ADVANCES IN DIALYSIS ACCESS:

1. PERCUTANEOUS AVF CREATION
2. URGENT START PERITONEAL DIALYSIS

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STATE OF ESRD VASCULAR ACCESS IN THE US

2105 USRDS ANNUAL DATA REPORT:

- 80% of patients start HD with a central venous catheter (CVC) 2005 -2013
- At 90 days post initiation 68% of pts were still using a CVC – 2013
- Proportion of patients using an AVF at initiation is 17%, at 1 year 65%
- Proportion of patients using an AVG at initiation is 3%, at 1 year 15%
- At 1 year after hemodialysis initiation are using either an AVF or AVG

PATIENTS STARTING DIALYSIS WITH A CENTRAL VENOUS CATHETER HAVE HIGH MORTALITY/COST:

- Patient’s started on dialysis with a CVC have an 80% higher mortality compared to dialysis initiation with AVF, AVG or PD catheter. – Perl et. Al.
- Yearly dialysis costs by access:
  - AVF: $64,000 a year
  - AVG $79,000 a year
  - CVC: $90,000 a year

PATIENTS STARTING HEMODIALYSIS ARE OVERWHELMINGLY STARTING WITH A CENTRAL VENOUS CATHETER- WITH HIGH COST AND MORTALITY.
WHAT DO WE DO ABOUT LIMITING THE CVC?

WHAT WE TRY TO DO NOW:
- EARLIER REFERAL FOR AV ACESS IN ADVANCED CKD PATIENTS
- GREATER EDUCATION OF PATIENTS WITH ADVANCED CKD
- PUBLIC POLICY TO HELP INCREASE ACCESS TO CARE FOR PATIENTS WITH CKD
- INCENTIVE/DISINCENTIVE POLICIES TO HELP LIMIT CVCS

SOME CURRENT/SOON TO BE CURRENT OPTIONS:
- PERCUTANEOUS AVF PLACEMENT
- URGENT START PERITONEAL DIALYSIS
Creation of an AVF suitable for hemodialysis using novel endovascular devices, avoiding or limiting need for general surgery or general anesthesia.
PERCUTANEOUS AVF CREATION

ADVANTAGES:

- Minimally invasive, generally safe, with reported outcomes equivalent or better than surgically created AVF.
- Can be done with regional or local anesthesia/conscious sedation
- Avoids general surgery
- Lowers costs
- Can be done readily in the outpatient setting
- Has the potential to get more AVF placed in patient’s who might otherwise start wit a CVC, thereby avoiding or limiting duration of the CVC.

DISADVANTAGES:

- Not all patients are candidates (More patients are candidates for surgical AVF creation- for the moment).
- May still require surgical revision/transposition, ligation of large collaterals, etc...
- Ideally suited (at this time) mainly for the patient’s 1st AVF.
- Technology is still in it’s infancy.
- Data on outcomes only from “advanced operators” and potential for selection bias in patients included in the studies. No randomized head to head comparison exists at this time comparing surgical and percutaneous AVF creation
SURGICALLY CREATED AVF:

- Average Maturation time 4-9 months
- 20%-60% of AVF do not mature and are unusable for dialysis (primary failure rate)
- Upto 25% of AVF thrombose per year
TVA MEDICAL EVERLINQ PERCUTANEOUS AVF
EVERLINQ OUTCOME STUDY (FLEX-1 STUDY)

Prospective study of 33 patients

- 97% technical success
- 96% Patency at 6 months
- 96% Initiated on dialysis
AVENU MEDICAL: ELLIPSYS SYSTEM
ELLIPYSIS DEVICE
PERCUTANEOUS AVF CREATION: CASE PRESENTATION
PERCUTANEOUS AVF BAM
PERCUTANEOUS AVF POST PTA
CASE PRESENTATION

- Right upper arm percutaneous AVF created 4/27/16
- Balloon assisted Maturation done 5/9/16
- Cleared for use 7/26/16
- Images on right taken March 2017:
  - AVF diameter 9.1mm
  - Flow 2.9L/min
ELLIPSYSS PERCUtANEous AVF (PRELIMINARY DATA > 100 PTS)

- Average time to maturation about 69 days
- Success rate in creating an AVF meeting maturation criteria of size and flow: 89%
- Average procedure time 23 minutes.
Definition of Urgent Start Peritoneal Dialysis Patient:

- Patients suitable for PD in need of renal replacement therapy/PD “sooner than normally accomplished”, where transplant is not an immediate option, and may not have a ready “plan for dialysis modality”
  - Includes those so uremic/hyperkalemic/volume overloaded/sick that they might need hospitalization for urgent dialysis - possibly HD via temp-cath for a few days vs. acute PD 1st, then transitioned to the outpatient setting either with a PD catheter placed in the hospital, or plans to place PD catheter quickly in the outpatient setting
  - Includes those that can stay as outpatients and need in-center PD i.e. low volume supine exchanges, usually thrice weekly
  - Includes patients that need to start sooner than the standard 2 weeks post catheter placement but might not need in-center PD
RATIONAL FOR URGENT START PERITONEAL DIALYSIS

- Can eliminate or limit the duration of CVCs, thereby decreasing mortality
- Urgent start PD patients tend to have similar long-term clinical outcomes as those started on “regular” PD
- Patients started on Peritoneal Dialysis are more likely to become long-term PD patients than those started on HD, and short-term outcomes are similar between Urgently started PD, and “normally” started PD –Ghaffari et. al.
- Peritoneal Dialysis preserves “vascular real-estate” for future access- especially valuable for younger patients, or those with limited options for vascular access
- Peritoneal dialysis patients costs Medicare on average $20,000 less per year than HD patients
- In the Initially uninsured patient with ESRD, initiating peritoneal dialysis can lead to reimbursement starting with the month PD training is initiated.

![Diagram of risk of bacteremia/hospitalized sepsis](image1)

**Risk of Bacteremia/Hospitalized Sepsis**

- AV Fistula
- PD Catheter
- AV Graft
- Permanent Catheter
- Temporary Catheter

*Results expressed as a hazard ratio, which is the relative risk of developing a bacteremia or hospitalized sepsis episode for a particular catheter compared to an arteriovenous fistula.*

![Graph of catheter event & complication rates for PD vs HD](image2)

**Catheter Event & Complication Rates For PD Versus HD**

**FIRST YEAR DIALYSIS PATIENTS**

- HD Catheter Events
  - Removal
  - Replace w/ catheter
  - Replace w/ internal device
  - Sepsis
- PD Catheter Events
  - Removal
  - Replace with PD catheter
  - Replace with HD catheter
  - Replace with internal HD access
  - Sepsis

![Bar graph of PD vs HD costs](image3)

**PD can offer significantly lower private payer and Medicare overall annual healthcare costs**

- **PD**
  - Medicare: $53,686
  - HD: $72,291
  - Private: $129,997
  - Total: $173,507

*Overall costs include dialysis, access placement, hospitalization, medications etc. PD patients’ median healthcare costs for Private Payers were $43,510 lower for the 12-month period and $18,605 lower for Medicare patients.*
BARRIERS TO URGENT START PERITONEAL DIALYSIS

- Obtaining PD catheters quickly often a barrier as they are usually placed laparoscopically and require OR time, general anesthesia.
- HD catheters are quicker, cheaper
- Hemodialysis in an acutely uremic patient is far more efficient at correcting metabolic derangements than PD
- Familiarity with low volume supine peritoneal dialysis that was once ubiquitous is now not as much.
- In Center PD is not readily available- requires different staffing models and subject to various regulatory conditions.
OVERCOMING BARRIERS TO URGENT START PD

- **Step 1:** Identifying the patient and suitability for PD
  - Involve PD nurse immediately to evaluate the patient, talk to family, perhaps do home visit while patient is still in the hospital
  - Assess manual dexterity and likely compliance with therapy

- **Step 2:** Getting rapid, reliable CAPD catheter placement
  - Percutaneous peritoneoscopic or fluoroscopic catheter placement facility with catheter placed by IN or IR
  - Reliable surgeon who does not mind placing PD catheters urgently and possibly not getting paid for a while, or in some cases, not at all (A Rare bird!)
  - Acute PD catheters that need to be changed out in 2-3 days are largely not needed nowadays.

- **Step 3:** Get Case Management/Social Work/PD nurse/PD unit working on getting the patient admitted to a PD unit ASAP, draw Hepatitis serology and other labs.
  - In Center PD is a separate certification- but in center PD can usually be done under the auspices of training- but the patient must be well enough to actually train.
PERCUTANEOUS PD CATHETER PLACEMENT

- Can be done safely with good long-term patency either by peritoneoscopic or fluoroscopic methods.
- Success rates comparable to (standard) laparoscopic placement in most patients with uncomplicated abdomen.
- Allows the PD catheter to be placed as an outpatient and in many cases can avoid having the patient admitted at all.
- Incidence of peri-catheter leak is low, especially if the deep cuff is sutured at time of insertion.
- Unless you have an extremely willing and altruistic surgeon to help you out, many of us will need to either be able to place a PD catheter fluoroscopically or peritoneoscopically, or find someone (IR/IN) who can do it for them in an expedient manner- at least the outpatient setting.
FLUOROSCOPIC PD CATHETER INSERTION HAS SIMILAR OUTCOMES TO STANDARD LAPAROSCOPIC PLACEMENT.

- Meta-analysis of 13 studies with 2,681 subjects.
- No difference in 1 year catheter survival in percutaneous vs surgical PD catheter placement, or in incidence of catheter dysfunction.
- Incidence of fluid leaks similar in both surgical and percutaneous methods.
- Incidence of peritonitis rates were significantly lower with percutaneous placement.
Rectus sheath is typically whitish and striated
GAIN ENTRY TO PERITONEUM
• After dilating with 10 or 12fr dilator, advance peel-away sheath under direct fluoroscopic guidance.

• Resistance should be MINIMAL to advancement of peel-away sheath.
CAPD catheter is advanced under real-time fluoroscopy with lubricated stylet, and watched uncoil from CAPD catheter. An Additional 500-700cc of heparinized warm saline (500 units/liter) is then instilled...
CATHETER INSERTED
DATA FROM OUR CENTER (SAN ANTONIO) URGENT START PROGRAM

Average Age: 58 +/- 17 (1 STD)

Obese with BMI > 30: 43%
Prior Abdominal Surgery: 43%
Diabetes: 54%
Gender: Female 43%, Male 57%

1 year unassisted catheter survival: 87%
1 year fluoroscopically assisted catheter survival: 94%