Distal anastomotic vein adjunct usage in infrainguinal prosthetic bypasses

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Objective: **Single-segment saphenous vein remains the optimal conduit for infrainguinal revascularization. In its absence, prosthetic conduit may be used. Existing data regarding the significance of anastomotic distal vein adjunct (DVA) usage with prosthetic grafts are based on small series.**

Methods: **This is a retrospective cohort analysis derived from the regional Vascular Study Group of New England as well as the Brigham and Women's hospital database. A total of 1018 infrainguinal prosthetic bypass grafts were captured in the dataset from 73 surgeons at 15 participating institutions. Propensity scoring and 3:1 matching was performed to create similar exposure groups for analysis. Outcome measures of interest included: primary patency, freedom from major adverse limb events (MALEs), and amputation free survival at 1 year as a function of vein patch utilization. Time to event data were compared with the log-rank test; multivariable Cox proportional hazard models were used to evaluate the adjusted association between vein cuff usage and the primary end points. DVA was defined as a vein patch, cuff, or boot in any configuration.**

Results: **Of the 1018 bypass operations, 94 (9.2%) had a DVA whereas 924 (90.8%) did not (no DVA). After propensity score matching, 88 DVAs (25%) and 264 no DVAs (75%) were analyzed. On univariate analysis of the matched cohort, the DVA and no DVA groups were similar in terms of mean age (70.0 vs 69.0; $P = .55$), male sex (58.0% vs 58.3%; $P > .99$), and preoperative characteristics such as living at home (93.2% vs 94.3%; $P = .79$) and independent ambulatory status (72.7% vs 75.7%; $P = .64$). The DVA and no DVA groups had similar rates of major comorbidities such as hypertension chronic obstructive pulmonary disease, diabetes mellitus, coronary artery disease, and dialysis dependence ($P > .05$ for all). Likewise, they had similar rates of distal origin grafts (13.6% vs 12.5%; $P = .85$), critical limb ischemia indications ($P = .53$), and prior arterial bypass (58% vs 47%; $P = .08$). The DVA group had a higher rate of completion angiogram performed (55.7% vs 37.5%; $P = .002$) and were more likely to be discharged on coumadin (53.4% vs 37.1%; $P = .01$). By multivariable analysis, use of a distal DVA was protective against MALEs (hazard ratio, 0.36; 95% confidence interval, 0.14-0.90; $P = .03$).**

Conclusions: **This contemporary multi-institutional propensity-matched study demonstrates that patients that receive distal anastomotic vein adjuncts as part of infrainguinal prosthetic bypass operations in general have more extreme comorbidities and more technically challenging operations based on level of target vessel and prior bypass attempts. After propensity-matched analysis, the use of a DVA may protect against MALEs in prosthetic bypass surgery and should be considered when feasible. (J Vasc Surg 2013;57:982-9.)**

Prosthetic conduit reconstructions for infrainguinal occlusive disease are at times necessary despite the known superiority of single segment great saphenous vein. Greater than 20% of patients may have unusable superiority of single segment great saphenous vein because of poor vein quality, varicosities, or prior procurement for reconstruction in other vascular beds, obliging the surgeon to consider alternative conduit sources.[1,2] The relative performance of prosthetic conduit compared with alternative vein sources such as arm vein, composite vein segments, and cryopreserved conduits have been the subject of multiple studies.[3-6] Despite their known limitations, however, prosthetic grafts remain an important option for lower extremity bypass when more desirable choices are unavailable.

Data regarding adjunctive techniques to enhance the performance of prosthetic grafts have mostly come from small case series or trials, and the reported results have been inconsistent.[7-10] Some studies examining the utility of anastomotic distal vein adjuncts (DVAs) have demonstrated an association between DVA and superior graft patency[9] or improved limb salvage,[7] whereas others have found no difference in patency or limb salvage with anastomotic DVA usage in prosthetic bypasses.[8]

The purpose of this study was to evaluate the utilization of DVAs for prosthetic lower extremity revascularizations among academic and community vascular surgeons. An additional aim was to determine if this technique improves the performance of these disadvantaged conduits in a "real world" cross-section of academic and community hospitals from a regional quality improvement database.

METHODS

Patients and databases. This study was comprised of a combined cohort derived from the Vascular Study Group

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of New England (VSGNE) database merged with the Brigham and Women's Hospital institutional database. The VSGNE is a cooperative regional database started in 2002 with the mission of quality improvement for participating institutions, the details of which have been previously described.[11,12] Further information regarding VSGNE participating institutions and surgeons can be found at www.vsgne.org. The Brigham and Women's hospital (BWH) database is a prospectively maintained registry of all lower extremity revascularization procedures performed by all members of the division of vascular and endovascular surgery.[13,14]

From the VSGNE database, any patient undergoing an infrainguinal reconstruction for occlusive disease with a prosthetic conduit from January 1, 2003 to June 30, 2010 was included. From the BWH database, any patient that received a distal anastomotic vein adjunct to the below-knee popliteal artery/tibioperoneal trunk from January 1, 1995 to June 30, 2010 was included. As the Brigham and Women's Hospital joined the VSGNE database in September 2011, there was no patient overlap between the two databases.

Each patient was analyzed only once based on the first leg undergoing revascularization in the final dataset to avoid confounding related to "within-patient" dependence.[15] Inflow vessels included iliac, femoral, or popliteal arteries. Outflow vessels included popliteal, tibial, or pedal targets. Prosthetic conduits included those made of Dacron or polytetrafluoroethylene (PTFE). Nonautogenous biologic material and composite grafts of prosthetic and vein were excluded from the final model. Use of the distal anastomotic vein adjunct is entered into the VSGNE database as a binary yes/no variable, and more detailed information on the configuration of the adjunct constructed (eg, vein patch, vein cuff, or boot, etc) is unavailable. Of the 17 DVA patients from the BWH database, eight were cuffs whereas nine were vein patches. In addition, information regarding adjunctive outflow arteriovenous fistula creation is not routinely captured in the dataset.

Outcome measures. The main outcome measures of interest were 1-year rates of primary patency, amputation-free survival (AFS), and freedom from major adverse limb events (MALEs).[16] As recommended by the Society for Vascular Surgery in their description of Objective Performance Goals as study end points in critical limb ischemia (CLI) studies, MALE was defined as the occurrence of one of the following: ipsilateral major amputation, graft revision, graft thrombectomy, or graft thrombolysis during the follow-up interval.[12,17] Patency rates were defined by standard criteria.[18] Immediate postoperative outcomes were additionally evaluated and included in-hospital mortality, wound infection, blood transfusion, myocardial infarction, and discharge disposition.

Statistical analysis. Approval from the Brigham and Women's Hospital Institutional Review Board was obtained. All analyses were performed using SAS v. 9.3 (SAS Institute, Cary, NC). Univariate analysis of categorical variables was performed using the χ^2 or Fisher exact test where appropriate. Continuous variables were assessed for normality using the Shapiro-Wilk test and compared using the Student *t*-test (two-tailed) or Wilcoxon rank sum test depending on the normality of distribution. A P value of $<.05$ was considered statistically significant. Survival curves were created using the Kaplan-Meier technique and comparisons were made using the log-rank test.

Three separate multivariable Cox regression models were constructed to determine whether DVA usage was associated with the end points of primary patency, AFS, and freedom from MALEs after adjustment for other factors. These analyses were stratified into overall results as well as "high risk grafts," which were defined as those done for CLI indications with a distal anastomosis to below-knee recipient vessels (below-knee popliteal, tibioperoneal trunk, tibials, and pedals). This was performed by a backward elimination technique with independent factors with an alpha level of <0.2 remaining in the final model. Possible confounders were considered and included in the regression models as follows: age, sex, diabetes, smoking history, hemodialysis, coronary artery disease, preoperative independence level, preoperative ambulatory status, prior operative bypass, ipsilateral CLI symptoms, preoperative statin use, preoperative antiplatelet use, urgency of case, surgeon identification, registry medical center, graft origin level, distal anastomotic level, completion study, postoperative complications such as myocardial infarction, wound infection, and blood transfusion, discharge ambulatory status, discharge disposition, and discharge antiplatelet, statin, and warfarin medication use. Regardless of significance, DVA was forced into each regression model as it was the main exposure variable of interest.

Propensity analysis. Because of the inherent selection bias related to "confounding by indication" in this type of study, a matched propensity score analysis was performed to create similar exposure groups for outcome analysis. The initial dataset ($n = 1018$) was evaluated, and patients were scored based on their propensity to receive a DVA based on other demographic, comorbid, and technical factors (age, sex, race, diabetes, dialysis dependence, prior bypass graft, surgical indication, graft inflow vessel, urgency of case, and preoperative medications). Because of the nonequivalent size of the initial exposure groups (DVA, $n = 94$; no DVA, $n = 914$), matching was performed in a 3:1 fashion (three no DVA patients to each one DVA patient). After matching, our final dataset for analysis included 88 DVA and 264 no DVA patients. At an alpha level of .05, this provides 67% power to detect a 10% difference in the DVA and no DVA proportions using the χ^2 test.

RESULTS

A total of 1018 patients that underwent an infrainguinal prosthetic graft reconstruction for occlusive disease in the period of interest were identified. The procedures were performed at 15 institutions by 73 different vascular surgeons. Of these bypasses, 94 (9.2%) were performed with a DVA whereas 924 (90.8%) were not. After propensity score regression analysis and 3:1 matching based on

Table I. Baseline characteristics of patients with and without DVA

	Total cohort			*Propensity-matched cohort*		
	DVA (%)	*No DVA (%)*	P *value*	*DVA (%)*	*No DVA (%)*	P *value*
N	94 (9.2)	924 (90.8)		88 (25.0)	264 (75.0)	
Characteristics						
Male sex	51 (54.3)	593 (64.2)	.07	51 (58.0)	154 (58.3)	>.99
White race	92 (97.9)	909 (98.4)	.52	86 (97.7)	260 (98.5)	.64
Living at home	88 (93.6)	884 (95.7)	.43	82 (93.2)	249 (94.3)	.79
Ambulates w/o assist	66 (70.2)	707 (76.5)	.2	64 (72.7)	200 (75.7)	.64
Age						
Mean age [SD]	70.5 [10.8]	68.8 [11.1]	.17	70 [10.9]	69.0 [11.2]	.55
Median age [range]	71 [42-95]	69 [38-96]		69.5 [42-95]	69 [38-91]	
Smoking (prior/current)	70 (74.5)	799 (86.8)	.003	65 (73.9)	223 (84.5)	.03
Comorbid conditions						
Hypertension	83 (88.3)	806 (87.2)	.87	79 (89.8)	234 (88.6)	.85
COPD	29 (30.9)	316 (34.2)	.57	27 (30.7)	96 (36.4)	.37
Diabetes	55 (58.5)	451 (48.8)	.08	50 (56.8)	140 (53.0)	.62
CAD	49 (52.7)	395 (42.7)	.08	45 (51.7)	116 (43.9)	.22
Dialysis dependent	11 (11.7)	54 (5.8)	.003	8 (9.1)	17 (6.4)	.47
Pre-op medications						
Antiplatelet	61 (64.9)	702 (76.0)	.06	59 (67.0)	186 (70.4)	.59
Statin	60 (63.8)	605 (65.5)	.88	55 (62.5)	169 (64.0)	>.99
Beta-blocker	82 (87.2)	731 (80.1)	.1	77 (87.5)	197 (74.9)	.02
Surgical indication			.02			.53
Claudication	25 (26.6)	367 (39.7)		25 (31.2)	90 (34.1)	
Rest pain	34 (36.2)	236 (25.5)		30 (34.1)	76 (28.8)	
Tissue loss	35 (37.2)	321 (34.7)		33 (37.5)	98 (37.1)	
Previous arterial bypass	55 (58.5)	252 (27.3)	.014	51 (58.0)	124 (47.0)	.08
Operative details						
Urgency of case			.005			.62
Elective	61 (64.9)	720 (77.9)		59 (67.0)	191 (72.3)	
Urgent	31 (33.0)	174 (18.8)		27 (30.7)	67 (25.4)	
Emergent	2 (2.1)	30 (3.2)		2 (2.3)	6 (2.3)	
Graft origin			.75			.85
Proximal (CFA/EIA)	80 (85.1)	796 (86.2)		76 (86.4)	231 (87.5)	
Distal (SFA or below)	14 (14.9)	127 (13.8)		12 (13.6)	33 (12.5)	
Graft recipient						
Above-knee popliteal	20 (21.3)	531 (57.5)	<.0001	20 (22.7)	162 (61.4)	<.0001
Below-knee popliteal	55 (58.5)	252 (27.3)	<.0001	53 (60.2)	78 (29.6)	<.0001
Tibial vessel	18 (19.1)	104 (11.3)	.03	15 (17.0)	22 (8.3)	.02
Pedal vessel	1 (1.1)	37 (4.0)	.24	0 (0)	1 (.38)	>.99
Completion study						
Any study	62 (66.0)	430 (46.5)	.0003	56 (63.6)	111 (42.0)	.0005
Angiogram	53 (56.4)	394 (42.6)	.01	49 (55.7)	99 (37.5)	.002
Duplex ultrasound	8 (8.5)	40 (4.3)	.07	6 (6.8)	14 (5.3)	.60

CAD, Coronary artery disease; *CFA,* common femoral artery; *COPD,* chronic obstructive pulmonary disease; *EIA,* external iliac artery; *DM,* diabetes mellitus; *DVA,* distal vein adjunct; *SD,* standard deviation; *SFA,* superficial femoral artery.

those scores, the final cohort had 88 (25.0%) DVA patients and 264 (75.0%) no DVA patients. Table I displays the baseline characteristics of the overall cohort as well as the propensity-matched cohort. The baseline similarity between the comparison groups improved dramatically after propensity matching. The remainder of the outcome analysis was performed on the matched cohort.

In the matched cohort, the DVA and no DVA groups had similar baseline characteristics. The mean age was similar for the DVA and no DVA groups (70.0 vs 69.0; $P = .55$). Likewise, both groups were predominantly male (58.0% vs 58.3%; $P > .99$) and white (97.7% vs 98.5%; $P = .64$). In terms of baseline functional status, most of the DVA and no DVA groups lived in a private home (93.2% vs 94.3%; $P = .79$) and ambulated independently prior to surgery (72.7% vs 75.7%; $P = .64$). The two groups were also well matched in terms of baseline comorbid conditions such as hypertension, chronic obstructive pulmonary disease, diabetes, coronary artery disease, dialysis dependence, and smoking history ($P > .05$ for all). Likewise, the two groups were similar in terms of CLI indications (71.6% vs 65.9%; $P = .36$), urgency of case ($P = .62$), and CFA graft origin (86.4% vs 87.5%; $P = .85$). The DVA and no DVA groups differed based on their level of distal anastomosis with the DVA group having a higher proportion of below-knee level of distal anastomosis ($P < .0001$). DVA patients were also much more likely to undergo completion imaging (63.6% vs 42.0%; $P = .0005$) (Table I).

Table II. Postoperative outcomes

	DVA (%)	*No DVA (%)*	P *value*
N	88	264	
Complications			
In-hospital mortality	1 (1.1)	10 (3.8)	.30
Wound infection	7 (7.9)	10 (3.8)	.15
Blood transfusion	12 (15.0)	7 (3.0)	.0001
Myocardial infarction	2 (2.3)	18 (6.8)	.18
Data			
Discharged on coumadin	47 (53.4)	98 (37.1)	.009
Ambulation status			
Independent	36 (40.9)	146 (55.3)	.02
Disposition			.003
Discharge to home	50 (57.5)	190 (74.8)	
Discharge to nursing facility	37 (42.5)	64 (25.2)	

DVA, Distal vein adjunct.

Postoperatively, the DVA and no DVA cohorts had in-hospital mortality rates of 1.1% and 3.8%, respectively ($P = .30$; Table II). In addition, both groups had similarly low rates of postoperative myocardial infarction (2.3% vs 6.8%; $P = .18$) and wound infection (7.9% vs 3.8%; $P = .15$). The DVA group had a significantly greater requirement for postoperative blood transfusion than did the no DVA group (15.0% vs 3.0%; $P = .01$) and of note, the DVA group was more likely to be discharged on coumadin (53.4% vs 37.1%; $P = .009$). A smaller proportion of the DVA patients were discharged directly to home postoperatively (57.5% vs 74.8%; $P = .003$; Table II).

As shown in Fig 1, *A*, the DVA and no DVA groups had similar overall rates of primary patency at 1 year (73.8% ± 5.8% vs 70.6% ± 3.8%; $P = .94$). Likewise, the two groups had similar primary patency rates for the subset of higher risk patients with CLI as their presenting indication and below-knee distal anastomoses (69.8% ± 7.9% vs 67.0% ± 7.4%; $P = .75$; Fig 1, *B*).

The DVA and no DVA groups had similar rates of AFS overall (70.6% ± 5.5% vs 75.8% ± 3.6%; $P = .83$), as well as for the highest risk grafts, (60.6% ± 7.5% vs 71.3% ± 7.6%; $P = .94$; Fig 2, *A* and *B*).

DVA patients trended toward higher rates of freedom from MALEs at 1 year compared with no DVA patients overall (84.7% ± 5.5% vs 74.8% ± 3.6%; $P = .33$). When limited to patients with CLI and with below-knee distal anastomosis, the DVA group trended toward improved freedom from MALEs compared with the no DVA group (83.1% ± 5.9% vs 63.7% ± 8.0%; $P = .25$; Fig 3, *A* and *B*). The MALEs are demonstrated in Table III.

Of note, when the main outcome measures were stratified by the medical center performing the procedure (n = 14), there was no difference for primary patency ($P = .68$), AFS ($P = .67$) and freedom from MALEs ($P = .73$) across hospital designations (data not shown).

By multivariable Cox regression analysis, the use of DVA was not independently associated with primary patency overall, (hazard ratio [HR], 1.0; 95% CI, 0.54-1.9), as well as for the high risk grafts (HR, 1.8; 95% CI, 0.73-4.6). After adjustment for other factors, DVA usage had a significantly protective association with freedom from MALEs overall (HR, 0.36; 95% CI, 0.14-0.90) and a nonsignificant protective association for the high risk group (HR, 0.23; 95% CI, 0.04-1.3). Usage of DVA was not associated with AFS overall (HR, 0.79; 95% CI, 0.41-1.5) or for the high-risk patients (HR, 1.0; 95% CI, 0.44-2.5) (Table IV).

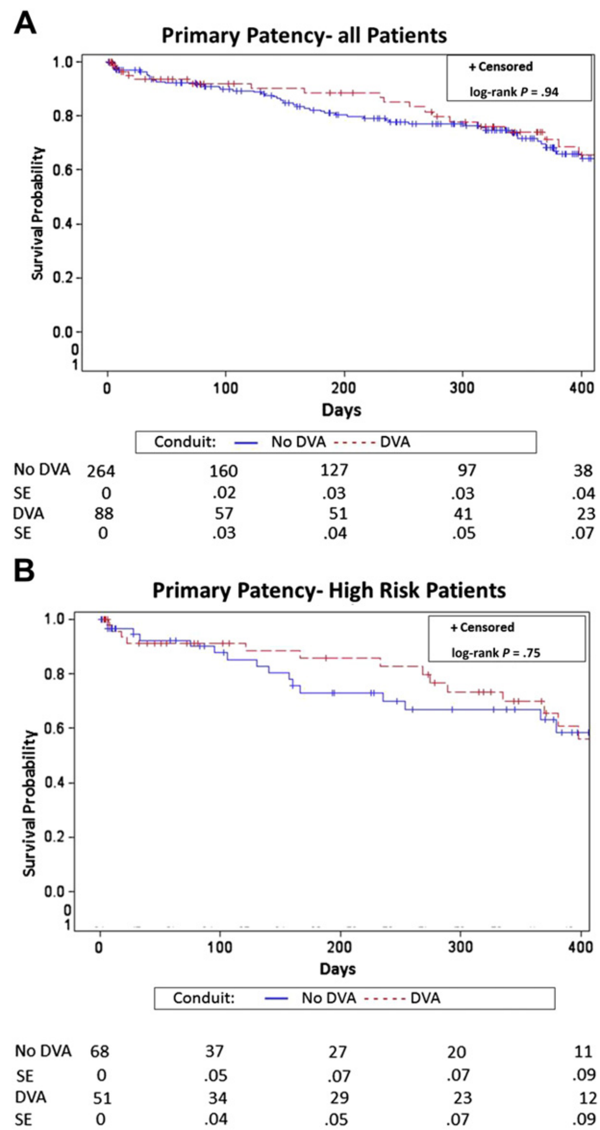
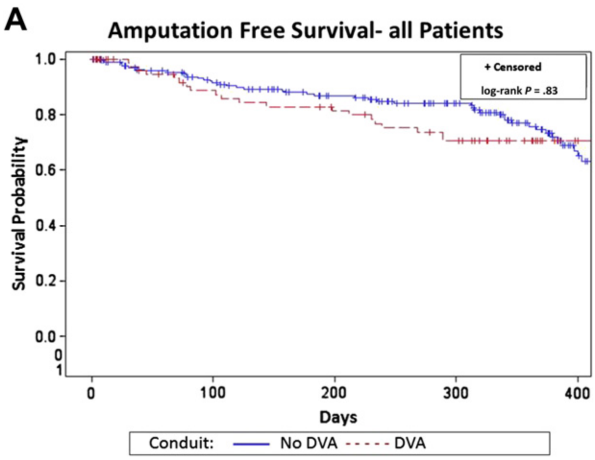


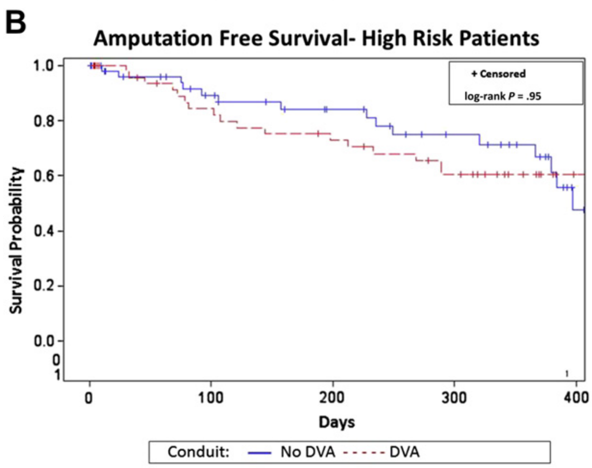
Fig 1. These unadjusted Kaplan-Meier curves demonstrate similar 1-year primary patency rates for the distal vein adjunct (*DVA*) and no DVA patients overall **(A)** as well as for high-risk patients **(B)**. *SE,* Standard error.

DISCUSSION

Distal anastomotic vein adjuncts were first described in 1979.[19] They were later modified in the manner of a cuff in 1984[20] and again as a patch in 1992,[21] and 2001.[22,23]

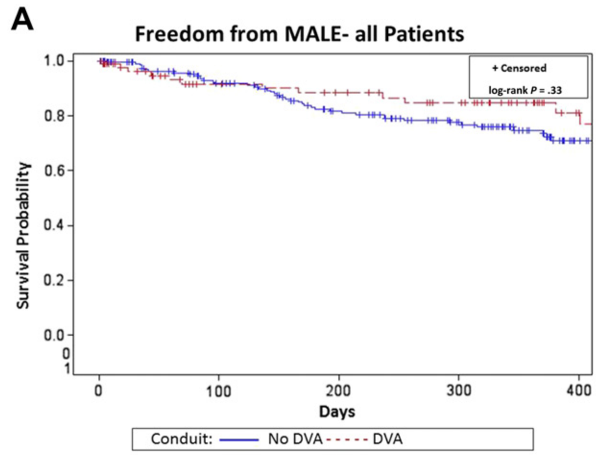


	0	100	200	300	400
No DVA	264	164	138	106	35
SE	0	.02	.03	.03	.05
DVA	88	60	54	44	22
SE	0	.04	.05	.05	.05

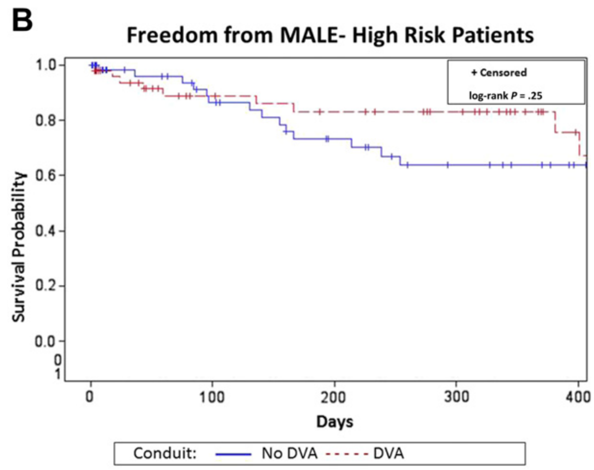


	0	100	200	300	400
No DVA	68	37	29	21	6
SE	0	.05	.06	.07	.1
DVA	51	36	31	23	10
SE	0	.06	.07	.07	.07

Fig 2. These unadjusted Kaplan-Meier curves demonstrate similar 1-year rates of amputation free survival (AFS) for all distal vein adjunct (*DVA*) and no DVA patients **(A)** as well as those performed on high-risk patients **(B)**. *SE,* Standard error.



	0	100	200	300	400
No DVA	263	158	124	96	38
SE	0	.02	.03	.03	.04
DVA	88	56	50	43	20
SE	0	.03	.04	.04	.05



	0	100	200	300	400
No DVA	68	35	25	17	10
SE	0	.05	.07	.08	.08
DVA	51	31	27	22	9
SE	0	.05	.06	.06	.09

Fig 3. These unadjusted Kaplan-Meier curves demonstrate similar 1-year rates of freedom from major adverse limb events (*MALEs*) for distal vein adjunct (*DVA*) and no DVA patients overall **(A)** as well as those performed only on high-risk patients **(B)**. *SE,* Standard error.

Theories as to why interposing an autogenous vein segment between a prosthetic graft and native artery might be beneficial abound and include improved flow dynamics,[24] decreased mechanical injurious forces,[25] an increased capacitance to allow for intimal hyperplastic overgrowth while preserving a flow lumen,[7] constant flow/washout of the anastomosis,[26] and lower flow resistance at the distal target than directly suturing a prosthetic graft to native artery.[27] Despite these postulated benefits, results assessing the performance of vein adjuncts have been nonuniform and even contradictory.

The main finding of this multi-institutional propensity-matched study with 1-year follow-up was that infrainguinal prosthetic bypass grafts performed with DVAs are associated with lower rates of MALEs. Across the variety of academic and community hospitals surveyed in the current report, the highest risk groups (CLI indications with below-knee distal anastomoses) demonstrated similar patency and complication rates when compared with their counterparts. Of note, a greater proportion of patients that received a DVA underwent completion imaging and was discharged on coumadin, supporting the commonly held view that vascular surgeons are most likely to use a DVA when concerned about the postoperative viability of a graft. While

Table III. MALEs[a]

	DVA (%)	*No DVA (%)*
N	88	264
Surgical revision/thrombectomy	15	40
Catheter based lysis	0	4
Major amputation	8	25

DVA, Distal vein adjunct; *MALEs,* major adverse limb events.
[a]Some patients had more than one event.

Table IV. Results: Cox proportional hazards for primary patency, MALEs, and AFS[a]

	HR	*95% CIs*		P *value*
Lost primary patency		Lower	Upper	
All patients				
DVA	1.0	.54	1.9	.98
High-risk patients[b]				
DVA	1.8	.73	4.6	.19
MALEs				
All patients				
DVA	.36	.14	.90	.03
High-risk patients				
DVA	.23	.04	1.3	.1
AFS				
All patients				
DVA	.79	.41	1.5	.49
High-risk patients				
DVA	1.0	.44	2.5	.91

AFS, Amputation-free survival; *CIs,* confidence intervals; *CLI,* critical limb ischemia; *DVA,* distal vein adjunct; *HR,* hazard ratio; *MALEs,* major adverse limb events.
[a]Backward elimination regression model included age, sex, smoking history, diabetes, dialysis dependence, coronary artery disease, prior bypass, indication for surgery, preoperative/postoperative medications (statin, beta blocker, coumadin, antiplatelet), case urgency, preoperative ambulatory/living status, graft origin level, graft recipient level, registry medical center, surgeon identification, postoperative complications, transfusion, and completions study.
[b]Indicates CLI patients with distal anastomosis below the knee level (popliteal, tibial, and pedal).

the benefit of coumadin use with prosthetic graft bypasses has been debated,[28,29] its institution typically reflects a concern by the surgeon of certain high-risk characteristics of the graft or patient.

Lundgren and colleagues recently published the Scandinavian Miller Collar Study (SCAMICOS) in which 352 patients recruited between 1995 and 1998 and undergoing below-knee popliteal and tibial PTFE bypass grafts primarily for CLI (>90%) were randomized to a distal vein collar versus no collar.[8] Of relevance, participating surgeons were free to perform the cuff technique of their choosing and follow-up extended to 5 years. The SCAMICOS results were notable for similar patency and limb salvage rates in both groups at both the below-knee popliteal as well as tibial level. However, while the randomized design of the trial allowed for comparable baseline matching of the two groups, the variability of surgical technique (eg, inclusion of 5 mm grafts) and the lack of data on postoperative anticoagulation management (eg, no information on coumadin use provided) reduce the generalizability of this study.

Contrasting results were reported from a second contemporary randomized trial, this one performed in the UK by the Joint Vascular Research Group on a nonconsecutive cohort of 261 patients with initial 2-year[10] and later 3-year follow-up.[9] All patients had a 6 mm graft, and those randomized to the vein adjunct group had a standardized cuff created distally. The UK research group found that a DVA was associated with improved patency rates at the below-knee location, but was not at the above-knee location. The observed patency benefit did not translate into improved limb salvage rates, which were similar across all strata in the study. While their cohorts were well-matched in terms of baseline characteristics, details such as type and duration of postoperative anticoagulation were also lacking in this report. Similar to our study, the UK trialists included claudicants as well as grafts with above-knee (n = 145) and below-knee distal anastomotic targets. While 1-year primary patency rates overall compared favorably between the UK study and ours, the predominance of above-knee vein cuffs (61%) included in the UK study potentially limits the clinical applicability of their findings given that most surgeons would not find this routinely necessary. As they did not stratify their results by surgical indication, it is also unclear if the benefit of the cuff in the below-knee group was affected by the inclusion of claudicants. In our study, those patients with CLI and below-knee targets, the primary patency rates were similar between the DVA and no DVA groups.

An additional proposed benefit of DVA usage is that in the event of graft thrombosis, the native outflow may be preserved and serve to effectively lessen the ischemic insult of graft occlusion.[7,30] This protective benefit could conceivably translate into improved limb-salvage rates as outflow vessels may be preserved from thrombotic sequelae, preserving the patient's preoperative baseline condition. Much like the UK trialists finding, the current work found that DVA usage was protective against MALEs (HR, 0.36), lending support to this notion. Our findings were in contrast to the single-institution report of Kreienberg et al comparing DVA with distal anastomotic arteriovenous fistula in 48 patients. Though poorly powered, they noted that DVAs were associated with improved limb salvage and may ultimately facilitate graft revision.[7] Of interest, four of 35 DVA patients in their series not compliant with coumadin postoperatively all experienced graft failure.

The use of "pre-cuffed" prosthetic grafts have the same theoretic benefits as autogenous vein cuffs and have been shown to perform at the same level in at least one trial.[31] Unfortunately, such PTFE graft configurations are not distinctively coded in the VSGNE database, precluding relevant subanalysis that would allow comment on their performance in this study.

A principle limitation of an observational study evaluating a surgical technique relates to the selection bias of "confounding by indication." Namely, the choice to use a vein cuff is ultimately at the discretion of the operating surgeon and will typically be dictated by factors that may not be captured in a retrospective database analysis. In the current work, factors such as arterial calcification, luminal size, and quality as well as quality of runoff vessels is not reliably captured. The goal of the propensity score is to evaluate those factors that predicted the use of the distal vein cuff and find matching patients in the no DVA group to allow for meaningful comparison. The current work did find adequate matching patients but this required the sacrifice of some power by excluding >600 non-matching patients. Ultimately, the loss of sample size associated with matching the exposure groups (DVA vs no DVA) limits this study's ability to determine small differences between exposure groups because of the lack of power that may explain the lack of significant difference in the univariate analysis of MALEs by the log-rank test. As seen in Table I, the unmatched cohort had vastly different baseline characteristics that would make comparative analysis difficult, which prompted the decision to proceed with the matched analysis despite the diminished sample size. Despite propensity-matched analysis, there are persistent unmeasured confounders (vessel quality, runoff, lumen diameter) that are not able to be accounted for in a nonrandomized study design.

Other limitations in this study relate to its retrospective cohort design derived from prospectively maintained datasets. The VSGNE relies on participating surgeon self-reporting of cases with follow-up data abstracted by nursing and other personnel at participating centers. The potential for reporting bias has been previously described[12] and is ideally limited to some degree by the voluntary nature of the regional database participation through which surgeons are less likely to report erroneous information. While the VSGNE is a robust source of data, not all clinical characteristics such as graft size and distal vein cuff configuration are captured leading to possible information bias. An additional limitation was the inclusion of a sample of nonconsecutive patients from the BWH vascular registry. Unfortunately, vein cuff information is not routinely captured from the BWH dataset and was available for only a select cohort used for a different analysis. Although the sampled time period overlapped with that of the VSGNE, a dedicated institutional registry likely has more complete follow-up information and by including only a self-selected subset of such patients, selection bias is potentially introduced. Lastly, follow-up information beyond 1 year is currently unavailable with the VSGNE dataset, limiting the utility of the current results to clinical decision-making.

In summary, the use of a distal vein cuff with prosthetic lower extremity bypass appears to be used preferentially in higher-risk patients (CLI patients, dialysis dependence, and more distal anastomoses) as reflected in the initial total cohort (Table I). Upon analysis of the propensity-matched cohort, after adjustment for other factors, the selective use of vein cuffs was protective against MALEs overall and trended toward being protective for the high risk cohort (CLI indications with below-knee distal anastomoses).

In conclusion, when feasible, the use of a distal vein cuff with a prosthetic bypass graft should be considered (at all anastomotic levels) as it is associated with a lower rate of MALEs.

AUTHOR CONTRIBUTIONS

Conception and design: JM, MM
Analysis and interpretation: JM, PG
Data collection: JM
Writing the article: JM
Critical revision of the article: JM, MM, AS, PG, MB
Final approval of the article: MM
Statistical analysis: JM, SS
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Overall responsibility: JM

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