Proof is in the Evidence

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ESRD Symposium: Sponsored by Becton, Dickinson Interventional
Disclosure
Dierk Scheinert, MD

Advisory Board /Consultant:
Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies
Lack of Solid Clinical Evidence

Traditionally, A-V Access Literature has consisted of retrospective case-control studies or case reports.
Lack of Solid Clinical Evidence

Example: Nitinol Stent Data

- Retrospective review
- Observational only
- No pre-defined criteria
- Open to bias

"Our study is limited by the retrospective review of hard-copy images, and therefore our method of measurement is less precise than quantitative angiography."

Commitment to Clinical Evidence

Bard/Becton, Dickinson Interventional have made a commitment to Level 1 Clinical Evidence in the A-V space:

**Level 1 Clinical Evidence**: Prospective Randomized, multicenter, concurrently-controlled trials:


The FLAIR Pivotal Study: PTA vs PTA/Flair (prospective, randomized, multicenter, concurrently-controlled trial)

- Better 6-month TLPP & ACPP with FLAIR compared to PTA only when used to treat venous anastomotic stenosis in A-V grafts
The FLAIR Pivotal and RENOVA Studies demonstrated that a covered stent (FLAIR) provided better results when treating A-V graft venous outflow obstructions than PTA alone.

- Confirmed the 6-month results of the FLAIR Pivotal Study
- ACPP and TLPP at 12- and 24-month was superior with FLAIR compared to PTA when used to treat venous anastomotic stenosis in A-V grafts
- 12- and 24 month device and/or procedure related adverse events with FLAIR were non-inferior to PTA alone
RESCUE: A Prospective, Multicenter, Randomized, Concurrently-Controlled Study of the FLUENCY Plus Covered Stent vs. PTA for In-Stent Restenosis in the Venous Outflow Circuit

Treatment Lesion Primary Patency (TLPP) through 24 Months

- TLPP was greater for the FLUENCY Plus group vs. the PTA group at 6, 12, and 24 months
- Safety was non-inferior to PTA

RESCUE included patients with in-stent restenosis in the venous outflow tract of both fistula and A-V graft patients
AVeNEW: A Prospective Multicenter, Randomized, Concurrently-Controlled Clinical Study Comparing the COVERA Covered Stent to PTA for the Treatment of Dysfunctional Fistulae

Kaplan-Meier Analysis of TLPP through 180 Days

**Primary Outcomes:**

- Freedom from a Primary Safety Event (30 days): 95.0% (non-inferior to PTA)
- TLPP (6 months): 78.7% (superior to PTA)
Lutonix AV: A Prospective Multicenter, Randomized, Concurrently-Controlled Clinical Study Comparing the Lutonix DCB to PTA for the Treatment of Dysfunctional Fistulae

Kaplan-Meier Analysis of TLPP through 12 Months

- First drug-coated balloon IDE trial in fistulae
- Non-inferior safety to PTA
- Primary patency suggests efficacy benefit
- 26.2% fewer interventions required to maintain TLPP in DCB arm
Commitment to Clinical Evidence

Current Status: Five - Level 1, Prospective, Randomized, Multicenter, Controlled Clinical Trials Designed to Help Better Manage Access Failure with Covered Stents and Drug-Coated Balloons

Future: Create durable A-V access circuits and reduce intervention rates
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