

STENT vs. ANGIOPLASTY FOR TREATMENT OF THROMBOSED AV GRAFTS: LONG TERM OUTCOMES.

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Arteriovenous (AV) grafts are used as vascular access in 40-50% of hemodialysis patients. Thrombosis of the AV graft is a frequent complication, usually occurs in presence of stenosis at the venous anastomosis. Standard of care is a radiologic approach of mechanical thrombectomy and angioplasty of the lesion. Primary graft patency after thrombectomy is quite poor. Deployment of stents at the stenotic site may improve outcomes. Preliminary data suggest stent deployment significantly prolongs primary graft patency following thrombectomy.

Single-center, open label, prospective randomized clinical trial, in which patients with a thrombosed AV graft are allocated to either mechanical thrombectomy plus angioplasty (control) or to mechanical thrombectomy plus a PTFE covered stent deployment (study). Inclusion criteria: AV Grafts recently thrombosed (<96 hours) with no more than 4 prior thrombectomies and >50% stenosis at the venous anastomosis. Primary endpoint is primary graft patency. Secondary endpoints are secondary graft patency and overall access-related costs.

Statistical analysis will be performed on an intend-to-treat basis. Power calculations estimate a sample of 130 patients evenly divided sufficient to detect a tripling in median graft survival (power 0.80). Ninety patients have been screened and 35 have been randomized since October 2006. No interim data analysis has been performed yet.

Individuals Entered				
Racial/Ethnic Composition	Male		Female	
	Age	Number	Age	Number
Caucasian	<u>72</u>	<u>1</u>	<u>68</u>	<u>1</u>
African-American	<u>35-80</u>	<u>20</u>	<u>30-66</u>	<u>13</u>

Future directions: If the hypothesis holds to be true then a second study will prolong the stent arm by randomizing half of this population into those receiving an anti-thrombotic agent (clopidogrel) and those receiving placebo. This will identify if clopidogrel will prolong the primary patency of AV grafts treated with stent deployment. A third study is projected to evaluate drug-eluting stents.

