Session 1

Current state of bypass for lower extremity revascularization: What are the real results?

Role of Surgical Bypass in a Limb Preservation Program

Who needs a bypass and what is the best conduit?

BY RICHARD F. NEVILLE, MD

There are approximately seven million chronic wounds treated annually in the United States—the treatment of which costs the health care system $20 billion per year. A multidisciplinary, limb preservation program brings together a team of experts whose goal is to achieve healing and preserve functional limbs, and raise awareness about successful limb preservation. The major vascular and podiatric societies have recognized the benefits of such a collaborative program to patients and physicians.[1] Such programs are particularly useful for patients with the added complexities presented by diabetes mellitus and end-stage renal disease. While the purpose of a limb preservation center is to preserve the limb, experts acknowledge that amputation is an important option for the patient in certain cases, and rehabilitation and optimal prosthetics are an important part of the program. Due to the complex nature of this health problem, a patient with a limb threatened by peripheral artery disease may require multiple visits with different physicians and diagnostic tests to determine and carry out a treatment plan. This is not an insignificant issue in patients with limited mobility. Multidisciplinary programs can streamline this process via an integrated team approach that combines a multispecialty physician team with supportive staff. This care increases patient satisfaction and therapeutic success by more rapidly providing care in situations in which time is of the essence. It is important to appoint a program director to oversee operational details of the entire process, as well as a core group of physicians who have a passion for limb preservation.

A dedicated space is important to the identity and smooth performance of the program. A noninvasive vascular diagnostic vascular laboratory is critical to the program, ideally with diagnostic imaging capable of assessing tissue perfusion. Access to arterial and soft tissue imaging by computed tomography and/or magnetic resonance

	GSV	SPLICED VEIN	ARM VEIN	PROS	PROS + VP	COMPOSITE
OP time (hrs) **	4.4 (1.8)	6.1 (1.9)	5.1 (2.3)	3.7 (1.6)	4.4 (1.8)	4.7 (2.0)
Transfusion**	0.5 (1.1)	1.2 (1.7)	0.4 (0.8)	0.5 (1.2)	0.7 (1.1)	0.6 (1.2)
30-day graft failure **	300 (7.5%)	9 (5.6%)	4 (4.3%)	94 (10.5%)	11 (9.8%)	14 (15.4%)

Figure 1. A comparison of perioperative parameters for different bypass conduits; great saphenous vein (GSV), spliced vein, arm vein, prosthetic (PROS), prosthetic with an anastomotic vein patch (PROS+VP), prosthetic with a vein segment (COMPOSITE). Reprinted from J Vasc Surg, 59, Nguyen BN, Neville RF, Abugidieri M, et al, The effect of graft configuration on 30-day failure of infrapopliteal bypasses, 1003-1008, 2014, with permission from Elsevier.

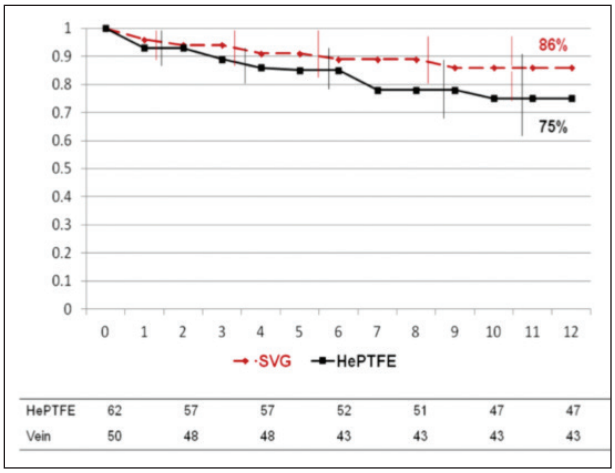

Figure 2. Primary patency at 1 year for tibial bypass using great saphenous vein (SVG) and heparin-bonded ePTFE with a distal vein patch (HePTFE). Reprinted from J Vasc Surg, 56, Neville RF, Capone A, Amdur R, et al, A comparison of tibial artery bypass performed with heparin-bonded expanded polytetrafluoroethylene and great saphenous vein to treat critical limb ischemia, 1008-1014, 2012, with permission from Elsevier.

imaging is required. However, there is still a major diagnostic and therapeutic role for catheter-based arteriography, especially for distal tibial occlusive disease. Thus, in addition to new imaging modalities, the program needs convenient access to a cath lab, hybrid operating room, and/or an on-site, office-based angiography suite.

The program must offer the entire range of therapeutic options, including wound care, hyperbaric oxygen therapy, and certainly a method of revascularization (both endovascular and surgical bypass). In our practice, approximately 70% of patients are best treated with an endovascular-first approach. The remaining 30% are bested treated with initial surgical bypass. This patient cohort includes those presenting with large-volume tissue loss or ulcerative disease (> 2 cm), good life expectancy, long segment occlusive arterial disease (TASC D), and/or previous unsuccessful endovascular intervention. In the group requiring bypass, 30% to 50% will not have a quality venous conduit, and bypass with a prosthetic graft may be required for revascularization. Data suggest that prosthetic graft performance can be enhanced with a venous adjunct at the distal anastomosis (distal vein patch [DVP])[2] and by heparin bonding on the inner surface of the graft. Heparin-bonded grafts have been used extensively in Europe, with excellent results.[3-5] The CBAS® Heparin Surface (Gore & Associates) technology and the heparin-bonded grafts have been a great addition to the armamentarium of the limb preservation center for patients who require prosthetic grafts. With these adjuncts (DVP and heparin bonding), a 50% patency can be achieved at 4 years.[6]

The current state of bypass in today's practice was reflected in an analysis of the National Surgical Quality Improvement Program database including only tibial bypasses, the majority (75%) of which used the greater saphenous vein (GSV).[7] Several factors were identified as contributing to decreased 1-year patency in the cohort; end-stage renal disease and nonhealing ulceration as the indication for revascularization. With regard to perioperative outcomes, the database revealed that spliced vein grafts had a longer operative time and a higher transfusion requirement. Arm vein bypasses also had a longer operative time. Standard prosthetic grafts and composite grafts had higher 30-day perioperative graft failure when compared to bypasses with GSV (Figure 1).

In 2012, we published our experience with the GORE® PROPATEN® Vascular Graft (Gore & Associates) with a DVP compared to quality saphenous vein.[8] The study was a retrospective analysis of prospectively collected data, and included suitable follow-up of patients by pulse examination, ankle-brachial index, and duplex graft surveillance. The bypass procedures included 62 heparin-bonded polytetrafluoroethylene (HePTFE) grafts and 50 GSV grafts. Most of the vein grafts (80%) were translocated veins. The main differences in patient demographics between the two groups were a slightly higher incidence of gangrene in the vein group and a higher incidence of previous bypass in the heparin-bonded group, hence the need for a prosthetic conduit. The amputation-free survival was similar between the two groups and the difference in primary patency was not statistically significant (Figure 2).

SUMMARY

Revascularization is an integral part of a limb preservation program and surgical bypass remains the optimal method of revascularization in 20% to 30% of patients in such a program. Prosthetic grafts will continue to play a role in limb preservation, and adjuncts can be used to improve prosthetic graft performance. Adjuncts include the distal vein patch technique and the heparin surface on the GORE® PROPATEN® Vascular Graft. ■

Richard F. Neville, MD, is from the George Washington University MFA in Washington, DC. He has disclosed that he is on the scientific advisory board for Gore & Associates, has received compensation from Gore for participating in the Summit, and has received honoraria from Gore for writing this article. Dr. Neville may be reached at rneville@mfa.gwu.edu.

1. Sumpio BE, Armstrong DG, Lavery LA, Andros G; SVS/APMA writing group. The role of interdisciplinary team approach in the management of the diabetic foot: a joint statement from the Society for Vascular Surgery and the American Podiatric Medical Association. J Vasc Surg. 2010;51:1504-1506.
2. Neville RF, Tempesta B, Sidway AN. Tibial bypass for limp salvage using polytetrafluoroethylene and a distal vein patch. J Vasc Surg. 2001;33:266-271.
3. Pulli R, Dorigo W, Castelli P, et al. Midterm results from a multicenter registry on the treatment of infrainguinal critical limb ischemia using a heparin-bonded ePTFE graft. J Vasc Surg. 2010;51:1167-1177 e1161.
4. Peeters P, Verbist J, Deloose K, et al. Results with heparin bonded polytetrafluoroethylene grafts for femorodistal bypasses. J Cardiovasc Surg (Torino). 2006;47:407-413.
5. Wallus check K. Heparin-bonded expanded polytetrafluoroethylene vascular graft for occlusive vascular disease of the lower extremity. Ital J Vasc Endovasc Surg. 2006;13:137-147.
6. Neville RF, Lidsky M, Capone A, et al. An expanded series of distal bypass using the distal vein patch technique to improve prosthetic graft performance in critical limb ischemia. Eur J Vasc Endovasc Surg. 2012;44:177-182.
7. Nguyen BN, Neville RF, Abugideiri M, et al. The effect of graft configuration on 30-day failure of infrapopliteal bypasses. J Vasc Surg. 2014;59:1003-1008.
8. Neville RF, Capone A, Amdur R, et al. A comparison of tibial artery bypass performed with heparin-bonded expanded polytetrafluoroethylene and great saphenous vein to treat critical limb ischemia. J Vasc Surg. 2012;56:1008-1014.

Alternative Conduits

Are arm vein and spliced vein conduits effective?

BY EFTHYMIOS D. AVGERINOS, MD, PHD

Ipsilateral, single-segment great saphenous vein (GSV) remains the ultimate conduit for below-the-knee bypass in critical limb ischemia. The choice of conduit becomes problematic, however, when GSV is unavailable or not usable. The results of alternative autologous veins (AAV) are variable and, despite a general consensus favoring them as a second choice conduit, their benefit has been controversial, particularly for the below-the-knee popliteal targets.[1-5]

Contemporary data from the University of Pittsburgh

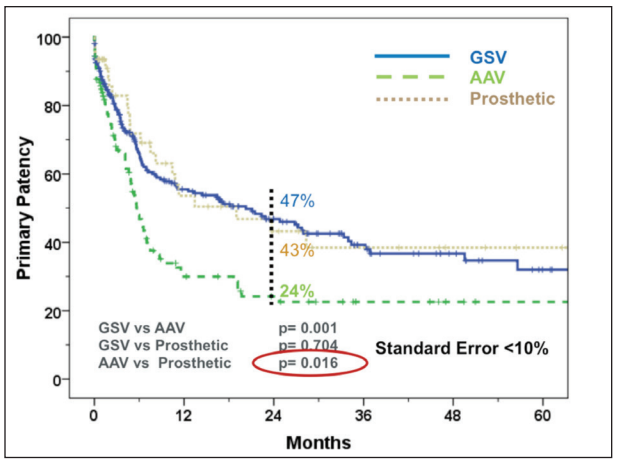

Figure 1. Primary patency curves by type of conduit. Dashed line cutting the curve at 24 months indicates that the number of grafts at risk thereafter is small. Reprinted from J Vasc Surg, Avgerinos ED, Sachdev U, Naddaf A, et al, Autologous alternative veins may not provide better outcomes than prosthetic conduits for below-knee bypass when great saphenous vein is available, 2015, with permission from Elsevier.

Medical Center (UPMC) add some insight in the controversy. In a retrospective review of consecutive below-the-knee bypasses for critical ischemia from 2007–2011, single-segment GSV, alternative autologous veins, and prosthetic grafts were compared.[6] This is the first study to feature this three-group comparison. Two hundred fifty-five patients received GSV, 106 patients received alternative vein conduits, and 46 patients received prosthetic grafts. Of the 106 patients who received AAVs, most received spliced veins (n = 74) and the rest received single-segment arm veins. The prosthetic group included primarily heparin-bonded grafts (n = 41) and approximately half had a distal anastomotic adjunct.

The postoperative outcomes for the entire cohort were a 12% major adverse limb event rate (reintervention or amputation), a 6.5% major adverse cardiac event rate (myocardial infarction, stroke, or death), a 16.5% wound complication rate, and a 2.5% mortality rate at 30 days. The prosthetic group had significantly fewer 30-day major adverse limb events (4.3%), whereas the AAV group had the most (16%) and the GSV group fell in between (11.8%). The remaining 30-day outcomes (major adverse cardiac events, wound complications) did not differ among the three groups. At 2 years, the AAV group had the worst primary patency (24%), whereas the GSV and prosthetic groups had a fairly similar patency (47% and 43%, respectively) (Figure 1). The AAVs tended to fail early and required reintervention. A multivariate analysis confirmed that the conduit was a predictor of patency, with prosthetic graft and GSV performing significantly better than AAV (Table 1). Not surprisingly, surgeons' level of experience affected patient outcomes and was a predictor of patency.

The AAV and prosthetic groups showed no statistically significant difference with regard to primary assisted patency: 53% for AAVs versus 45% for prosthetic grafts. This was further confirmed by multivariate analysis. The GSV performed significantly better when compared to the other two conduits. Similar results, also confirmed by multivariate analysis, were seen with secondary patency: the performance of AAVs was not significantly different than prosthetic grafts and both were inferior to GSV. Limb salvage at 2 years was 86% for GSV, 78% for alternative veins, and 72% for prosthetic grafts. Multivariate analysis showed no statistically significant difference between these groups.

In subgroup analysis dividing bypasses in popliteal and infrapopliteal targets, primary patency, primary assisted patency, and secondary patency rates at 2 years were better for the GSV compared to the other groups. AAVs showed worse primary patency but better primary assisted and secondary patency compared to prosthetic conduits, although these differences were not significant. Single-segment AAVs did not have different outcomes when compared with spliced AAVs.

As a retrospective study, these results may be confounded by several biases and limitations that should be taken into consideration when interpreting the findings.

SUMMARY

There is no clear mid-term advantage of AAV conduits over prosthetic grafts. AAVs have poor primary patency because of early failures and frequent reintervention and, despite "catching up" later on, primary assisted and secondary patencies remain comparable between AAVs and prosthetic grafts. Thus, candidates for AAV should be thoughtfully selected. We recommend that AAVs should

TABLE 1. INDEPENDENT RISK FACTORS ASSOCIATED WITH BYPASS PRIMARY PATENCY

	Cox Regression Analysis	
	Hazard Ratio	***P* Value**
Primary Patency		
Conduit (reference AAV)		< .001
Conduit GSV	0.55	< .001
Conduit prosthetic	0.37	< .001
Female gender	1.47	.028
Prior procedures	1.36	.035
Experience (reference 6–10/yr)		.000
0–5 procedures/yr	.97	.918
>10 procedures/yr	.52	< .001

Reprinted from J Vasc Surg, Avgerinos ED, Sachdev U, Naddaf A, et al, Autologous alternative veins may not provide better outcomes than prosthetic conduits for below-knee bypass when great saphenous vein is available, 2015, with permission from Elsevier.

be reserved for distal tibial or pedal bypasses, patients with good life expectancy (> 5 years) and low risk for perioperative complication, and in the setting of infection. For all other patients, heparin-bonded prosthetic grafts can be an equal—if not better—alternative in the absence of GSV. ■

Efthymios D. Avgerinos, MD, PhD, is from the University of Pittsburgh Medical Center, Presbyterian University Hospital in Pittsburgh, Pennsylvania. He has disclosed that he has received compensation from Gore for participating in the Summit and has received honoraria from Gore for writing this article. Dr. Avgerinos may be reached at avgerinose@upmc.edu.

1. Calligaro KD, Syrek JR, Dougherty MJ, et al. Use of arm and lesser saphenous vein compared with prosthetic grafts for infrapopliteal arterial bypass: are they worth the effort? J Vasc Surg. 1997;26:919-924.
2. Faries PL, Arora S, Pomposelli FB Jr, et al. The use of arm vein in lower-extremity revascularization: results of 520 procedures performed in eight years. J Vasc Surg. 2000;31:50-59.
3. Kreienberg PB, Darling RC 3rd, Chang BB, et al. Early results of a prospective randomized trial of spliced vein versus polytetrafluoroethylene graft with a distal vein cuff for limb-threatening ischemia. J Vasc Surg. 2002;35:299-306.
4. McPhee JT, Barshes NR, Ozaki CK, et al. Optimal conduit choice in the absence of single-segment great saphenous vein for below-knee popliteal bypass. J Vasc Surg. 2012;55:1008-1014.
5. Neville RF, Capone A, Amdur R, et al. A comparison of tibial artery bypass performed with heparin-bonded expanded polytetrafluoroethylene and great saphenous vein to treat critical limb ischemia. J Vasc Surg. 2012;56:1008-1014.
6. Avgerinos ED, Sachdev U, Naddaf A, et al. Autologous alternative veins may not provide better outcomes than prosthetic conduits for below-knee bypass when great saphenous vein is unavailable. J Vasc Surg. 2015; May 2 [Epub ahead of print].

Vein Versus Heparin-Bonded ePTFE

What do the data really say?

BY PROF. RAFFAELE PULLI; WALTER DORIGO, MD; AND PROF. CARLO PRATESI, ON BEHALF OF THE ITALIAN REGISTRY GROUP*

The great saphenous vein (GSV) is superior to polytetrafluoroethylene (PTFE), and therefore should be preferentially used. Dr. Neville reviewed this topic[1] and described data indicating that the GORE® PROPATEN® Vascular Graft (Gore & Associates) performed better than standard PTFE in a European-run randomized trial.[2] Dr. Samson presented his single-center experience at Charing Cross in 2013, suggesting the GORE® PROPATEN® Vascular Graft performed better than standard GORE-TEX® Vascular Grafts (Gore & Associates) and ADVANTA PTFE Vascular Grafts (Atrium).[3] Over the past decade there have been several other reports published on the subject, most of which were from Italian surgeons. The extensive Italian experience warranted creation of an Italian registry encompassing seven institutions throughout Italy. While not a randomized controlled trial, the registry provides insight into the real world of surgery and reflects what surgeons face in their daily practice.

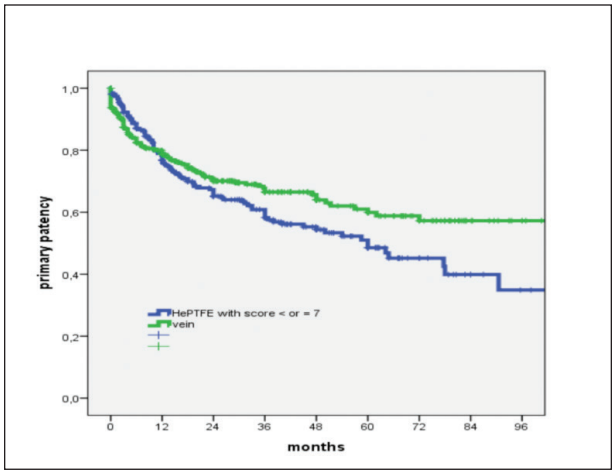

Figure 1. Kaplan-Meier curve of estimated primary patency in patients undergoing a GORE® PROPATEN® Vascular Graft bypass with a score ≤ 7 (blue line) compared with that obtained in patients undergoing a vein bypass (green line) (Log-rank 3.1; *P* = .08).

Patients in the Italian Registry who received a below-the-knee bypass using vein had better primary patency than patients who received a bypass with heparin-bonded expanded polytetrafluoroethylene (ePTFE). Based upon these results, a GORE® PROPATEN® Vascular Graft score was created to summarize the circumstances under which the GORE® PROPATEN® Vascular Graft might perform as well as vein. A univariate analysis revealed the factors that affected primary patency (Table 1), and these factors were assigned point values (Table 2). For example, male gender was assigned one point and female gender was assigned two points. A low total point score indicated that a particular patient was a good candidate for receiving a GORE® PROPATEN® Vascular Graft preferentially to vein because the risk of thrombosis was low. An ANOVA test for thrombosis during follow-up was applied to the patients in the registry, and 7.502 was determined to be the cutoff score value ($P < .001$; R = 0.09), below which the GORE® PROPATEN® Vascular Graft could be used preferentially due to low risk of thrombosis, and above which vein would be likely to perform better. To validate this analysis, primary patency results for patients with a GORE® PROPATEN® Vascular Graft score of ≤ 7 who received bypasses with this device were compared to the primary patency results for vein bypasses (Figure 1). Although there was a trend toward better patency with vein, in contrast to the overall cohort, the difference was not statistically significant.

By definition, registry results have no inclusion or exclusion criteria, and there was no request of homogeneous indication for the choice of grafts. Thus, the study was

TABLE 1. UNIVARIATE AND MULTIVARIATE ANALYSIS FOR FACTORS AFFECTING PRIMARY PATENCY IN PATIENTS RECEIVING A HEPARIN-BONDED GRAFT

	Univariate Analysis				Multivariate Analysis		
	Log-rank	*P* value	95% CI	OR	95% CI	OR	*P* value
Female gender	6.2	.002	1.1–2.2	1.6	1–1.9	1.5	.02
Chronic renal failure	0.1	.4	0.7–1.7	1.1			
Reintervention	19.7	.001	0.4–0.8	0.6	0.4–1	0.6	.003
Diabetes	0.1	.3	0.8–1.5	1.1			
Tibial anastomosis	4.6	.02	1–2	1.4	0.8–1.7	1.2	.2
Distal procedures	1.7	.08	0.9–1.7	1.2			
Runoff score < 2	6.4	.003	1.1–1.9	1.5	0.9–1.6	1.2	.2
Rutherford 5–6†	0.9	.1	0.9–1.6	1.2			

CI = confidence interval, OR = odds ratio.
†This factor affects limb salvage, but not primary patency.

TABLE 2. SCORES ASSIGNED BASED ON RESULTS OF UNIVARIATE ANALYSIS

Gender	Male = 1 point	Female = 2 points	—
Reintervention	No = 1 point	Yes = 2 points	—
Tibial anastomosis	No = 1 point	Yes = 2 points	—
Runoff score	2 vessels = 2 points	< 2 vessels = 3 points	—
Rutherford class	Class 4 = 1 point	Class 5 = 2 points	Class 6 = 3 points

limited by the fact that it was registry-based and not randomized, and therefore the two treatment groups differed in several ways that likely reflected different approaches and patient selection among participating surgeons. As such, the calculated scores are primarily hypothesis generating, and should be validated in prospective studies and in other series of patients.

SUMMARY

The GORE® PROPATEN® Vascular Graft offers satisfactory results in terms of patency and limb salvage rates. Moreover, venous adjuncts at the distal anastomosis seem to offer improved outcomes. Vein remains the best choice; however, in the case of unsuitable vein, a heparin-bonded PTFE graft is a good alternative with a comparable limb salvage rate. In some situations, on the basis of the above mentioned score, patients may benefit from the GORE® PROPATEN® Vascular Graft as a first choice. ■

**The results presented in this article are first-line results and the Italian registry group is looking to prospectively validate their scoring system in another region.*

Prof. Raffaele Pulli is from the University of Florence in Florence, Italy. He has disclosed that he has received compensation from Gore for participating in the Summit and has received honoraria from Gore for writing this article. Dr. Pulli may be reached at rpulli@unifi.it.

Walter Dorigo, MD, is from the University of Florence in Florence, Italy. He has stated that he has no financial interests related to this article.

Prof. Carlo Pratesi is from the University of Florence in Florence, Italy. He has disclosed that he has received compensation from Gore for participating in the Summit.

1. Neville RF. Role of surgical bypass in a limb preservation program. Endovascular Today. 2015;14(Suppl):5-6.
2. Lindholt JS, Gottschalksen B, Johannesen N, et al. The Scandinavian Propaten((R)) trial: 1-year patency of PTFE vascular prostheses with heparin-bonded luminal surfaces compared to ordinary pure PTFE vascular prostheses: a randomised clinical controlled multi-centre trial. Eur J Vasc Endovasc Surg. 2011;41(5):668-673.
3. Samson RH. Surgical bypass summit. Endovascular Today. 2015;14(Suppl):4.

Is Vein Still the First Choice When a Leg Bypass Is Needed?

Examining the evidence.

BY JOSEPH L. MILLS, SR, MD

The Bypass versus Angioplasty in Severe Ischemia of the Leg (BASIL) trial is the only large, prospective, randomized trial published to date to compare surgical bypass and endovascular therapy as treatments for patients with severe limb ischemia.[1] It indicated that autogenous vein is superior to prosthetic conduits for patients undergoing bypass in this setting. Multiple studies have confirmed the overall superiority of vein conduits for leg bypass.[2,3]

When autogenous vein is truly lacking, there is general consensus that a short graft above the knee joint is the most favorable location for use of a prosthetic conduit. Below the knee, many of the published studies are confounded by the use of patches and cuffs; different surgeons employ a variety of distal anastomotic adjuncts. The challenge therefore lies in determining whether improved clinical outcomes are the result of the conduit or a result of the adjunct. Taylor vein patches likely improve prosthetic bypass outcomes below the knee.[4] Dr. Neville's distal vein patch is another important prosthetic bypass adjunctive technique.[5] Dr. Neville has published research suggesting that even at 1 year, a separation in outcomes between patients who receive heparin-bonded expanded polytetrafluoroethylene and patients who receive saphenous vein may begin to appear.[6]

The spectrum of peripheral artery disease (PAD) is broad, and therefore surgical outcomes will be markedly different depending upon which patient is selected for which intervention. Critical limb ischemia was defined in 1982 in a one-page consensus document[7] written by vascular surgeons. There are major problems with this definition, in particular its lack of applicability to patients with diabetes. The Society for Vascular Surgery (SVS) Wound, Ischemia, and foot Infection (WIfI) limb classification system may be a useful tool for controlling study outcomes and determining which therapeutic option is best for a particular patient.

The classification is based on three major factors that influence amputation risk and clinical management.[8] When the WIfI scores are combined, patients can be classified into four clinical stages of disease. Two recent studies have already validated the concept of the SVS WIfI classification and confirm its utility in predicting amputation risk.[9,10]

SUMMARY

A uniform classification system is required in order to accurately assess outcomes and relative efficacy of interventions intended to prevent limb amputation in patients with PAD and diabetes. The WIfI index includes critical factors that must be considered and graded for patient evaluation. In many ways, the WIfI index is similar to the TNM (tumor, nodes, metastasis) classification of malignant tumors because it is intended to allow assessment, comparison, and improvement of outcomes. It is acknowledged that therapies will change over time, so therefore WIfI is not intended to dictate therapy. The WIfI index would also benefit from an updated practical arterial anatomic classification system. ■

Joseph L. Mills, Sr, MD, is from the Division of Vascular Surgery and Endovascular Therapy, Michael E. DeBakey Department of Surgery, Baylor College of Medicine in Houston, Texas. He has disclosed that he has received compensation from Gore for participating in the Summit and has received honoraria from Gore for writing this article. Dr. Mills may be reached at joseph.mills@bcm.edu.

1. Adam DJ, Beard JD, Cleveland T, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005;366:1925-1934.
2. Mills JL. Infrainguinal bypass. In: Cronenwett JC, Johnston W, editors. Rutherford's Textbook of Vascular Surgery. 8th edition. Philadelphia: Elsevier Saunders; 2014:1758-1781.
3. Mills JL. Open bypass and endoluminal therapy: complementary techniques for revascularization in diabetic patients with critical limb ischemia. Diabetes Metab Res Rev. 2008;24(Suppl 1):S34-39.
4. Yeung KK, Mills JL, Hughes JD, et al. Improved patency of infrainguinal PTFE bypass with distal Taylor vein patch. Am J Surg. 2001;182:578-83.
5. Neville RF, Tempesta B, Sidway AN. Tibial bypass for limb salvage using polytetrafluoroethylene and a distal vein patch. J Vasc Surg. 2001;33:266-271; discussion 271-262.
6. Neville RF, Capone A, Amdur R, et al. A comparison of tibial artery bypass performed with heparin-bonded expanded polytetrafluoroethylene and great saphenous vein to treat critical limb ischemia. J Vasc Surg. 2012;56:1008-1014.
7. Bell PRF, Charlesworth D, DePalma RG, et al. The definition of critical ischemia of a limb. Working Party of the International Vascular Symposium. Br J Surg. 1982;69(Suppl):S2.
8. Mills JL Sr, Conte MS, Armstrong DG, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIfI). J Vasc Surg. 2014;59:220-234, e221-222.
9. Cull DL, Manos G, Hartley M, et al. Prospective analysis of wound characteristics and degree of ischemia on time to wound healing and limb salvage: an early validation of the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System. J Vasc Surg. 2014;59:28s.
10. Zhan LX, Branco BC, Armstrong DG, Mills JL. The Society for Vascular Surgery (SVS) lower extremity threatened limb classification system based on Wound, Ischemia, and foot Infection (WIfI) correlates with risk of major amputation and time to wound healing. J Vasc Surg. 2015;61:939-944.

TAKE HOME POINTS

RICHARD F. NEVILLE, MD

A multidisciplinary limb preservation program assembles experts dedicated to healing and limb preservation in a challenging group of patients. Such a program requires an aggressive approach to lower extremity revascularization that will involve surgical bypass in 25% to 30%. Of those patients best treated with surgical bypass, as many as one half will not have quality autogenous conduit and will require a prosthetic graft for bypass. The performance of prosthetic conduit for distal bypass has been improved through venous adjuncts at the distal anastomosis and heparin bonding to the graft. Although quality large saphenous vein remains the ideal conduit for distal bypass, these improvements in prosthetic graft performance through anastomotic adjuncts and heparin bonding on the surface of the graft (as per the GORE® PROPATEN® Vascular Graft [Gore & Associates]) have made this technique a critically important alternative for those patients needing bypass for limb preservation.

EFTHYMIOS D. AVGERINOS, MD, PhD

There is no clear mid-term advantage of AAV conduits over prosthetic grafts. AAVs have poor primary patency because of early failures and frequent reintervention and, despite "catching up" later on, primary assisted and secondary patency rates remain comparable between AAVs and prosthetic grafts. Thus, candidates for AAVs should be thoughtfully selected. We recommend that AAVs should be reserved for distal tibial or pedal bypasses, patients with good life expectancy (> 5 years) and low risk for perioperative complication, and in the setting of infection. For all other patients, heparin-bonded prosthetic grafts can be an equal—if not better—alternative in the absence of GSV.

PROF. RAFFAELE PULLI

An autologous saphenous vein of small diameter, of poor quality, or previously used, is no longer a contraindication to below-the-knee femoropopliteal bypass in patients with CLI. Heparin-bonded ePTFE bypass grafts have been shown, in large multicenter studies with a robust number of patients, to provide equivalent long-term secondary patency and limb salvage rates with respect to autologous vein. However, autologous vein maintains its superiority in terms of primary patency. Moreover, an accurate subgroup analysis seems to indicate that in the presence of an adequate autologous vein, heparin-bonded ePTFE can be used primarily in highly selected patients (ie, male patients undergoing primary intervention rather than reintervention, with more than one patent tibial vessel and with rest pain rather than ulcers). In fact, in such patients, prosthetic graft provides similar results to autologous vein in terms of primary patency, allowing to preserve the vein for further revascularizations or for different therapeutic uses.

JOSEPH L. MILLS, Sr, MD

Endovascular therapy and open surgical bypass both have major roles to play in lower extremity revascularization. Appropriate patient selection is a key determinant of successful outcomes. A limb risk stratification system, such as SVS WIfI classification predicts baseline limb amputation risk and will likely be useful in selecting intervention type and allowing the comparison of outcomes using different, alternative approaches. Autogenous vein remains the most durable conduit for leg bypass. Prosthetic conduits, most likely with adjuncts such as cuffs, patches, and heparin bonding, seem to improve intermediate outcomes in patients requiring leg bypass in the absence of suitable vein conduit.