A prospective randomized study of bovine carotid artery biologic graft and expanded polytetrafluoroethylene for permanent hemodialysis access

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ABSTRACT

Objective: Arteriovenous grafts (AVGs) remain reliable substitutes for permanent hemodialysis access in scenarios that preclude the placement of native arteriovenous fistulas (AVFs). The majority of AVGs are constructed of expanded polytetrafluoroethylene (ePTFE), which is relatively inexpensive and readily available, but synthetic AVGs have poor patency rates. On the other hand, biologic grafts confer an advantage by virtue of their inherent similarity to the native human vasculature. However, evidence to support the current preference of synthetic conduits over biologic grafts in clinical practice is scarce. The aim of this protocol is to propose a contemporary re-evaluation and comparison between ePTFE and bovine carotid artery (BCA) grafts.

Methods: This prospective randomized controlled trial is being conducted at an academic hospital center. A total of 100 patients at least 18 years of age and undergoing AVG placement will be recruited and prospectively randomized into two parallel groups with a 1:1 allocation ratio. Patients eligible to receive AVF and those with a known allergic reaction or history of intolerance to any ePTFE or BCA component will not be included in the study. Moreover, patients with a recent active infection at the site of previous AVG placement and patients with a bleeding disorder, an active malignant disease, or a life expectancy <1 year or who refuse blood transfusion and pregnant women will be excluded. Patients will receive either BCA (experimental) or standard ePTFE grafts (control) in compliance with the National Kidney Foundation Kidney Disease Outcomes Quality Initiative guidelines for AVG creation. Primary end points include primary, primary assisted, secondary, and functional patency at 1 year and 2 years after graft placement. Secondary outcomes include complications (pseudoaneurysms, infections, and steal syndrome) and reintervention rates during the first and second postoperative years. Outcomes will be assessed and documented every 6 months.

Results: Once the study is completed, analysis of the data will be performed using univariate methods, and Kaplan-Meier and multivariate Cox proportional regression analyses will be employed to evaluate and to compare outcomes between BCA and ePTFE over time.

Conclusions: The creation of a functional and durable dialysis vascular access is crucial in the treatment of patients with end-stage renal disease and is a challenging quest for vascular surgeons. The proposed study compares the outcomes of synthetic and biologic AVG options in patients who are poor candidates for a native AVF. This will help derive contemporary evidence and improve the care of vascular access patients. (J Vasc Surg 2018;67:1606-12.)

It is known that arteriovenous fistulas (AVFs) confer a clear benefit for hemodialysis access in patients with end-stage renal disease (ESRD). As a result, national guidelines stipulate AVF as the preferred mode of permanent hemodialysis access.[1] In practice, not all patients are good candidates for AVF because of unavailable or inadequate venous conduits. In these patients, arteriovenous grafts (AVGs) serve as reliable substitutes.

Synthetic grafts, such as those made from expanded polytetrafluoroethylene (ePTFE), are the most common AVGs in current use. In patients requiring urgent hemodialysis, early-access vascular grafts such as the trilaminate PTFE vascular graft or the Flixene (Maquet-Atrium Medical, Hudson, NH) early cannulation prosthetic graft were used to reduce the need for temporary hemodialysis catheters and their resultant complications. Those grafts also showed decreased overall graft complication

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rates and improved or equivalent 1-year patency rates compared with standard ePTFE grafts.[2-5] In 2006, heparin-bonded ePTFE grafts became available and were used to decrease rates of graft thrombosis.[6] Cohort studies and randomized clinical trials of heparin-bonded ePTFE grafts in lower extremity bypass have shown promising results.[7-10] However, studies comparing them with standard ePTFE grafts in the creation of arteriovenous dialysis accesses failed to show improved outcomes in terms of long-term patency or number of interventions.[6,11]

Despite the continuous improvement and widespread use of ePTFE, significant drawbacks of synthetic grafts have been reported in relation to long-term patency and infection rates.[12-14] Factors leading to AVG failure include neointimal hyperplasia and thrombosis due to the lack of a functional endothelium and the inflammatory reactions that trigger hyperproliferation of surrounding tissues in addition to infections, surgical experience, and anastomotic techniques. These inadequacies inform the need to develop and to evaluate biologic conduits that achieve closer mimicry of native human vessels and as result may overcome the disadvantages associated with synthetic grafts. Bovine carotid artery (BCA) grafts became commercially available in the 1970s, but their use in hemodialysis access decreased after ePTFE grafts became available and because of concerns of aneurysmal degeneration of the biologic graft.[15-18] Since then, significant advances have been made in conduit design and techniques for AVG placement and postoperative endovascular management. However, there is lack of current evidence of a clear advantage of biologic conduits over ePTFE grafts. Previous comparative studies were based on cohorts of patients drawn from prior decades,[19-21] which questions the bases for the preference of synthetic conduits in this age. In addition to the lack of current evidence, more recent studies were based on a small cohort of patients.[20] These inadequately powered studies were unable to establish superiority between AVG options. A retrospective study[22] of 120 consecutive grafts at our institution between January 2011 and June 2014 showed similar primary and primary assisted patencies between BCA and ePTFE grafts and higher secondary patency for BCA.

There are >400,000 patients in the United States who are currently on hemodialysis. An estimated 110,000 new patients annually develop ESRD, requiring dialysis or kidney transplantation.[23] A conduit that confers better outcomes based on objective evidence will have a significant impact on patients' quality of life and health care cost. To address the knowledge gaps, we propose a prospective randomized study comparing the functional long-term outcomes including 1- and 2-year patency (functional, primary, primary assisted, and secondary), complication rates, and reintervention rates of BCA biologic grafts (Artegraft; Artegraft, Inc, North Brunswick, NJ) and standard PTFE grafts in a large cohort of patients. We hypothesize that eligible vascular patients who receive the BCA graft will have improved patency as well as lower complication and reintervention rates compared with those receiving the standard ePTFE graft. This objective comparison of nonautogenous graft options that are available to patients and their surgeons will help derive contemporary evidence and improve the care of vascular access patients.

METHODS

The study is a prospective randomized clinical trial performed at an academic hospital center. Two parallel groups with a 1:1 allocation ratio will be included to establish the superiority of BCA grafts over standard ePTFE grafts for permanent hemodialysis access in patients with ESRD.

Patients. Patients at least 18 years of age who are undergoing AVG placement and have been informed of the nature of the study, provided a written informed consent, and agreed to return for all required clinical follow-up will be included. Any patient who is eligible to receive an AVF will be excluded. In addition, patients with a known allergic reaction or history of intolerance to any ePTFE or BCA component, those with a recent active infection at the site of previous AVG placement at the time of surgery, patients with a bleeding disorder or who refuse blood transfusion, and patients with an active malignant disease or a life expectancy <1 year will not be included in the study. Women of childbearing age will be given a urine pregnancy test preoperatively per standard of care. If a woman is pregnant or plans on becoming pregnant for the duration of the study, she will be excluded.

Study devices. The ePTFE grafts used are the Flixene, Advanta VXT (Maquet-Atrium), GORE-TEX Stretch Vascular Graft for Vascular Access (W. L. Gore & Associates, Flagstaff, Ariz), and Venaflo (Bard Peripheral Vascular, Tempe, Ariz). The choice of graft used is at the surgeon's discretion. The graft is offered in both large and small diameters as well as in thin-wall and rapidly tapering designs for cases in which arterial steal syndrome is a potential complication. A 6-mm graft featuring external supporting rings in 5-cm centered or 7-cm offset sections enables tight loop configurations and crossing of the cubitus. A 4- to 7-mm tapered graft with 10 or 15 cm of removable rings allows tailoring or exact placement of the ringed section. On the other hand, the BCA biologic grafts (Artegraft) consist of a biologic fibrous matrix processed to enhance long-term patency and to provide a tightly woven, cross-linked conduit that is flexible and compliant. Available Artegraft inner diameters range between 6 and 8 mm. Selection of the graft must be of comparable cross-sectional diameter to the host artery, particularly at the distal end, to avoid early thrombosis.

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