CLINICAL STUDY

The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access

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ABSTRACT

Purpose: To evaluate safety and efficacy of arteriovenous fistulas (AVFs) created with a thermal resistance anastomosis device.

Materials and Methods: A prospective single-arm trial at 5 sites enrolled 107 patients. Patients underwent ultrasound (US)-guided anastomosis creation between the proximal radial artery and perforating vein with the Ellipsys Vascular Access System (Avenu Medical, Inc, San Juan Capistrano, California) followed by separate maturation procedures. Primary endpoints were brachial artery flow volume $\geq$ 500 mL/min and target vein diameter $\geq$ 4 mm in $>$ 49% of patients and absence of device-related complications at 90 days.

Results: AVFs with fused anastomoses were created in 95% (102/107) of patients. Maturation procedures included anastomotic balloon dilation in 72% (77/107), brachial vein embolization in 32% (34/107), cubital vein ligation in 31% (33/107), and surgical transposition in 26% (28/107) of patients. Primary flow and diameter endpoints were achieved in 86.0% (92/107) of patients, exceeding performance goal of 49% ($P < .0001$). No major adverse events were attributed to the device. Cumulative patency was 91.6%, 89.3%, and 86.7% at 90 days, 180 days, and 360 days. Target dialysis veins were cephalic, basilic, and brachial veins in 74% (73/99), 24% (24/99), and 2% (2/99) of patients. Two-needle dialysis was achieved in 88% (71/81) of patients on hemodialysis at a mean 114.3 days $\pm$ 66.2. Functional patency was 98.4%, 98.4%, and 92.3% at 90 days, 180 days, and 360 days.

Conclusions: The Ellipsys® Vascular Access System met primary safety and efficacy endpoint goals in the US pivotal trial.

ABBREVIATIONS

AVF = arteriovenous fistula, ITT = intent-to-treat, SAE = serious adverse event, TRAD = thermal resistance anastomosis device

Over the 50 years since its inception, the arteriovenous fistula (AVF) remains widely acknowledged as the most effective access for hemodialysis in terms of morbidity and mortality (1–3). Despite this success, timely placement and development of functional fistulas for hemodialysis remains a difficult logistical problem (4–6). Percutaneous anastomosis devices have been developed as an alternative to surgical fistula creation (7,8). The Ellipsys Vascular Access System (Avenu Medical, Inc, San Juan Capistrano, California) is a thermal resistance anastomosis device (TRAD) that was developed to create percutaneous proximal radial artery–to–perforating vein fistulas with a side-to-side anastomosis. The TRAD uses tissue fusion to form an immediate and permanent bond between the anastomosed artery and vein (9). The minimally invasive TRAD fistula leaves the vessels in situ but otherwise mimics the anatomy and develops the functionality of the proximal radial artery fistula described by Toledo-Pereyra et al in 1977 (10). The present study was a prospective ultrasound (US) multicenter trial to evaluate the safety and efficacy of the TRAD in creating percutaneous AVFs in the office-based laboratory.

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J.E.H. is paid consultant for and has stock in Avenu Medical, Inc (San Juan Capistrano, California) and has a patent issued for systems and methods for creating arteriovenous fistulas. W.C.J., R.I.C., U.W., M.E.S., and R.N. have stock in Avenu Medical Inc.

Appendix A, Tables E1–E3, Figure E1, and Video 1 are available online at *www.jvir.org*.

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MATERIALS AND METHODS

The US pivotal trial of the Ellipsys Vascular Access System was a prospective, multicenter, single-arm comparison of the TRAD with a 90-day performance goal based on meta-analysis of surgical results obtained from the literature (**Appendix A**, **Tables E1–E3**, **Fig E1** [available online at *www.jvir.org*]) (11–18). The study complied with Declaration of Helsinki guidelines for research in human subjects. The initial study was performed under the US Food and Drug Administration Investigational Device Exemption (ClinicalTrials.gov identifier: NCT02363972) and an independent investigational review board approval (Western Institutional Review Board, Puyallup, Washington). All data related to endpoints and adverse events were collected at the sites with final adjudication by the medical monitor. Three contract research organizations were involved in electronic data capture (eClinicalOS; IBM Corp, Armonk, New York), monitoring and auditing (Headlands Consulting, San Juan Capistrano, California), and data management and analysis (Willes Consulting Group, Encinitas, California).

The primary efficacy endpoint were brachial artery flow volume $\geq$ 500 mL/min and target vein diameter $\geq$ 4 mm in $>$ 49% of patients at 90 days. The primary safety endpoint was absence of serious device-related complications, such as vessel perforation, vessel dissection, and electrical shock during index procedure and embolization in a previously uninvolved arterial territory within 90 days. Procedures were performed by 8 physicians, including 1 interventional radiologist and 7 interventional nephrologists, following device training and 2 proctored cases per site. Additional follow-up through 12 months included assessments of fistula patency, function, and comprehensive review of adverse events.

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria
Age $>$ 18 y and $<$ 80 y
Chronic kidney disease classification stage IV or V
Adequate quality vein based on preoperative assessment
Adjacent vein diameter $\geq$ 2.0 mm at target anastomosis site
Confirmed adequate outflow vein $\geq$ 2.0 mm
Within 1 cm of surface
Adequate quality radial artery based on preoperative assessment
Arterial lumen diameter $\geq$ 2.0 mm at target anastomosis site
Adequate proximity of proximal radial artery and adjacent vein $\leq$ 1.5 mm vessel edge to vessel edge
Negative Allen test for ulnar artery insufficiency
Exclusion criteria
Pregnant or currently breastfeeding
Diagnosed hypercoagulable state
Recent surgery or other major illness within 6 weeks
Acute or active infection
Use of immunosuppressive medication
History of organ transplantation
Upper extremity arterial stenosis ($>$ 20 mm/Hg systolic blood pressure difference between arms)

Patient Population

Patients requiring permanent access for hemodialysis were evaluated for study inclusion from February 2015 through June 2016 by 8 investigators at 5 sites. Of 261 patients evaluated, 117 met the inclusion and exclusion criteria (**Table 1**) and were enrolled in the study. All enrolled patients provided signed informed consent and had medical history and physical examination, laboratory studies, and Doppler ultrasound (US) examination data. Of 261 patients, the 144 who did not meet screening criteria included 73 (28%) who had unsuitable anatomy, 16 (6%) who declined to participate, 13 (5%) who were candidates for wrist fistula, 1 (0.4%) who failed Allen test, and 41 (16%) who were excluded for other medical reasons. Each of the 5 study sites completed 2 proctored percutaneous AVF procedures (n = 10 procedures) with 107 consecutive patients comprising the intent-to-treat (ITT) population (**Fig 1**). Access failure occurred in 4 patients, in whom wire access into the radial artery was not possible and the TRAD was not used, resulting in 103 patients treated with the TRAD. The demographics of the ITT population are summarized in **Table 2**. Mean patient age of 56.7 years (range, 30–80 y), mean body mass index was 31.2 kg/m^2 (range, 18.3–48.9 kg/m^2), and 73% of patients were men. All patients but 1 were treated with antiplatelet medications before the procedure. Suggested doses were 325 mg aspirin and 75 mg clopidogrel (Plavix; Bristol-Myers Squibb, New York, New York) orally, administered for up to 72 hours before the procedure and then daily through the 90-day follow-up period.

Procedure

The TRAD device and procedure are demonstrated in **Video 1** (available online at *www.jvir.org*). Briefly, the TRAD consists of a 6-F catheter and power controller that fuses and cuts an elliptical anastomosis between adjacent artery and vein using pressure and thermal resistance energy. Tissue fusion creates an immediate and permanent bond between artery and vein without the need for an indwelling implant. The tissue fused anastomosis tolerates balloon dilation, allowing increased blood flow without loss of anastomosis integrity. Balloon dilation and other maturation procedures were performed to adjust and direct the flow into an arm vein suitable for hemodialysis (7).

Procedures were performed in the office-based laboratory under locoregional anesthesia consisting of brachial plexus block (19) or local anesthesia with or without conscious sedation based on operator and patient preference. Initial venous access was retrograde through the cubital vein or brachial vein using a standard micropuncture needle and wire (Cook Medical, Bloomington, Indiana). The access needle was advanced intravenously under US guidance to the point of contact with the radial artery and then advanced

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