What Does it Take to Improve Dialysis Access Outcomes?

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Common scenario

- **The patient:**
- ESKD patient w/episodic hypotension sent to ER with clotted AVG on Friday, K+ 5.8 → admitted → thrombectomy consult placed

- **Questions with no clear answers:**
- Should BP meds be held? Continue Plavix/ASA?
- Optimal timing for successful thrombectomy? Long-term patency?
- Most efficacious approach? Mechanical vs. lysis? Dose?
- Additional pharmacologic therapy to improve declot success?

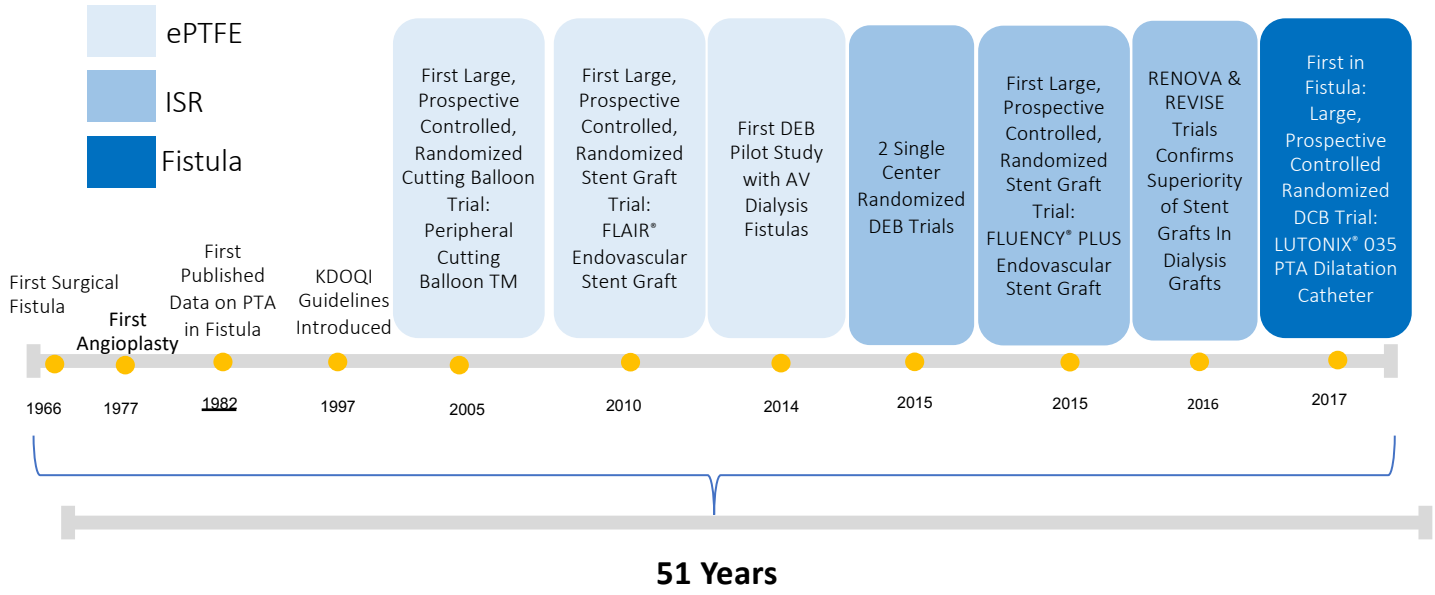
Progress has been made with MI & stroke management and algorithms, yet we're doing the same old thing with vascular access



Why aren’t there evidence-based treatment pathways for dialysis access?



History of Therapeutic Interventions for Hemodialysis Access



From S Trerotola, MD. Modified by J Aruny, MD.

Guidelines: Progress Made, But Key Questions Remain

- 1997: KDOQI
  - Guidelines & highlighted research areas
- 2002: DOPPS
  - Indicated U.S. is behind in AVF use vs. Europe
- 2003: NAVII (later “Fistula First”)
  - Improve patient outcomes by increasing AVF use
- 2019: KDOQI
  - Updated guidelines focused on individualizing access and an access life-plan



Lack of consensus among specialties on trial endpoints



Variability of trial endpoints

- All RCT's on vascular access outcomes in adult HD patients (AKI excluded) between 1/2011- 6/2016

- 168 trials (29,038 participants)

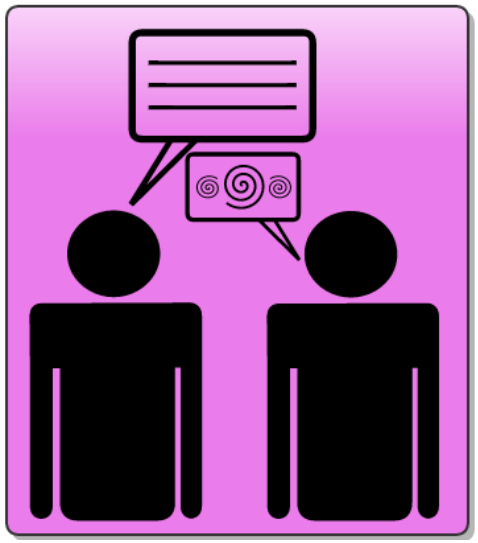
- 3 most common outcomes
  - Function: Measured 489 different ways & at 46 different time points
  - Infection: Reported in 136 different ways & 20 different time points
  - Maturation: Measured in 43 different ways & at 15 different time points

Viecelli AK et al. AJKD, 2018

How can we move toward standardization of treatment?

- Use a common lexicon

- Use core outcome panel of standard outcome measures & definitions that must be measured & reported in all clinical trials of a certain disease/population
  - Allows for comparative assessment of study outcomes across trials to guide evidence-based clinical practice



Kidney Health Initiative: Building Consensus

- Consensus clinical trial endpoints for vascular access trials created & published 4-paper series published in 2018
  - All stakeholders included : patients, nurses, nephrologists, surgeons, radiologists, industry partners, international advisors, FDA

Clin J Am Soc Nephrol. 2018 Mar 7; 13(3): 495–500.
Published online 2017 Jul 20. doi: 10.2215/CJN.12011116
PMCID: PMC5967684
PMID: 28729382

Recommended Clinical Trial End Points for Dialysis Catheters

Michael Allon,[✉] Deborah J. Brouwer-Maier, Kenneth Abreo, Kevin M. Baskin, Kay Bregel, Deepa H. Chand, Andrea M. Easom, Leonard Mermel, Michele H. Mokrzycki, Priti R. Patel, Prabir Roy-Chaudhury, Surendra Shenoy, Rudolph P. Valentini, and Haimanot Wasse

Clin J Am Soc Nephrol. 2018 Mar 7; 13(3): 490–494.
Published online 2018 Feb 27. doi: 10.2215/CJN.13321216
PMCID: PMC5967685
PMID: 29487092

Clinical Trial End Points for Hemodialysis Vascular Access
Background, Rationale, and Definitions

Surendra Shenoy,[✉] Michael Allon, Gerald Beathard, Deborah Brouwer-Maier, Laura M. Dember, Mark Glickman, Celeste Lee,[a] Terry Litchfield, Charmaine Lok, Thomas Huber, Prabir Roy-Chaudhury, Jack Work, Melissa West, and Haimanot Wasse[✉]

Clin J Am Soc Nephrol. 2018 Mar 7; 13(3): 513–518.
Published online 2017 Jul 24. doi: 10.2215/CJN.02900317
PMCID: PMC5967664
PMID: 28739575

FDA Regulatory Perspectives for Studies on Hemodialysis Vascular Access

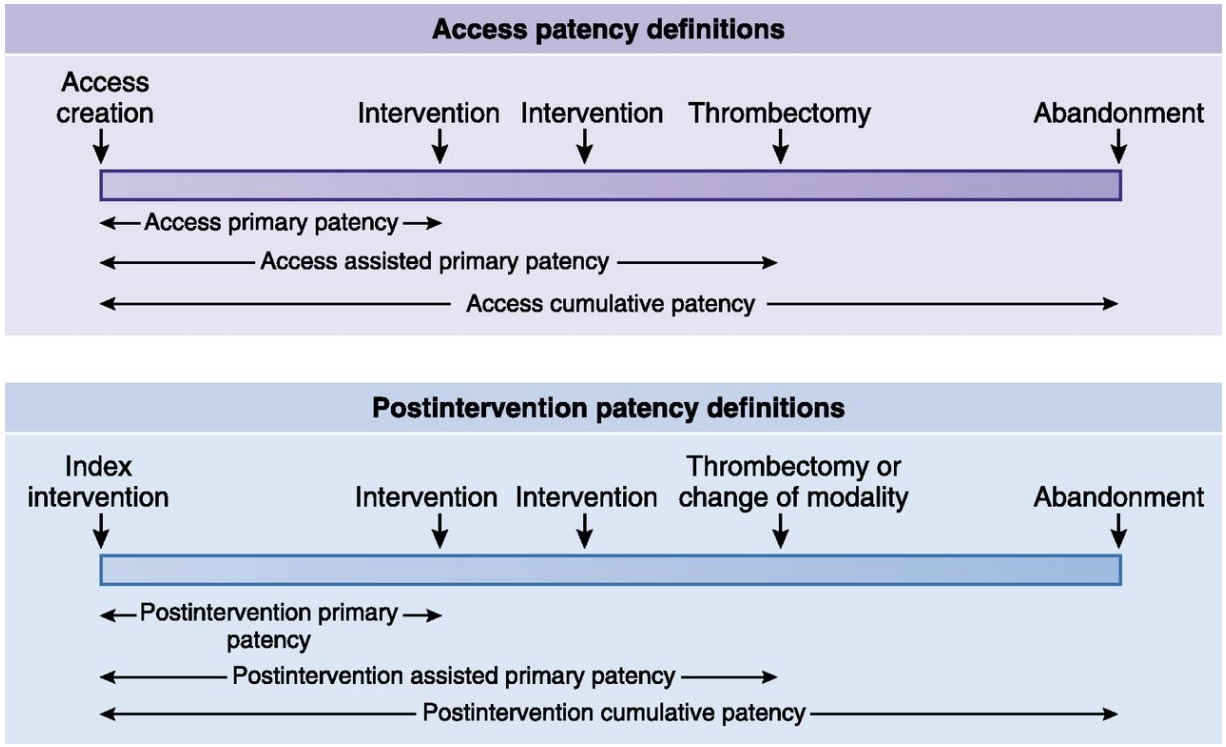
Frank P. Hurst,[✉1] Robert E. Lee,[1] Aliza M. Thompson,[2] Brian D. Pullin,[1] and Douglas M. Silverstein[1]

Clin J Am Soc Nephrol. 2018 Mar 7; 13(3): 501–512.
Published online 2017 Jul 20. doi: 10.2215/CJN.11531116
PMCID: PMC5967683
PMID: 28729383

Definitions and End Points for Interventional Studies for Arteriovenous Dialysis Access

Gerald A. Beathard,[✉] Charmaine E. Lok, Marc H. Glickman, Ahmed A. Al-Jaishi, Donna Bednarski, David L. Cull, Jeffery H. Lawson, Timmy C. Lee, Vandana D. Niyyar, Donna Syracuse, Scott O. Trerotola, Prabir Roy-Chaudhury, Surendra Shenoy, Margo Underwood, Haimanot Wasse, Karen Woo, Theodore H. Yuo, and Thomas S. Huber

Temporal vascular access patency definitions.



Patency definitions after placement of AV access

Patency definitions after an intervention

Surendra Shenoy et al. CJASN 2018;13:490-494

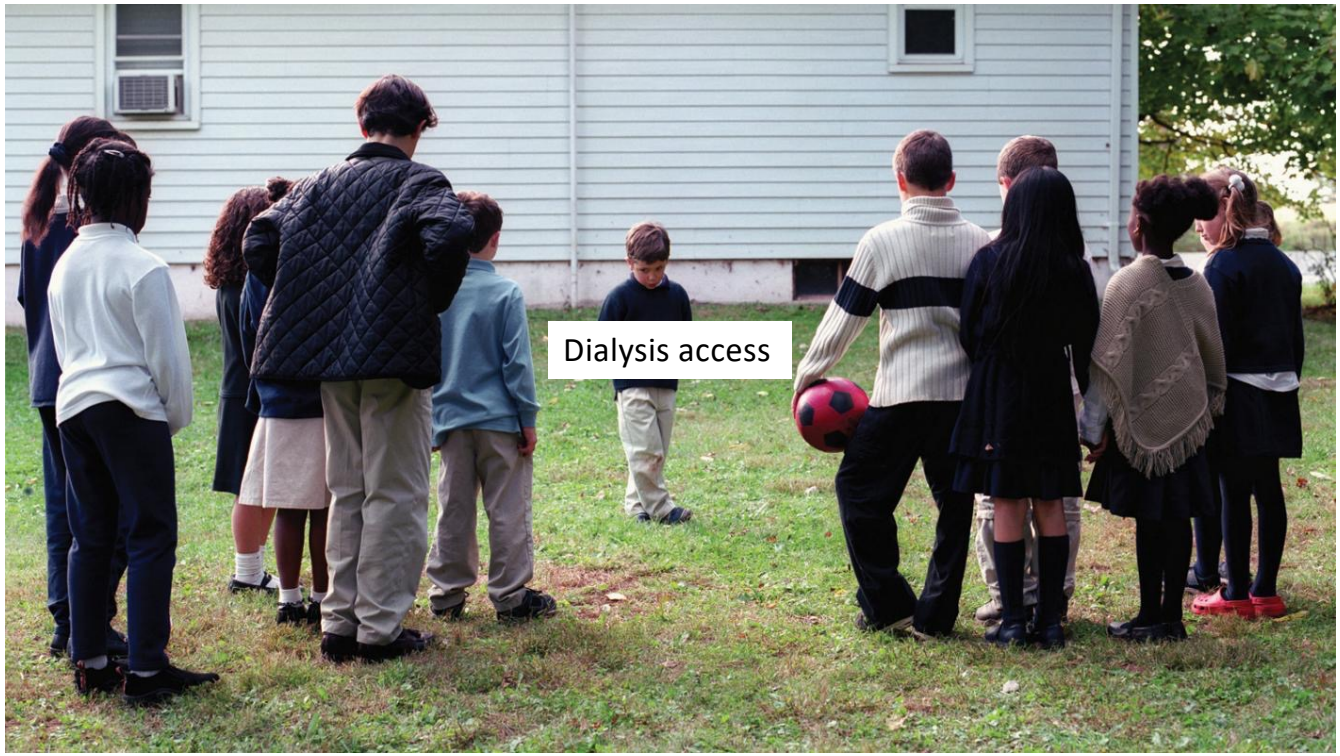
CJASN

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Barriers to dialysis access education & better outcomes



Dialysis access has an image problem



Dialysis access has an image problem

How practitioners view dialysis access:

Sisyphean task • Nuisance • Complex patients • “Anyone can do it” • Low reimbursement



Consequences:

Procedures not perceived as complex; attitude passed to trainees

Few practices even indicate they treat dialysis access patients

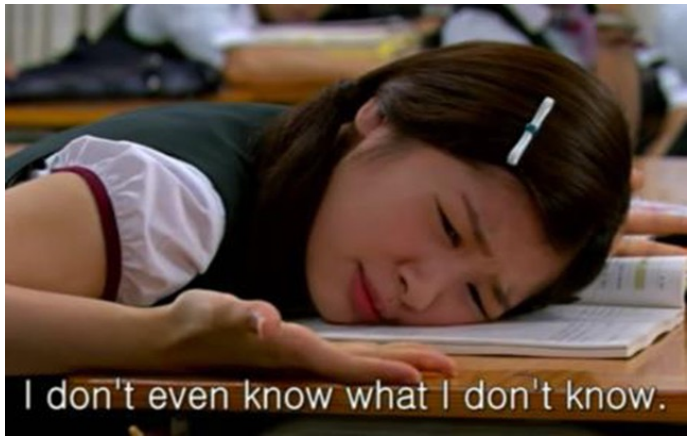
Limited pursuit of research; majority don’t attend dialysis access scientific meetings

Result:

Under-trained practitioners, driven by reimbursement over patient interest — and no one measuring outcomes

Limited continuing education

- Majority of those doing procedures don’t stay apprised of data
- Dialysis access is a small part of society meetings
- Majority don’t attend dialysis access scientific meetings



Insufficient data: unaware of outcomes & how they compare nationally

- Root of the problem:
  - No established national benchmarks for dialysis access performance
  - No mandated outcome-reporting
  - Tendency to fault patient comorbidities for poor outcomes
  - No impetus for improvement



Addressing Gaps: Accountability, Education & Training

- **Fix the accountability gap:**
  - Work with policy stakeholders to create performance measures & mandate reporting
  - Establish national benchmarks; advocate to maintain appropriate reimbursement

- **Address education gaps:**
  - Virtual education via social media; partner with LDOs for dialysis nurses & techs
  - Renal, surgery & IR program directors: create cross-discipline training for fellows

- **Shift the culture:**
  - Feature collaborative leaders across specialties — demonstrate that dialysis access is rewarding, effective, and worth mastering

Take-away points

- Care pathways should be developed for vascular access (VASA, ASDIN, VAS working together)
- Establish consensus on what it takes to have expertise in dialysis access care
- Set standards; cross-discipline interactions during medical training
- Maintain reimbursement; expand opportunities for continuing education

Thank you for your attention

