To evaluate safety and efficacy of arteriovenous fistulas (AVFs) created with a thermal resistance anastomosis device” Hull et al (2017).

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 ≥ 500 mL/min and target vein diameter ≥ 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 ± 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.
Reference:


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