ESRD and endoAVF: A giant leap forward

Alison Tan, MD
Thomas Jefferson University

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ESRD and endoAVF
A giant leap forward

Allison Tan, MD
Assistant Professor of Radiology, Interventional Radiology
Thomas Jefferson University Hospital
July 29, 2020
Disclosures

- No financial disclosures
Chronic Kidney Disease (CKD)

- > 3 months of renal dysfunction
  - Albuminuria
  - Urine sediment abnormalities
  - Electrolyte abnormalities
  - Histologic abnormalities
  - Imaging structural abnormalities
  - Prior renal transplant

Most Common Comorbidities
Diabetes Mellitus
Cardiovascular Disease
<table>
<thead>
<tr>
<th>Stages of Chronic Kidney Disease</th>
<th>GFR*</th>
<th>% of Kidney Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>90 or higher</td>
<td>90-100%</td>
</tr>
<tr>
<td>Kidney damage with <strong>normal</strong> kidney function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 2</td>
<td>89 to 60</td>
<td>89-60%</td>
</tr>
<tr>
<td>Kidney damage with <strong>mild loss</strong> of kidney function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 3a</td>
<td>59 to 45</td>
<td>59-45%</td>
</tr>
<tr>
<td><strong>Mild to moderate</strong> loss of kidney function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 3b</td>
<td>44 to 30</td>
<td>44-30%</td>
</tr>
<tr>
<td><strong>Moderate to severe</strong> loss of kidney function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 4</td>
<td>29 to 15</td>
<td>29-15%</td>
</tr>
<tr>
<td><strong>Severe</strong> loss of kidney function</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 5</td>
<td>Less than 15</td>
<td>Less than 15%</td>
</tr>
<tr>
<td>Kidney <strong>failure</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
• When is dialysis initiated?
  • Signs and symptoms of uremia and volume overload

<table>
<thead>
<tr>
<th>Absolute Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Encephalopathy*</td>
</tr>
<tr>
<td>Pericarditis*</td>
</tr>
<tr>
<td>Pleuritis*</td>
</tr>
<tr>
<td>Declining nutrition</td>
</tr>
<tr>
<td>Refractory volume overload</td>
</tr>
<tr>
<td>Fatigue and malaise</td>
</tr>
<tr>
<td>Mild cognitive impairment</td>
</tr>
<tr>
<td>Refractory acidosis, hyperK+, hyperphos</td>
</tr>
</tbody>
</table>

*absolute indications
Data Source: Special analyses, USRDS ESRD Database. The special analyses exclude US territories, unknown age, and unknown/other races. Standardized to the age-sex-race distribution of the 2011 US population.

Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 US population.
Renal replacement therapy

ESRD

Dialysis

Transplant

Hemo-

Peritoneal

Catheter

Fistula

Graft
Renal replacement therapy

- ESRD
  - Dialysis
    - Hemo-
      - Catheter
    - Peritoneal
      - Fistula
      - Graft
  - Transplant
Renal replacement therapy - Transplant

Data Source: Reference Table D.1 and special analysis of USRDS ESRD Database.
Abbreviation: ESRD, end-stage renal disease.
### PREVALENT ESRD

<table>
<thead>
<tr>
<th>Age</th>
<th>Total</th>
<th>HD N</th>
<th>HD %</th>
<th>PD N</th>
<th>PD %</th>
<th>Transplant N</th>
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</tr>
</thead>
<tbody>
<tr>
<td>0-21</td>
<td>9,667</td>
<td>1,608</td>
<td>16.6</td>
<td>977</td>
<td>10.1</td>
<td>7,082</td>
<td>73.3</td>
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<tr>
<td>22-44</td>
<td>103,821</td>
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<td>9,124</td>
<td>8.8</td>
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<td>65-74</td>
<td>184,582</td>
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Data Source: Reference Table D.10 and special analyses, USRDS ESRD Database.
Renal replacement therapy

- ESRD
  - Dialysis
  - Transplant
    - Hemo-
      - Catheter
    - Peritoneal
      - Fistula
      - Graft
Peritoneal Dialysis

- 200,000 patients worldwide
- Given an informed choice, 50% of patients will choose PD first
Renal replacement therapy - PD

Data Source: Reference Table D.10 and special analyses, USRDS ESRD Database. The numbers in this table exclude "Uncertain Dialysis."

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Peritoneal Dialysis
Peritoneal Dialysis

- Falciform ligament
- Liver
- Anterior
- Visceral peritoneum
- Peritoneal cavity (with serous fluid)
- Stomach
- Kidney (retroperitoneal)
- Wall of body trunk
- Parietal peritoneum
- Posterior
Peritoneal Membrane

Peritoneal Space

Mesothelial Cell Layer

Interstitial Matrix

Capillary
• Peritoneal capillary is critical barrier to solute and water transport
  • BF ~ 50-100 mL/min
Peritoneal Capillary

RBC 6-8 μm
(6000-8000 nm)

Capillary Space
- Intercellular Cleft
- Intercellular Gap

Peritoneal Space
- 4-6 nm (numerous)
- >20 nm (1 gap: 10,000 clefts)

Transcellular Transport
- 0.4 - 0.6 nm (numerous)
Methods of Peritoneal Clearance

- Diffusion (solute)
- Ultrafiltration (water)
- Convection (solute)
Methods of Peritoneal Clearance

- Diffusion (solutes)
  - Solutes travel down a concentration gradient
  - Via small and large pores
- Ultrafiltration (water)
- Convection (solutes)
Methods of Peritoneal Clearance

- **Diffusion (solute)**
- **Ultrafiltration (water)**
  - H2O movement due to differences in osmotic pressure
  - Via small pores, large pores, and aquaporins
- **Convection (solute)**
Methods of Peritoneal Clearance

- Diffusion (solute)
- Ultrafiltration (water)
- Convection (solute)
  - “Solvent drag”
  - As H2O moves, other solutes move too
  - Independent of solute concentration gradients
Who places PD catheters?

Surgeon → Laparoscopy

Interventional Radiology → Fluoroscopic + US Guidance

Interventional Nephrology → US Guidance
Technique for IR placement
Technique for IR placement

- Anterior (Superficial)
- Rectus sheath
- Anterior portion
- Posterior portion
- Rectus abdominis
- Peritoneal cavity
- Tranversalis fascia

- Posterior (Deep)

- Linea semilunaris
- Rectus sheath (anterior portion)
- Rectus abdominis
- Linea alba
- Transversalis fascia
- External oblique
- Internal oblique

Philadelphia University + Thomas Jefferson University
Technique for IR placement
Technique for IR placement
Technique for IR placement
Technique for IR placement
Peritoneal Dialysis Prescriptions

• Continuous Ambulatory Peritoneal Dialysis (CAPD)
  • No machine needed
  • 24/7
Types of PD Rx

- Automated Peritoneal Dialysis (APD)
- Continuous Cycling Peritoneal Dialysis (CCPD)
- Machine run cycles
- 7 d/wk
Renal replacement therapy

ESRD

Dialysis

Hemo-

Catheter

Fistula

Graft

Peritoneal

Transplant
Renal replacement therapy

Data Source: Reference Table D.1 and special analysis of USRDS ESRD Database.
## Renal replacement therapy

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Renal replacement therapy

ESRD

Dialysis

Hemo-

Catheter

Fistula

Graft

Peritoneal

Transplant
Catheter-Based Hemodialysis

• Benefits
  • Rapid start
  • Quick and easy to place
  • Functional
  • Easily removed if renal recovery
  • Multiple placement options
Catheter-Based Hemodialysis

- Negatives
  - High associated morbidity and mortality
    - Infection
    - Hospitalization
    - Death
  - Accelerated vascular injury → lost access
Vascular access use at HD initiation

Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2005-2017.
Data Source: Special analyses, USRDS ESRD Database. Data from January 1, 2014 to May 30, 2017: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N = 104,102).
Data Source: Special analyses, USRDS ESRD Database. Data from January 1, 2014 to May 30, 2017: (a) Medical Evidence form (CMS 2728) at initiation and CROWNWeb for subsequent time periods. (b) ESRD patients initiating hemodialysis (N =104,102).
Goal: 66% national prevalent AVF use
- Resulted in a steady increase in the prevalence of AVF
  - 32% (2003) → 63% (2014)

Goal: reduce long-term tunneled catheter use
- Not including bridging catheters
- Has not been as successful

AVFs associated with lowest morbidity
- Higher primary patency
- Lower risk of infection
- Better durability
- Lower associated mortality
- Require fewer interventions

Grafts have their place
- Comparable secondary patency rates
- Potentially a better option in older patients
Renal replacement therapy

ESRD

Dialysis

Hemo-

Catheter

Fistula

Graft

Transplant

Peritoneal
Fistula versus Graft

**AV FISTULA**

- From the dialysis machine
- To the dialysis machine
- AV Fistula

**AV GRAFT**

- Artery
- Vein
- Synthetic bridge graft
- Blood to dialysis machine
- Blood from dialysis machine
Graft material

PTFE

DACRON

A: DACRON: https://digital.sciencehistory.org/works/1c18dg840
Graft material

Renal replacement therapy

ESRD

Dialysis

Hemo-

Catheter

Fistula

Graft

Transplant

Peritoneal
Poor maturation of surgical AVFs

  - Randomized, double-blind, placebo controlled, multicenter study
  - Of 758 patients, 60% of fistulas failed to be suitable for HD

  - Observational cohort study
  - USRDS Medicare claims data
  - 54.7% of fistulas used within 4 months of creation

- **Hemodialysis Fistula Maturation Study**
  - 602 AVFs
  - 43.7% matured unaided
  - 27.6% matured with intervention
  - 22.1% failed maturation completely
Technical factors

• Disruption of the vasa vasorum
• Torque and tension on the mobilized vessel
• Healing suture anastomoses can lead to scarring, intimal hyperplasia, and stenosis
Technical factors

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Renal replacement therapy

- ESRD
  - Dialysis
  - Transplant
    - Hemo-
      - Catheter
      - Fistula
    - Peritoneal
      - Graft
Traumatic AVFs
Deep vessels

- Brachial artery + vein
- Radial artery + vein
- Ulnar artery + vein
- Interosseous artery + vein
Superficial veins

- Basilic vein
- Cephalic vein
- Median cubital vein
- Brachial artery + paired veins
- Ulnar artery + paired veins
- Radial artery + paired veins
- Interosseous artery + paired veins
- Perforating vein
Perforating vein
Perforating vein
Percutaneous AVF devices

WAVELINQ™ 4F EndoAVF System

ELLIPSY®
Percutaneous AVF devices - Ellipsys
Percutaneous AVF devices - Ellipsys
Percutaneous AVF devices - Ellipsys
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Percutaneous AVF devices - Ellipsys
Percutaneous AVF devices - Ellipsys
Percutaneous AVF devices - Comparison

- Post balloon angioplasty to 5 mm
- Immediate tissue fusion
<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Device</th>
<th># pts</th>
<th>Technical success</th>
<th>Maturation 90d</th>
<th>Median time to maturation</th>
<th>Mean time to 2 needle cann</th>
<th>Patency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hull (2017)</td>
<td>E</td>
<td>107</td>
<td>95%</td>
<td>86%</td>
<td></td>
<td>114.3 d</td>
<td>86.7% for 24m, cum</td>
</tr>
<tr>
<td>Hebibi (2019)</td>
<td>E</td>
<td>34</td>
<td>97%</td>
<td>82%</td>
<td>(10d-6w)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mallios (2019)</td>
<td>E</td>
<td>34</td>
<td>97%</td>
<td></td>
<td></td>
<td></td>
<td>82% for prim, 94% sec</td>
</tr>
<tr>
<td>Beathard (2019)</td>
<td>E</td>
<td>105</td>
<td>Unkwn</td>
<td>100%</td>
<td></td>
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</tr>
<tr>
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<td>Device</td>
<td># pts</td>
<td>Intervention rate (ppy)</td>
<td>Major adverse event rate</td>
<td>Adverse events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>--------</td>
<td>-------</td>
<td>-------------------------</td>
<td>--------------------------</td>
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<tr>
<td>Hull (2017)</td>
<td>E</td>
<td>107</td>
<td>2.7</td>
<td>many</td>
<td>thrombosis, anast stenosis, steal, ven HTN, coil mig, vein rupture, neuropathy</td>
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<td></td>
</tr>
<tr>
<td>Hebibi (2019)</td>
<td>E</td>
<td>34</td>
<td>35%</td>
<td>--</td>
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<tr>
<td>Mallios (2019)</td>
<td>E</td>
<td>34</td>
<td>2.9%</td>
<td>0%</td>
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<td>E</td>
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Percutaneous AVF devices
Percutaneous AVF devices - WavelinQ
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Artery

Vein
Percutaneous AVF devices - WavelinQ
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Percutaneous AVF devices - WavelinQ
Post AVF creation
Percutaneous AVF devices
Pre AVF creation
Post AVF creation

Percutaneous AVF devices

Cephalic vein

Perforator

Artery

endoAVF
Percutaneous AVF devices - Comparison

- Post balloon angioplasty to 5 mm
- Immediate tissue fusion

- Coil 1 brachial vein
- Endothelialized tract ~30d (48h)
Percutaneous AVF devices - WavelinQ
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<tr>
<td>Rajan (2015)</td>
<td>W</td>
<td>33</td>
<td>97%</td>
<td>96%</td>
<td>58 d (37-168 d)</td>
<td>--</td>
<td>96% 6m</td>
<td>100%</td>
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<tr>
<td>Lok (2017)</td>
<td>W</td>
<td>60</td>
<td>98%</td>
<td>87%</td>
<td>--</td>
<td>111.8 d HD</td>
<td>84% 12m, cum</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>32.4 d nonHD</td>
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<tr>
<td>Radosa (2017)</td>
<td>W</td>
<td>8</td>
<td>100%</td>
<td>86%</td>
<td>63 d (26-137 d)</td>
<td>--</td>
<td>100% 6m</td>
<td>100%</td>
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<td>Berland (2019)</td>
<td>W</td>
<td>32</td>
<td>100%</td>
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<td>43 ± 14 d</td>
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<td>Rajan (2015)</td>
<td>W</td>
<td>33</td>
<td>0.1-0.6</td>
<td>3% (1)</td>
<td>brachial artery PSA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lok (2017)</td>
<td>W</td>
<td>60</td>
<td>0.46</td>
<td>8% (5)</td>
<td>closure device embo, brach art dissection and thrombus, PSA (access site, endoAVF site), steal syndrome</td>
<td></td>
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</tr>
<tr>
<td>Radosa (2017)</td>
<td>W</td>
<td>8</td>
<td>0.12</td>
<td>0%</td>
<td>--</td>
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<td></td>
</tr>
<tr>
<td>Berland (2019)</td>
<td>W</td>
<td>32</td>
<td>0.21</td>
<td>3% (1)</td>
<td>guidewire perf tx’d w/ stenting</td>
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</tr>
<tr>
<td>Hull (2017)</td>
<td>E</td>
<td>107</td>
<td>2.7</td>
<td>many</td>
<td>thrombosis, anast stenosis, steal, ven HTN, coil mig, vein rupture, neuropathy</td>
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<td></td>
</tr>
<tr>
<td>Hebibi (2019)</td>
<td>E</td>
<td>34</td>
<td>35%</td>
<td>--</td>
<td>--</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Mallios (2019)</td>
<td>E</td>
<td>34</td>
<td>2.9%</td>
<td>0%</td>
<td>--</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Beathard (2019)</td>
<td>E</td>
<td>105</td>
<td>--</td>
<td>--</td>
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</tr>
</tbody>
</table>
  - Meta analysis
  - WavelinQ and Ellipsys
  - 300 patients

<table>
<thead>
<tr>
<th></th>
<th>WavelinQ</th>
<th>Ellipsys</th>
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</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>99.45%</td>
<td>95.19%</td>
</tr>
<tr>
<td>90 d maturation</td>
<td>89.27%</td>
<td>89.35%</td>
</tr>
<tr>
<td>6 mo patency</td>
<td>85.71%</td>
<td>90.98%</td>
</tr>
<tr>
<td>Procedure AE</td>
<td>8.59%</td>
<td>2.48%</td>
</tr>
</tbody>
</table>

Maturation →
Diameter ≥4 mm
Flow rate: ≥500 mL/min
### Candidates for pAVF

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ Perforator vein</td>
</tr>
<tr>
<td>No prior upper arm AVF creation</td>
</tr>
<tr>
<td>No flow limiting central stenosis</td>
</tr>
<tr>
<td>Vessel size at target creation site ≥ 2 mm</td>
</tr>
<tr>
<td>No significant arterial calcification</td>
</tr>
<tr>
<td>Conscious sedation candidate</td>
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</tbody>
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</tr>
</tbody>
</table>
Renal replacement therapy

ESRD

Dialysis

Transplant

Hemo-

Peritoneal

Catheter

Fistula

Graft

Surgical

Percutaneous
<table>
<thead>
<tr>
<th>Author (Year)</th>
<th># pts</th>
<th>Technical success</th>
<th>Maturation 90d</th>
<th>Median time to maturation</th>
<th>Mean time to 2 needle cann</th>
<th>Patency</th>
<th>Use for &gt;75% of sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rajan (2015)</td>
<td>33</td>
<td>97%</td>
<td>96%</td>
<td>58 d (37-168 d)</td>
<td>--</td>
<td>96% 6m</td>
<td>100%</td>
</tr>
<tr>
<td>Lok (2017)</td>
<td>60</td>
<td>98%</td>
<td>87%</td>
<td>--</td>
<td>111.8 d <strong>HD</strong></td>
<td>69% 12m, primary</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>32.4 d <strong>nonHD</strong></td>
<td>84% 12m, cum</td>
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</tr>
<tr>
<td>Radosa (2017)</td>
<td>8</td>
<td>100%</td>
<td>86%</td>
<td>63 d (26-137 d)</td>
<td>--</td>
<td>100% 6m</td>
<td>100%</td>
</tr>
<tr>
<td>Berland (2019)</td>
<td>32</td>
<td>100%</td>
<td>91%</td>
<td>--</td>
<td>43 + 14 d</td>
<td>87% 6m, cum</td>
<td>74%</td>
</tr>
<tr>
<td>Surgical AVFs</td>
<td>--</td>
<td>93%</td>
<td>40-80%</td>
<td>159 d (77-285 d)</td>
<td>60% 12m, primary</td>
<td>71% 12m, cum</td>
<td></td>
</tr>
<tr>
<td>Author (Year)</td>
<td># pts</td>
<td>Major adverse event rate</td>
<td>Intervention rate (ppy)</td>
<td>Interventions needed</td>
<td></td>
<td></td>
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<tr>
<td>Surgical AVFs</td>
<td>--</td>
<td>--</td>
<td>1.5-3.3</td>
<td>Superficialization, angioplasty, stenting, revision, conversion to AVG, Steal syndrome, tributary ligation, thrombectomy, etc</td>
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</tbody>
</table>