Bovine carotid artery biologic graft outperforms expanded polytetrafluoroethylene for hemodialysis access



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ABSTRACT

Objective: Arteriovenous grafts remain reliable substitutes for permanent hemodialysis access in patients without a suitable autogenous conduit. Advances in conduit design and endovascular management of access-related complications question the preference for synthetic conduits over biologic grafts in contemporary practice. In this study, we compared outcomes between a bovine carotid artery (BCA) biologic graft and expanded polytetrafluoroethylene (ePTFE) grafts for hemodialysis access in a recent cohort of patients.

Methods: This was a single-institution retrospective review of 120 consecutive grafts placed in 98 patients between January 1, 2011, and June 30, 2014. Univariate methods (χ^2 , analysis of variance, t-test) were used to compare demographic and medical characteristics of patients who received each graft type. Kaplan-Meier, log-rank tests, univariate and multivariate logistic analyses, and Cox regression analyses were used to evaluate patency and graft complications. Outcomes were defined and analyzed according to reporting guidelines published by the Society for Vascular Surgery.

Results: Of the 120 grafts studied, 52 (43%) were BCA and 68 (57%) were ePTFE. Successful graft use for dialysis was 96% (95% confidence interval [CI], 90%-100%) for BCA and 84% (95% CI, 74%-93%) for ePTFE (P = .055). Comparing BCA vs ePTFE, estimates for primary patency were 30% vs 43% at 1 year and 16% vs 29% at 2 years (P = .27). Primary assisted patency was 36% vs 45% at 1 year and 24% vs 35% at 2 years (P = .57). Secondary patency was 67% vs 48% at 1 year and 67% vs 38% at 2 years (P = .05). There were no differences in primary (hazard ratio [HR], 0.70; 95% CI, 0.40-1.28; P = .25) and primary assisted (HR, 0.87; 95% CI, 0.46-1.65; P = .67) patency for BCA compared with ePTFE. However, secondary patency was higher for BCA compared with ePTFE (HR, 2.92; 95% CI, 1.29-6.61; P = .01). Graft infection rates during the study period were 15.4% for BCA and 20.6% for ePTFE (P = .47). The significant predictors of graft failure were higher body mass index (HR, 1.06; 95% CI, 1.00-1.11; P = .04) and hyperlipidemia (HR, 2.94; 95% CI, 1.27-6.76; P = .01).

Conclusions: In this study of a recent cohort of patients who received arteriovenous grafts, primary and primary assisted patencies were similar between BCA and ePTFE grafts. However, secondary patency was higher for BCA, indicating better durability for the biologic graft than for ePTFE grafts in patients whose anatomy preclude placement of an arteriovenous fistula. (J Vasc Surg 2017;65:775-82.)

The hemodialysis-dependent population is an ever expanding one. More than 600,000 patients in the United States have end-stage renal disease, and an

estimated 100,000 new cases are reported annually. Despite the well-recognized benefits of renal transplantation, only a limited proportion of patients with end-stage renal disease are able to receive compatible and durable transplants; hence >60% of these patients require maintenance on hemodialysis. 1

The evaluation of hemodialysis access conduits remains a critical and evolving subject. Repetitive puncture and the unique physiologic milieu of dialysis patients place a high premium on the most durable conduits for access. The type of vascular access used for hemodialysis has also been identified as key determinant of survival in these patients.²⁻⁵ Professional bodies, including the Society for Vascular Surgery and the National Kidney Foundation, as well as the Centers for Medicare and Medicaid Services have recommended the use of permanent access, with an arteriovenous fistula (AVF) or arteriovenous graft (AVG) as the preferred mode of dialysis access instead of a catheter.⁶⁻⁸ This preference is informed by the lower risks

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Copyright © 2016 by the Society for Vascular Surgery. Published by Elsevier Inc. http://dx.doi.org/10.1016/j.jvs.2016.10.080 of infection and hospitalization and better survival associated with the permanent access types.

Although AVF is the most preferred mode of access, not all patients are good candidates for an AVF because of inadequate veins. In such patients, AVGs serve as alternatives. The push for increasing use of permanent access implies that surgeons and their patients are increasingly faced with the choice of competing conduits. Recent advances have been made in the design and techniques for placement and use of xenografts for hemodialysis access. Progress has also been made in endovascular management of access-related complications.

Despite the widespread use of synthetic AVGs, such as expanded polytetrafluoroethylene (ePTFE), in contemporary practice, there is little evidence to support their superiority over decellularized xenografts in this era. The need for current evidence to inform conduit choice is critical. The objective of this study was to evaluate the durability of synthetic AVG (ePTFE) vs bovine carotid artery (BCA) grafts for hemodialysis access in a recent cohort of patients.

METHODS

A retrospective analysis was performed of all patients who received AVGs for dialysis access because they were not candidates for native AVF at Johns Hopkins Bayview Medical Center between January 1, 2011, and June 30, 2014. In accordance with national guidelines, an AVF, including the use of basilic and brachial veins, are the preferred dialysis access conduit in our center. AVGs are used in patients whose anatomy precludes the use of an AVF based on the size of their veins measured during preoperative and intraoperative vein mapping and clinical assessment. AVGs are also used in patients in whom multiple fistulas have failed and bilateral AVF options have been exhausted. This study was approved by the Johns Hopkins Institutional Review Board and the contributing dialysis access centers. The need for individual patient consent was waived.

Electronic medical records at the time of surgery were abstracted for the demographic and medical characteristics listed in Table I. All access placement operations were performed by two senior surgeons according to National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines for AVG creation. The BCA graft used was the Artegraft (Artegraft, Inc, North Brunswick, NJ), and the PTFE grafts used were the Flixene (Maquet-Atrium Medical, Hudson, NH), Advanta VXT (Maquet-Atrium), GORE-TEXStretch Vascular Graft For Vascular Access (W. L. Gore and Associates, Flagstaff, Ariz), or Venaflo (Bard Peripheral Vascular, Tempe, Ariz). The choice of graft used was at the surgeons' discretion.

Graft placement and follow-up. The configurations of grafts placed were C-shaped, with an arterial anastomosis to the brachial artery slightly proximal or at

Table I. Patient characteristics

	DOA FO	- DTEE	
Patient characteristics	BCA, 52 (43.3%)	ePTFE, 68 (56.7%)	P value
Age, mean (SD), years	58.5 (14.2)	59.6 (13.4)	.68
Male gender, No. (%)	31 (59.6)	37 (54.4)	.57
Race, No. (%)			
White	10 (19.2)	16 (23.5)	.76
Black	41 (78.9)	50 (73.5)	
Hispanic	0	1 (1.5)	
Other	1 (1.9)	1 (1.5)	
Body mass index, mean (SD), kg/m ²	30.4 (8.7)	30.4 (11.9)	.99
Hypertension, No. (%)	50 (96.2)	67 (98.5)	.41
Diabetes mellitus, No. (%)	33 (63.5)	43 (63.2)	.98
Hyperlipidemia, No. (%)	23 (44.2)	27 (39.7)	.62
Active smoking, No. (%)	31 (59.6)	34 (50.0)	.30
Coronary artery disease, No. (%)	19 (36.5)	26 (38.2)	.85
COPD, No. (%)	16 (30.8)	17 (25.0)	.48
Congestive heart failure, No. (%)	16 (30.8)	19 (27.9)	.74
Location, No. (%)			
Upper arm	30 (57.7)	45 (66.1)	.58
Forearm	5 (9.6)	8 (11.8)	
LE	17 (32.7)	15 (22.1)	
Looped configuration, No. (%)	13 (25)	14 (20.6)	

BCA, Bovine carotid artery; *COPD*, chronic obstructive pulmonary disease; *ePTFE*, expanded polytetrafluoroethylene; *LE*, lower extremity; *SD*, standard deviation.

the antecubital fossa and venous anastomosis to the axillary vein in the upper arm, looped brachial artery to cephalic vein in the forearm, and looped femoral artery to femoral vein in the thigh.

Patients were examined at the end of AVG placement surgery and at postoperative weeks 2, 4, and 6. Examination for thrills, bruits, circulatory, and neurologic function was performed at each visit. Hemodialysis via the graft was permitted in the absence of complications after the manufacturer's recommended waiting time had elapsed to allow adequate tissue-to-graft incorporation and perigraft swelling had subsided to allow for graft palpation. Subsequent graft cannulation was performed in accordance with KDOQI guidelines.

Graft functionality was monitored by nephrologists or trained dialysis nurses. Difficulty during dialysis, such as suboptimal flow or excessive bleeding, absence of a thrill or bruit, triggered subsequent evaluation. When necessary, patients underwent duplex ultrasound imaging for graft evaluation. A fistulogram was performed for significant stenosis established on duplex. The grafts were monitored for the occurrence of stenosis, thrombosis, infection, pseudoaneurysm, or abandonment. Also noted

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