diabetes is not a risk factor for vein graft failure.[1,8,17] On the other hand, there is general consensus regarding the role of diabetes in reducing limb salvage and long-term patient survival in comparison to people without diabetes.



Months	0	12	24	48
Group 1 (n. at risk)	178	109	70	19
SE	0.02	0.03	0.04	0.05
Group 2 (n. at risk)	128	92	62	24
SE	0.02	0.03	0.04	0.05

Fig 2. Kaplan-Meier curves for secondary patency rates during follow-up with number of patients at risk and standard error (*SE*) values.

In the present study, we have compared the results obtained in diabetic patients using the indexed ePTFE grafts with those obtained using autologous saphenous vein in the seven centers participating to the registry in the same time interval.

The modality of enrollment of our patients could be criticized, as no randomization was planned and, as a consequence, the two groups differed in several aspects. While there were no differences between the two groups in terms of clinical presentation and Rutherford's classification, run-off status was found to be significantly poorer in patients undergoing saphenous vein bypass, and in these cases, a tibial distal anastomosis became more frequent. On the other hand, among patients treated with the modified ePTFE graft, the percentage of reinterventions was significantly higher, and an adjunctive distal procedure to improve the run-off was more frequent, too. These differences probably reflect different approaches and different patient selection among the participating surgeons: because of its nature, the registry does not have either inclusion and exclusion criteria or homogenous indication for the choice of the grafts. This selection bias represents the main limitation of this study, affecting its the design, the comparison of the two groups, and the interpretation of the results. On the other hand, in our opinion, this study could provide a reliable cross-section of the everyday practice in Italian vascular centers.

Our results confirmed earlier results in terms of excellent safety, with a negligible rate of perioperative bleeding requiring surgical revision, graft patency, and amputation rates.

There was a trend toward a higher rate of perioperative deaths in group 1, which is probably related to the higher

Table III. Univariate and multivariate (for significant factors at univariate) analysis for primary patency during follow-up

	Univariate analysis				*Multivariate analysis*		
	Log-rank	P	*95% CI*	*OR*	*95% CI*	*OR*	P
Female gender	0.6	.4	0.4-1.1	0.6			
Chronic renal failure	0.04	.9	0.6-1.6	0.9			
Reintervention	10.6	.001	0.3-0.7	0.5	0.4-1	0.6	.05
Tibial anastomosis	0.03	.9	0.6-1.4	0.9			
Rutherford class 5-6	3.4	.06	0.9-2.1	1.4			
Distal procedures	1.9	.1	0.8-2.1	1.3			
Run-off score 0-1	5.1	.02	1-2.2	1.5	1-2.3	1.5	.03
Antiplatelet treatment	0.6	.4	0.8-1.6	1.1			
ePTFE graft	4.1	.03	1-2.4	1.6	0.9-2-2	1.4	.05

ePTFE, Expanded polytetrafluoroethylene.

Table IV. Univariate and multivariate (for significant factors at univariate) analysis for secondary patency during follow-up

	Univariate analysis				*Multivariate analysis*		
	Log-rank	P	*95% CI*	*OR*	*95% CI*	*OR*	P
Female gender	0.02	.8	0.6-1.6	1			
Chronic renal failure	0.01	.9	0.5-1.7	0.9			
Reintervention	4.3	.03	0.4-0.9	0.6	0.4-1.1	0.6	.06
Tibial anastomosis	1	.3	0.8-1.8	1.2			
Rutherford class 5-6	4	.04	1-2.4	1.5	0.9-2.4	1.5	.05
Distal procedures	1.2	.2	0.8-2.2	1.3			
Run-off score 0-1	5.9	.01	1.1-2.7	1.6	0.9-2.3	1.5	.05
Antiplatelet treatment	1.2	.1	0.8-1.9	1.2			
ePTFE graft	2.4	.1	0.9-2.1	1.4			

ePTFE, Expanded polytetrafluoroethylene.

percentage of coronary artery disease among these patients, acute myocardial infarction being the most common cause of perioperative death in our series.

Median duration of follow-up in our registry was more than 28 months, which is similar to the recent study from Daenens et al[16] who reported, in a 2-year monocenter retrospective study, similar results between autologous saphenous vein and heparin-bonded ePTFE in terms of primary patency and limb salvage, however, without an analysis of subgroups, such as diabetics.

Differently from the above-cited report, we found significantly poorer primary patency rates after 4 years among patients treated with the PTFE graft, despite the more frequent use of adjunctive procedures in these cases; even if secondary patency rates did not differ under a strict statistical standpoint, there was a trend for improved secondary patency with vein grafts (possible type 1 statistical error). However, an 11% increase in secondary patency rates in group 1 compared with primary patency seems to suggest the possibility of effectively treating occluded heparin-bonded grafts. On the other hand, the low rate of successful reinterventions in patients with occluded vein bypass seems to confirm what most surgeons can observe in their everyday practice, that it is really difficult to restore vein patency once occlusion has occurred. As a consequence, the detection of flow-limiting vein stenoses during follow-up and their prompt treatment prior to vein thrombosis frequently result in improved patency and, also, in our experience, confirming the need for a prolonged surveillance of these patients. The rate of 4-year amputations was not different between autologous vein and heparin-bonded ePTFE. This is an encouraging result, considering that limb salvage probably represents the main outcome in all these critical patients.

The analysis of the factors affecting follow-up outcomes demonstrated that, beyond the graft material, patients with poor run-off status and undergoing secondary interventions were more likely to lose primary patency at both univariate and multivariate analysis. These findings could support continuous use of autologous materials in these subgroups of patients; on the contrary, the good results after 4 years in primary interventions and in patients with more than one patent distal vessel, could suggest a significant role of this heparin-bonded graft in such subgroups.

As previously introduced, the present study has several limitations. Moreover, estimates of graft patency and amputation rates could have been biased by the competing risk of death for these other two outcomes, potentially reducing the value of our results. Despite these limits and bias, our

results demonstrated that the heparin-bonded ePTFE graft can represent a safe alternative to autologous saphenous vein, mainly when it is unsuitable or of poor quality.

CONCLUSIONS

Data from this large, retrospective registry confirmed that the indexed heparin-bonded ePTFE graft provides satisfactory early and midterm results in diabetic patients undergoing surgical treatment of CLI. While autologous saphenous vein maintains its superiority in terms of primary patency, secondary patency and limb salvage rates are not statistically different even in the presence of a trend for improved secondary patency with vein graft.

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AUTHOR CONTRIBUTIONS

Conception and design: CP, PC
Analysis and interpretation: WD, RP
Data collection: FF, FDB
Writing the article: WD, RP
Critical revision of the article: EV, VD
Final approval of the article: VM, CP
Statistical analysis: WD, RP
Obtained funding: Not applicable
Overall responsibility: CP

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APPENDIX. PROPATEN ITALIAN REGISTRY GROUP

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Participating Centers

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Terni: Fiore Ferilli, Paolo Ottavi
Varese: Patrizio Castelli, Gabriele Piffaretti