Thermal Resistance Anastomosis Device for the Percutaneous Creation of Arteriovenous Fistulae for Hemodialysis

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ABSTRACT

Purpose: To evaluate the safety and efficacy of arteriovenous fistula (AVF) creation with a thermal resistance anastomosis device (TRAD).

Materials and Methods: From January 2014 to March 2015, 26 patients underwent ultrasound (US)-guided percutaneous creation of proximal radial artery–to–perforating vein AVFs with a TRAD that uses heat and pressure to create a fused anastomosis. Primary endpoints were fistula creation, patent fistula by Doppler US, two-needle dialysis at the prescribed rate, and device-related complications.

Results: Technical success rate of fistula creation was 88% (23 of 26). Procedure time averaged 18.4 minutes (range, 5–34 min), and 96% of anastomoses (22 of 23) were fused. At 6 weeks, 87% of AVFs (20 of 23) were patent, 61% (14 of 23) had 400-mL/min brachial artery flow, 1 patient was receiving dialysis, 2 fistulae had thrombosed, and 1 patient had died unrelated to the procedure. Eighty percent (16 of 20), 70% (14 of 20), and 60% (12 of 20) of patients were receiving dialysis at 3, 6, and 12 months; 4 patients died, 3 fistulae failed, and one patient was lost to follow-up. Overall, 87% of AVFs (20 of 23) had an additional procedure at a mean of 56 days (range, 0–239 d), including balloon dilation in 43% (n = 10), brachial vein embolization in 26% (n = 6), basilic vein ligation in 17% (n = 4), venous transposition in 30% (n = 7), and valvulotomy in 4% (n = 1). There were no major complications related to the device.

Conclusions: Percutaneous AVFs created with a TRAD met the safety endpoints of this study. Midterm follow-up demonstrated intact anastomoses and fistulae suitable for dialysis.

ABBREVIATIONS

AVF = arteriovenous fistula, TRAD = thermal resistance anastomosis device

The arteriovenous fistula (AVF) is the preferred access for hemodialysis in the United States and throughout the world (1–3). The predominant method of creating an AVF with a sutured anastomosis has remained unchanged since the original description by Brescia et al in 1966 (4). Minimally invasive methods for AVF creation have recently been developed. A two-catheter electrosurgical radiofrequency anastomosis device that cuts precisely aligned linear incisions has successfully created ulnar artery–to–ulnar vein fistulae in the interventional suite with promising initial results (5). The thermal resistance anastomosis device (TRAD) was designed as a single-catheter venous access system to create percutaneous fistulae under ultrasound (US) guidance. This anastomosis device uses applied pressure and thermal resistance energy (ie, direct heat) to fuse artery and vein adventitia

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J.H. receives personal fees from and is a stockholder in Avenu Medical (San Juan Capistrano, California) and has a patent issued for the creation of arteriovenous fistulae. G.E.-R. receives grants and clinical study support from Avenu Medical. W.B. receives personal fees from Avenu Medical. Y.L.V.-R. receives financial support for training from Avenu Medical.

Video 1 is available online at www.jvir.org.

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together and then cut an elliptical anastomosis between the proximal radial artery and perforating vein. The present report prospectively evaluates the initial safety of the use of a TRAD in a 6-week study with 12–24-month follow-up.

MATERIALS AND METHODS

The study was a single-arm prospective 6-week evaluation of the Ellipsys Vascular Access System (Avenu Medical, San Juan Capistrano, California) for the creation of AVFs for hemodialysis access (ClinicalTrials.gov: NCT02816398). The primary efficacy endpoints were (*i*) creation of a fistula with the TRAD device and (*ii*) fistula patency by Doppler US examination. The secondary endpoints were brachial artery flow volume > 400 mL/min and/or three sessions of two-needle dialysis at the prescribed rate. The safety endpoints were (*i*) less than a 50% incidence of minor complications and (*ii*) less than a 1% incidence of major device-related complications as defined in vascular access reporting standards (6,7). Additional complications evaluated included electrical shock causing tissue injury and significant embolization in a previously uninvolved arterial territory with associated tissue ischemia. Inclusion and exclusion criteria are listed in Table 1. Continued follow-up of the 20 patients with patent fistulae after the initial 6-week evaluation was performed by review of dialysis records, Doppler US examination results, and additional procedures for a period of 12 months or greater.

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria

1. Age > 18 y and < 80 y
2. Patients diagnosed with CKD classification stage IV/V
3. Adequate quality vein based on preoperative assessment
   a. Adjacent vein diameter of > 2.0 mm at target anastomosis site
   b. Confirmed adequate outflow vein ≥ 2.0 mm
4. Adequate quality radial artery based on preoperative assessment
   a. Arterial lumen diameter of > 2.0 mm at target anastomosis site
5. Adequate collateral arterial perfusion
6. Negative Allen test results for ulnar artery insufficiency.

Exclusion Criteria

1. Pregnancy or patients currently breast feeding
2. Diagnosed hypercoagulable state
3. Acute or active infection
4. Use of immunosuppressive medication
5. History of organ transplantation
6. Upper-extremity arterial stenosis (> 20 mm/Hg systolic BP difference between arms)
7. Radial artery–adjacent vein proximity > 1.5 mm

BP = blood pressure; CKD = chronic kidney disease.

Patient Population

The present study complies with Declaration of Helsinki guidelines for research in human subjects. The initial 6-week protocol and the extended follow-up data collection had regulatory approval from the Federal Commission for the Protection against Health Risks and hospital investigational review board approval. Between January 2014 and March 2015, patients eligible for a surgical fistula were evaluated for the study. Screening resulted in 26 of 45 patients being enrolled as meeting inclusion criteria for the study. All patients enrolled had an assessment of medical history and a physical examination, laboratory studies, and Doppler US examination, and signed informed consent. All patients were Hispanic, 38% were male, 62% were female, and all were undergoing catheter hemodialysis. Patient demographics are summarized in Table 2. The pre- and postprocedural Doppler US vein-mapping examination was performed with a SonoSite M-Turbo linear 5–13-MHz transducer (SonoSite, Bothell, Washington) according to a modification of the Society of Vascular US guidelines as previously described (8).

The TRAD consists of three main components: an access needle, an over-the-wire tissue fusion and cutting catheter, and a power controller. The TRAD catheter has a 6-F proximal diameter with opposing active surfaces between the base and the coned 5-F distal tip (Figs 1, 2c). The power controller delivers direct current to the catheter heating element that is controlled with feedback from two temperature sensors and a gap sensor detecting the temperature and the opening distance of the catheter. A thumb tab in the handle of the device controls the catheter opening and closing and the fusion pressure. The combination of time, temperature, and pressure results in tissue fusion and cutting of an elliptical anastomosis.

Table 2. Demographic Characteristics of Study Patients

Characteristic	Value
Hispanic race	26 (100)
Sex (M/F)	10/16
Age (y)	45.5 ± 13.6
BMI (kg/m^2)	26.7 ± 5.1
Obesity*	7 (27)
IDDM	11 (42)
NIDDM	6 (23)
Hypertension	24 (92)
Left arm fistula	24(93)
Previous AVF	2 (8)
Previous catheter	26 (100)

Note–Values presented as mean ± standard deviation where applicable. Values in parentheses are percentages.
AVF = arteriovenous fistula; BMI = body mass index; HTN = hypertension; IDDM = insulin-dependent diabetes mellitus; NIDDM = non–insulin-depended diabetes mellitus.
*Defined as BMI > 30 kg/m^2.