

The COVERA stentgraft for the treatment of recurrent cephalic arch stenosis in hemodialysis accesses.

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OBJECTIVE:

Cephalic arch stenosis (CAS) is a frequent challenging lesion of brachiocephalic fistulas. Natural tortuosity of the cephalic arch requires special consideration in selecting a treatment modality. Percutaneous angioplasty treatments provide a short-term solution for CAS without a durable effect. Bare-metal stent (BMS) should not be used. This study assessed the COVERA stent grafts (SGs) as a percutaneous option to provide a more durable treatment for CAS.



METHODS:

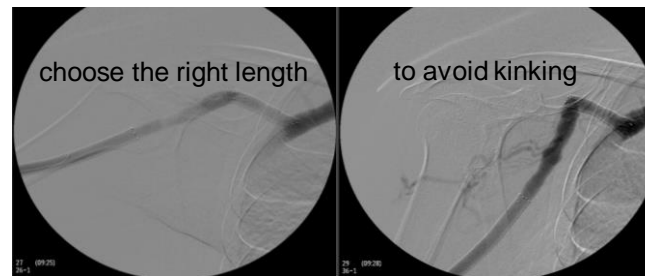
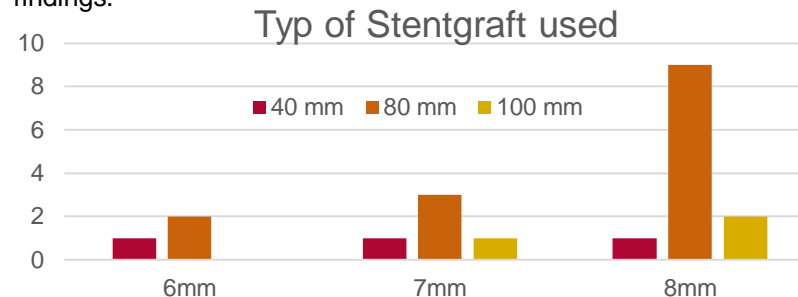
A single-arm, prospective, observational study was conducted of 20 consecutive CAS patients treated from 2017-2019 with angioplasty followed by deployment of COVERA SGs. Outcomes included target lesion primary patency and access circuit patency (primary and secondary) at 3 and 6 month. Results were compared with historic cohorts of percutaneous balloon angioplasty.

Patient Characteristics	
Patients evaluated	20
Dialysis patients	20/20 (100 %)
Age (median, min.-max.)	74 (56-92)
Gender: male	12/8 (60%)
Diabetes	15/20 (75%)
Hypertension	16/20 (80%)
Hyperuricemia	5/20 (25%)

Stentgrafts used in AV access at our institution	
2016	4
2017	11
2018	42
2019	77

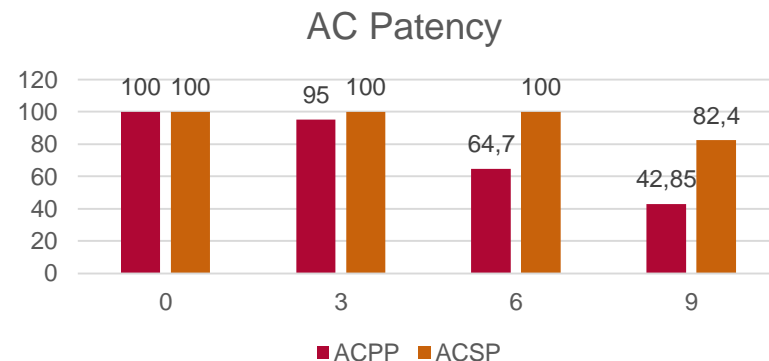
DIAGNOSING CEPHALIC ARCH STENOSIS

The development of clinical signs or abnormal dialysis monitoring criteria leads to early referral to Doppler ultrasound. Patients with abnormal findings (blood flow velocity > 4 m/s at the cephalic arch with an insonation angle of 60° or a peak systolic velocity ratio between the stenosis and an adjacent normal segment of > 3) are referred for angiography and angioplasty. Patients with asymptomatic cephalic arch stenosis detected on Doppler ultrasound are carefully followed and referred for treatment at the first appearance of clinical findings.



RESULTS:

Technical success was 100%. Study Population Mortality was 15 % at 6 month, 17 Patient were available for a complete follow up at 6 and 9 month. The SG cohort access circuit primary patency reported at 3 and 6 months was 95% (19/20) and 64,7 % (11/17) respectively. Access circuit secondary patency reported at 3 months was 100% and at 6 months 100%. Compared with historic cohorts, the SG cohort demonstrated superior access circuit primary patency with a reduced reintervention rate per access-year. Secondary access patency was also superior compared with the published percutaneous balloon angioplasty cohorts.



Trial	Mean age	Sex	Smoking status	Diabetes	BCF (n)	RCF (n)	Presenting symptom
Rajan <i>et al</i> , 2003 ⁶	66	75% male	NR	NR	24	2	AVF dysfunction
Chen <i>et al</i> , 2005 ²²	66	45% male	NR	27%	9	2	Dysfunctional AVF
Kian <i>et al</i> , 2008 ²¹	59,9	54% male	NR	NR	13	0	Dysfunctional AVF
Shemesh <i>et al</i> , 2008 ²⁰	67	68% male	NR	NR	25	0	Dysfunctional AVF
Heerwagen <i>et al</i> , 2010 ¹⁸	62	76% male	NR	12%	NR	NR	Dysfunction and thrombosis
Miller <i>et al</i> , 2010 ²³	NR	NR	NR	NR	33	0	Steal and dysfunctional AVF
Shawyer <i>et al</i> , 2013 ³	56,7	36% male	NR	NR	11	0	AVF dysfunction, thrombosis, failure to mature, arm swelling

AVF = Arteriovenous fistula; BCF = brachiocephalic fistula; RCF = radiocephalic fistula; NR = Not reported; UD = ultrasound dilution

Outcomes of trials for management of cephalic arch stenosis (CAS)

Trial	Duration	Type	Interventions	Number	Primary Patency	Secondary Patency	Complications	Notes
Rajan <i>et al</i> , 2003 ⁶	48 months	Retrospective review	Angioplasty, stent insertion	26	76% (3 months) 42% (6 months) 23% (12 months)	96% (3 Months) 83% (6 Months) 75% (12 Months)	3 cephalic arch ruptures, 1 with AVF loss	
Chen <i>et al</i> , 2005 ²²	NR	Retrospective review	Venovenostomy (transposition to patent outflow)	11 (7 cephalic)	91% (AVF functional)	90% (39 months)	-	
Kian <i>et al</i> , 2008 ²¹	NR	Prospective randomised trial (recurrent stenosis)	Cephalic to basilica transposition	13	92% (3 months) 69% (6 months) 39% (12 months)	92% (3 months) 92% (6 months) 92% (12 months)	All patients required anastomosis angioplasty	3.5 interventions per patient year, reduced to 1 intervention per patient year
Shemesh <i>et al</i> , 2008 ²⁰	13.7 months	Retrospective review (recurrent)	Angioplasty with stent graft, BMS	25	Stent graft: 82% (3 months) 32% (12 months) BMS: 39% (3 months) 0% (12 months)	NR	-	36% mortality by 13.7 months
Heerwagen <i>et al</i> , 2010 ¹⁸	60 months	Retrospective review	Cutting balloon angioplasty	17	94% (3 months) 81% (6 months) 38% (12 months) 22% (15 months)	100% (3 months) 94% (6 months) 77% (12 months) 63% (15 months)	1 minor vein rupture	0.9 interventions per patient, per dialysis year
Miller <i>et al</i> , 2010 ²³	14.5 months	Retrospective review	Access flow reduction (banding BCF of recurrent CAS)	33 (6 bandings)	91% (3 months) 76% (6 months) 57% (12 months)	97% (3 months) 97% (6 months) 97% (12 months)	-	3.3 interventions per year, reduced to 0.9 per year
Shawyer <i>et al</i> , 2013 ³	543 days	Retrospective review (recurrent)	Viabahn stent graft	11	82% (6 months) 73% (12 months)	91% (6 months)	-	

AVF = Arteriovenous fistula; BCF = brachiocephalic fistula; BMS = bare metal stent; NR = Not reported

CONCLUSIONS:

In treatment of a CAS, the COVERA SG study group demonstrated superior target lesion patency and required fewer subsequent interventions compared with historic cohorts treated with angioplasty. Given the significant improvement in target lesion primary patency, future randomized studies should challenge COVERA SGs as a primary percutaneous treatment modality vs DCB angioplasty or vs surgical alternatives to get Level I evidence in this treatment area.

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