COVERA covered stent to treat stenosis in arteriovenous fistula: 6-month results from the prospective, multi-center, randomized AVeNEW study

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Disclosure

Speaker name: Panagiotis Kitrou

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I have the following potential conflicts of interest to report:

× Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest

AVeNEW Study

Arterio**ven**ous (AV) Stent Graft vs. PTA alone in the Treatment of Stenoses in the V**e**nous Outflo**w** of AV Fistula Access Circuits

Objective: Compare the performance of the COVERA™ Vascular Covered Stent to a concurrent, randomized PTA control for the treatment of stenotic lesions in the venous outflow tract of upper extremity, autogenous AV fistula

COVERA is a trademark of Becton, Dickenson and Company. In the United States, the COVERA™ Vascular Covered Stent is currently indicated for the treatment of stenoses at the venous anastomosis of ePTFE or other synthetic arterio-venous (AV) access grafts.

AVeNEW Study Design

- **Design:** Prospective, Multicenter, Concurrently-controlled, Randomized
  - Patient Population: 280 patients
  - 24 International Sites: USA, Europe, Australia, and New Zealand
- **Independent Analysis:**
  - Clinical Events Committee (CEC): adjudicate serious adverse events
  - Angiographic assessment of lesions (Yale Core Lab)
  - Data Safety Monitoring Board: oversee overall patient safety
- **Follow Up:** 6 month data presented today - ongoing through 2 years

Key Inclusion Criteria

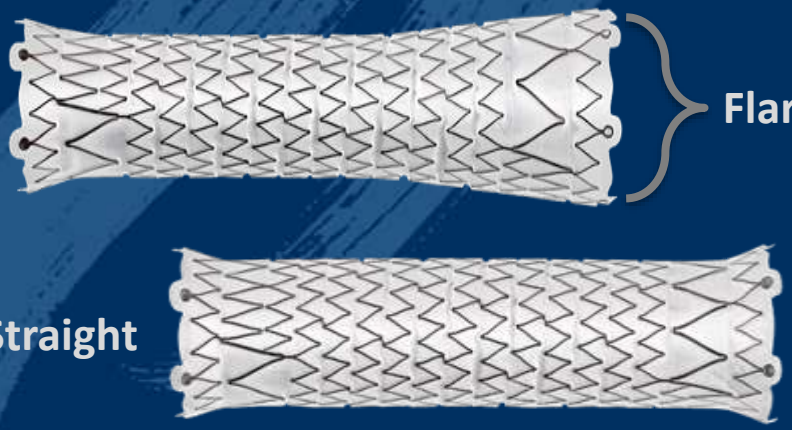
- Upper extremity AV fistula (including cephalic arch)
- ≥ 1 successful dialysis session
- Angiographic stenosis ≥ 50%
- Clinical or hemodynamic fistula dysfunction in the venous outflow circuit
- Target lesion(s): ≤ 9 cm in length
- Vessel diameter: 5.0 - 9.0mm

Key Exclusion Criteria

- AV graft or lower extremity access
- Uncontrolled infection (local or systemic)
- Additional stenotic lesions in the venous outflow not successfully treated prior to the study procedure
- Aneurysm or pseudoaneurysm in the treatment area
- Lesion location: across the elbow joint, cannulation zone, within a stent, or central veins

Study Device: COVERA™ Vascular Covered Stent

Flared and **Straight** configurations



- ePTFE encapsulated nitinol stent
- Radiopaque tantalum markers
- Diameters: 6-10 mm
- Lengths: 40, 60, 80, and 100 mm (30 mm straight only)

Thumbwheel Delivery System:

- Sheath compatibility: 8-9 F
- Working length: 80 & 120 cm
- 0.035” over-the-wire system with atraumatic tip

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Patient Demographics

	Covered Stent Group	PTA Group	p-value
Number of Patients (ITT), N	142	138	
Mean Age, years ± SD	63 ± 13.2	62 ± 11.5	0.70
Male/Female, %/%	62.7/37.3	60.9/39.1	0.76
Race, % (n)			0.08
Caucasian	70.4 (100)	66.7 (92)	
African American	25.4 (36)	26.1 (36)	
Mean BMI, kg/m^2 ± SD	30.8 ± 6.3	28.9 ± 5.8	0.01
Risk Factor, % (n)			0.54
Hypertension	97.9 (139)	96.4 (133)	
Smoker (Current & Former)	43/7 (62)	44.9 (62)	
Diabetes (Type 2)	71.1 (101)	68.1 (94)	
Congestive Heart Failure, % (n)	24.6 (35)	29.0 (40)	0.41
Coronary Artery Disease, % (n)	32.4 (46)	37.7 (52)	0.35
Peripheral Artery Disease, % (n)	16.9 (24)	21.0 (29)	0.38

AV Access Circuit & Lesion Characteristics

	Covered Stent Group	PTA Group
Upper Arm Access Position, % (n)	93.0 (132)	94.2 (130)
Brachial Artery Inflow, % (n)	90.1 (128)	92.0 (127)
Outflow Vein, % (n)		
Cephalic	73.9 (105)	68.8 (95)
Basilic	24.6 (35)	30.4 (42)
Months on Dialysis (mean), months ± SD	28.0 ± 23.2	31.5 ± 24.7
Lesion Type (Restenotic), % (n)	75.4 (107)	71.0 (98)
Lesion Location, % (n)		
Cephalic Arch	54.9 (78)	50.7 (70)
Cephalic Vein Outflow	17.6 (25)	17.4 (24)
Basilic Vein Swing Point & Outflow	20.4 (29)	23.9 (33)
Reference Vessel Diameter, mm ± SD	8.1 ± 1.4	8.0 ± 0.9
Mean Lesion Length, mm ± SD	28.8 ± 17.4	29.7 ± 17.0
Mean Baseline Target Lesion Stenosis, % ± SD	72.5 ± 12.4	72.5 ± 12.7

Procedural & Post-Procedural Observations

	Covered Stent Group	PTA Group
Mean Balloon Diameter/Length, mm ± SD/mm ± SD	8.5 ± 1.0/46.8 ± 14.9	8.4 ± 1.1/49.0 ± 16.8
Mean Maximum Inflation Pressure, atm ± SD	20.6 ± 5.4	21.2 ± 5.8
Mean Duration of Inflation, sec ± SD	43.4 ± 52.8	41.2 ± 41.0
Flared/Straight Stent Graft Configuration, %/%	46.1/53.9	na
Most Used Covered Stent Diameters, %		
10 mm	48.2	na
9 mm	29.8	na
Most Used Covered Stent Lengths, %		
40 mm	41.8	na
60 mm	36.9	na
Final Mean Residual Stenosis, % ± SD	2.2 ± 5.8	15.0 ± 18.0
Dialysis Resumed at 30 Days, % (n)	96.5 (137)	97.8 (135)

Primary Safety Endpoint

Freedom from a Primary Safety Event (30 days)

- ✓ Freedom from an event resulting in additional intervention, hospitalization, or death
- ✓ **Hypothesis:** The safety rate with COVERA is *non-inferior* to PTA alone

Primary Safety Endpoint (Proportional Analysis)	Covered Stent Group	PTA Group	Difference 90% CI[1]	p-value[2]
Proportion Free from a Primary Safety Event	95.0% (133/140)	96.4% (132/137)	-1.4% (-7.3%, 4.6%)	0.002

COVERA was *non-inferior* to PTA

[1] Confidence interval estimated using Farmington and Manning method)
[2] Farrington Manning non-inferiority test with margin = 10%

Primary Efficacy Endpoint

Target Lesion Primary Patency (TLPP) at 6 months

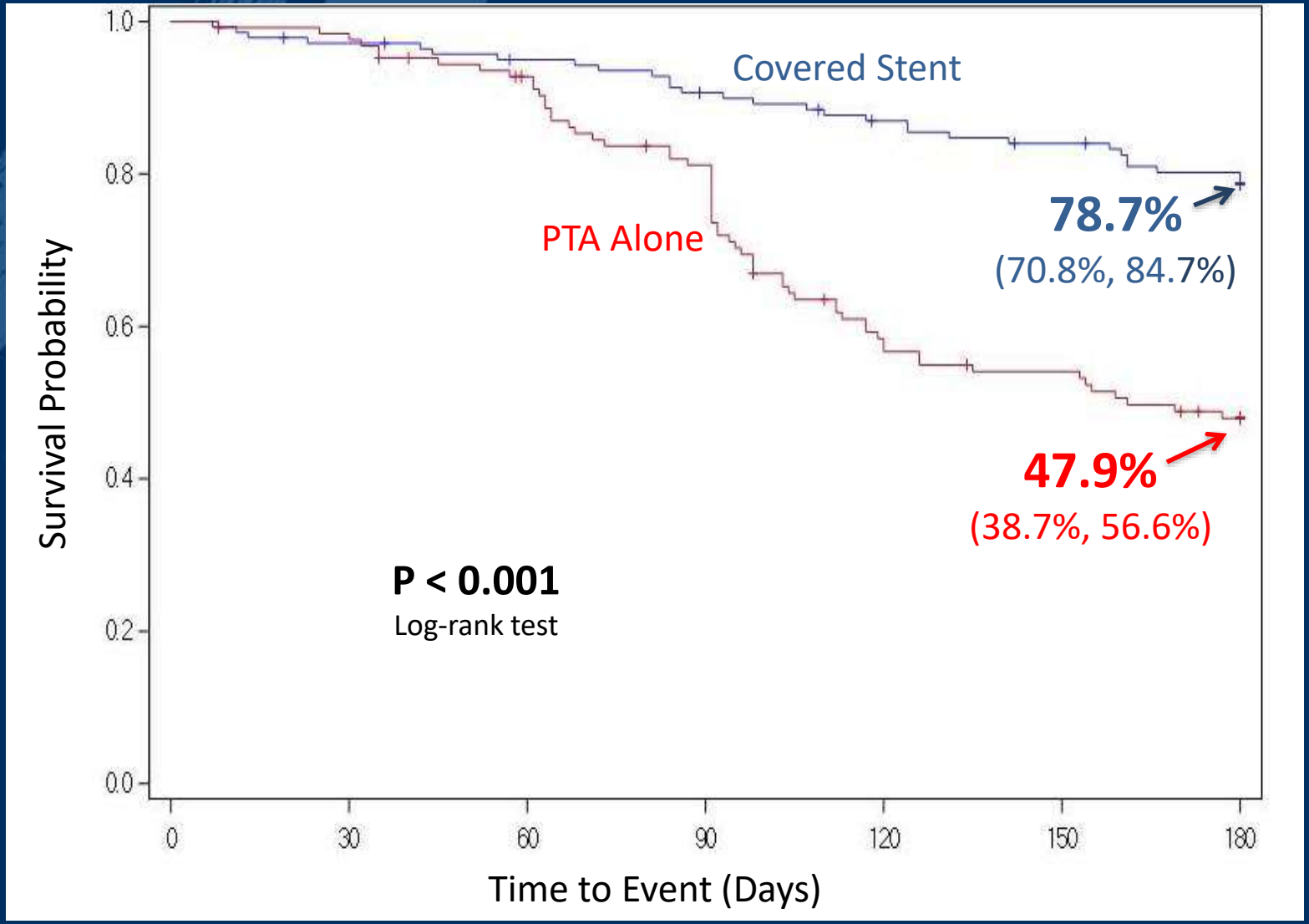
- ✓ Time until the next clinically-driven re-intervention at the treatment site or permanent access abandonment
- ✓ **Hypothesis:** 6-month TLPP with COVERA is *greater than* PTA alone

Target Lesion Primary Patency (TLPP) (Kaplan-Meier Analysis)	Covered Stent Group (95% CI)[2]	PTA Group (95% CI)	Hazard Ratio[3] (95% CI)	p-value[4]
Estimated Survival (TLPP) at 6 months[1]	78.7% (70.8%, 84.7%)	47.9% (38.7%, 56.6%)	0.322[5] (0.213, 0.519)	<0.001

COVERA was *superior* to PTA

[1] Rates are estimated using the Kaplan-Meier method
[2] 95% confidence intervals are estimated using Greenwood's formula
[3] Hazard ratio calculated using the COX regression with treatment in the model
[4] One-sided p-value calculated using the log-rank test

Freedom from Loss of TLPP (K-M Curve*)



*The rates are estimated using the Kaplan-Meier method, and the 95% confidence intervals are estimated using Greenwood's formula

AVeNEW 6-Month Summary

Primary Outcomes:

- Freedom from a Primary Safety Event (30 days): **95.0%** (non-inferior to PTA)
- Target Lesion Primary Patency (6 months): **78.7%** (superior to PTA)

In this prospective, randomized, concurrently-controlled, multicenter trial, the COVERA™ Vascular Covered Stent demonstrated a primary patency benefit compared to PTA (6 months) while showing equivalent safety (30 days) when used to treat venous outflow stenosis in AV Fistula patients

Follow up in the AVeNEW Trial is ongoing through 2 years

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