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Distal vein patch use and limb events after infragenicular prosthetic bypasses

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ABSTRACT

Objective: In the absence of suitable autologous vein, the use of prosthetic grafts for infragenicular bypasses in peripheral arterial disease has become standard practice. The purpose of this study was to investigate whether creating a vein patch at the distal anastomosis would further improve patency and freedom from major adverse limb events (MALEs). Furthermore, we sought to investigate whether the use of a distal vein patch (DVP) was associated with lower rates of acute limb ischemia (ALI) for those presenting with occluded prosthetic bypass graft.

Methods: The cases of all patients undergoing infragenicular prosthetic bypass grafts between January 2009 and July 2016 were retrospectively reviewed. Demographics of the patients, clinical data, and outcomes (graft patency and MALEs) were collected. Patients were compared according to treatment group (DVP vs no DVP). A Cox regression analysis was used to analyze follow-up results.

Results: During the study period, a total of 373 patients underwent infragenicular bypass at our institution; of those, 93 (24.9%) had prosthetic grafts (DVP, 39; no DVP, 54). Overall, 92 (98.9%) patients were male; the mean age was 63.3 ± 6.6 years and did not differ between the two groups. Patients undergoing prosthetic bypass with DVP were more likely to have chronic obstructive pulmonary disease (38.5% vs 14.8%; $P = .009$) and less likely to have chronic kidney disease (2.6% vs 20.4%; $P = .011$). Follow-up data were available for all patients for a median of 7.8 months (range, 1-89 months). After adjustment for differences in demographics and clinical data between the two groups, when outcomes were analyzed, MALEs were significantly lower in the DVP group (35.9% vs 57.4%; odds ratio [OR], 0.4; 95% confidence interval [CI], 0.2-0.9; $P = .041$). Similarly, reintervention rates were significantly lower in the DVP group (30.8% vs 50.0%; OR, 0.4; 95% CI, 0.2-0.9; $P = .044$). There was a trend toward higher primary patency in the DVP group (46.2% vs 35.2%; OR, 1.5; 95% CI, 0.7-3.5; $P = .206$) and lower rates of ALI after bypass occlusion (30.0% vs 42.9%; OR, 0.6; 95% CI, 0.2-1.8; $P = .345$). A Cox regression time-to-event analysis revealed late separation of freedom from MALEs for DVP relative to no DVP (log rank, $P = .269$).

Conclusions: In this evaluation of infragenicular prosthetic bypass grafts, the creation of a vein patch at the distal anastomosis was associated with lower reintervention rates and a trend toward improved primary patency and MALEs. Furthermore, for those presenting with occluded prosthetic bypass graft, the use of a DVP was associated with a trend toward lower rates of ALI. (J Vasc Surg 2018;68:145-52.)

Some surgeons elect to use a distal vein patch (DVP) during infragenicular prosthetic bypasses to optimize outcomes when autogenous vein of sufficient length and caliber is not available. Previous studies have suggested that there may be some (albeit weak or inconsistent) increase in patency rates and a decrease in major adverse limb events (MALEs) with the use of DVPs.[1-5] With regard to graft patency benefits related to DVP use, two randomized clinical trials have been published reaching different conclusions.[2,4] In 2004, Griffiths et al[2] analyzed 235 patients (120 with a Miller cuff and 115 without) undergoing below-the-knee bypass operations. The cumulative 3-year patency rate was 45% for Miller cuff bypasses and 19% for noncuffed bypasses ($P = .018$). Six years later, the Scandinavian Miller Collar Study (SCAMICOS) failed to demonstrate any benefit of a vein patch for femorodistal bypass in an elderly and predominantly female population.[4]

Much less understood has been the impact of a DVP on limb salvage rates, MALEs, and acute limb ischemia (ALI) events. The occlusion of polytetrafluoroethylene (PTFE) bypasses is known to cause ALI much more frequently than the occlusion of vein graft bypasses.[6-8] The

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underlying reasons for this are unclear, and some have hypothesized that PTFE bypasses may not only occlude but also cause occlusion of the outflow target artery.[6] Furthermore, anastomotic intimal hyperplasia, tissue elasticity, proximal collateral circulation, and limb metabolic adaptive process have also been shown to play a role in determining the hemodynamic and clinical consequences after occlusion of PTFE femorotibial grafts.[6] The addition of a vein patch to the distal anastomosis would at least in theory allow a less robust and more gradual myointimal hyperplasia process and also less deterioration of the distal arterial tree.[9] The question of whether the addition of a DVP during infragenicular prosthetic bypass would lower reintervention rates and improve primary patency and MALEs remains unanswered in contemporary vascular practice.

We conducted a retrospective review of infrainguinal PTFE bypasses performed at our institution to assess whether the use of an adjunctive DVP would decrease the incidence of subsequent ALI or limb loss, as this would make DVP use worthwhile even if no patency benefit occurs. We hypothesized that the creation of a vein patch at the distal anastomosis would be associated not only with lower reintervention rates and improved primary patency and MALEs but also with lower rates of ALI for those presenting with occluded prosthetic bypass graft.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective cohort study
- **Take Home Message:** Of 93 patients who underwent infragenicular prosthetic bypass, adding a distal vein patch in 39 patients was associated with lower reintervention rates. There was a trend toward higher primary patency and less acute limb ischemia after bypass occlusion.
- **Recommendation:** The authors suggest using a distal vein patch in patients who undergo prosthetic infragenicular bypass.

METHODS

After Institutional Review Board approval, a retrospective review of the institutional vascular registry at the Michael E. DeBakey Veterans Affairs Medical Center was performed. Because of the retrospective nature of this study, no individual patient consent was obtained. All cases of lower extremity infragenicular prosthetic bypass grafts between January 1, 2009, and July 31, 2016, identified through a prospectively maintained operating room registry, were retrospectively reviewed. Patient variables abstracted included age, sex, ethnicity, body mass index, comorbidities (systemic hypertension, hyperlipidemia, coronary artery disease, congestive heart failure, cerebrovascular disease, chronic pulmonary obstructive disease, diabetes mellitus, chronic kidney disease), smoking and alcohol use, medications, and admission laboratory data (albumin, creatinine, hemoglobin, and glycated hemoglobin concentrations). Operative data including the type of prosthetic bypass (DVP vs no DVP), inflow and outflow vessels, and operative time were also extracted. The primary outcome was MALE, defined as the need for amputation (transtibial or above) or any major vascular intervention (eg, thrombectomy, thrombolysis, new bypass graft, or graft revision).[10] ALI was defined as decrease in limb perfusion that threatens the viability of the limb presenting within 2 weeks of symptom onset. Other outcomes, such as intensive care unit (ICU) length of stay (LOS), intraoperative and postoperative transfusion requirements, patency (primary, primary assisted, and secondary),[11] and mortality were also obtained.

Prosthetic bypasses were performed using PTFE when no suitable lower or upper extremity vein (adequate length and ≥3 mm in diameter) was available for use. During the study period, a total of six vascular surgeons performed prosthetic bypasses at our institution. The decision of using DVP and the type of DVP to use was at the discretion of the operating surgeon. We excluded patients undergoing bypasses for lower extremity aneurysms or trauma.

Patients were seen postoperatively at 2 weeks for wound check and at 1 month, 3 months, 6 months, 12 months, and annually thereafter with an arterial duplex ultrasound examination for bypass graft surveillance. At least two follow-up visits were available for all patients in this cohort.

Statistical analysis. Patients were compared for demographics, clinical data, and outcomes according to the treatment group (DVP vs no DVP). The primary outcome measure examined was MALE; the secondary outcome measures were patency (primary, primary assisted, and secondary), complications, ICU LOS, hospital LOS, and mortality.

Patients were compared for differences in demographics and clinical characteristics using bivariate analysis. The χ^2 and Fisher exact tests were used to compare proportions, and unpaired Student *t*-test and Mann-Whitney *U* tests were performed to compare means.

Logistic regression modeling was performed to control for confounders that were significantly different at the $P < .05$ level between the two groups. Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) were calculated for each group.

A Cox regression analysis was used to evaluate the association between treatment group (DVP vs no DVP) and MALEs. A Cox proportional hazard regression model was performed including all factors that had a $P < .2$ from the bivariate analysis. Values are reported as means ± standard deviation and median (range) for

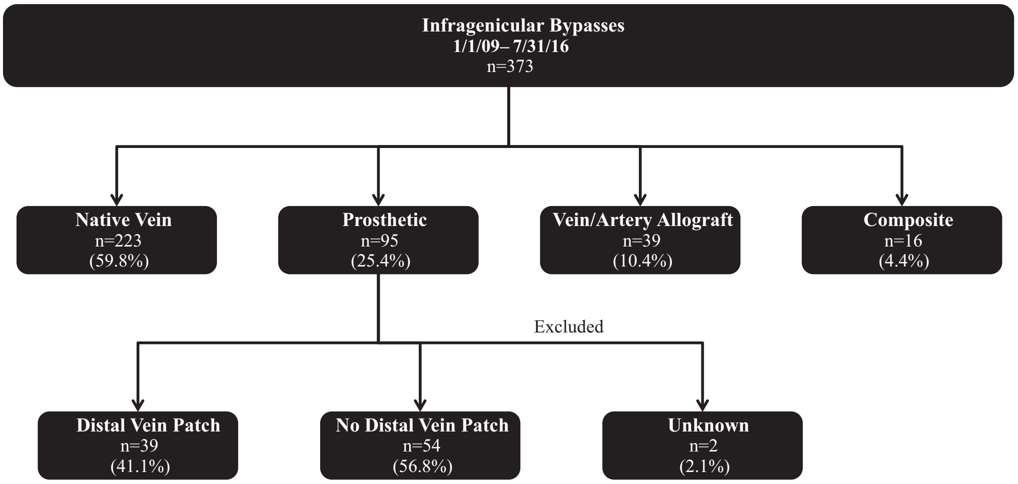

Fig 1. Study outline.

continuous variables and as percentage for categorical variables. All analyses were performed using the Statistical Package for Social Sciences (SPSS Mac, version 21.0; IBM Corp, Armonk, NY).

RESULTS

During the 7.5-year study period, 373 patients underwent infragenicular bypass at the Michael E. DeBakey Veterans Affairs Medical Center. Of those, 93 (24.9%) had a prosthetic graft (39 with DVP and 54 without DVP; Fig 1). During the study period, the rates of DVP increased from 25% (7/28) during the first study quarter (years 2009-2010) to 68.4% (13/19) during the last study quarter (years 2015-2016; $P = .007$).

There were no significant differences in age (64.0 ± 6.6 years for DVP vs 62.7 ± 6.5 years for no DVP; $P = .372$) or sex (male: 100.0% for DVP vs 98.1% for no DVP; $P = 1.000$) between the two groups. Patients undergoing bypasses with DVPs had significantly lower body mass index (24.9 ± 4.7 kg/m^2 vs 27.2 ± 5.3 kg/m^2; $P = .033$), were more likely to have chronic obstructive pulmonary disease as associated comorbidity (38.5% vs 14.8%; $P = .009$), and were less likely to have chronic kidney disease (2.6% vs 20.4%; $P = .011$). There was no significant difference with regard to diabetes mellitus rates (56.4% vs 42.6%; $P = .188$). A total of 73 (78.5%) bypasses were performed for tissue loss (71.8% for DVP vs 83.3% for no DVP; $P = .181$) and 20 (21.5%) for rest pain (28.2% vs 16.7%; $P = .181$). The demographic and clinical characteristics of the patients are summarized by group in Table I.

Comparisons of operative data are depicted in Table II. Overall, patients undergoing prosthetic bypass graft with DVPs were less likely to have had a previous ipsilateral endovascular intervention (28.6% vs 50.0%; $P = .048$). No significant differences in the rates of previous open ipsilateral interventions and inflow vessels were found. Patients undergoing prosthetic grafts with DVPs more often had the posterior tibial artery as the outflow vessel (33.3% vs 24.1%; $P < .001$) whereas patients without vein patches were more likely to have the popliteal artery used as the outflow vessel (57.4% vs 15.4%; $P < .001$). Patients undergoing prosthetic grafts with DVPs were less likely to have two or more patent runoff vessels (31.3% vs 65.9%; $P = .003$). Operative time was significantly longer for those receiving a DVP (354 ± 131 minutes vs 288 ± 134 minutes; $P = .019$; Table II).

Follow-up data were available for all patients for a median of 7.8 months (range, 1-89 months) and a mean of 16.7 ± 20.7 months. After adjustment for differences in demographics and clinical data between the two groups, when outcomes were analyzed, there was no difference with regard to 30-day mortality (10.3% for DVP vs 9.3% for no DVP; OR, 1.1; 95% CI, 0.3-4.4; $P = .872$). No significant differences in intraoperative or postoperative blood transfusion requirements, ICU LOS, or hospital LOS between the groups were found. MALEs were significantly lower in the DVP group (35.9% vs 57.4%; OR, 0.4; 95% CI, 0.2-0.9; $P = .041$). Similarly, reintervention rates, such as for repeated angioplasty and stenting, thrombolysis, or open thrombectomy for occluded bypass, were lower in the DVP cohort (30.8% vs 50.0%; OR, 0.4; 95% CI, 0.2-1.1; $P = .064$). There was a trend toward higher primary patency in the DVP group (46.2% vs 35.2%; OR, 1.6; 95% CI, 0.6-3.7; $P = .286$) and lower rates of ALI after bypass occlusion (30.0% vs 42.9%; OR, 0.6; 95% CI, 0.2-1.8; $P = .345$; Table III). A Cox regression time-to-event analysis revealed late separation of freedom from MALEs for DVP relative to no DVP that did not reach statistical significance (log rank, $P = .269$; Fig 2). The same analysis for primary and primary assisted patencies is shown in Fig 3.

Subset analysis of popliteal and tibial outflow targets according to treatment group revealed similar trends. There were no significant differences in demographics and clinical data between popliteal artery with DVP and without DVP groups. Similarly, there were no

Table I. Demographics and clinical and laboratory data of the study population

	Total (N = 93)	DVP (n = 39)	No DVP (n = 54)	*P*
Demographics and clinical data				
Male	98.9 (92)	100.0 (39)	98.1 (53)	1.000
Age, years	63.3 ± 6.6; 63 (47-84)	64.0 ± 6.6; 64 (51-84)	62.7 ± 6.5; 62 (47-80)	.372
White	58.1 (54)	59.0 (23)	57.4 (31)	.782
BMI, kg/m^2	26.2 ± 5.1; 26 (17-41)	24.9 ± 4.7; 25 (17-37)	27.2 ± 5.3; 26 (20-41)	.033[a]
Rest pain	21.5 (20)	28.2 (11)	16.7 (9)	.181
Tissue loss	78.5 (73)	71.8 (28)	83.3 (45)	.181
HTN	90.3 (84)	94.9 (37)	87.0 (47)	.207
HLD	81.7 (76)	79.5 (31)	83.3 (45)	.636
CAD	53.8 (50)	51.3 (20)	55.6 (30)	.683
Previous MI	25.8 (24)	23.1 (9)	27.8 (15)	.609
CHF	14.0 (13)	10.3 (4)	16.7 (9)	.379
CVD	12.9 (12)	12.8 (5)	13.0 (7)	.984
COPD	24.7 (23)	38.5 (15)	14.8 (8)	.009[a]
Current smokers	51.6 (48)	43.6 (17)	57.4 (31)	.188
Quit smoking ≤6 months	34.4 (32)	43.6 (17)	27.8 (15)	.113
DM on insulin or oral agents	48.4 (45)	56.4 (22)	42.6 (23)	.188
CKD	12.9 (12)	2.6 (1)	20.4 (11)	.011[a]
EtOH	4.6 (20)	4.1 (2)	4.6 (18)	.866
Antiplatelet therapy on admission	88.2 (82)	94.9 (37)	83.3 (45)	.089
Antilipid therapy on admission	86.0 (80)	89.7 (35)	83.3 (45)	.379
Beta blockers	65.6 (61)	71.8 (28)	61.1 (33)	.285
Admission laboratory data				
Albumin, g/dL	3.5 ± 0.5; 3.6 (2.1-4.4)	3.5 ± 0.5; 3.6 (2.1-4.4)	3.6 ± 0.5; 3.6 (2.2-4.4)	.641
Creatinine, mg/dL	1.1 ± 0.4; 1.0 (0.5-3.0)	1.1 ± 0.3; 1.0 (0.6-1.9)	1.1 ± 0.4; 1.0 (0.5-3.0)	.333
Hgb, mg/dL	12.6 ± 2.2; 12.7 (7.5-18.8)	12.6 ± 2.5; 12.7 (7.7-18.8)	12.6 ± 2.0; 12.7 (7.5-17.6)	.865
Glycated Hgb, mg/dL	7.1 ± 1.8; 6.4 (5.2-13.6)	7.6 ± 2.3; 6.9 (5.2-13.6)	6.7 ± 1.1; 6.3 (5.4-9.1)	.073

BMI, Body mass index; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *CKD,* chronic kidney disease; *COPD,* chronic obstructive pulmonary disease; *CVD,* cerebrovascular disease; *DM,* diabetes mellitus; *DVP,* distal vein patch; *EtOH,* ethanol; *Hgb,* hemoglobin; *HLD,* hyperlipidemia; *HTN,* hypertension; *MI,* myocardial infarction.
Categorical variables are presented as % (No.). Continuous variables are presented as mean ± standard deviation; median (range). The *P* values for categorical variables were derived from χ^2 or Fisher exact test; *P* values for continuous variables were derived from Student *t*-test or Mann-Whitney *U* test.
[a]*P* values are significantly different ($P < .05$).

significant differences in baseline characteristics between tibial arteries with DVP and without DVP. For popliteal targets, MALEs were significantly lower in the DVP group (33.3% vs 54.8%; OR, 0.4; 95% CI, 0.1-2.5; $P =$ .335), and so was ALI after bypass occlusion (50.0% vs 66.7%; OR, 0.5; 95% CI, 0.2-26.3; $P = .593$). For tibial targets, MALE (41.4% vs 66.7%; OR, 0.3; 95% CI, 0.1-1.1; $P = .077$) and ALI (25.0% vs 37.5%; OR, 0.6; 95% CI, 0.1-2.6; $P = .446$) were also significantly lower in the DVP group.

Ten patients (25.6%) had upper extremity vein harvested for DVP. Subset analysis of MALE and ALI events according to the type of vein used (upper extremity vein vs great saphenous vein vs small saphenous vein) revealed no significant differences in outcomes.

DISCUSSION

Up to 40% of patients requiring lower extremity bypass surgery lack suitable native vein conduit because of inadequate size, length, or previous use.[12,13] In these instances, prosthetic grafts have been shown to be satisfactory alternative conduits when native vein is not available.[12,13]

Most studies describing outcomes after infrainguinal PTFE bypasses focus on patency and "limb salvage" rates, but with this approach, clinically significant events such as ALI and all its attendant morbidity, such as fasciotomy incisions, residual paresthesias, and persistent weakness, are often overlooked. The use of MALE as an end point is a significant advance in that these events are incorporated as part of a composite measure.[10]

Previous studies have investigated the hemodynamic consequences after occlusion of PTFE compared with vein grafts.[6,8] The most recent one by Cavallaro et al[6] included 20 patients with occluded femoropopliteal bypasses admitted to a hospital in Rome, Italy (10 patients had reversed saphenous vein graft and 10 patients had

Table II. Operative data of the study population

	Total (N = 93)	DVP (n = 39)	No DVP (n = 54)	*P*
Previous ipsilateral endovascular intervention	41.2 (35)	28.6 (10)	50.0 (25)	.048[a]
Previous ipsilateral open intervention	45.3 (39)	42.9 (15)	47.1 (24)	.701
Redos ≥2	16.1 (15)	12.8 (5)	18.5 (10)	.461
Inflow vessel				
CFA	52.7 (49)	59.0 (23)	48.1 (26)	.438
PFA	6.5 (6)	5.1 (2)	7.4 (4)	
SFA	4.3 (4)	2.6 (1)	5.6 (3)	
Other[b]	36.6 (34)	33.4 (13)	38.9 (21)	
Outflow vessel				
Popliteal artery	39.8 (37)	15.4 (6)	57.4 (31)	<.001[a]
AT	15.1 (14)	20.5 (8)	11.1 (6)	
PT	28.0 (26)	33.3 (13)	24.1 (13)	
Peroneal artery	10.8 (10)	20.5 (8)	3.7 (2)	
Unknown	6.5 (6)	10.3 (4)	3.7 (2)	
≥2 patent runoff vessels	51.3 (39)	31.3 (10)	65.9 (29)	.003[a]
Operative time, minutes	316 ± 136; 299 (118-806)	354 ± 131; 326 (171-668)	288 ± 134; 280 (118-806)	.019[a]

AT, Anterior tibial artery; *CFA*, common femoral artery; *DVP*, distal vein patch; *PFA*, profunda femoris artery; *PT*, posterior tibial artery; *SFA*, superficial femoral artery.
Categorical variables are presented as % (No.). Continuous variables are presented as mean ± standard deviation; median (range). The *P* values for categorical variables were derived from χ^2 or Fisher exact test; *P* values for continuous variables were derived from Student *t*-test or Mann-Whitney *U* test.
[a]*P* values are significantly different ($P < .05$).
[b]External iliac artery, aortofemoral bypass, axillofemoral bypass, femoral-femoral bypass, and iliofemoral bypass.

PTFE). Nine of 10 patients with occluded PTFE grafts presented with ALI symptoms, whereas that was the case for only 4 of 10 in the vein group. In addition, noninvasive studies demonstrated marked differences in post-occlusion ankle pressure index favoring vein conduit and also lower amputation rates.

Clear inferiority compared with vein grafts also with regard to patency and limb salvage has led to a search for adjunctive techniques to enhance the performance of prosthetic grafts in the infragenicular region. The creation of distal arteriovenous fistulas, vein cuffs, and use of anticoagulants have been described with variable efficacy in the literature.[4,5,14] With regard to the utility of DVPs as a performance-enhancing adjunct, previous studies including level I data with primary focus on patency have yielded conflicting results; some studies have demonstrated an association between DVP and improved graft patency or limb salvage,[2,3,5,12,15] whereas others have found no difference in outcomes with anastomotic DVP use.[4] These studies were recently pooled and analyzed in a systematic fashion by Khalil et al.[1] Despite demonstrating an overall improvement in primary patency for below-the-knee vein cuffed PTFE graft, they concluded that the evidence supporting the use of vein patches at distal anastomosis is "weak and based on underpowered studies."

Our analysis found that MALEs—and more specifically, ALI and reinterventions—are lower when DVP is used as an adjunct in infrainguinal PTFE bypasses despite no significant difference in patency. In other words, even though graft occlusions were not significantly decreased by a DVP, the benefit of DVP seems to be realized only when a graft occluded. The differences in clinical situations seen after occlusion of PTFE grafts with and without DVPs may be caused by many factors. Intimal hyperplasia at the distal anastomosis has been shown to be more common in synthetic grafts than in native veins.[16] This is particularly relevant for below-the-knee vessels, for which small caliber makes them more susceptible to the effects of intimal hyperplasia and therefore more prone to early thrombosis in conditions of low flow and high resistance. This could lead to sudden occlusion and ALI symptoms in instances in which collateral circulation is underdeveloped or metabolic tissue demands are high. Furthermore, PTFE grafts are more thrombogenic and do not usually endothelialize even many years after implantation.[16,17] The lack of endothelial surface creates a space for platelets, fibrin, and other thrombogenic products to colonize the inner surface of the graft and to further microembolize distally, leading also to occlusion of the outflow tract. This theory is supported by the observation that anticoagulation given after prosthetic bypass implantation for thrombosis prevention is generally effective.[18] The benefits of adding a DVP to a prosthetic infragenicular bypass on decreasing intimal hyperplasia at the distal anastomosis and slowing down progression of atherosclerosis at outflow vessels in general tend to occur after

Table III. Outcomes

	Total (N = 93)	DVP (n = 39)	No DVP (n = 54)	Adjusted mean difference (95% CI)	Adjusted *P*
Intraoperative pRBCs, units	1.7 ± 2.0	1.8 ± 2.4	1.6 ± 1.7	0.2 (−1.0 to 1.1)	.606
ICU LOS	2.2 ± 3.0	2.3 ± 3.5	2.1 ± 2.7	0.2 (−1.4 to 1.1)	.783
Hospital LOS	12.6 ± 11.3	12.3 ± 11.1	12.9 ± 11.5	−0.6 (−5.4 to 4.1)	.794
	Total (N = 93)	**DVP (n = 39)**	**No DVP (n = 54)**	**Adjusted OR (95% CI)**	**Adjusted *P***
Intraoperative blood transfusion	57.0 (53)	53.8 (21)	59.3 (32)	0.9 (0.6-1.3)	.603
Postoperative blood transfusion	31.8 (28)	40.0 (14)	26.4 (14)	1.8 (0.7-4.6)	.181
Hospital readmission	43.0 (4)	41.0 (16)	44.4 (24)	0.9 (0.3-2.0)	.742
MALEs	48.4 (45)	35.9 (14)	57.4 (31)	0.4 (0.2-0.9)	.041[a]
Ipsilateral limb reintervention[b]	41.9 (39)	30.8 (12)	50.0 (27)	0.4 (0.2-1.1)	.064
AKA	26.9 (25)	23.1 (9)	29.6 (16)	0.7 (0.3-1.8)	.482
BKA	6.5 (6)	7.7 (3)	5.6 (3)	1.4 (0.3-7.4)	.679
Primary patency	39.8 (37)	46.2 (18)	35.2 (19)	1.6 (0.6-3.7)	.286
Primary assisted patency	41.9 (39)	51.3 (20)	35.2 (19)	1.9 (0.8-4.5)	.121
Secondary patency	52.7 (49)	53.8 (21)	51.9 (28)	1.1 (0.5-2.4)	.849
Readmitted with ALI	38.2 (21)	30.0 (6)	42.9 (15)	0.6 (0.2-1.8)	.345
30-Day mortality	9.7 (9)	10.3 (4)	9.3 (5)	1.1 (0.3-4.4)	.872
1-Year mortality	18.3 (17)	17.9 (7)	18.5 (10)	0.9 (0.3-2.8)	.944

AKA, Above-the-knee amputation; *ALI,* acute limb ischemia; *BKA,* below-the-knee amputation; *CI,* confidence interval; *DVP,* distal vein patch; *ICU,* intensive care unit; *LOS,* length of stay; *MALEs,* major adverse limb events; *OR,* odds ratio; *pRBCs,* packed red blood cells.
Categorical variables are presented as % (No.). Continuous variables are presented as mean ± standard deviation. The *P* values were derived from analysis of covariance for continuous variables and from binary logistic regression for categorical variables. The *P* values were obtained after adjustment for differences in demographics and clinical data presented in Tables I and II.
[a]*P* values are significantly different ($P < .05$).
[b]Repeated angioplasty with or without stenting, catheter-directed thrombolysis, open thrombectomy, or redo bypass.

6 months of bypass creation, therefore explaining late separation of the time-to-event curves for primary and secondary outcomes.

Limitations of this study include its retrospective design and small sample size. The small sample size, in particular, prevented many of the outcome measures examined, such as reintervention rates, primary patency, and primary assisted patency, from reaching statistical significance. Data on the type of DVP used (eg, Linton or Taylor patch) were not available for analysis, and therefore its relationship with primary and secondary outcomes was unable to be established. Furthermore, important intraoperative data, such as estimated blood loss and completion angiograms, were not reliably collected and therefore were unavailable for analysis. In this study, approximately 30% of the study population had an artificial source of inflow, such as an aortobifemoral bypass limb or an ilioprofunda bypass. Despite no significant difference in prevalence between the two groups (DVP, 33.4%; no DVP, 38.9%; $P = .438$), issues with the inflow could have been the primary reason for some of the occlusion events seen during the follow-up period and could have accounted for some of the differences seen in our primary and secondary outcome measures.

Last, follow-up information beyond 1 year was unavailable for a substantial proportion of patients. This limited our ability to evaluate long-term outcomes in this study population, essential in clinical decision-making.

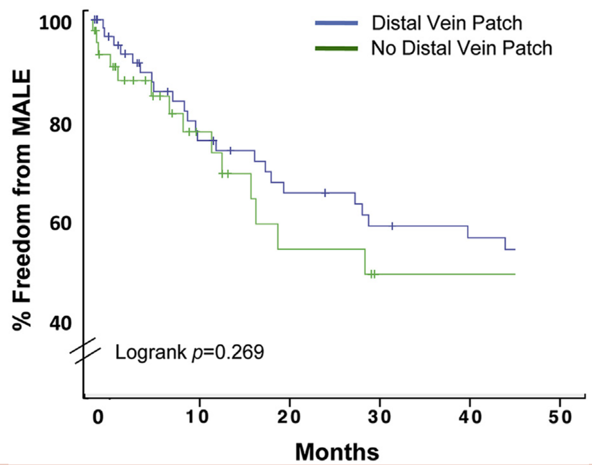

Fig 2. A Cox regression time-to-event analysis for freedom from major adverse limb event (*MALE*).

Our data demonstrate that size and number of outflow vessels were the two strongest factors associated with DVP use. For example, if the outflow vessel was the popliteal artery, only 6 (16.2%) of 37 patients required a DVP, whereas if the outflow vessel was the posterior tibial artery, 13 of 26 (50.0%) patients required DVP ($P < .001$).

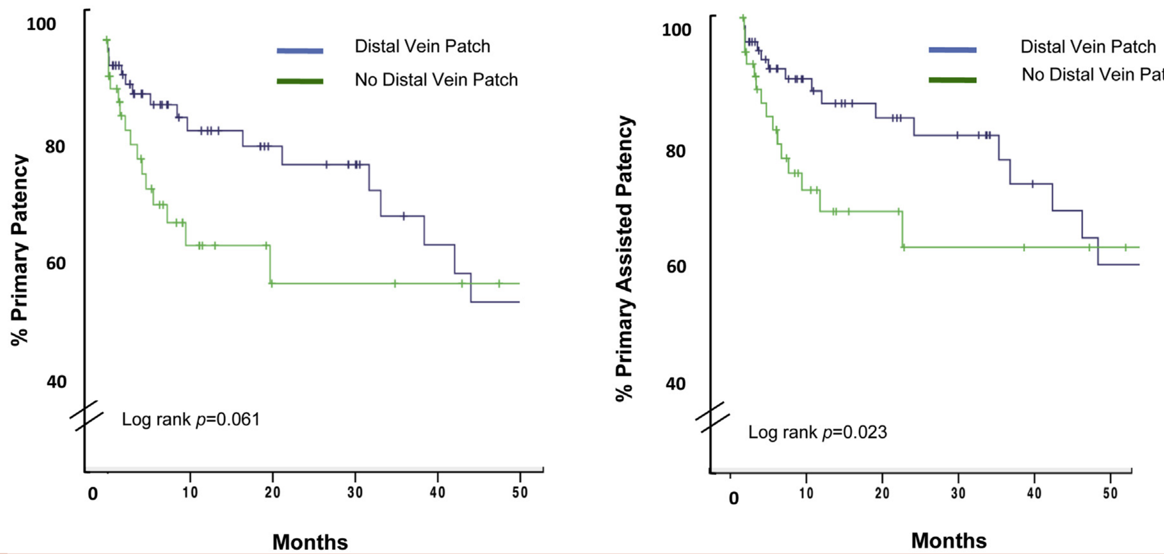

Fig 3. A Cox regression time-to-event analysis for primary patency and primary assisted patency. The secondary patency curve (not shown) appeared similar to the primary assisted patency curve (log rank, $P = .020$).

The number of outflow vessels was also another important predictor of DVP use. For two or more outflow vessels, only 10 of 39 (25.6%) patients required a DVP.

CONCLUSIONS

In this evaluation of infragenicular prosthetic bypass grafts, the creation of a vein patch at the distal anastomosis was associated with lower reintervention rates and a trend toward improved primary patency and MALEs. Furthermore, for those presenting with occluded prosthetic bypass graft, the use of a DVP was associated with a trend toward lower rates of ALI. The number of outflow vessels and vessel diameter were associated with DVP use. Many of the DVPs in this series required the harvest of arm vein. With few other disadvantages, surgeons should strongly consider the use of DVP for infrainguinal PTFE bypasses.

AUTHOR CONTRIBUTIONS

Conception and design: BB, PK, JB, JM, NB
Analysis and interpretation: BB, PK, JB, JM, NB
Data collection: BB, PK
Writing the article: BB, NB
Critical revision of the article: BB, PK, JB, JM, NB
Final approval of the article: BB, PK, JB, JM, NB
Statistical analysis: BB
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Overall responsibility: NB

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