9th MUNICH VASCULAR CONFERENCE 2019
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First-in-man clinical application of the TrackCath™ system in endovascular repair of aortic aneurysms – A prospective multi-centre clinical trial

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ABSTRACT

Background: The identification and cannulation of the aortic side branches can be challenging and require the use of X-ray and Contrast dye, leading to an increased risk of post-operative AKI.

Technology: The TrackCath™ System detects changes in Blood Flow Velocity and Direction and provides a technique for identifying side branches and targeting orifices without the use of X-ray and C-dye.

Methods: FIH study of 40 patients undergoing EVAR procedures for AAA and TAAA, in 4 German hospitals. Safety population: 38 patients; Performance population: 26 patients (50 orifices).
Primary endpoints:
- Safety: All SADEs
- Performance: successful delivery of the distal end of the guidewire or of the 4Fr catheter to the selected targeted orifices.

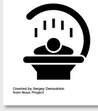
Results:
- Safety: 100% (No SADEs)
- Performance: 98% (49 out of 50 orifices performed with TrackCath™)
- C-dye use/orifice: median=1ml. Literature reports higher doses for the hypogastric and renal artery cannulation during standard EVAR.
- Target orifice identification and cannulation time: median=3min, in line with robotic system and lower than renal a. cannulation during standard fEVAR.
- User feedback on the Blood Flow Velocity: after the learning curve most users find it very good or rather good.

Conclusions: The Blood Flow Velocity Technology:
- Is safe
- Is capable to identify orifices and provides real-time information that allows to move the catheter within the vasculature without the use of X-ray
- Allows potential contrast dye and X-ray reduction during identification and cannulation of side branches
- It's easy to use and it offers an alternative technique without changing the standard practice of the physician.

BACKGROUND

Identification and cannulation of the aortic side branches can be challenging and require use of

X-ray & **Contrast dye**



1 EVAR ≈ 3500 chest X-rays

Increased risk of post-op AKI (20-25% incidence)*

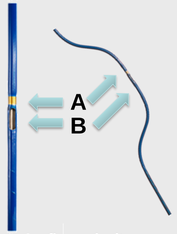
** Saratzis et al.*

PURPOSE

ACCESS Trial: assess the safety and performance of the Medyria TrackCath™ System

TECHNOLOGY

TrackCath™ System*:

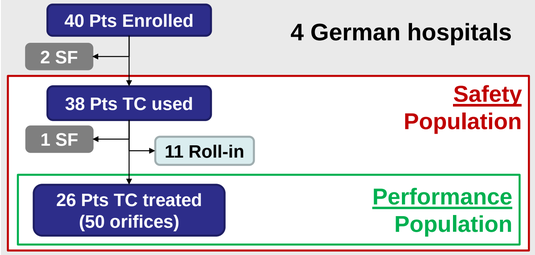


A – flow velocity sensor
B – side port (4Fr)

- Uses the low-energy hot-wire anemometry principle
- Detects changes in Blood Flow Velocity and Direction
- Provides a technique for identifying side branches and targeting orifices
- Does not require X-ray and contrast dye

***CAUTION: Investigational Device, not available for commercial use**

METHODS



SF: Screening Failures

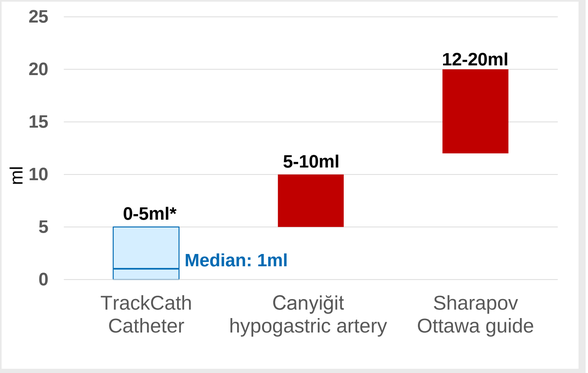
Primary Endpoints

- **Safety**: all Serious Adverse Device Effects (SADEs)
- **Performance**: successful delivery of the distal end of the guidewire or of the 4Fr catheter to the selected targeted orifices.

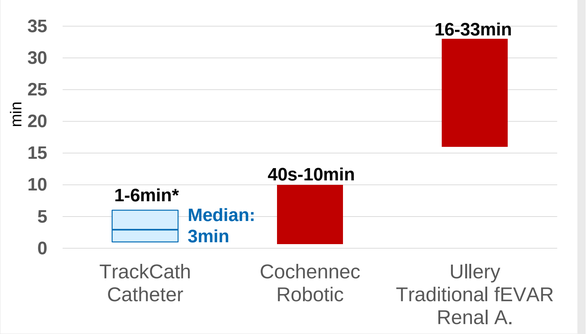
RESULTS

- ✓ **Safety**: 100%
  - ↳ No SADE (38 patients)
- ✓ **Performance**: 98% success rate
  - ↳ 49 orifices (out of 50) successfully treated with TrackCath™ System, in 26 patients

Contrast dye (ml)



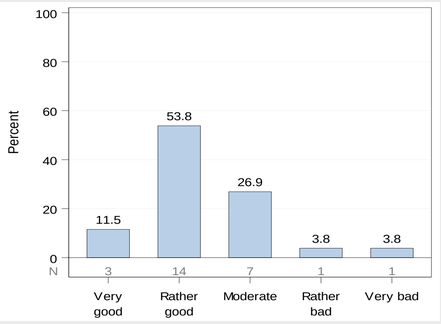
Target orifice identification & cannulation (min)



**** Lower and upper quartiles***

RESULTS

Surgeon feedback – use of Blood Flow Velocity



CONCLUSION

The Blood Flow Velocity Technology:

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DISCLOSURES

None