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ESRD and endoAVF: A giant leap forward

Alison Tan, MD
Thomas Jefferson University

Jefferson
Philadelphia University + Thomas Jefferson University

ESRD and endoAVF

A giant leap forward

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

Disclosures

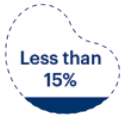
- No financial disclosures

- > 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

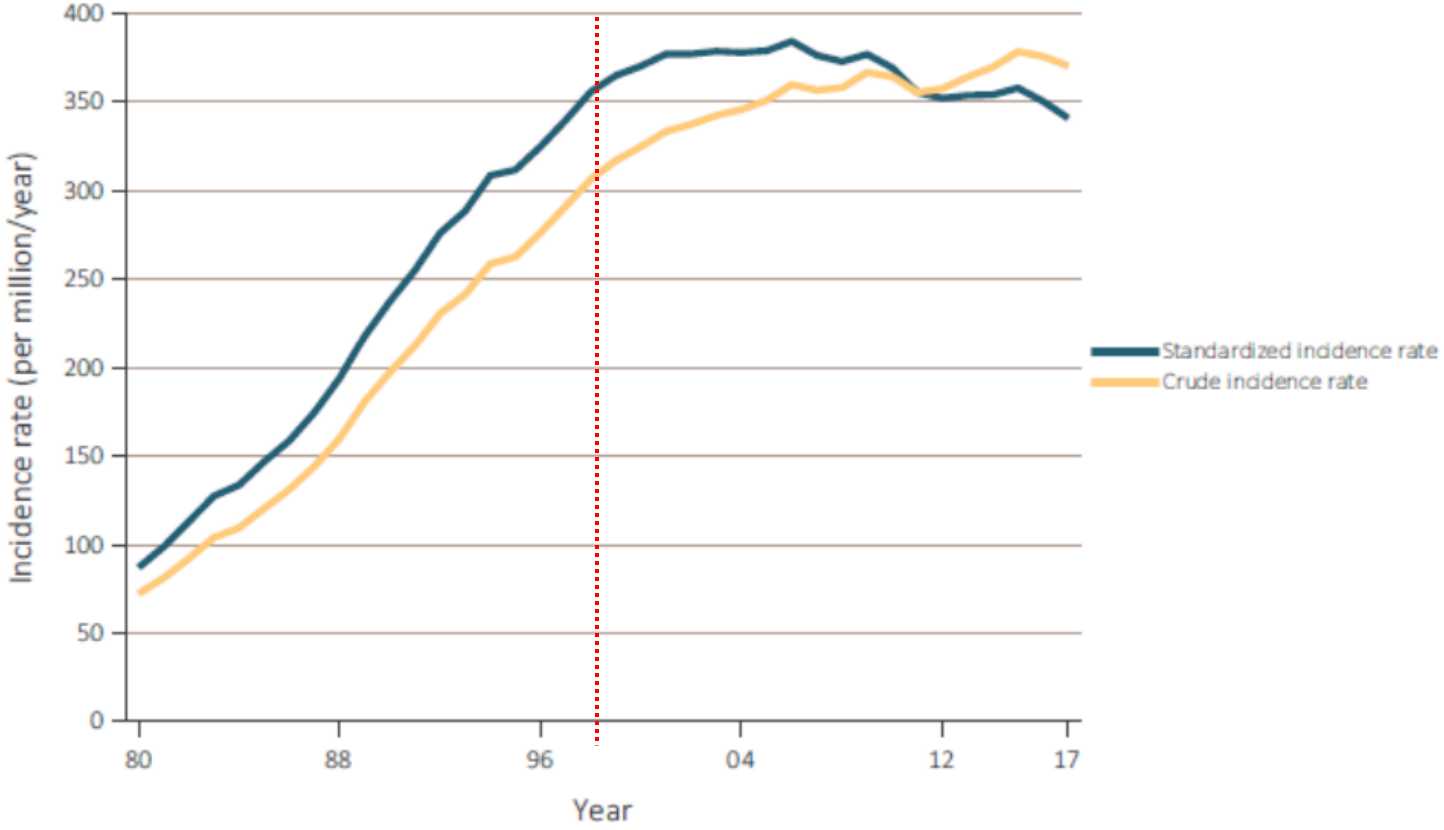
STAGES OF CHRONIC KIDNEY DISEASE		GFR*	% OF KIDNEY FUNCTION
Stage 1	Kidney damage with **normal** kidney function	90 or higher	
Stage 2	Kidney damage with **mild loss** of kidney function	89 to 60	
Stage 3a	**Mild to moderate** loss of kidney function	59 to 45	
Stage 3b	**Moderate to severe** loss of kidney function	44 to 30	
Stage 4	**Severe** loss of kidney function	29 to 15	
Stage 5	Kidney **failure**	Less than 15	

- When is dialysis initiated?
  - Signs and symptoms of **uremia** and **volume overload**

Encephalopathy*
Pericarditis*
Pleuritis*
Declining nutrition
Refractory volume overload
Fatigue and malaise
Mild cognitive impairment
Refractory acidosis, hyperK+, hyperphos

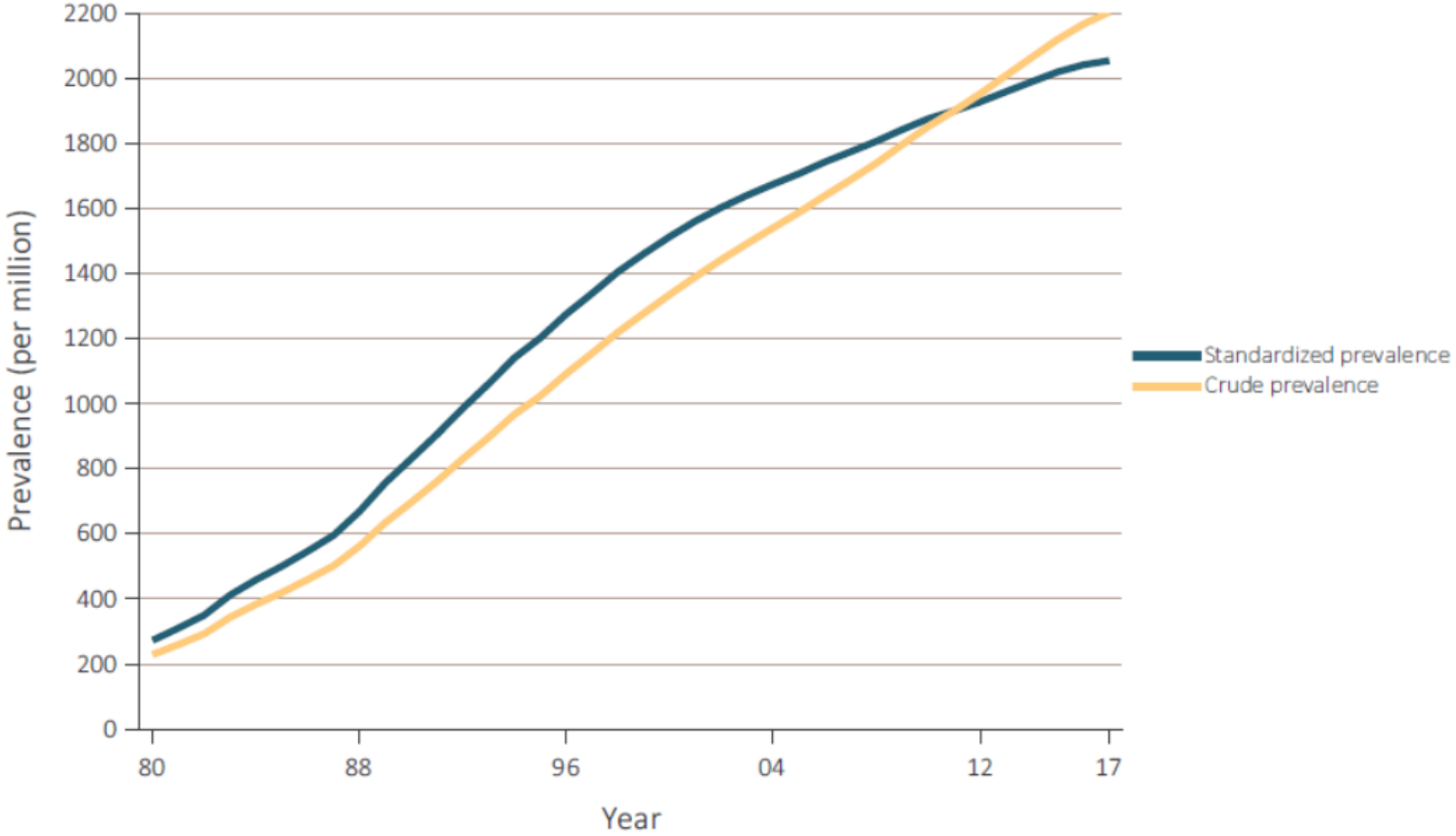
*absolute indications

Incidence of ESRD in US (1980-2016)



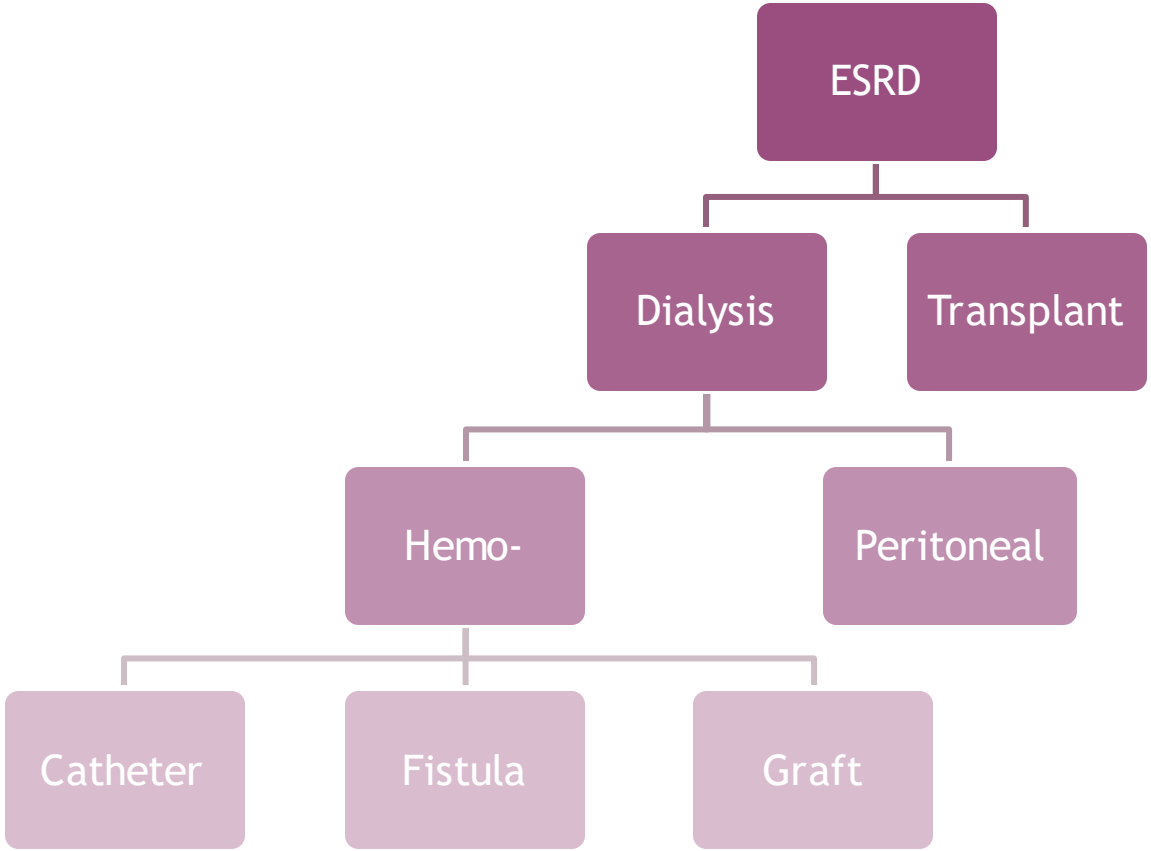
Data Source: Special analyses, USRDS ESRD Database. The special analyses exclude US territories, unknown age, and unknown/other races. Standardized to the age-sex-race distribution of the 2011 US population.

Prevalence of ESRD in US (1980-2016)

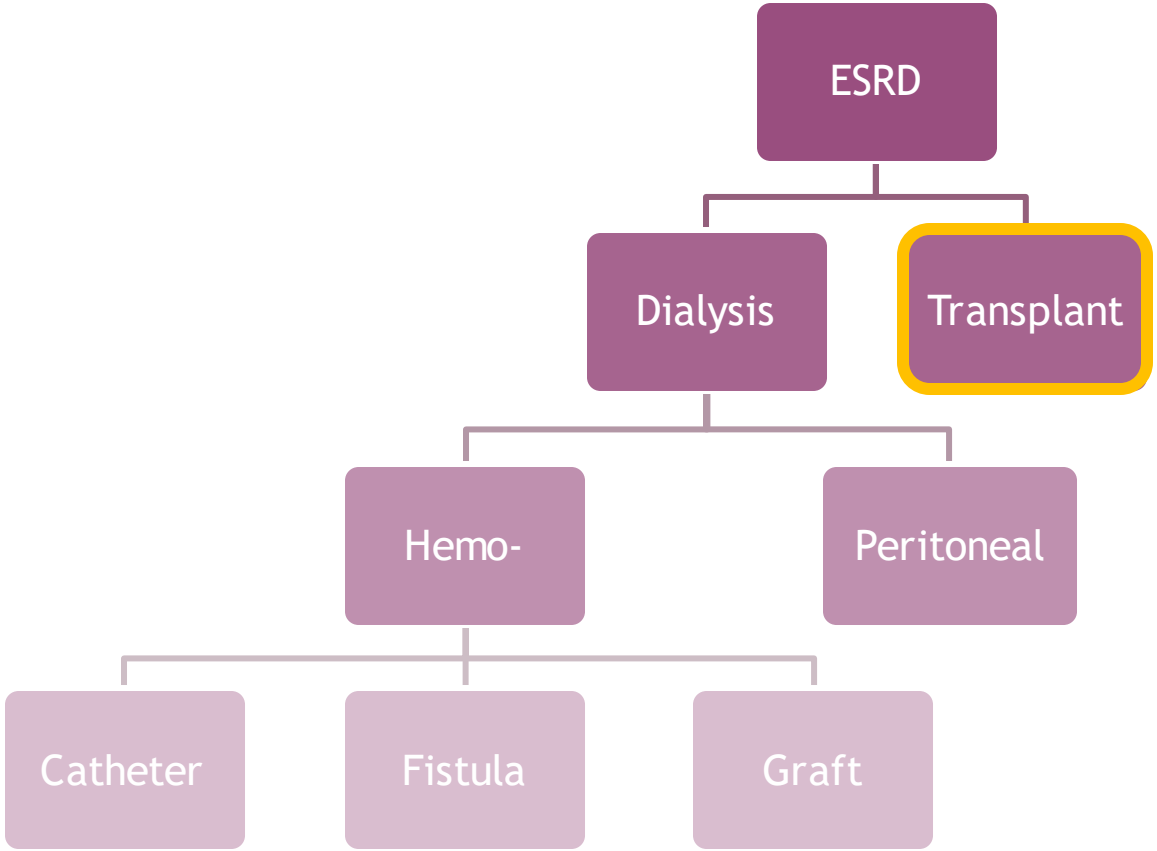


Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 US population.

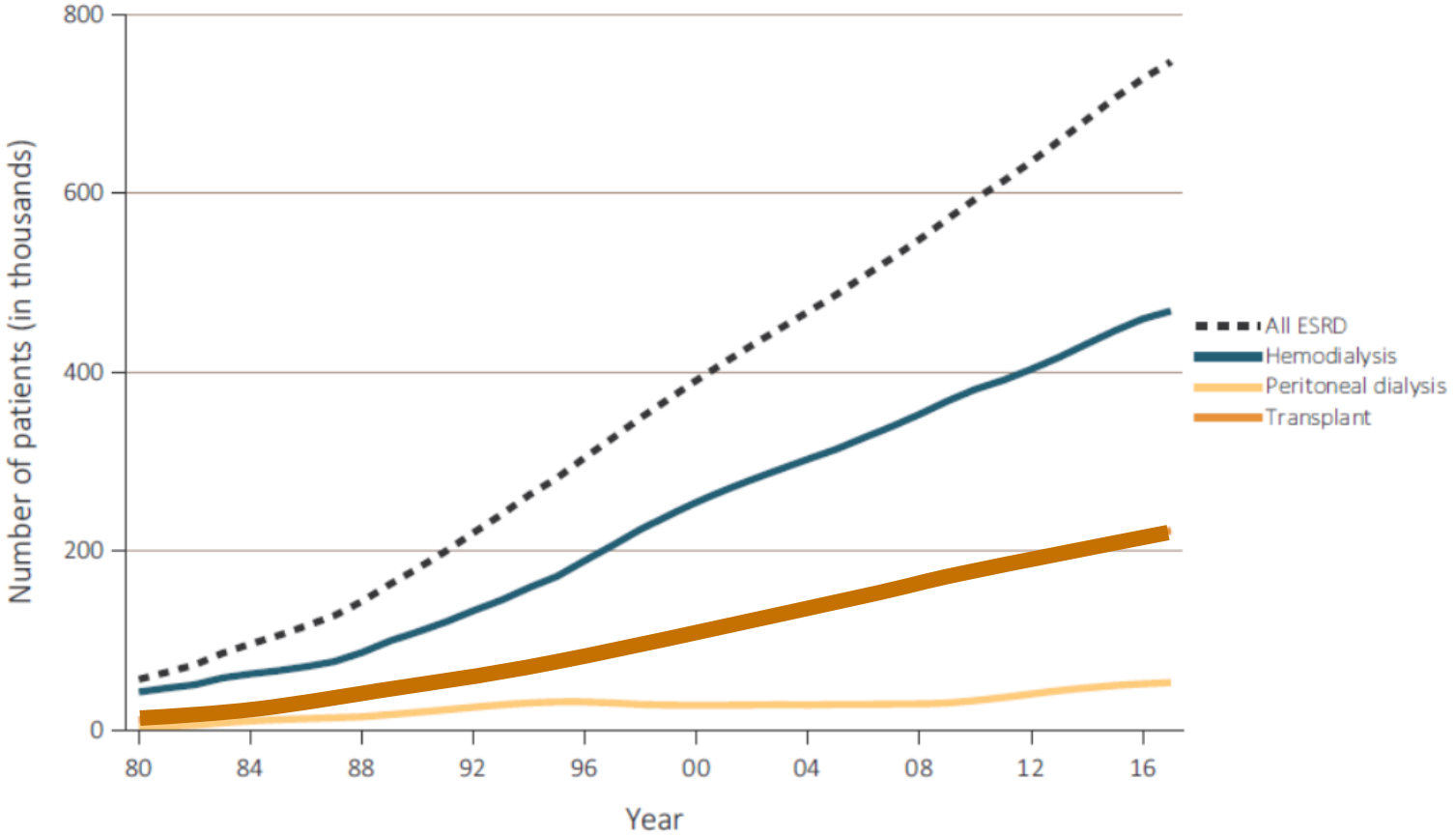
Renal replacement therapy



Renal replacement therapy



Renal replacement therapy - Transplant



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

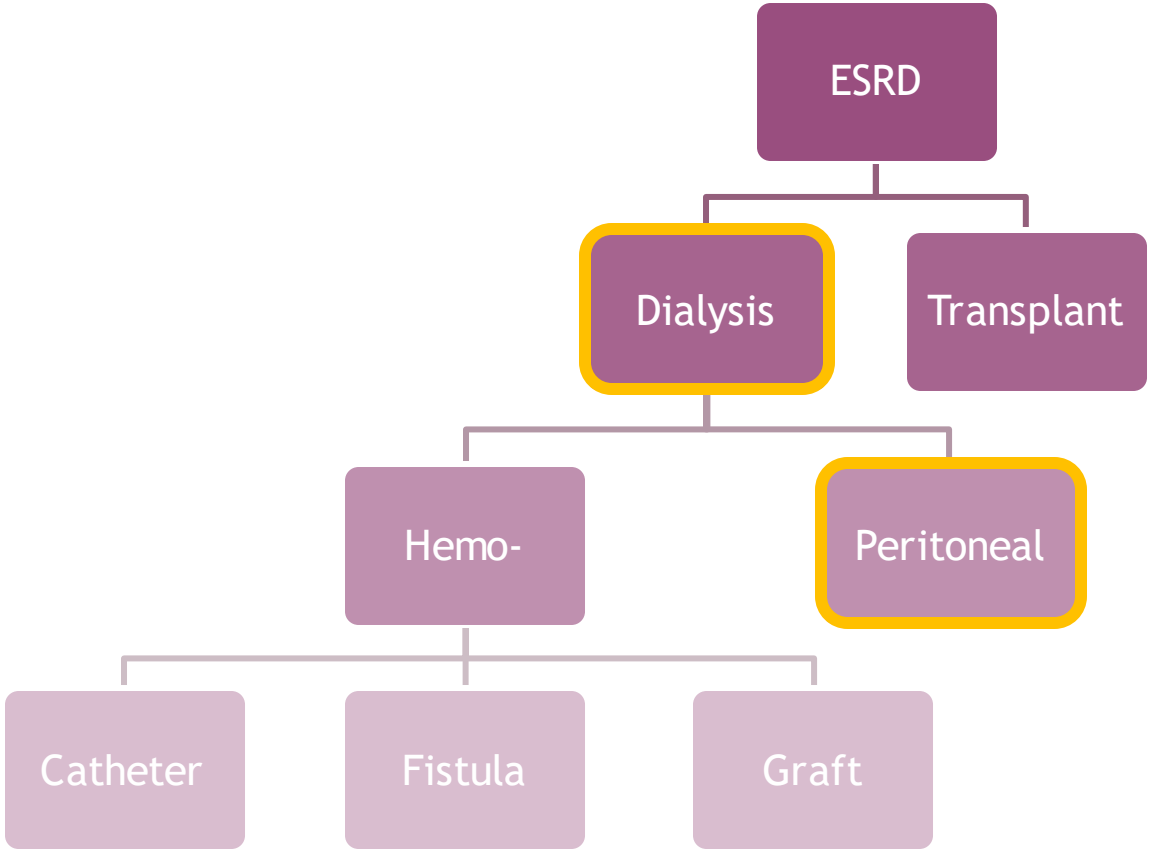
Renal replacement therapy - Transplant

PREVALENT ESRD

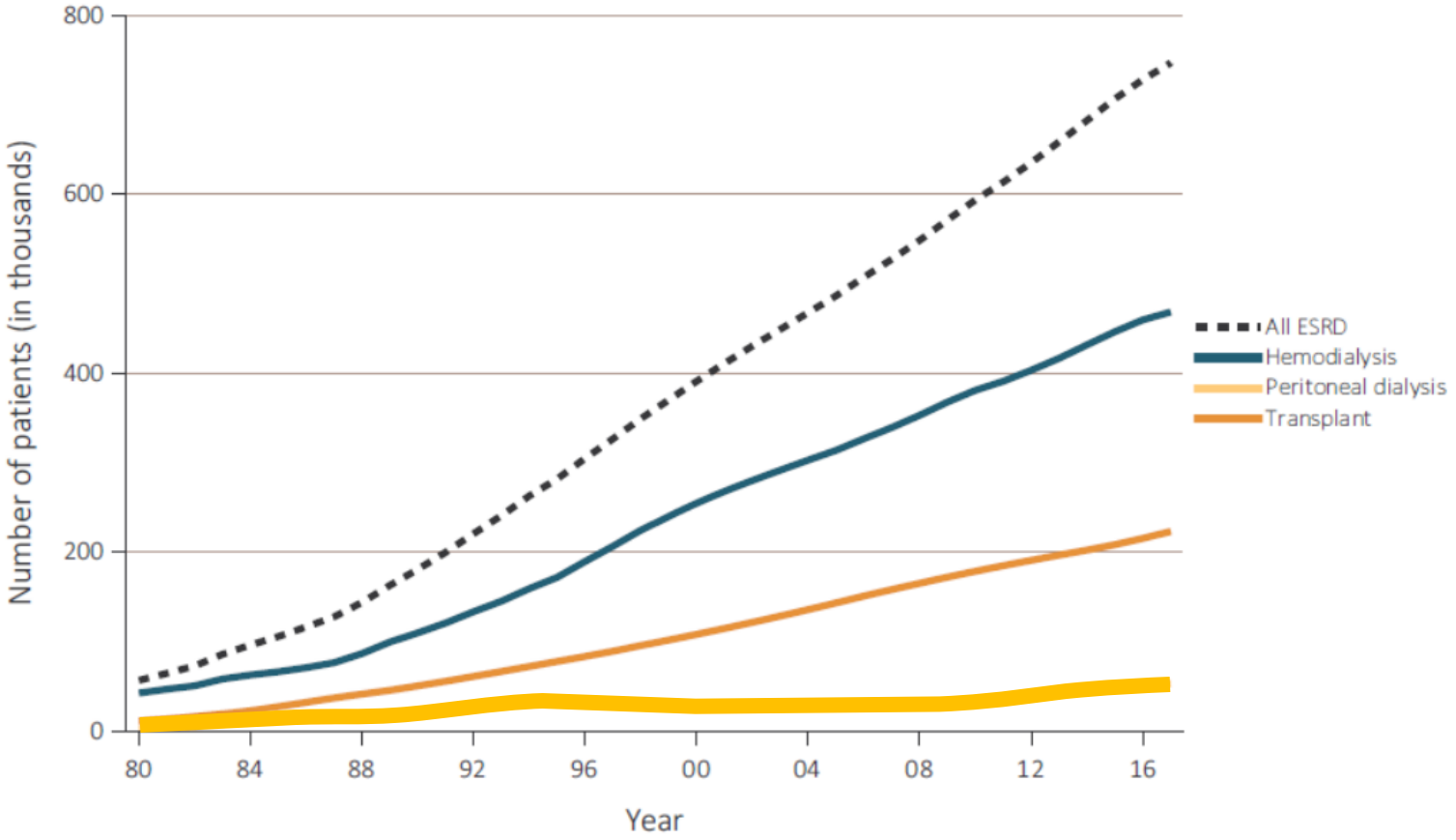
	Total	HD		PD		Transplant	
		N	%	N	%	N	%
Age							
0-21	9,667	1,608	16.6	977	10.1	7,082	73.3
22-44	103,821	50,835	49.0	9,124	8.8	43,862	42.2
45-64	321,810	190,655	59.2	22,899	7.1	108,256	33.6
65-74	184,582	123,915	67.1	12,293	6.7	48,374	26.2
75+	123,794	101,094	81.7	7,426	6.0	15,274	12.3

Data Source: Reference Table D.10 and special analyses, USRDS ESRD Database.

Renal replacement therapy



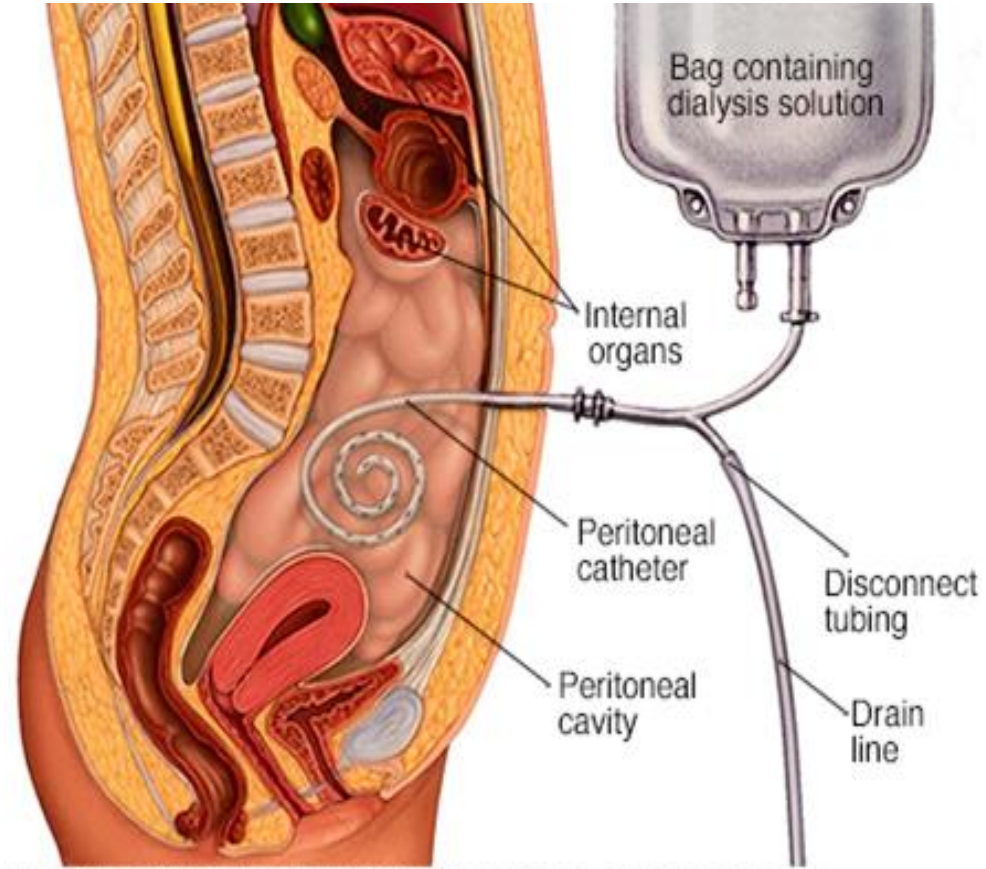
Renal replacement therapy – PD

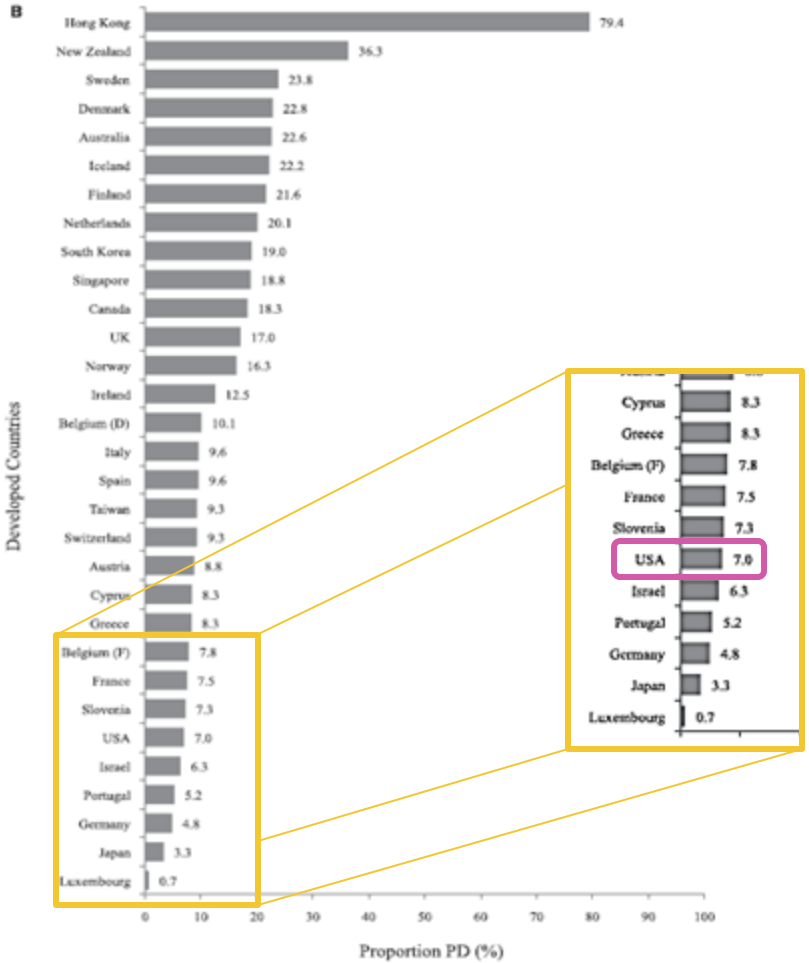


USRDS ESRD Database (2019) Reference Table D.1

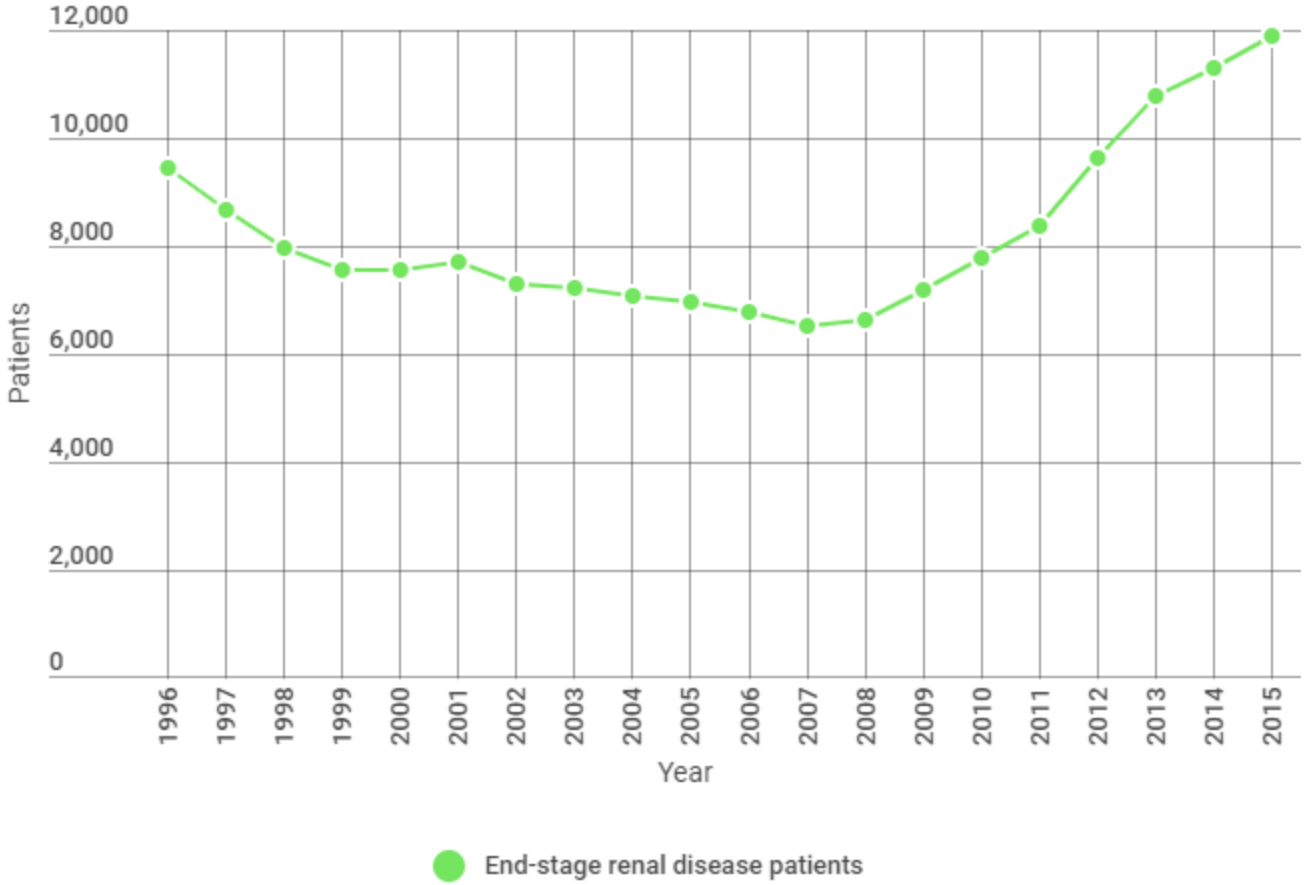
Peritoneal Dialysis

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





Jain AK, Blake P, Cordy P, Garg AX. Global trends in rates of peritoneal dialysis. J Am Soc Nephrol. 2012;23(3):533-544. doi:10.1681/ASN.2011060607


12,000
10,000
8,000
6,000
4,000
2,000
0
Patients
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
Year
End-stage renal disease patients

Renal replacement therapy - PD

PREVALENT ESRD

	Total	HD		PD		Transplant	
		N	%	N	%	N	%
Age							
0-21	9,667	1,608	16.6	977	10.1	7,082	73.3
22-44	103,821	50,835	49.0	9,124	8.8	43,862	42.2
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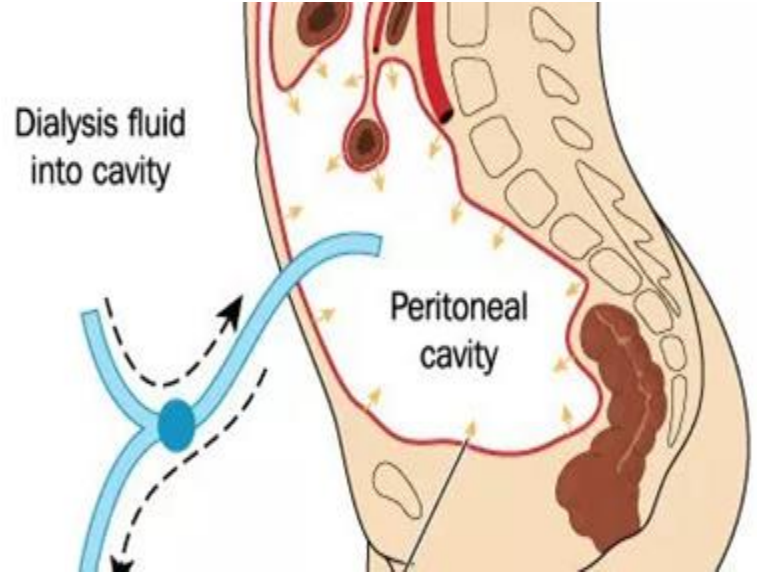
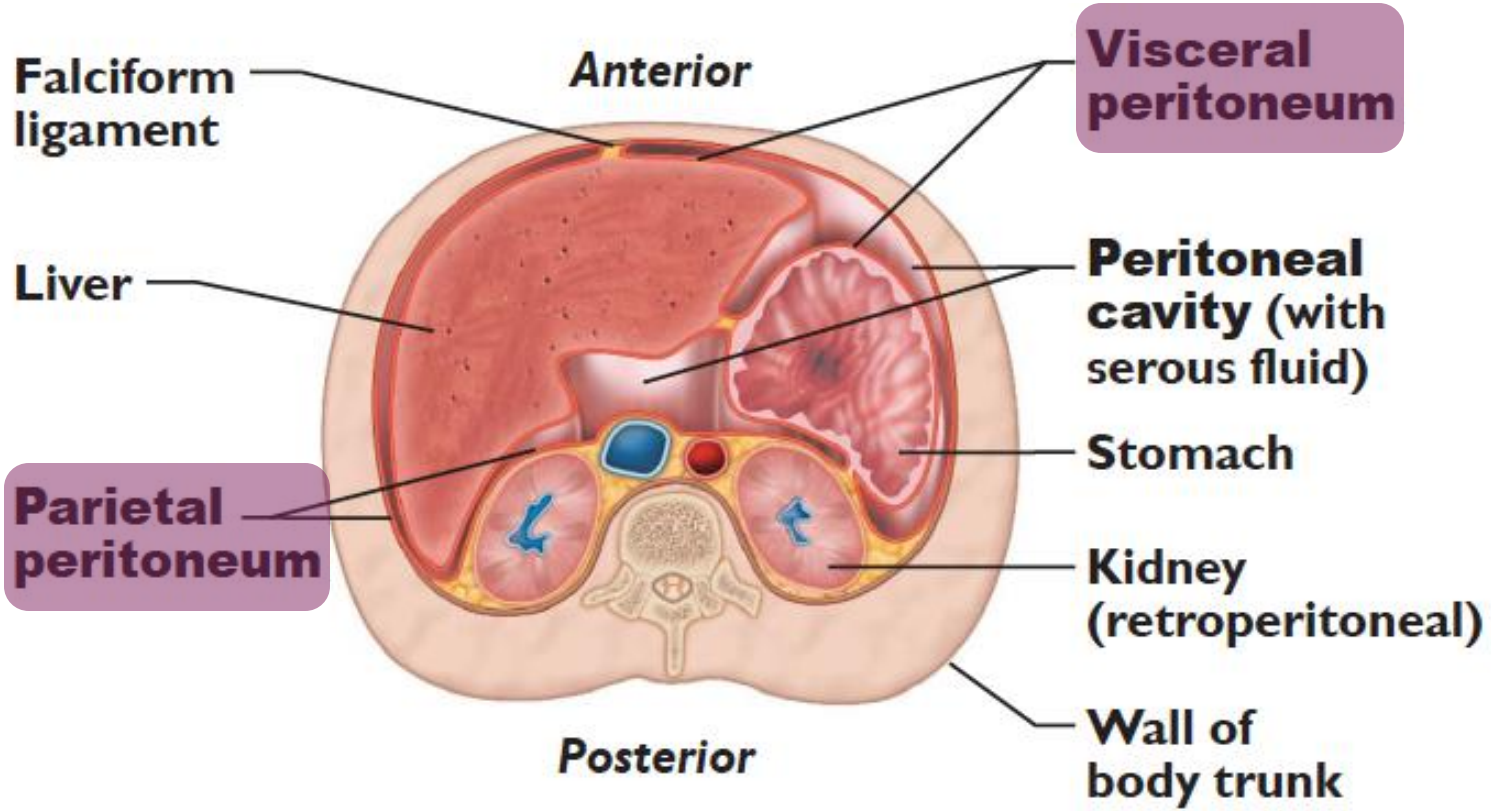
75+	123,794	101,094	81.7	7,426	6.0	15,274	12.3

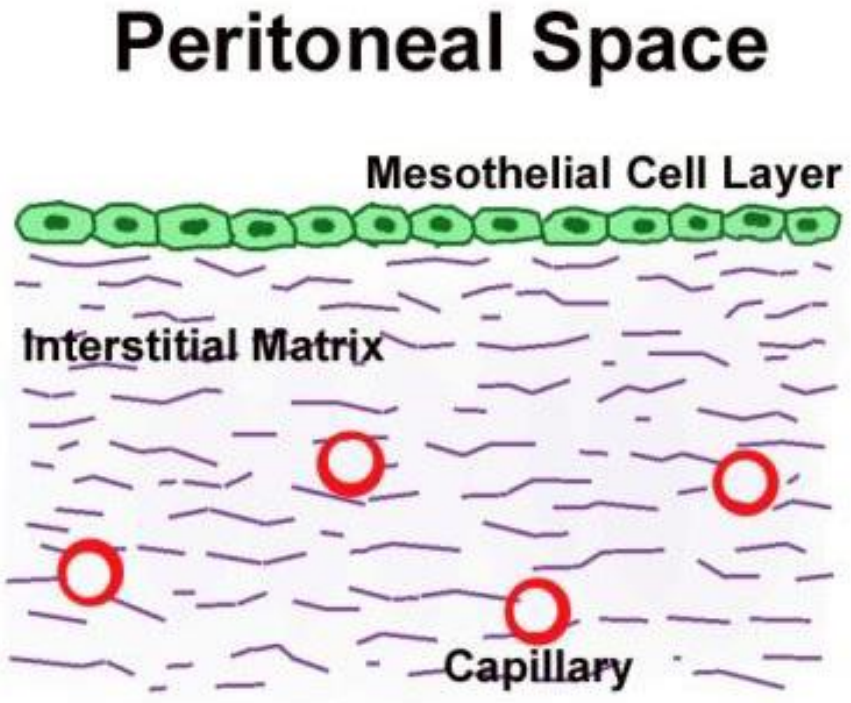
Data Source: Reference Table D.10 and special analyses, USRDS ESRD Database. The numbers in this table exclude "Uncertain Dialysis."

Peritoneal Dialysis

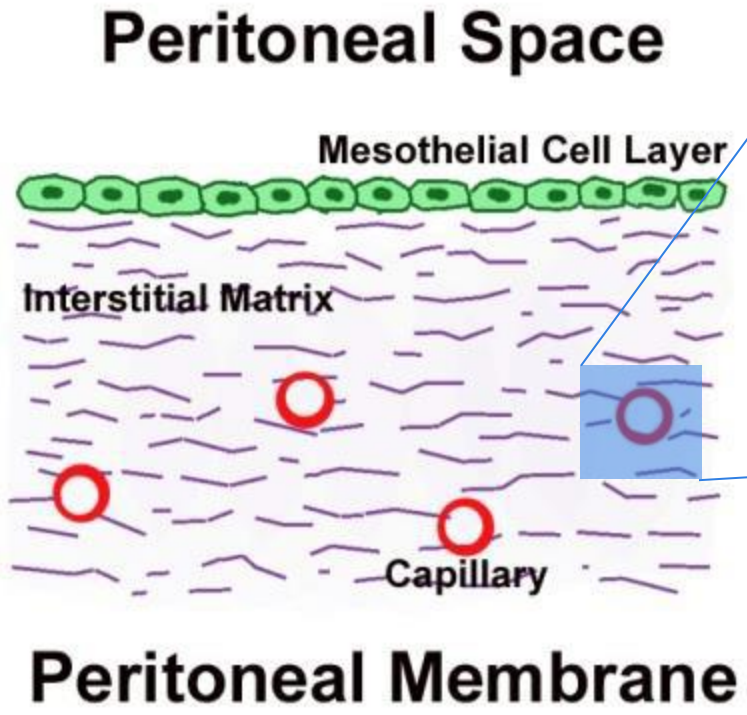


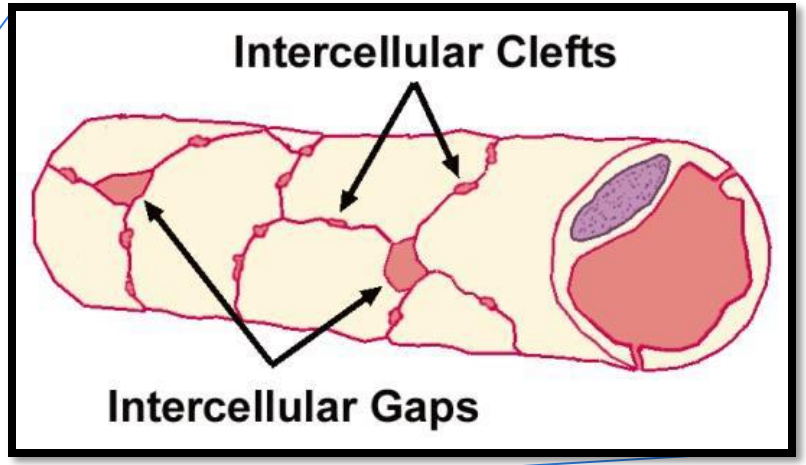
Peritoneal Dialysis




Peritoneal Space
Mesothelial Cell Layer
Interstitial Matrix
Capillary

Peritoneal Capillary

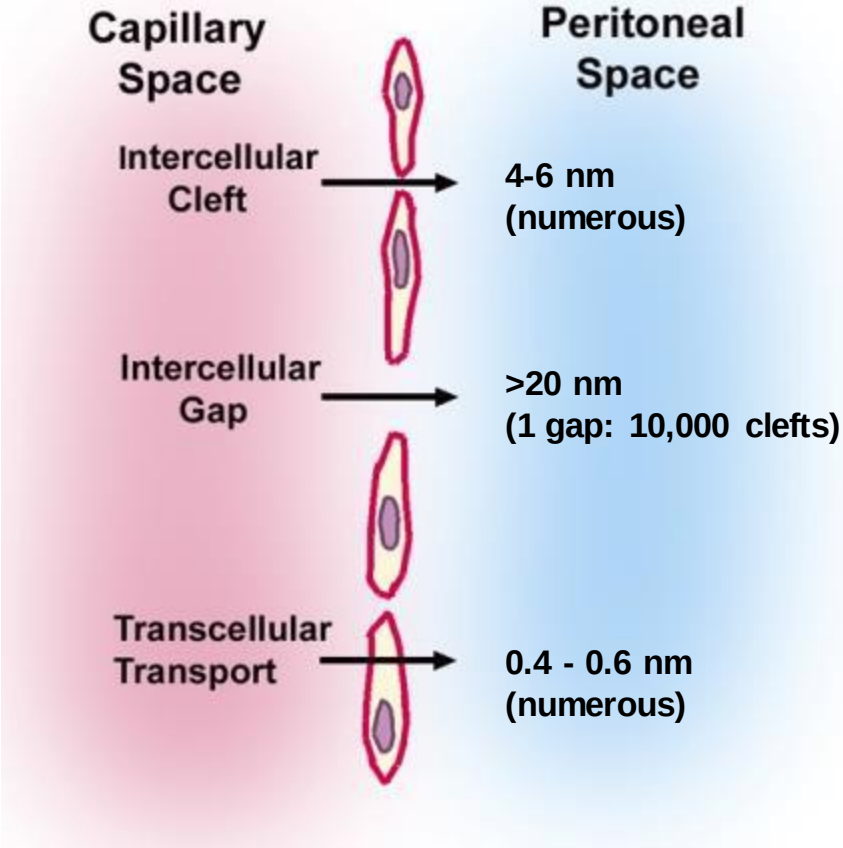




- Peritoneal capillary is critical barrier to solute and water transport
  - BF ~ 50-100 mL/min

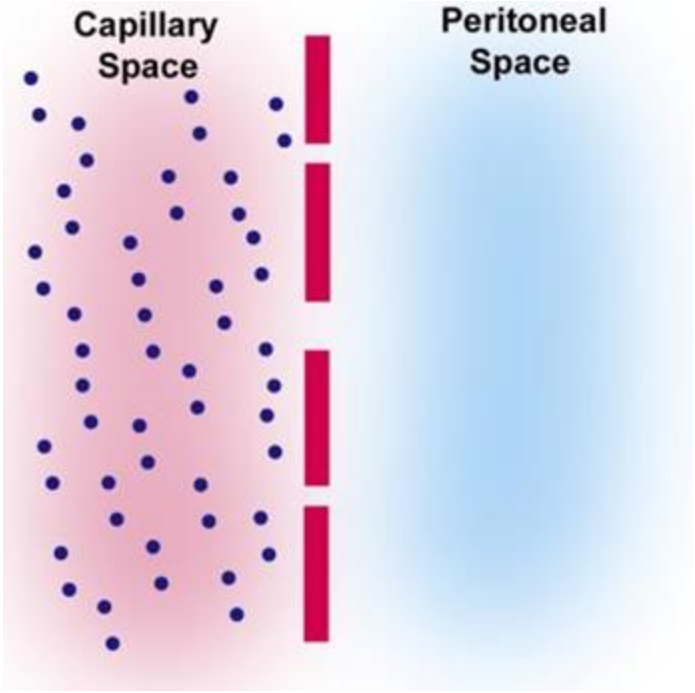
Peritoneal Capillary

RBC 6-8 µm
(6000-8000 nm)



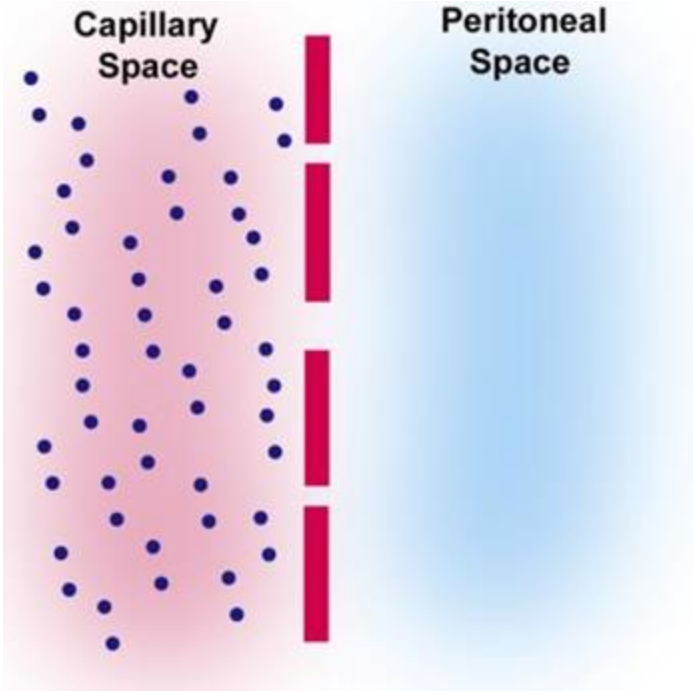
Methods of Peritoneal Clearance

- Diffusion (solutes)
- Ultrafiltration (water)
- Convection (solutes)



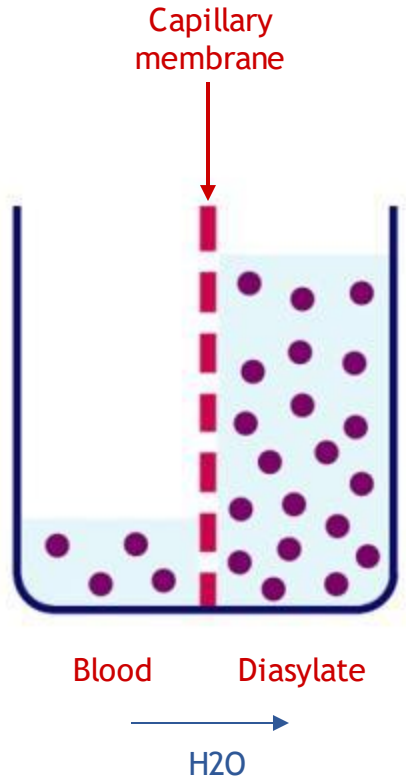
Methods of Peritoneal Clearance

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



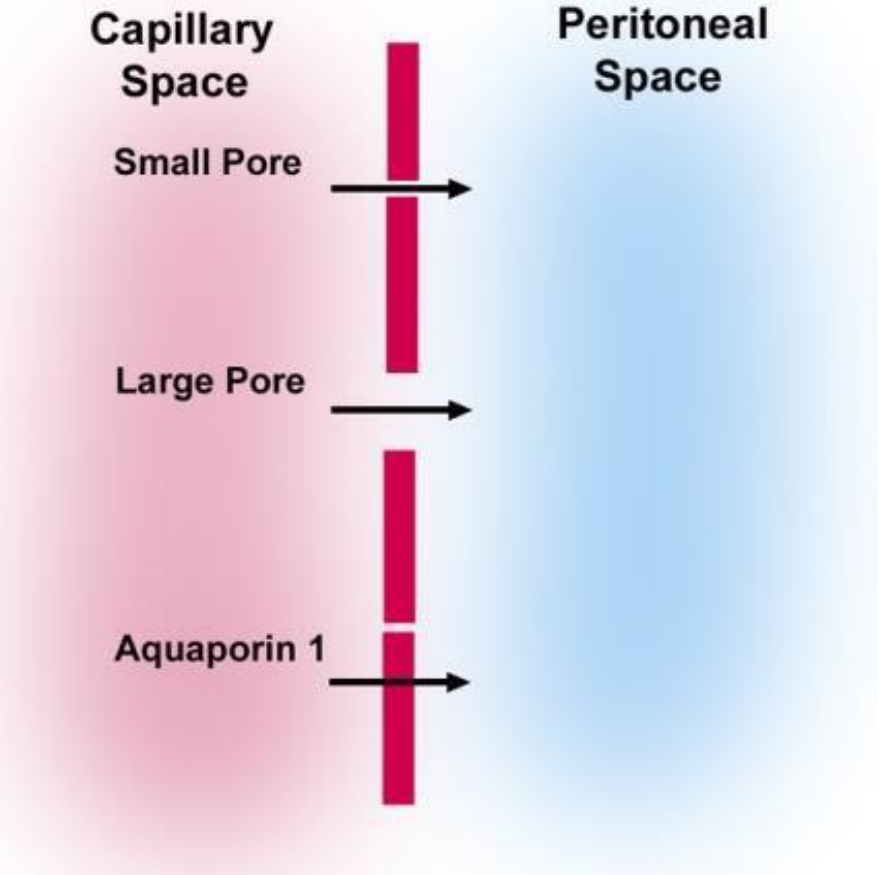
Methods of Peritoneal Clearance

- Diffusion (solutes)
- Ultrafiltration (water)
  - H2O movement due to differences in osmotic pressure
  - Via small pores, large pores, and aquaporins
- Convection (solutes)

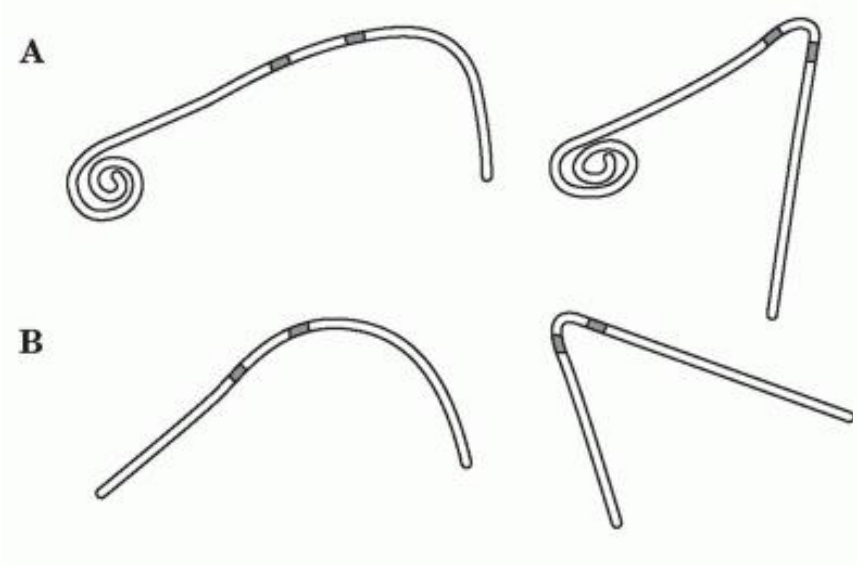


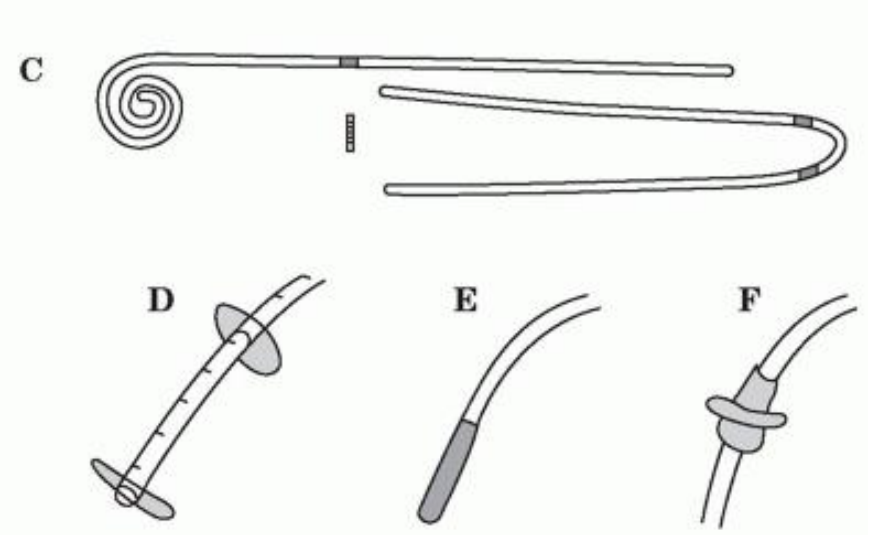
Methods of Peritoneal Clearance

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



All shapes and sizes





All shapes and sizes

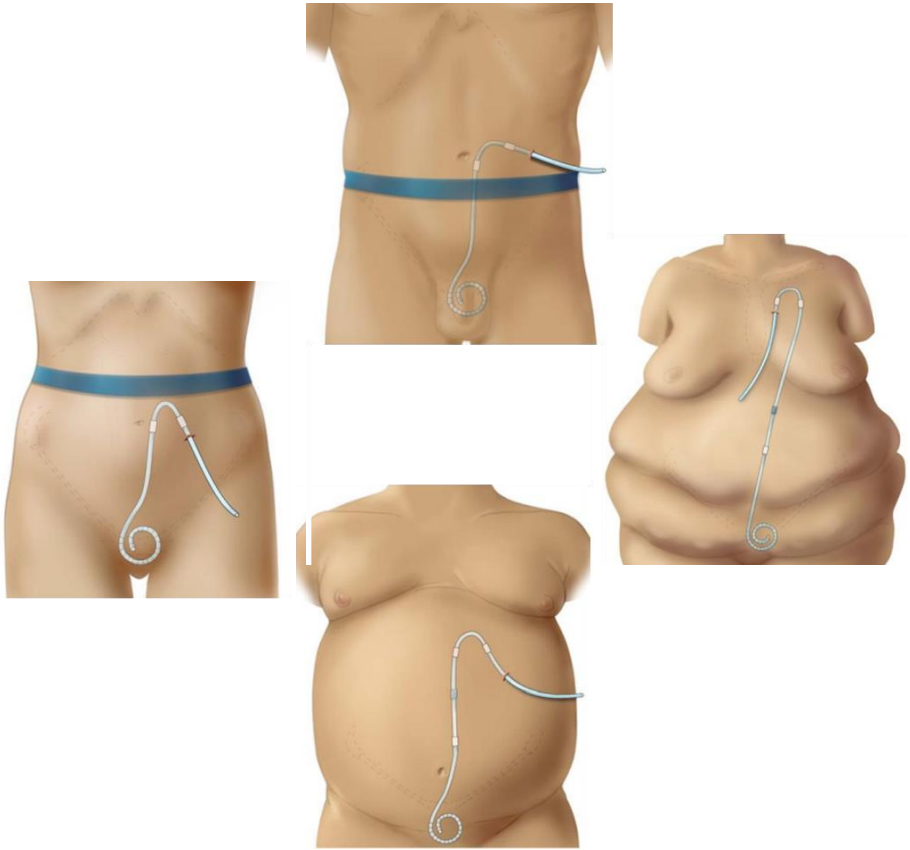
Who places PD catheters?

Surgeon → Laparoscopy

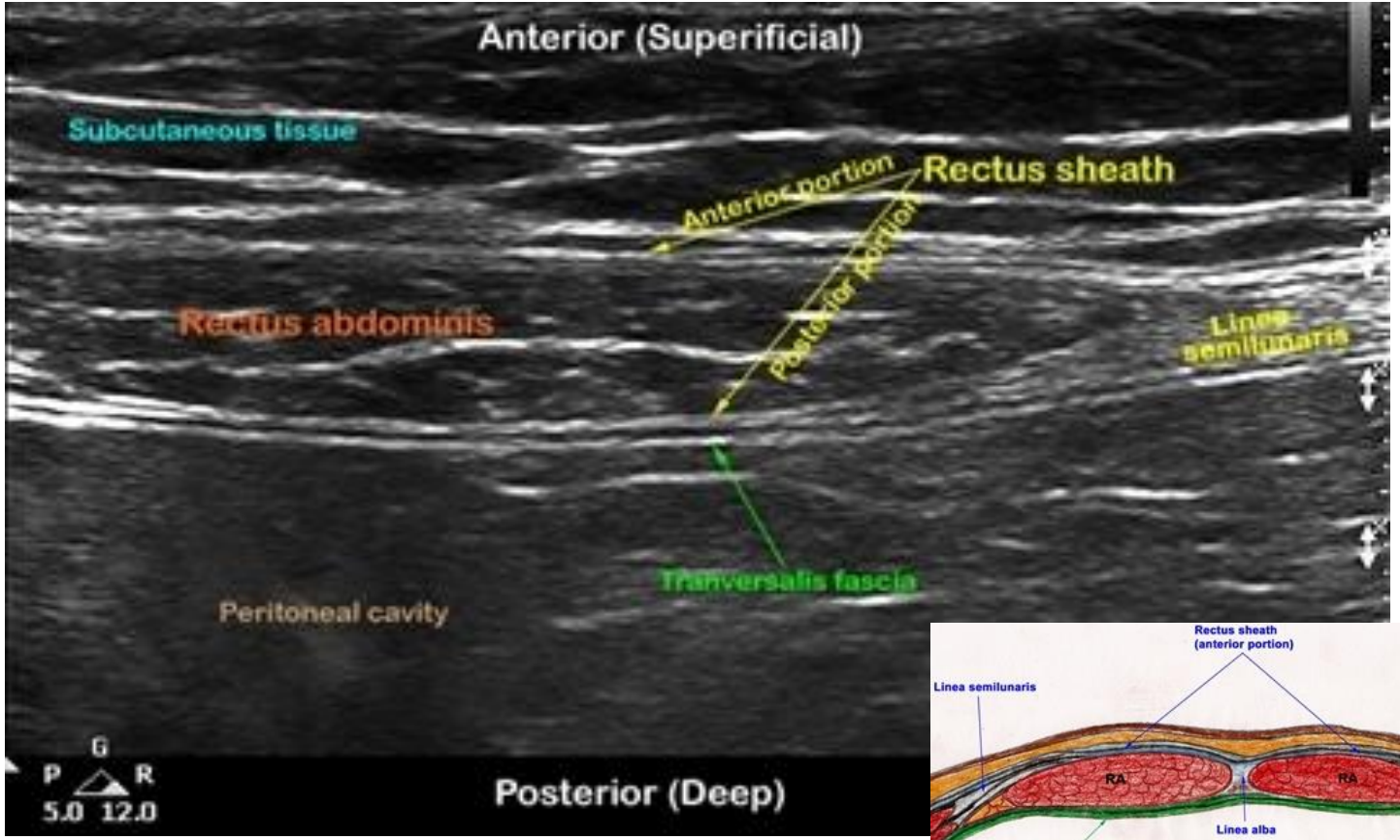
Interventional Radiology → Fluoroscopic + US Guidance

Interventional Nephrology → US Guidance

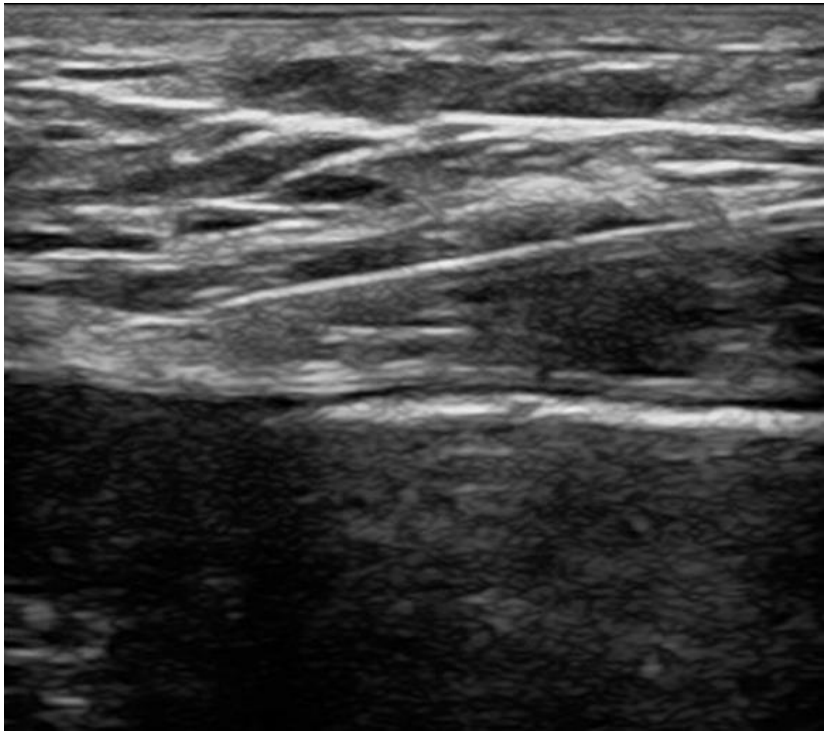
Technique for IR placement



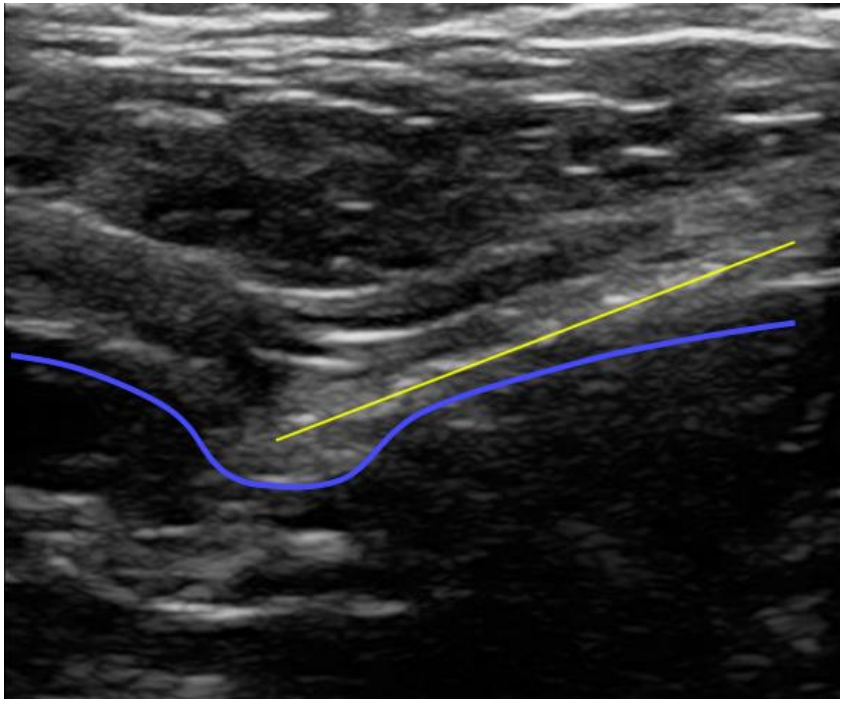
Technique for IR placement

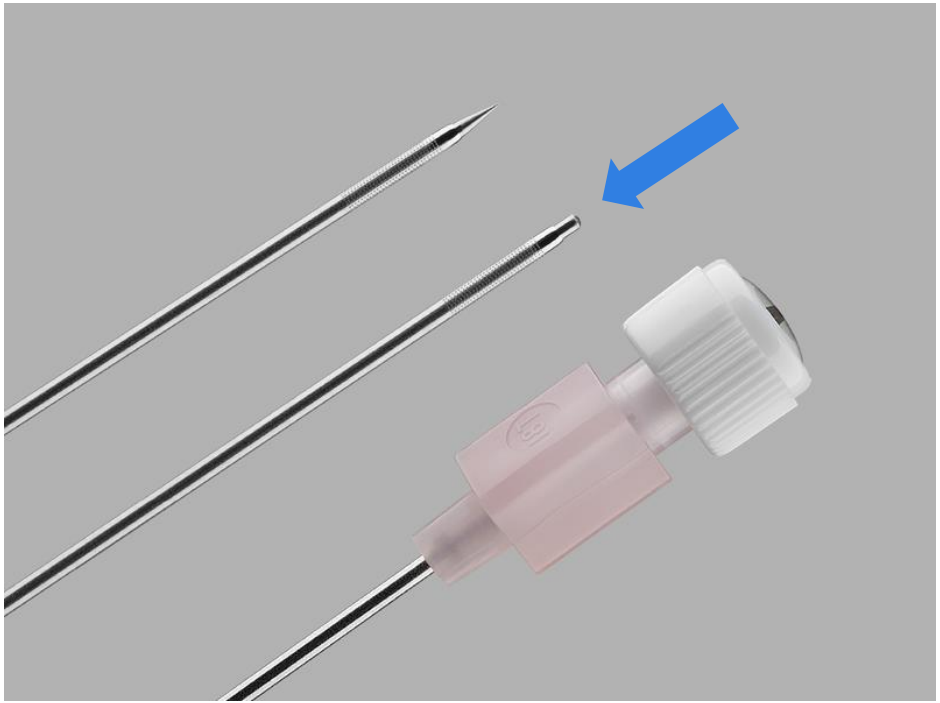


Technique for IR placement



Technique for IR placement

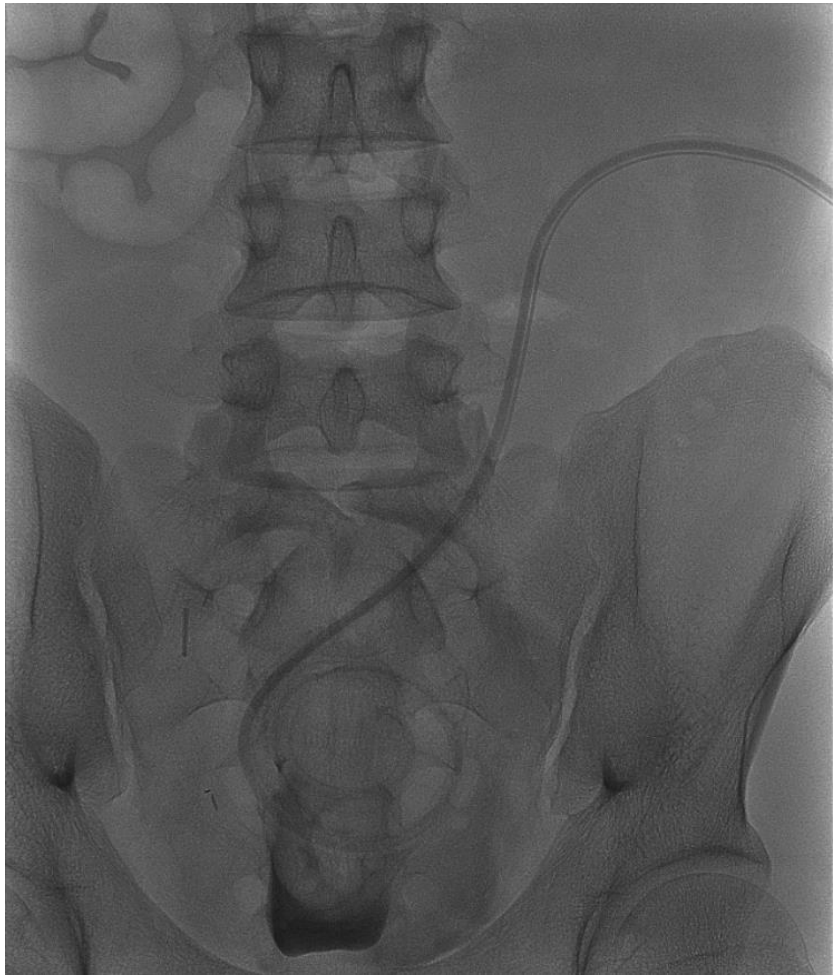




Technique for IR placement

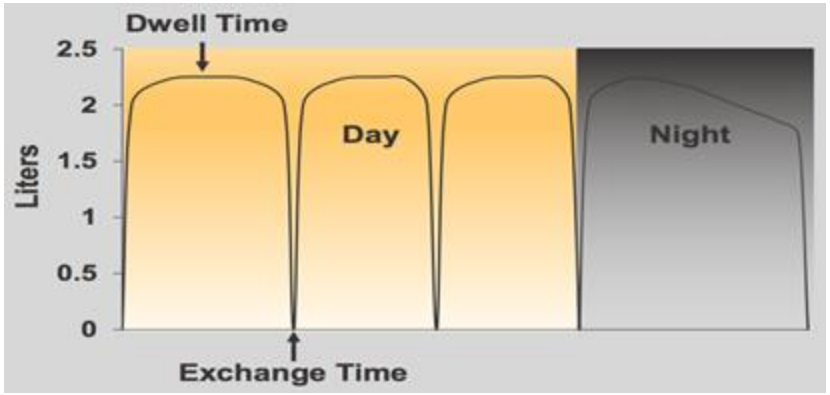
Technique for IR placement

Catheter Positioning



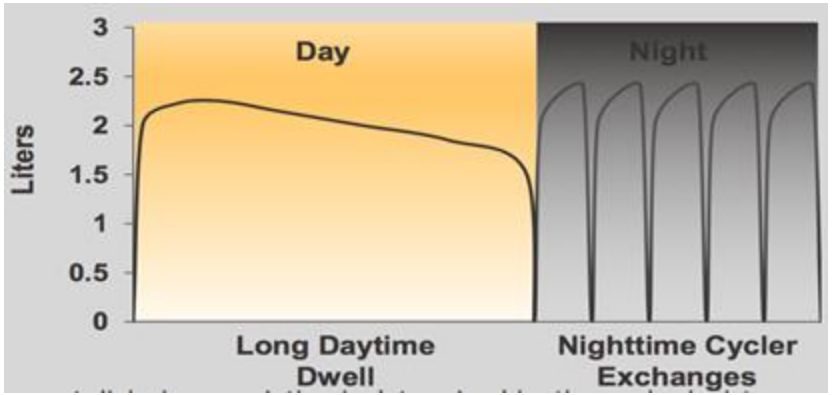
Peritoneal Dialysis Prescriptions

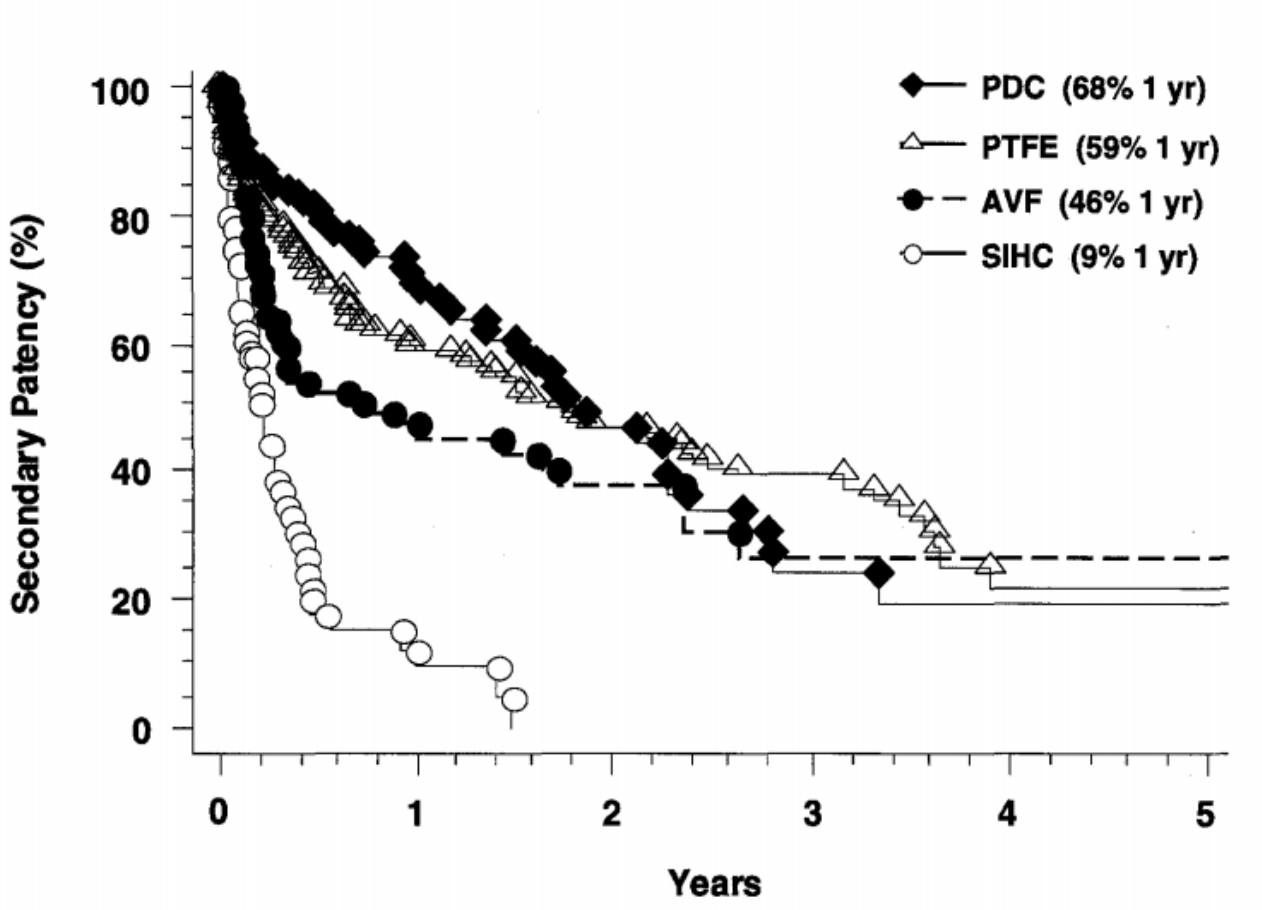
- Continuous Ambulatory Peritoneal Dialysis (CAPD)
  - No machine needed
  - 24/7



Types of PD Rx

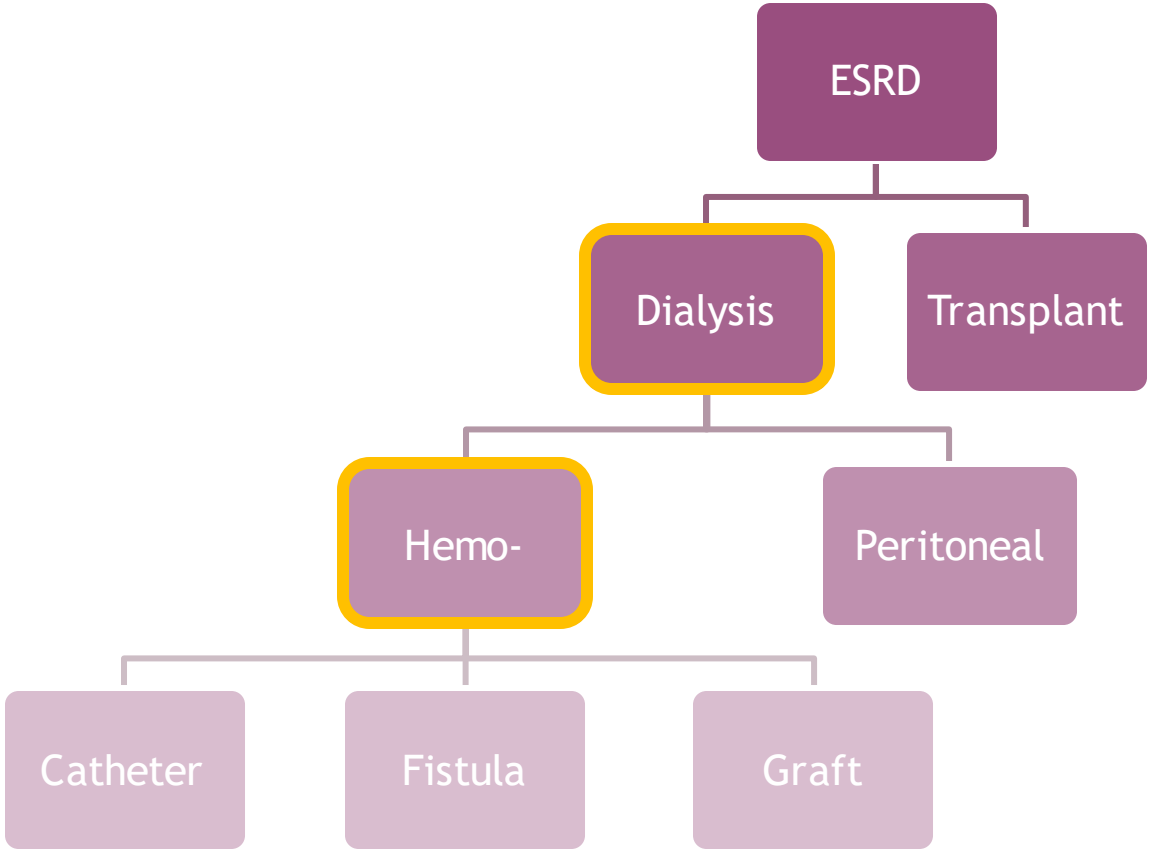
- Automated Peritoneal Dialysis (APD)
- Continuous Cycling Peritoneal Dialysis (CCPD)
- Machine run cycles
- 7 d/wk



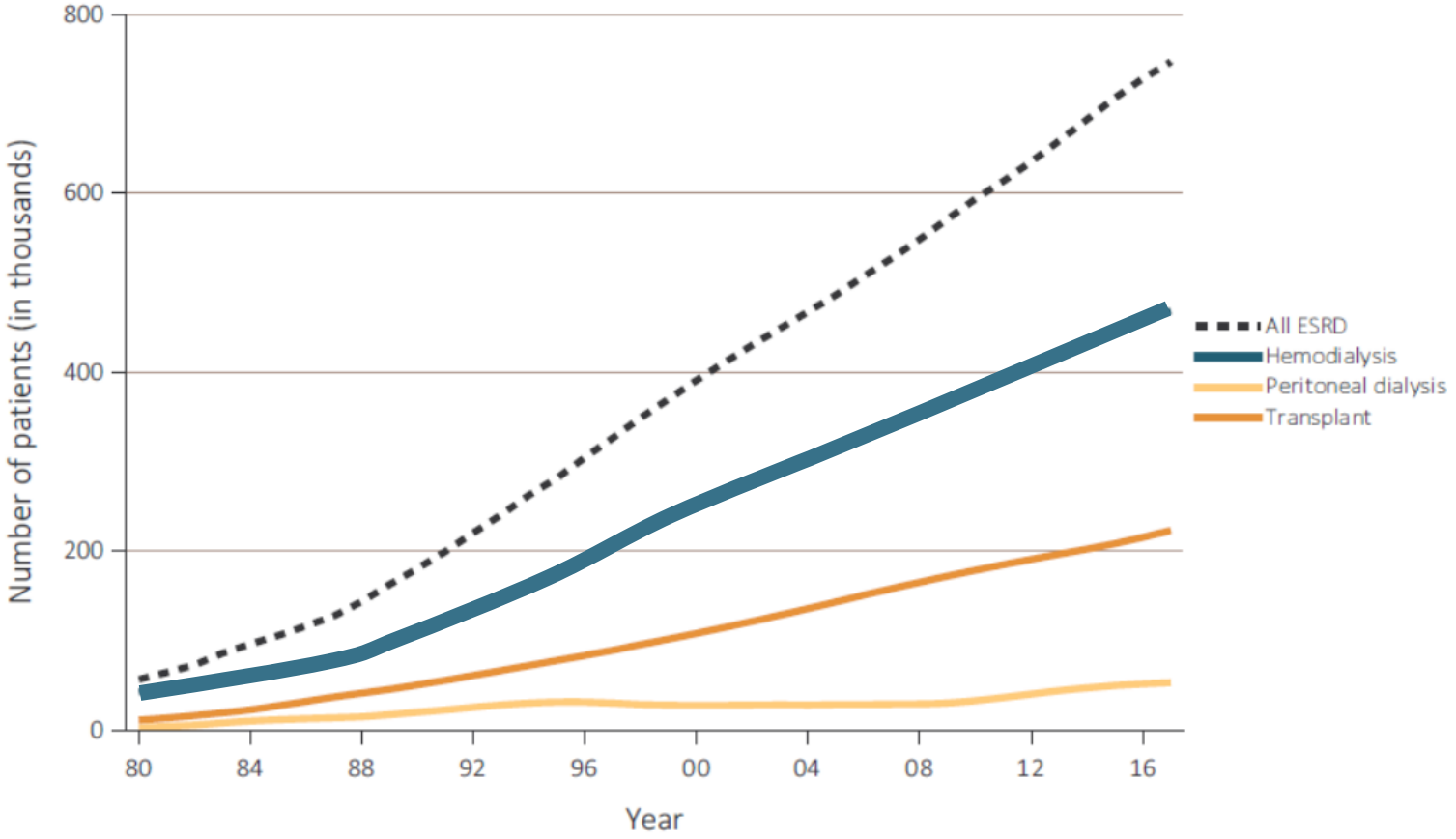


Hodges JC, Fillinger MF, Zwolak RM, et al. Longitudinal comparison of dialysis access methods: risk factors for failure. J Vasc Surg. 1997;26:1009-1019.

Renal replacement therapy



Renal replacement therapy



Data Source: Reference Table D.1 and special analysis of USRDS ESRD Database.

Renal replacement therapy

PREVALENT ESRD

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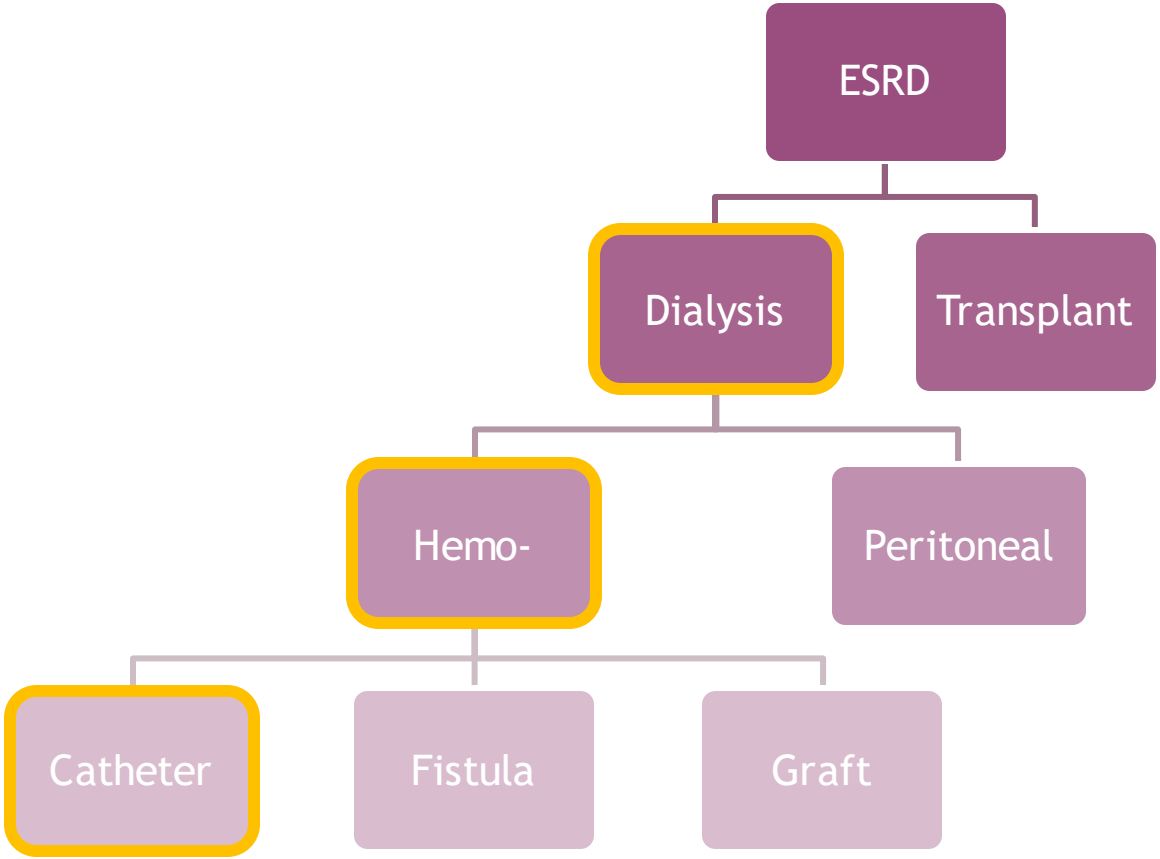
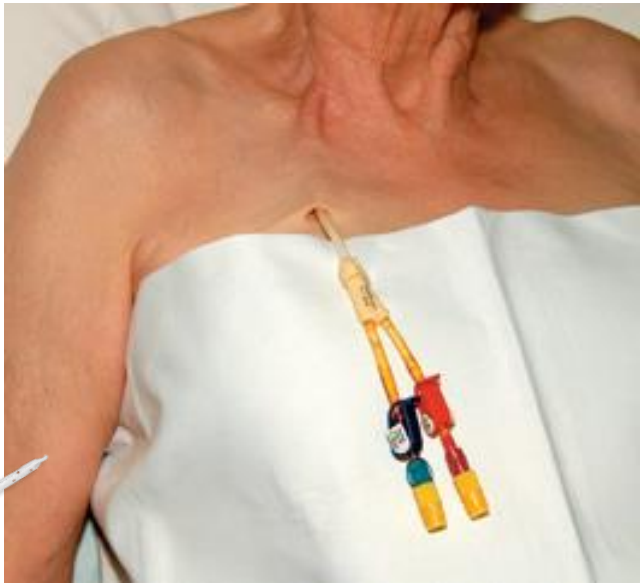
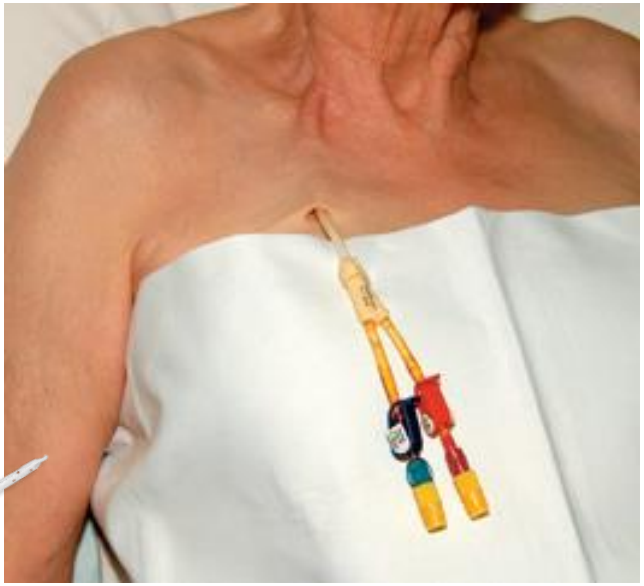
Renal replacement therapy



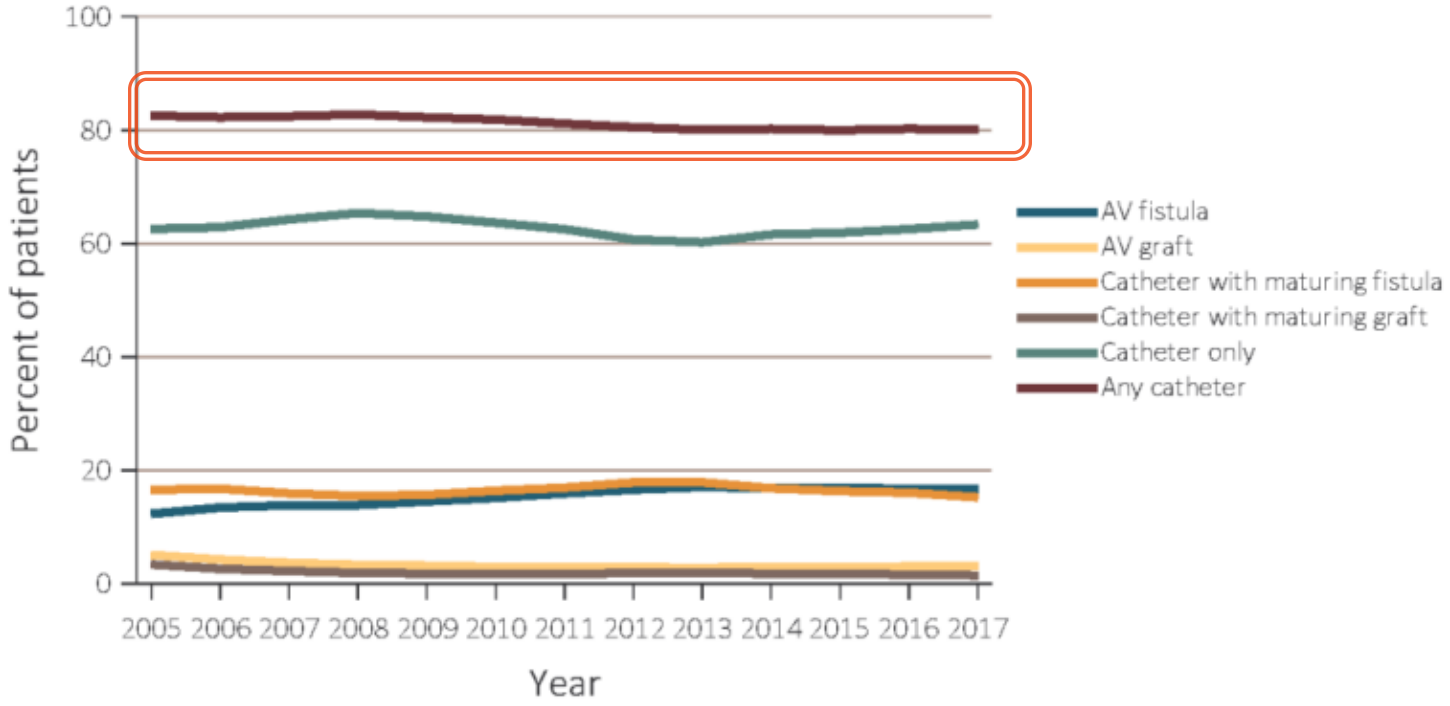
- Benefits
  - Rapid start
  - Quick and easy to place
  - Functional
  - Easily removed if renal recovery
  - Multiple placement options



- Negatives
  - High associated morbidity and mortality
    - Infection
    - Hospitalization
    - Death
  - Accelerated vascular injury → lost access

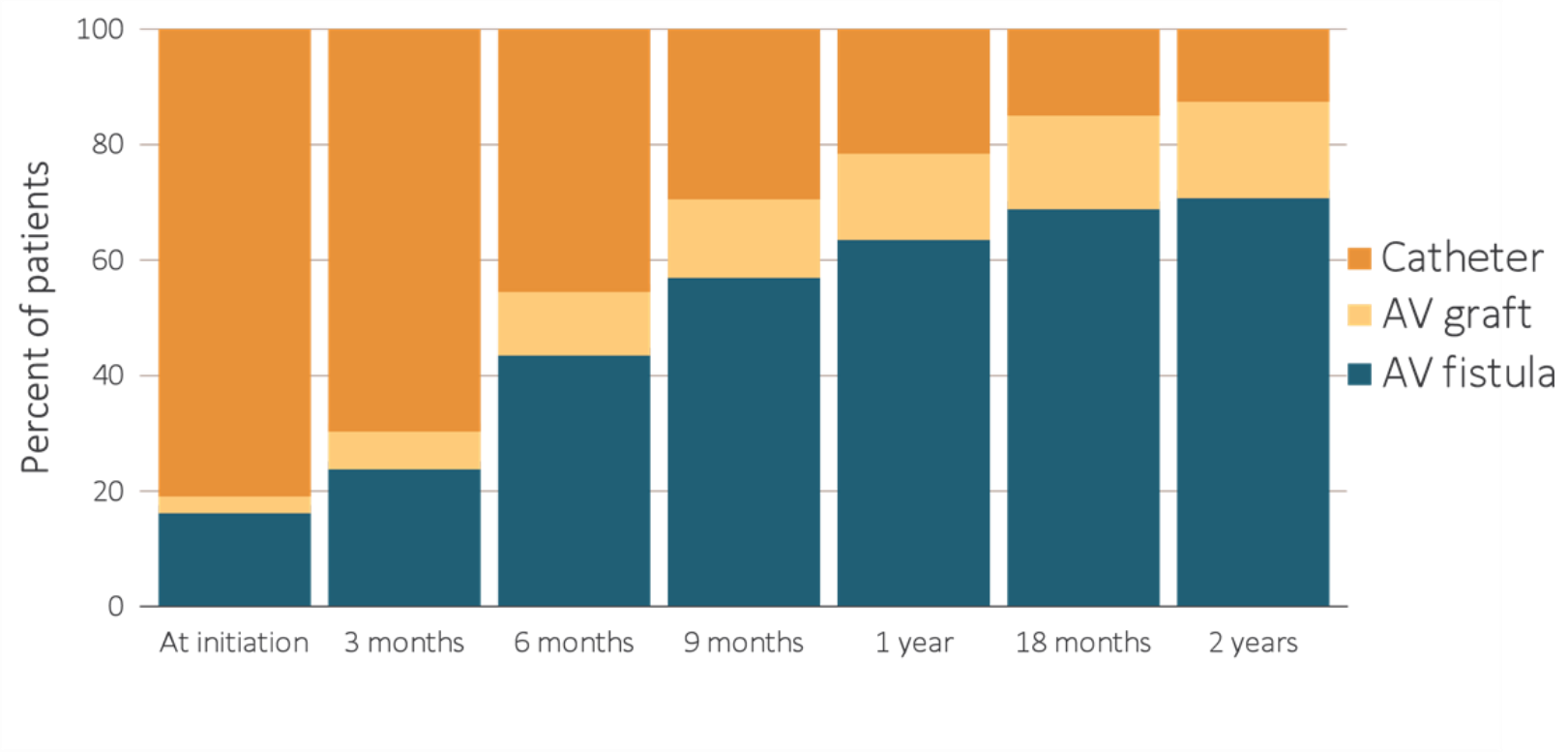


Vascular access use at HD initiation



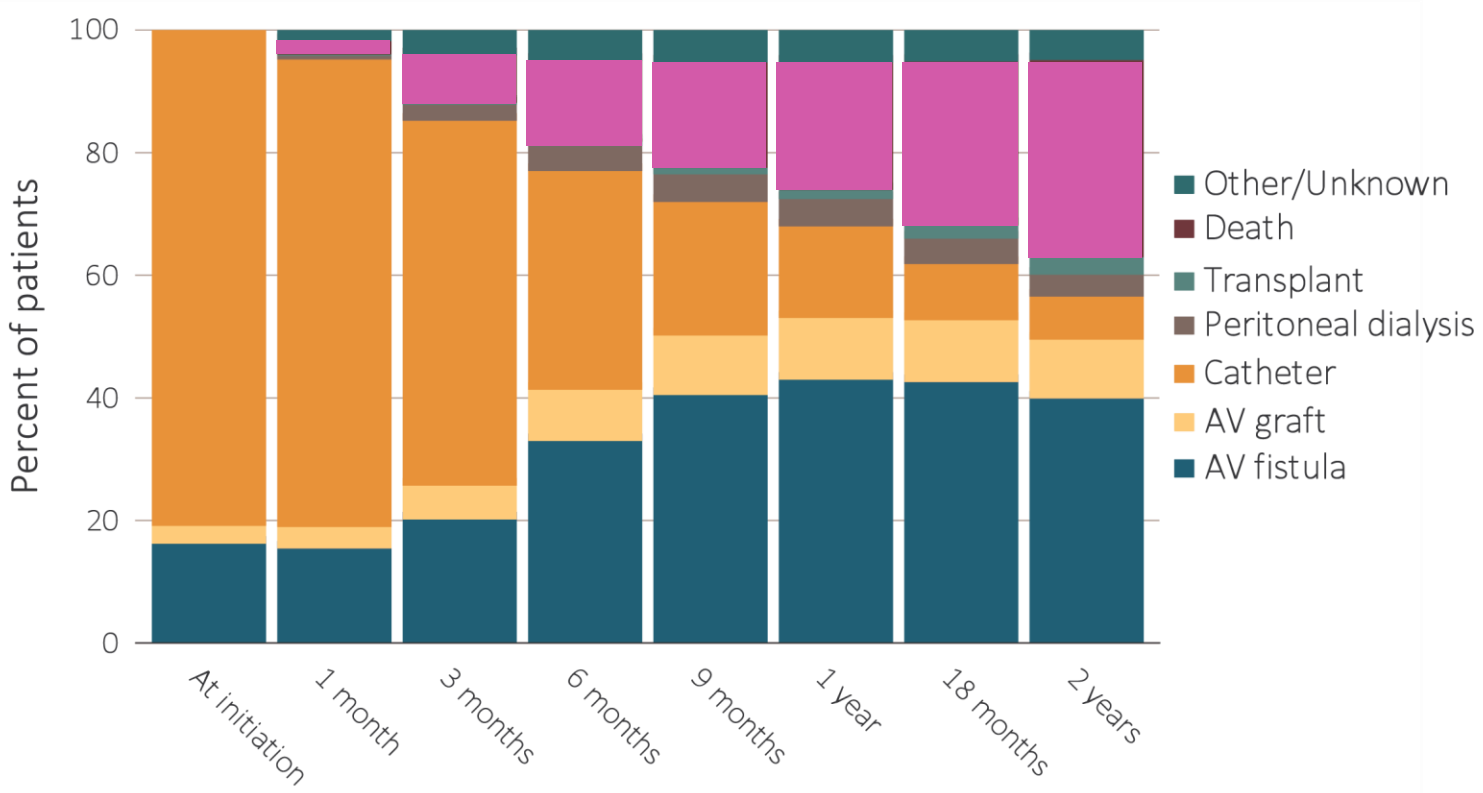
Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating hemodialysis in 2005-2017.

Hemodialysis access over time



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).

Change in HD access over time



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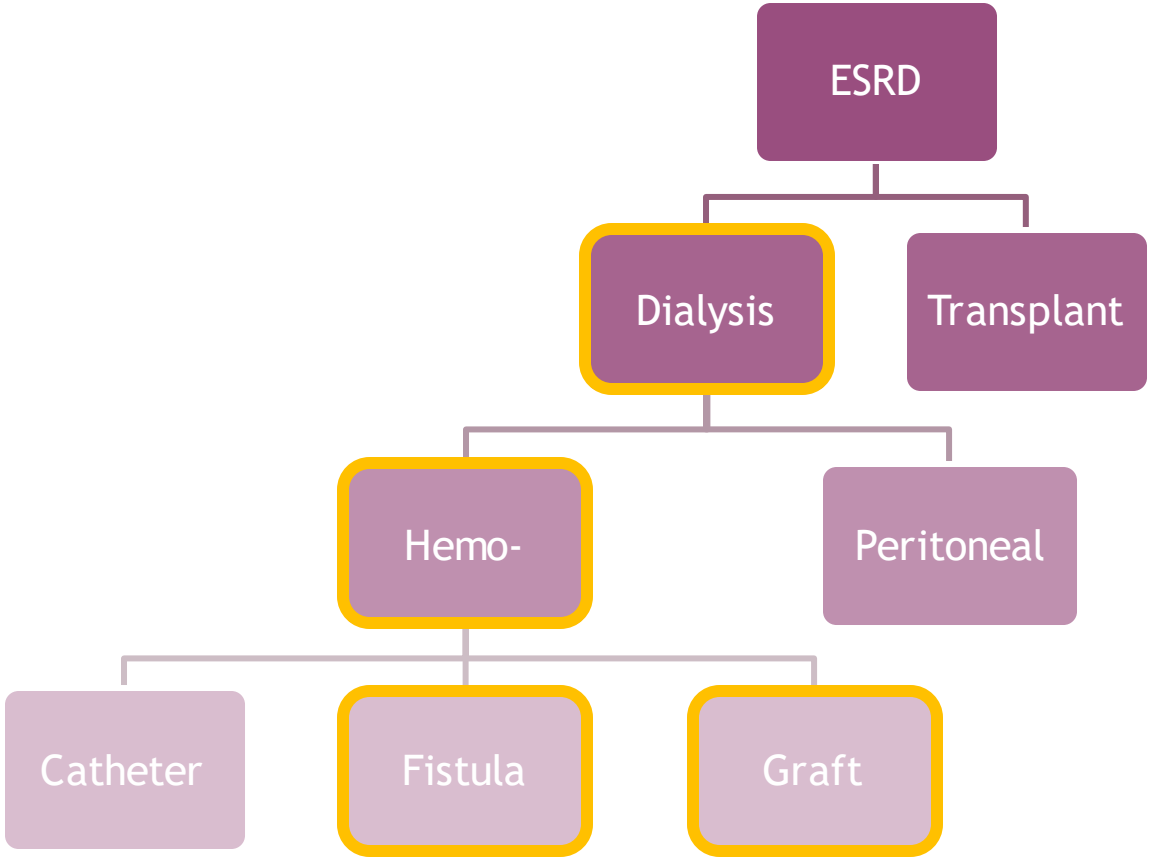
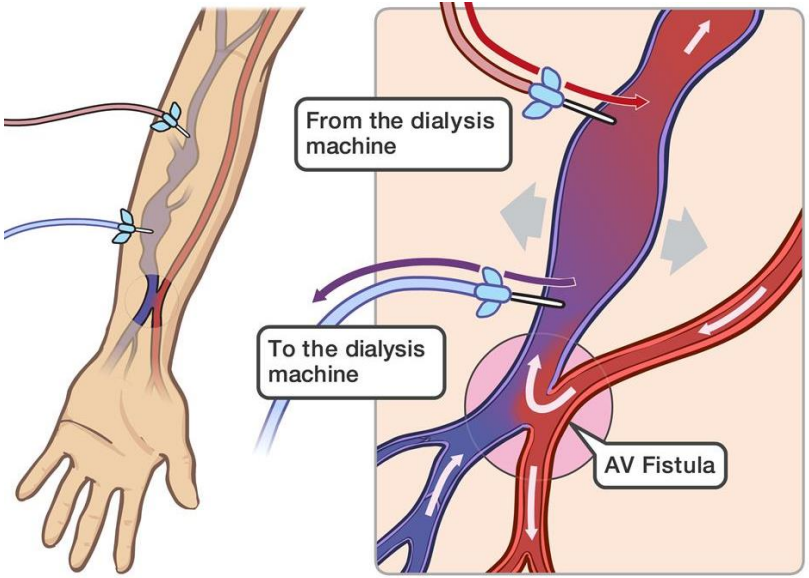
Fistula First Breakthrough Initiative → Fistula First/Catheter Last (2009)

- 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

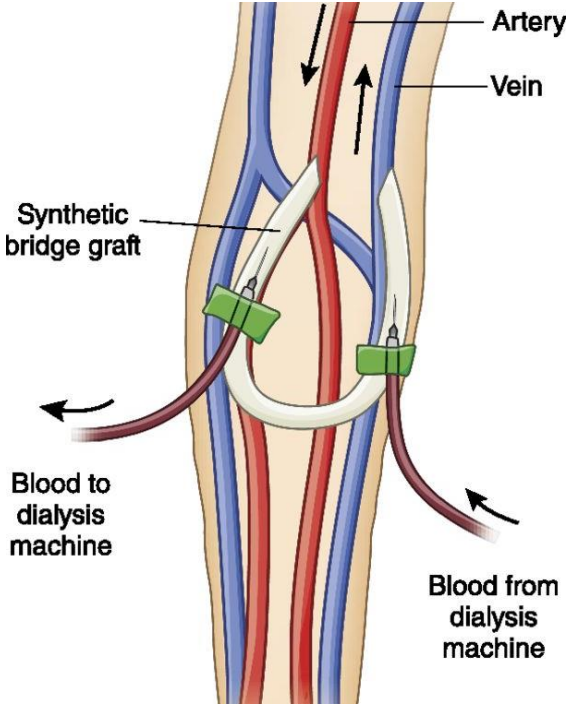
Renal replacement therapy



Fistula versus Graft



AV FISTULA



AV GRAFT

Graft material

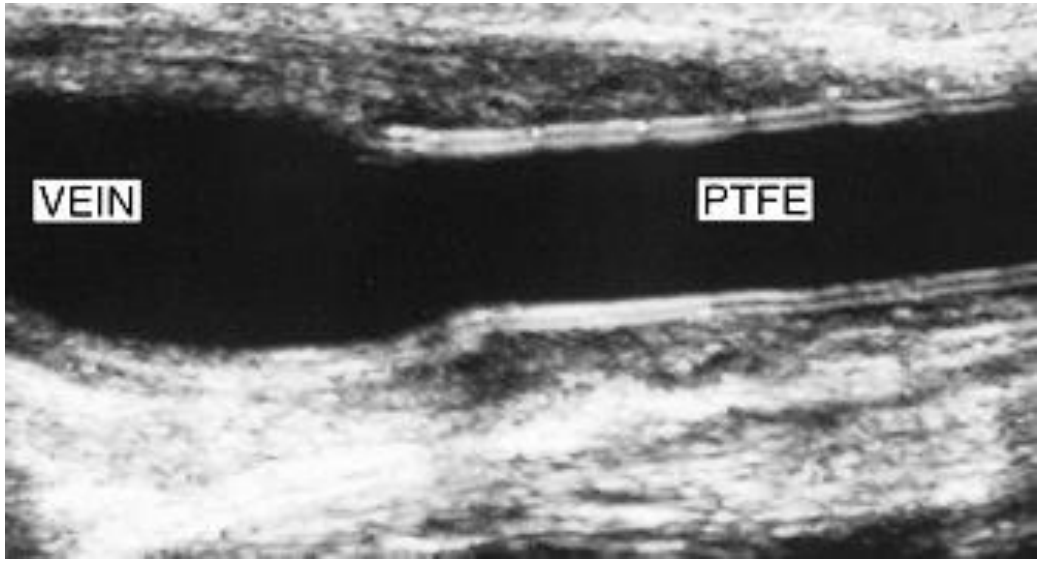
PTFE

DACRON

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

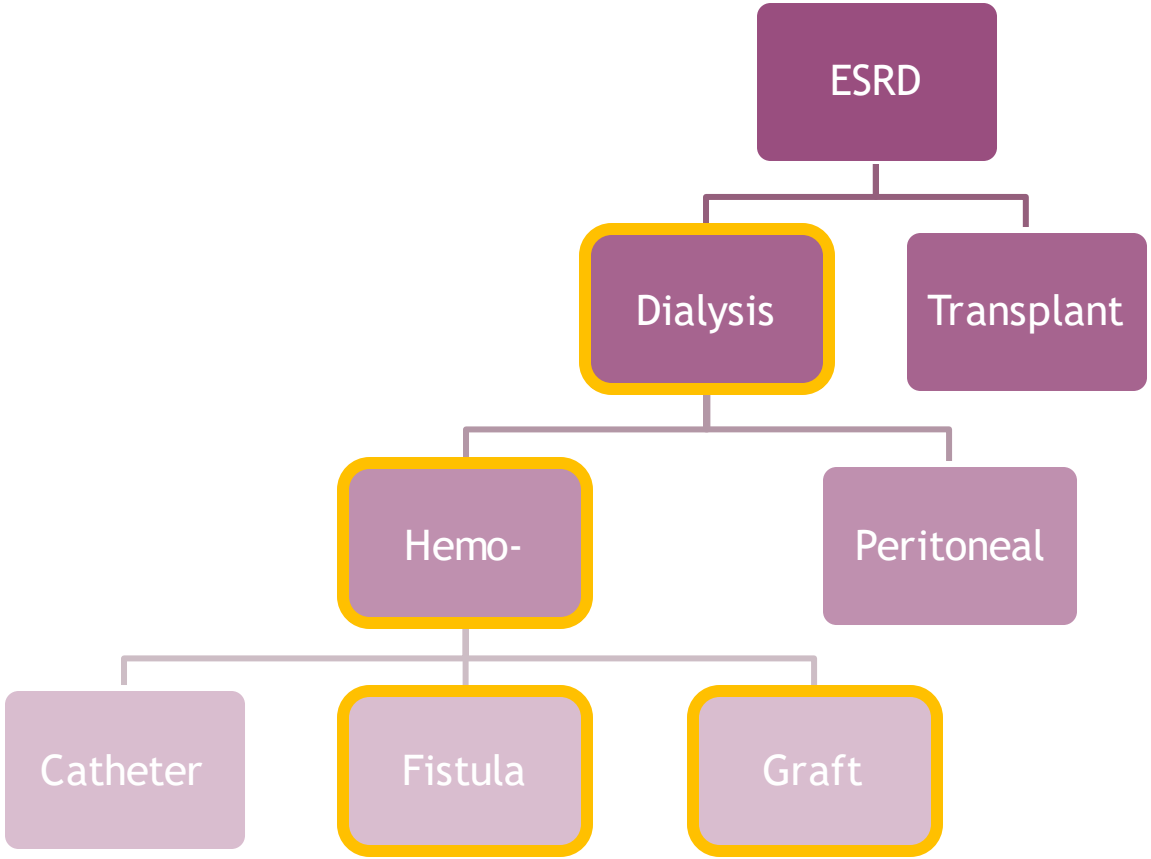
B: PTFE https://www.news-medical.net/FUSION-BIOLINE-Vascular-Grafts-from-Maquet

Graft material



https://radiologykey.com/graft-surveillance-and-preoperative-vein-mapping-for-bypass-surgery/

Renal replacement therapy




Introduction
The procedure consists of

Poor maturation of surgical AVFs

- Dember LM, et al (JAMA, 2008)
  - Randomize
    placebo co
  - Of 758 pati
    failed to be

- Woodside KJ, et al (AJKD, 2018)
  - Observational
  - USRDS Medica
  - 54.7% of fistul
    months of crea

- 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

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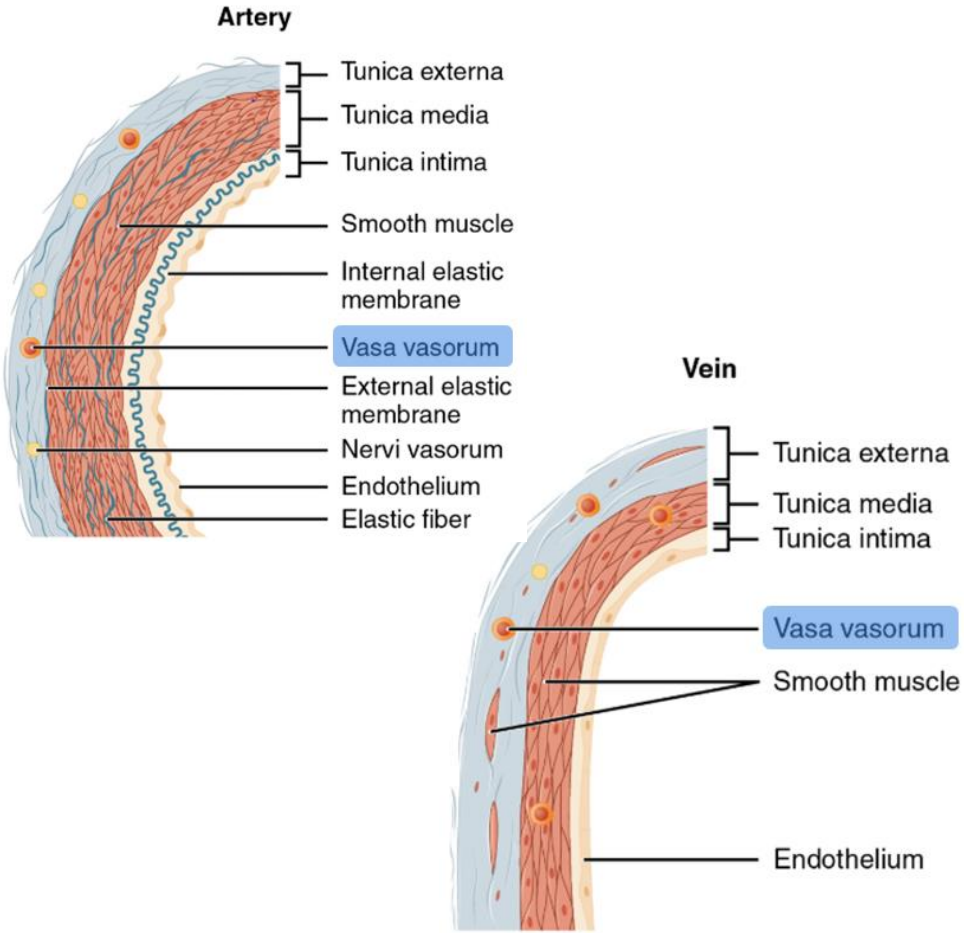

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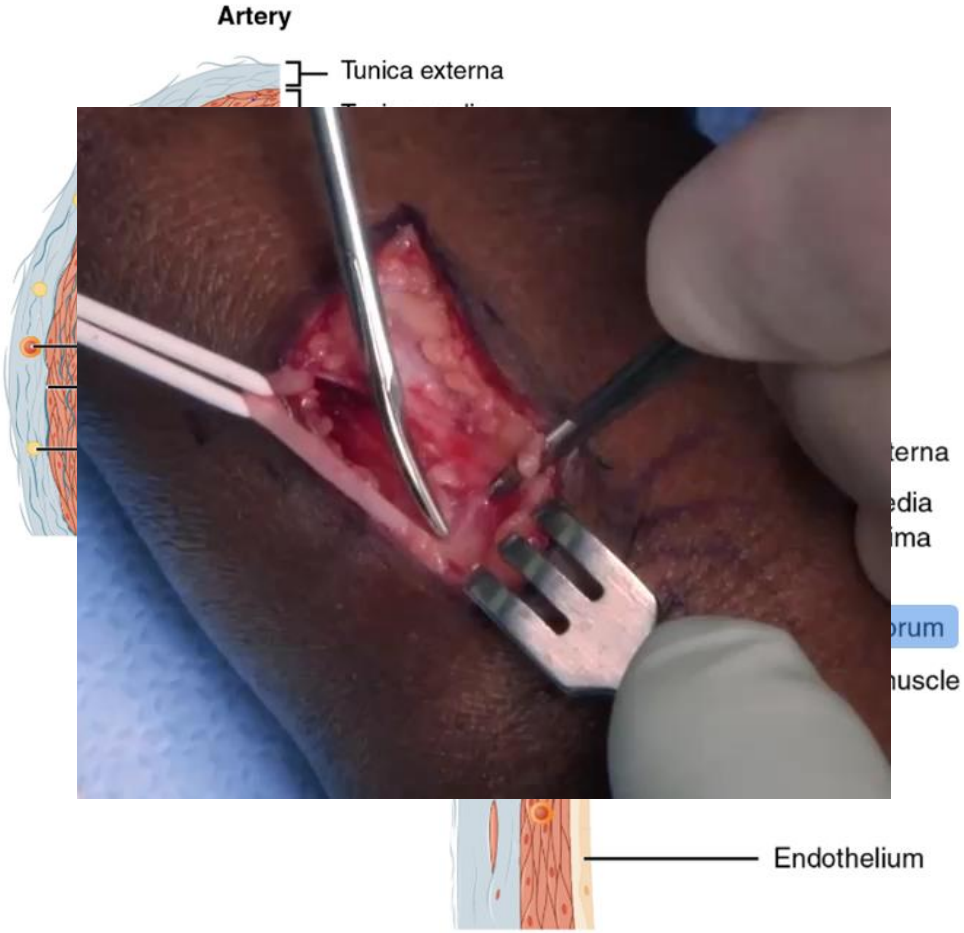

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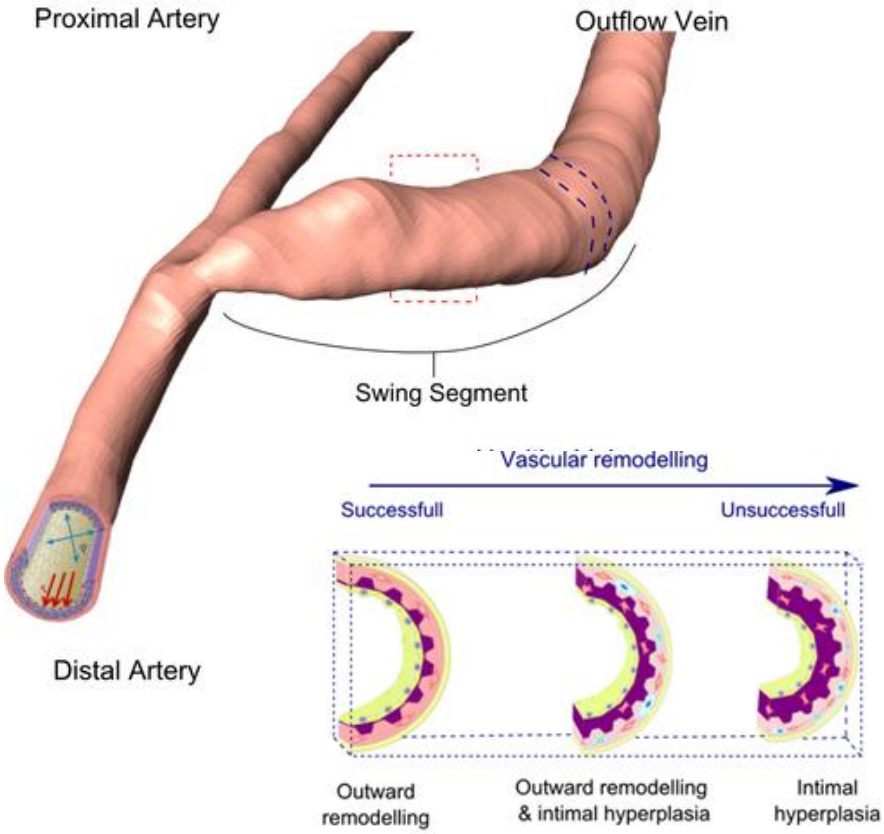

Browne, Leonard & Bashar, Khalid & Griffin, Philip & Kavanagh, Eamon & Walsh, Stewart & Walsh, Michael. (2015). The Role of Shear Stress in Arteriovenous Fistula Maturation and Failure: A Systematic Review. PloS one. 10. e0145795. 10.1371/journal.pone.0145795.

Technical factors

- Disruption of the vasa vasorum
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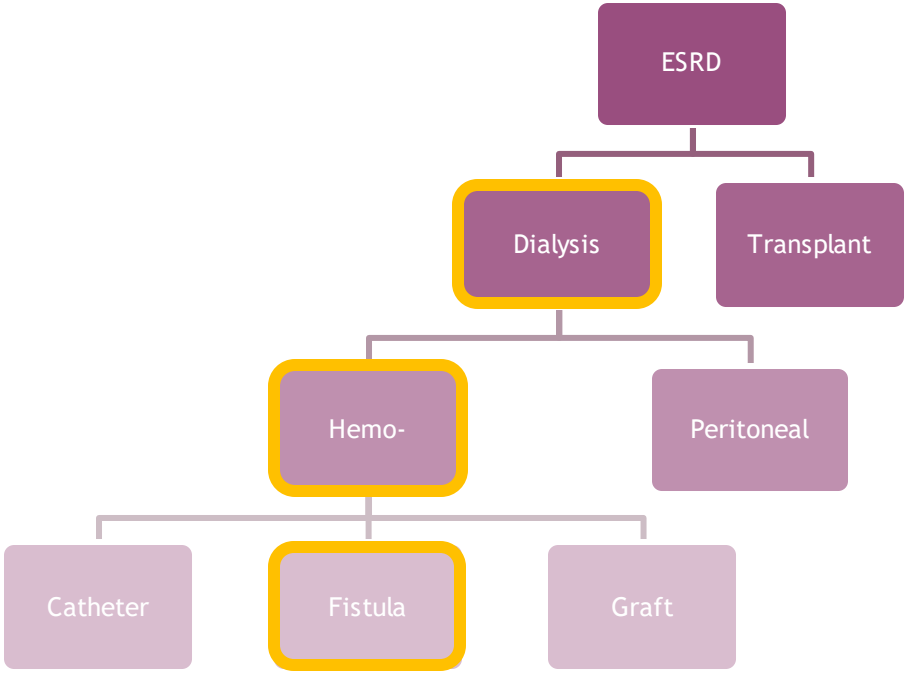
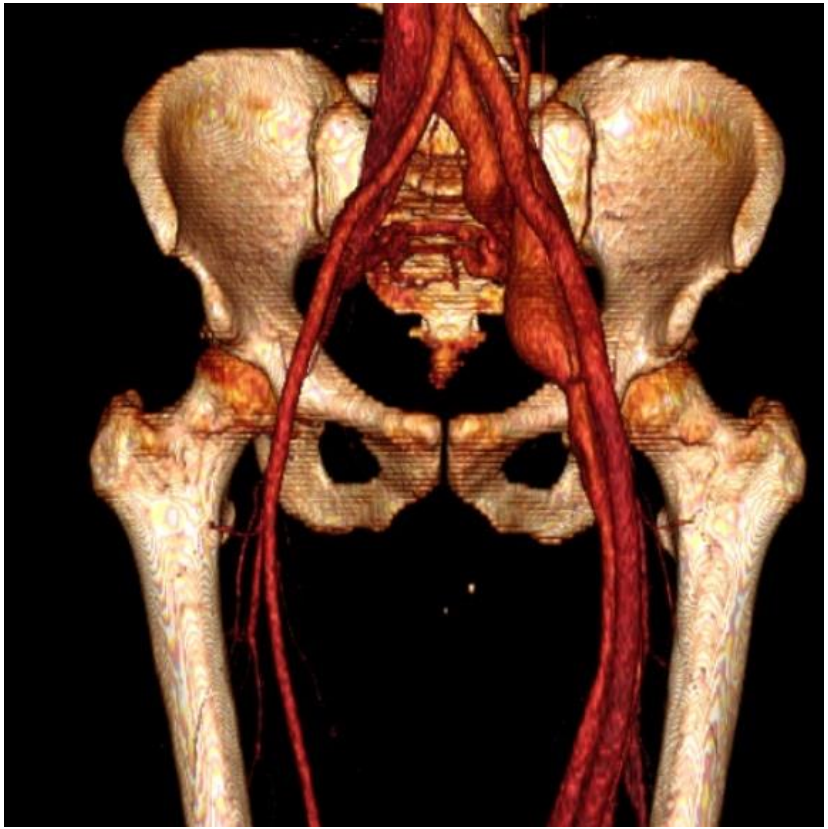
Renal replacement therapy

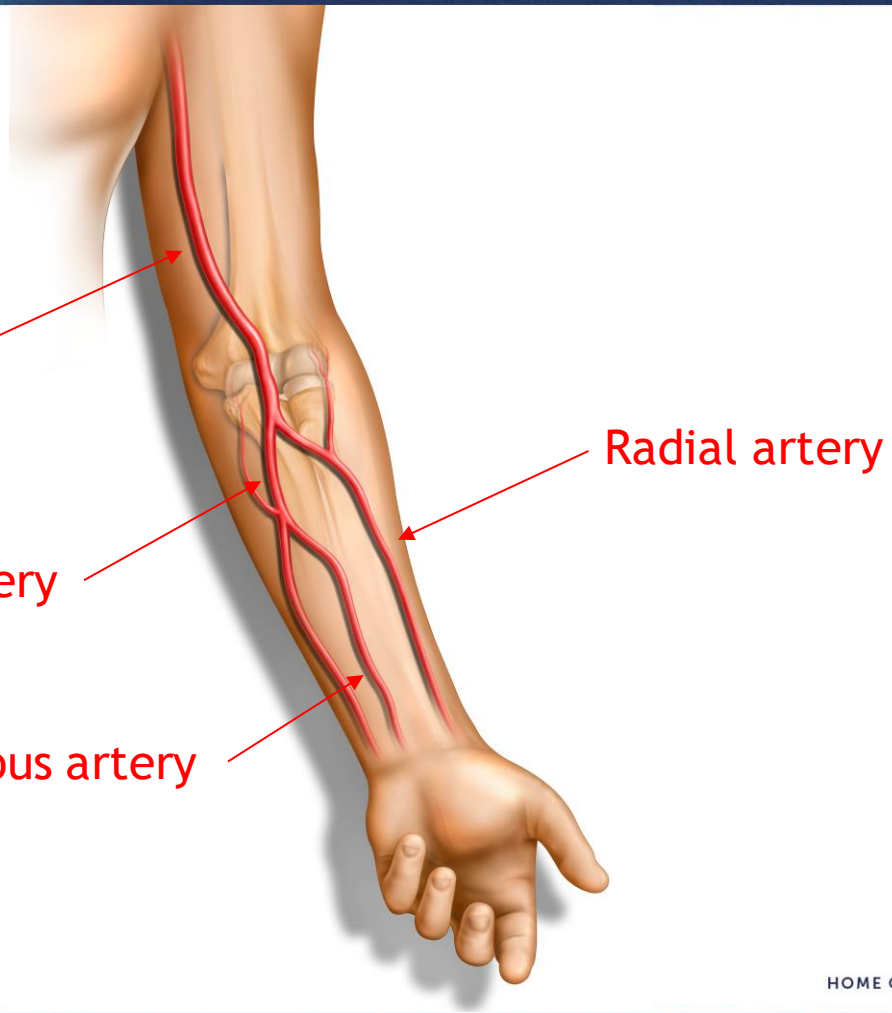


Traumatic AVFs

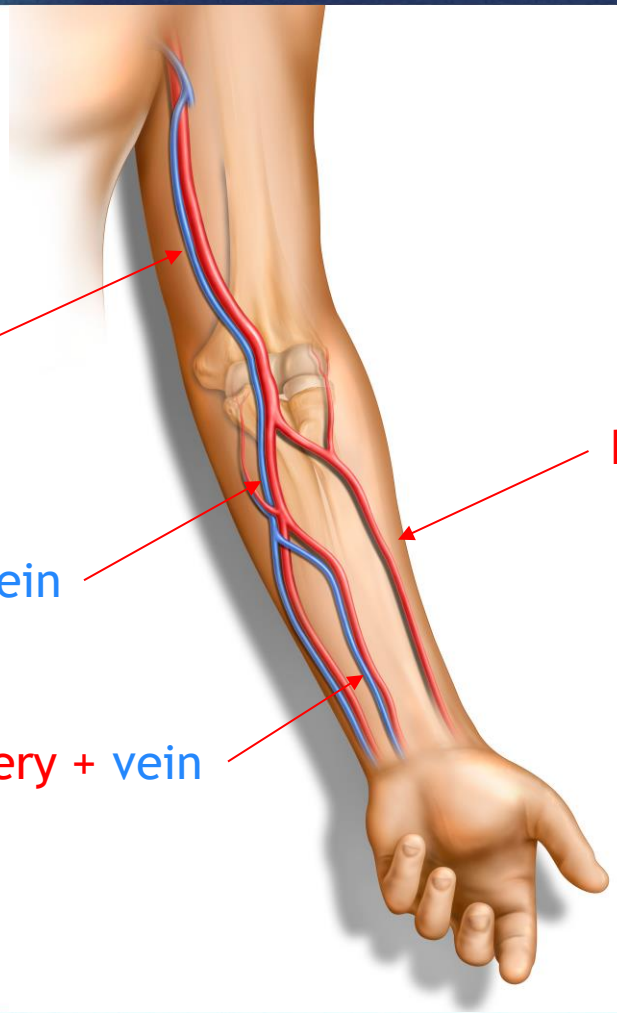


Mulatti, Grace Carvajal, et al. "Traumatic Arteriovenous Fistula." Arteriovenous Fistulas Diagnosis and Management, 2013.

Deep vessels



Deep vessels



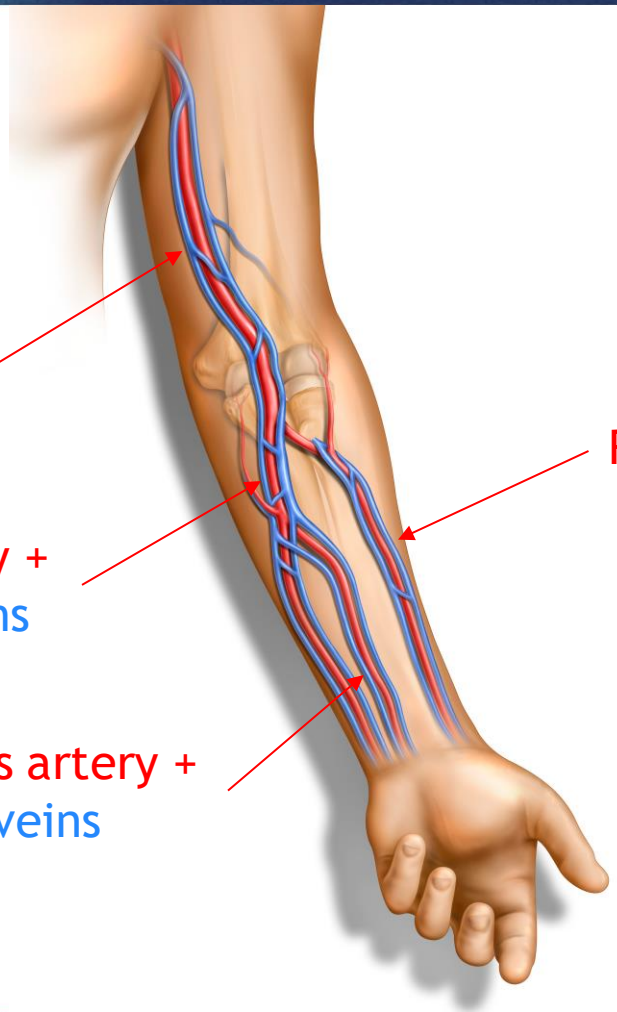
Brachial artery + vein

Radial artery + vein

Ulnar artery + vein

Interosseous artery + vein

Deep vessels



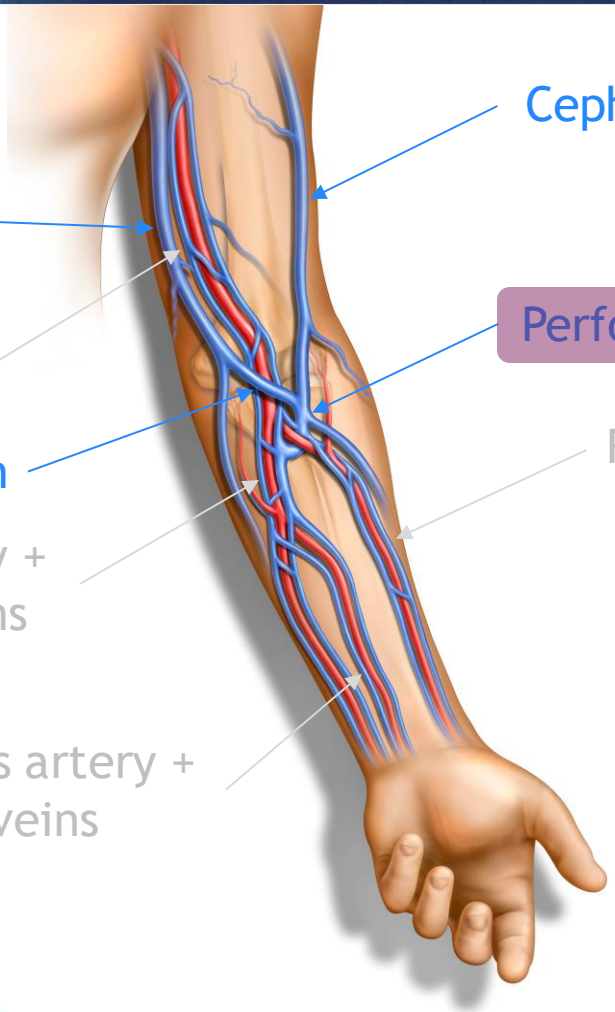
Brachial artery + paired veins

Radial artery + paired veins

Ulnar artery + paired veins

Interosseous artery + paired veins

Superficial veins



Cephalic vein

Basilic vein

Perforating vein

Brachial artery + paired veins

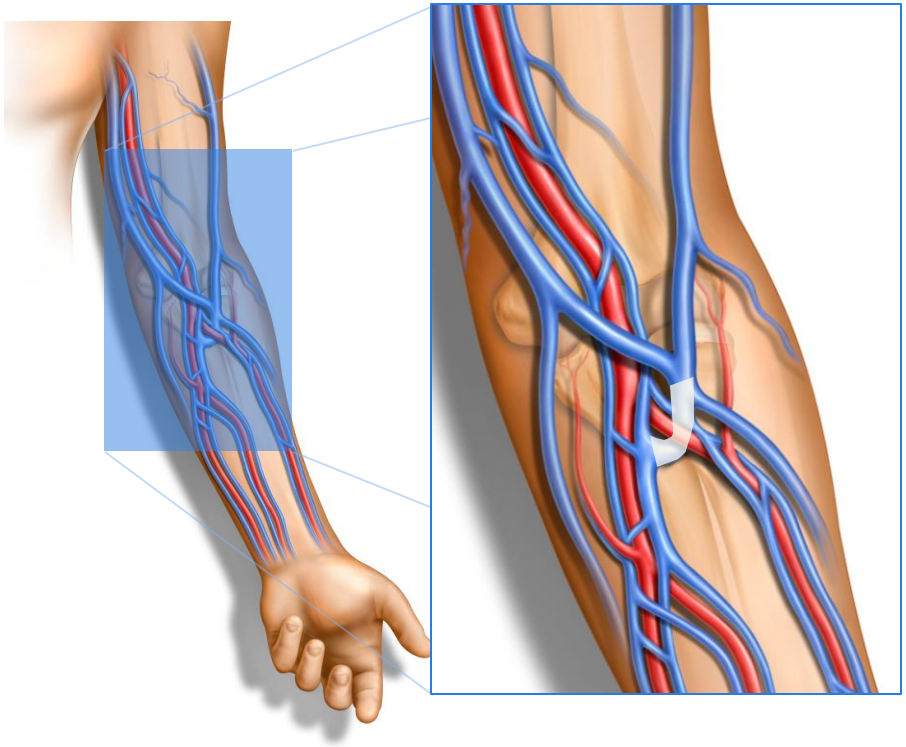
Radial artery + paired veins

Median cubital vein

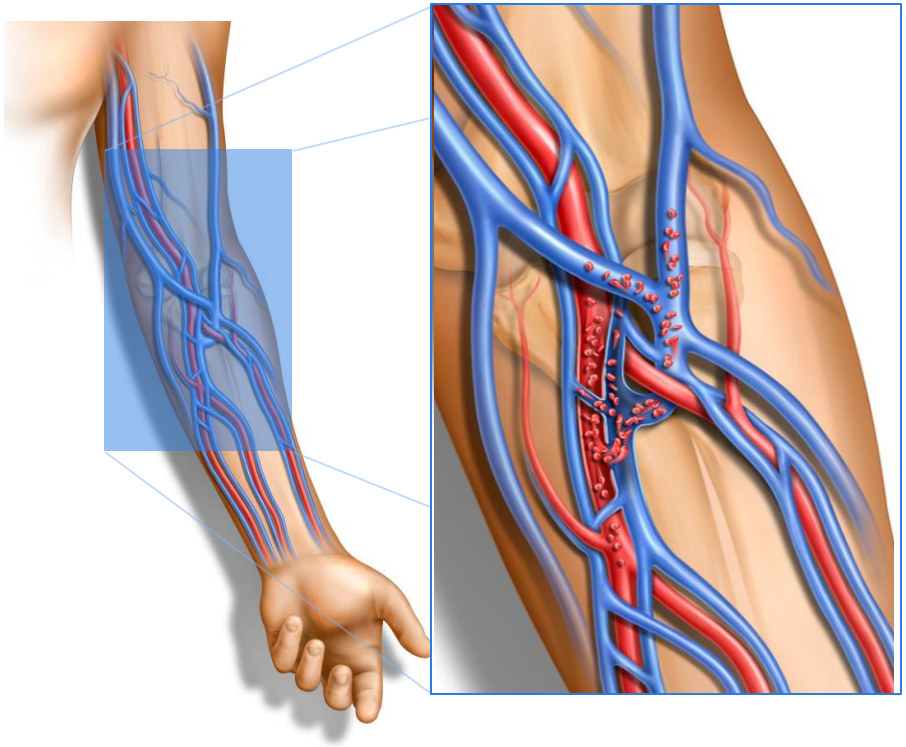
Ulnar artery + paired veins

Interosseous artery + paired veins

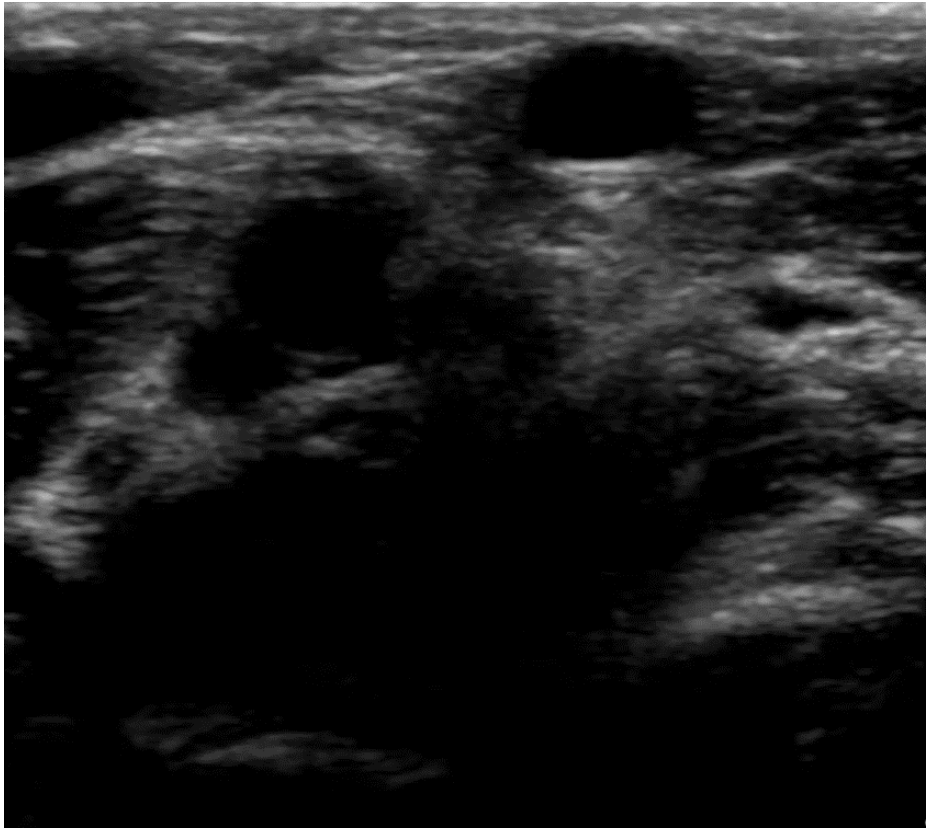
Perforating vein



Perforating vein

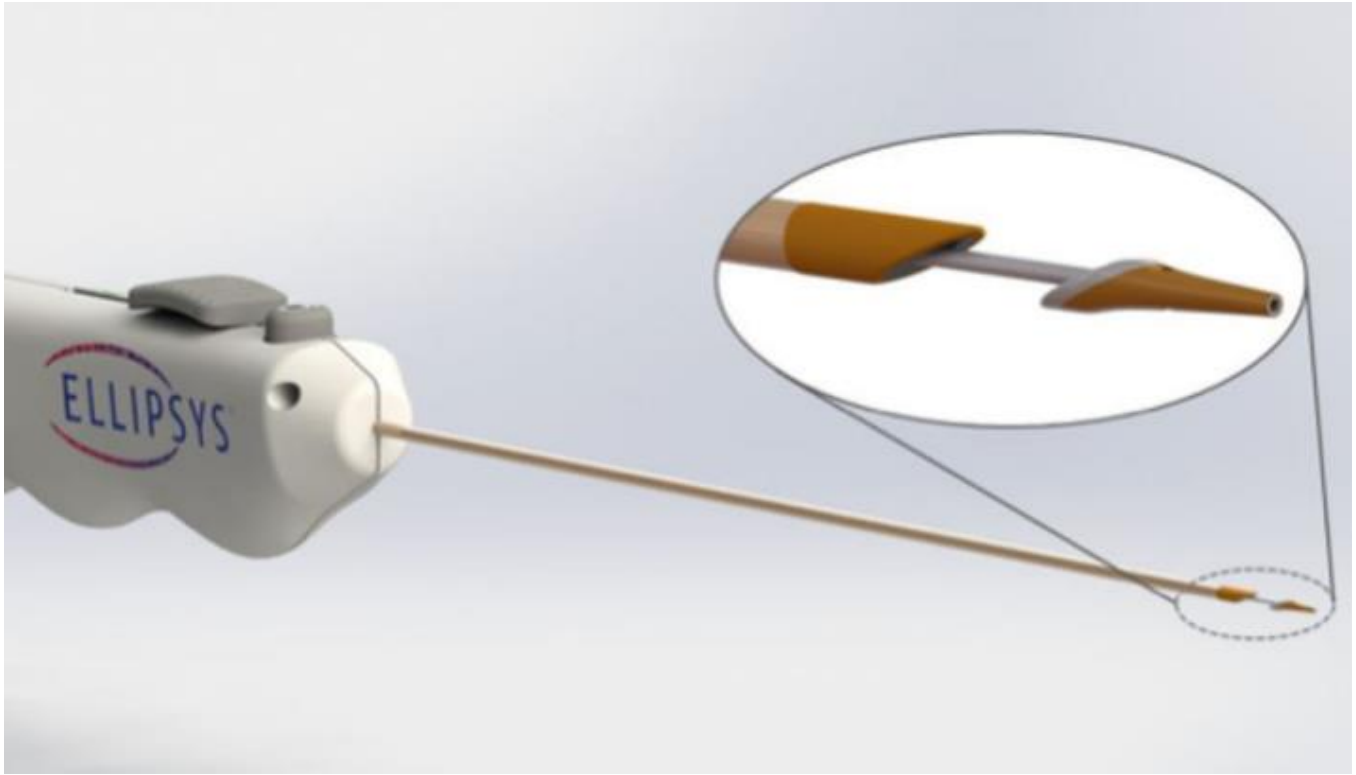


Perforating vein



Percutaneous AVF devices

Percutaneous AVF devices - Ellipsys



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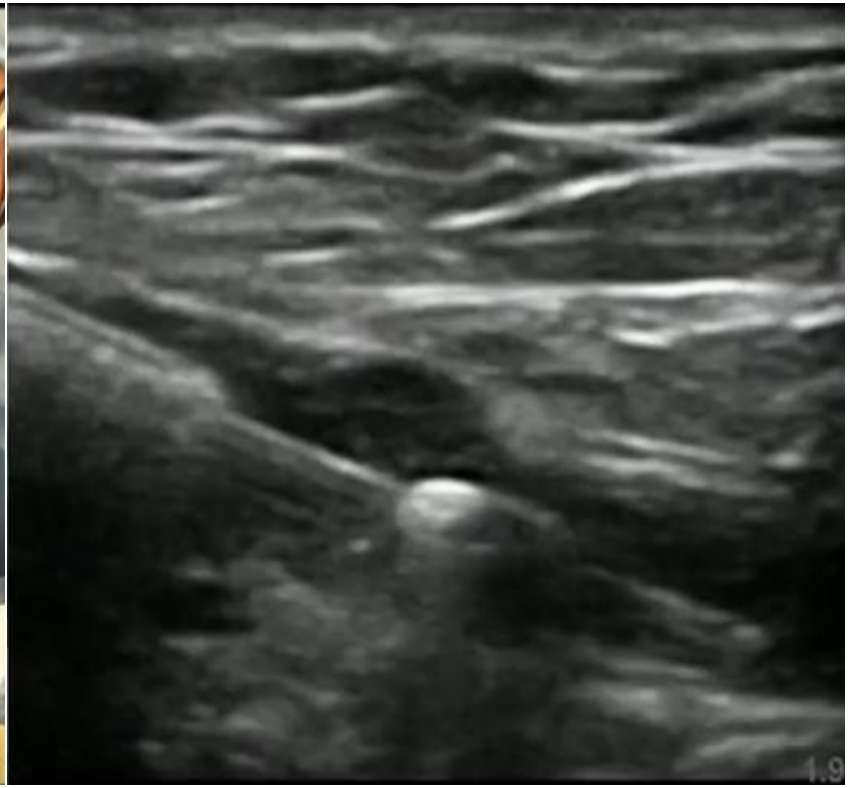

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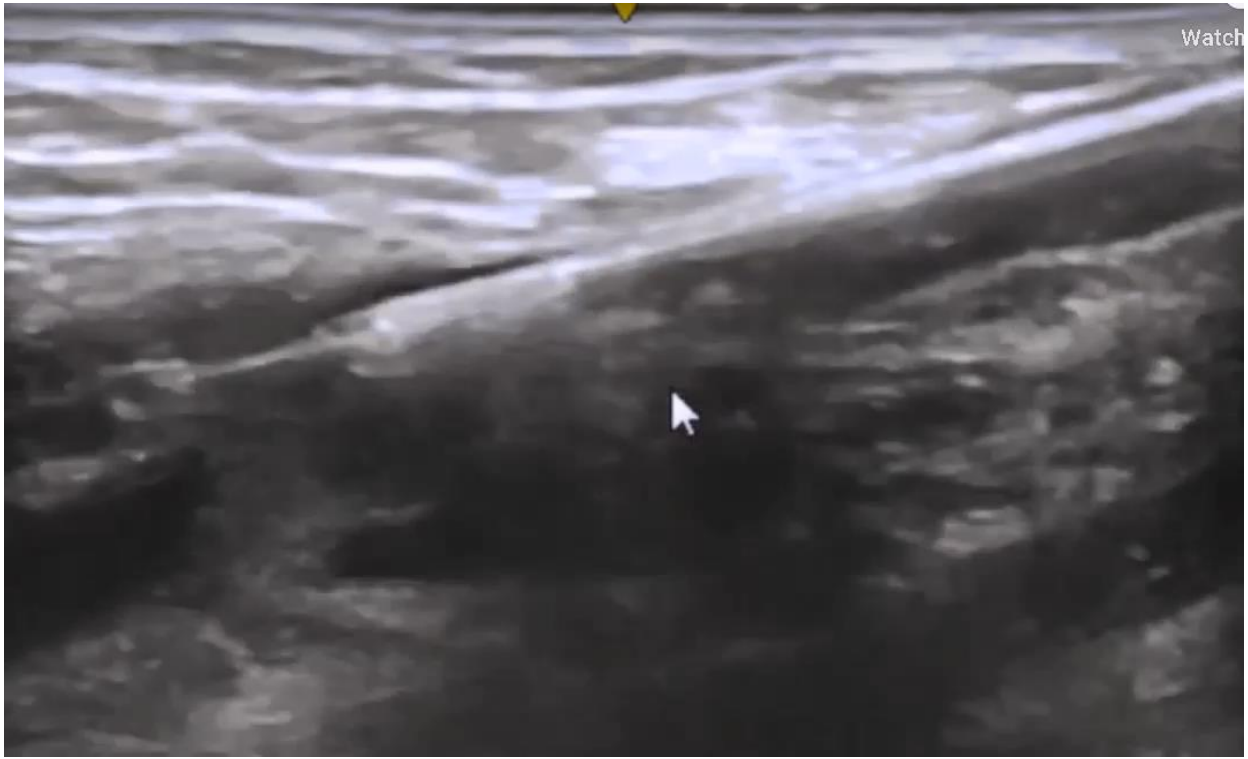
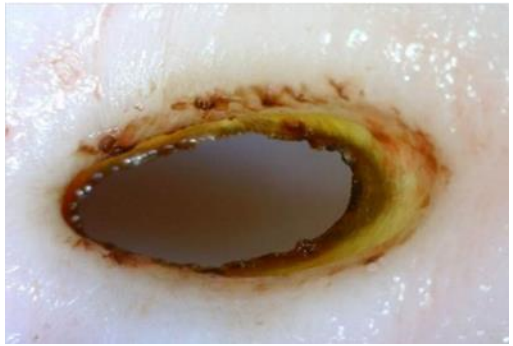


Percutaneous AVF devices - Comparison

ELLIPSYS



- Post balloon angioplasty to 5 mm
- Immediate tissue fusion

Author (Year)	Device	# pts	Technical success	Maturation 90d	Median time to maturation	Mean time to 2 needle cann	Patency
Hull (2017)	E	107	95%	86%		114.3 d	86.7% 24m, cum
Hebibi (2019)	E	34	97%	82%	(10d-6w)		
Mallios (2019)	E	34	97%				82% prim 94% sec
Beathard (2019)	E	105	Unkwn	100%			92.7% 24m, cum

Author (Year)	Device	# pts	Intervention rate (ppy)	Major adverse event rate	Adverse events
Hull (2017)	E	107	2.7	many	thrombosis, anast stenosis, steal, ven HTN, coil mig, vein rupture, neuropathy
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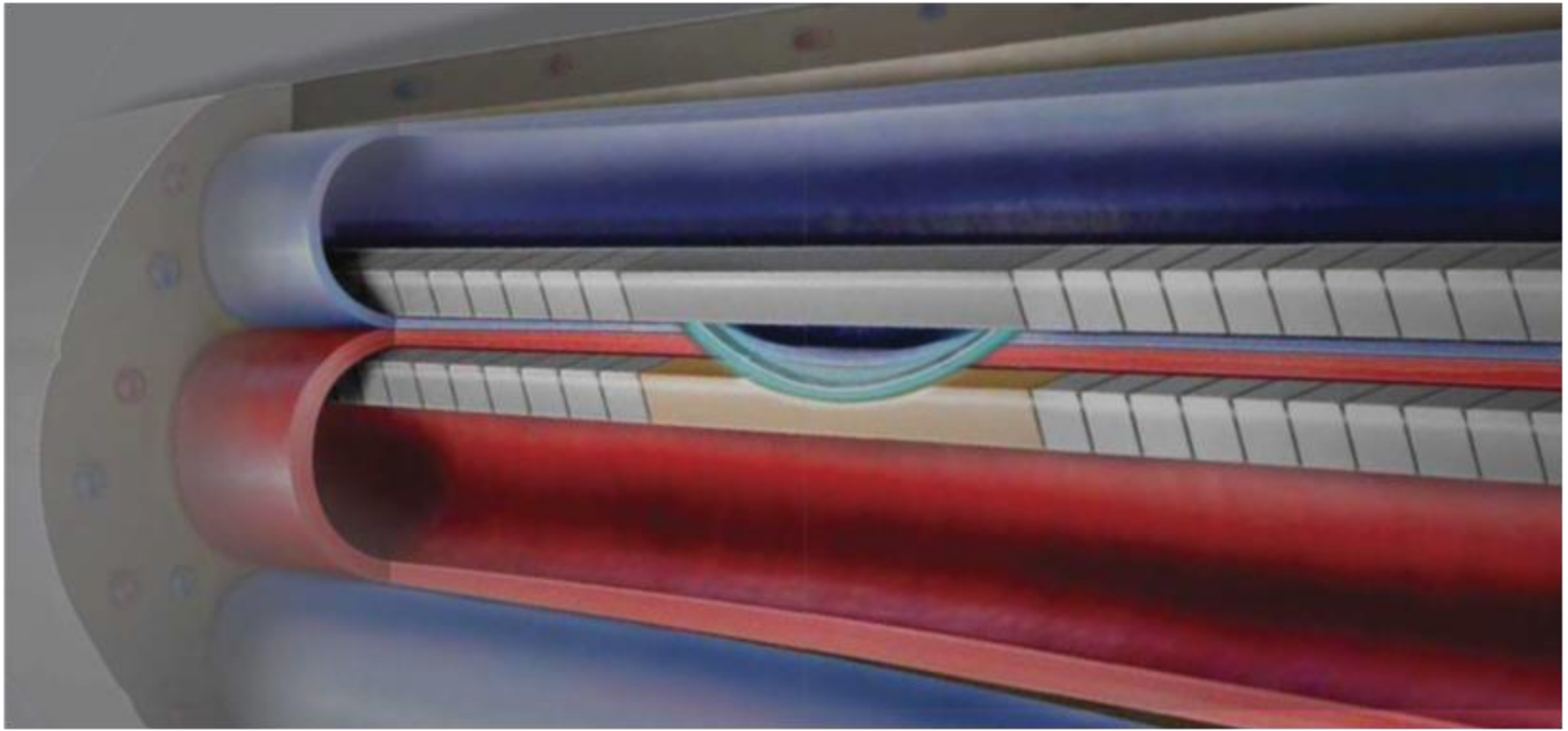
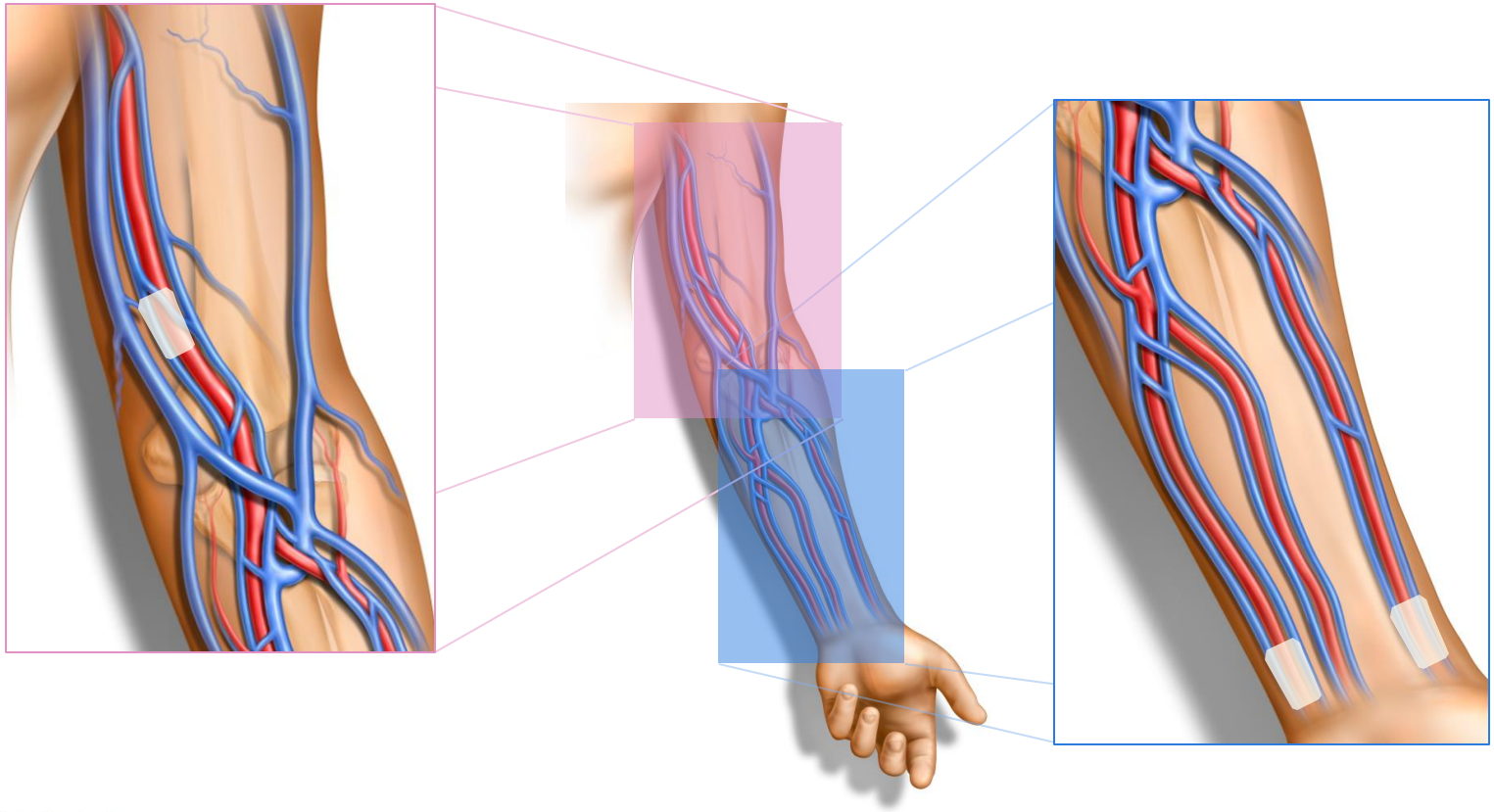
Percutaneous AVF devices

Percutaneous AVF devices - WavelinQ



Percutaneous AVF devices - WavelinQ



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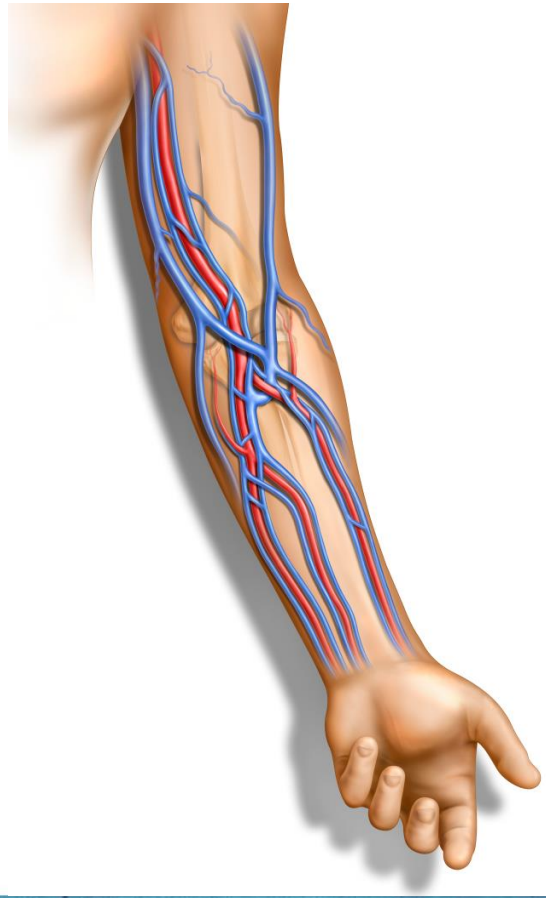

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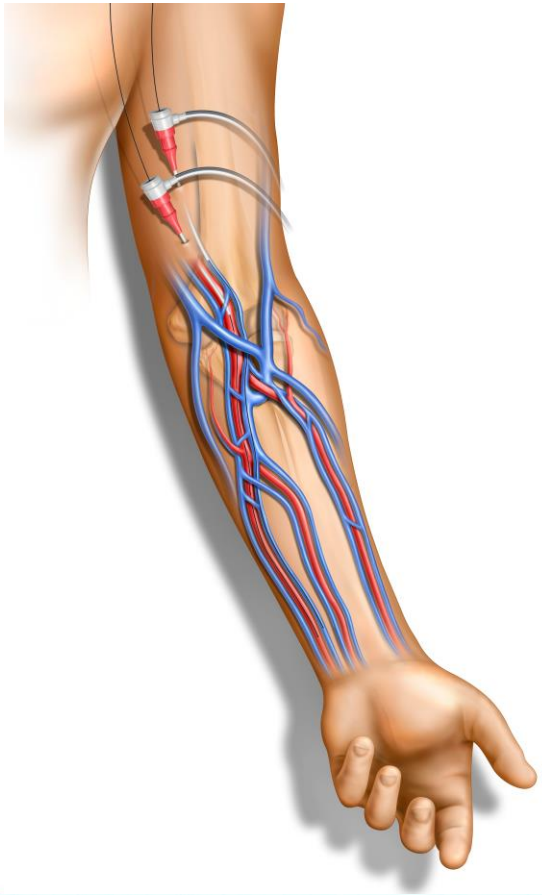

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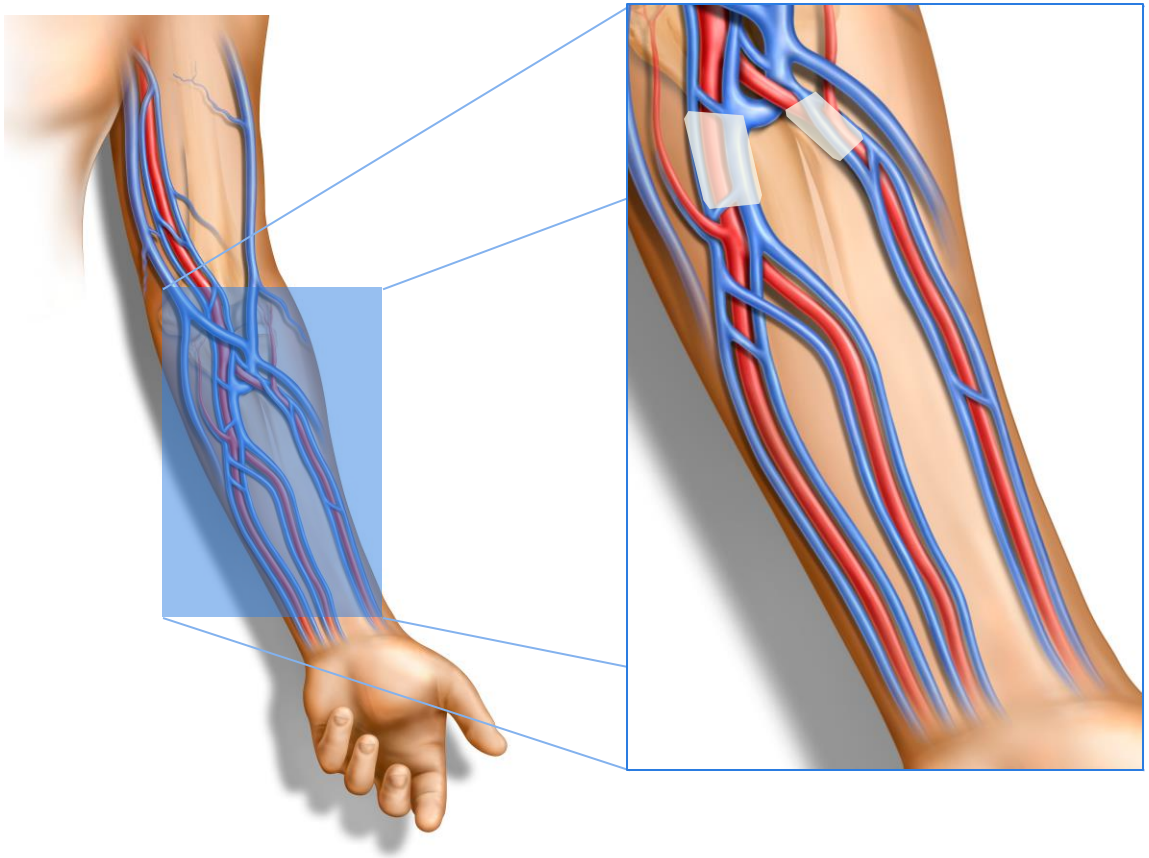
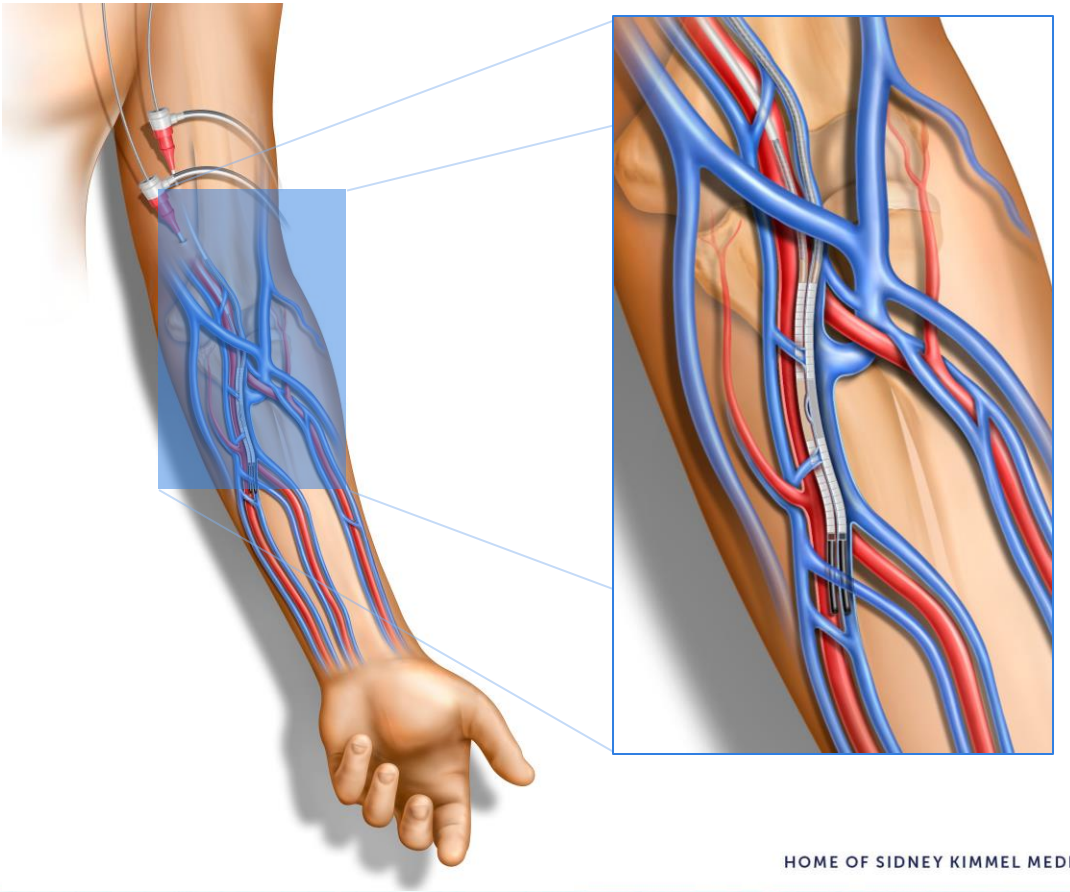


Percutaneous AVF devices - WavelinQ

Artery

Vein



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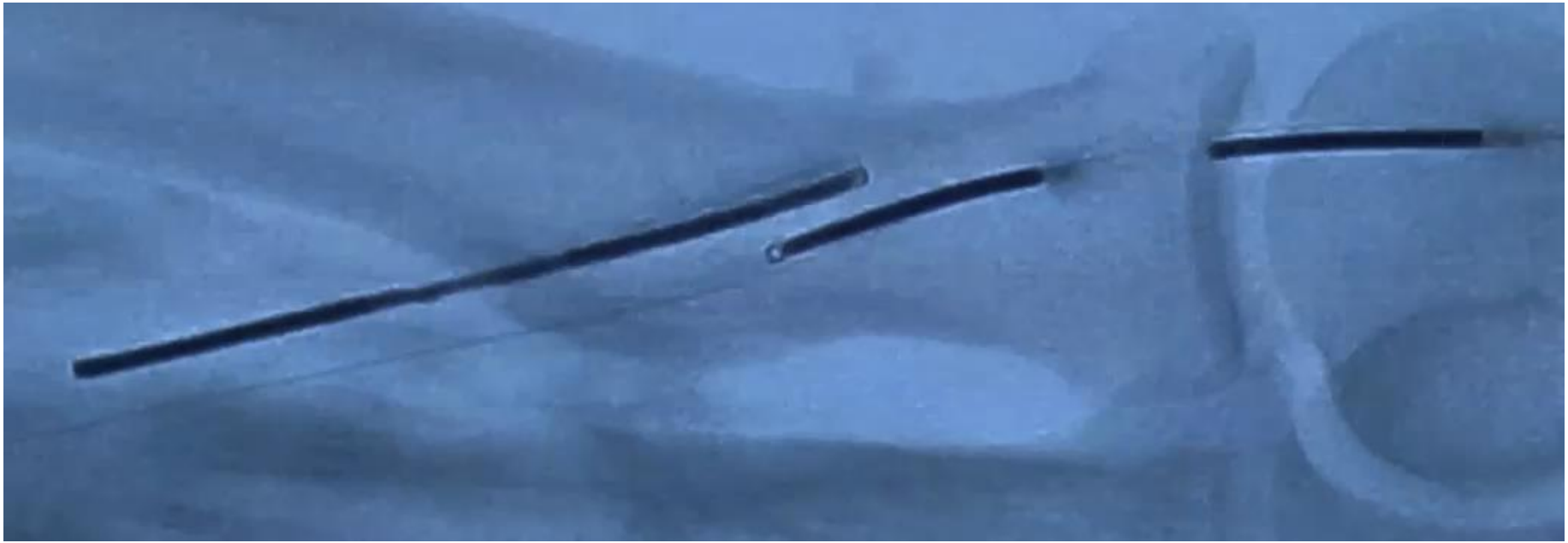

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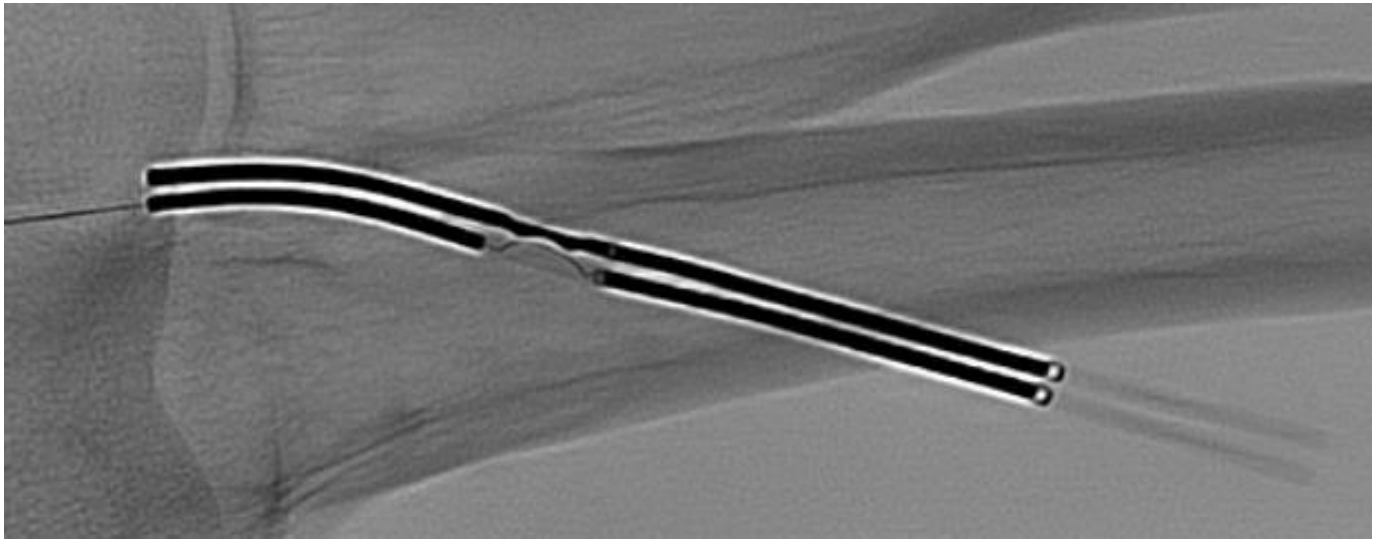

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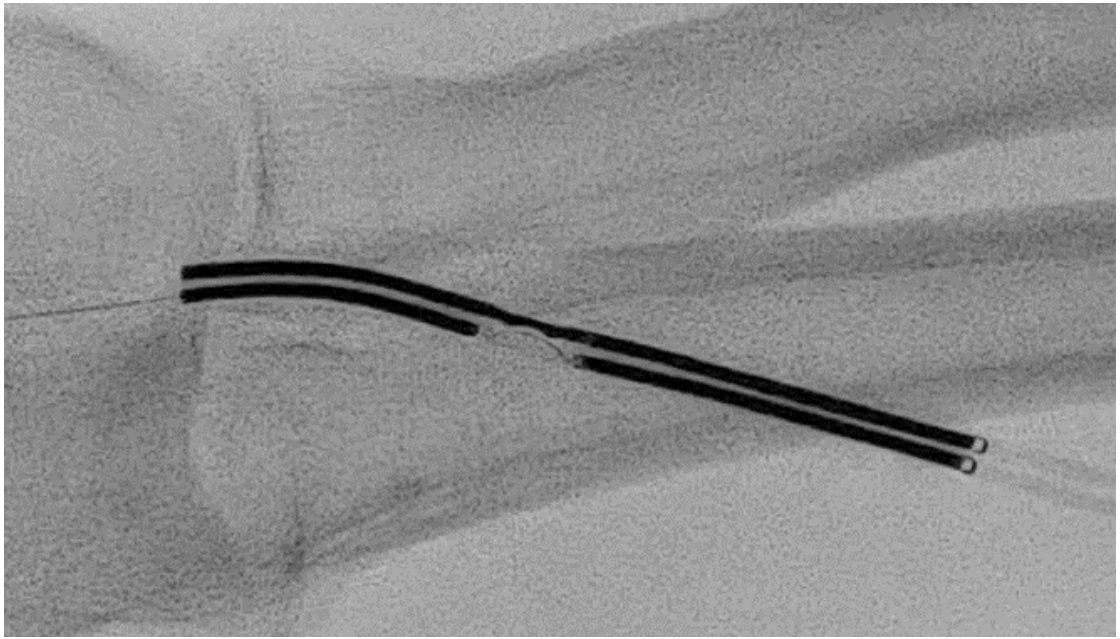

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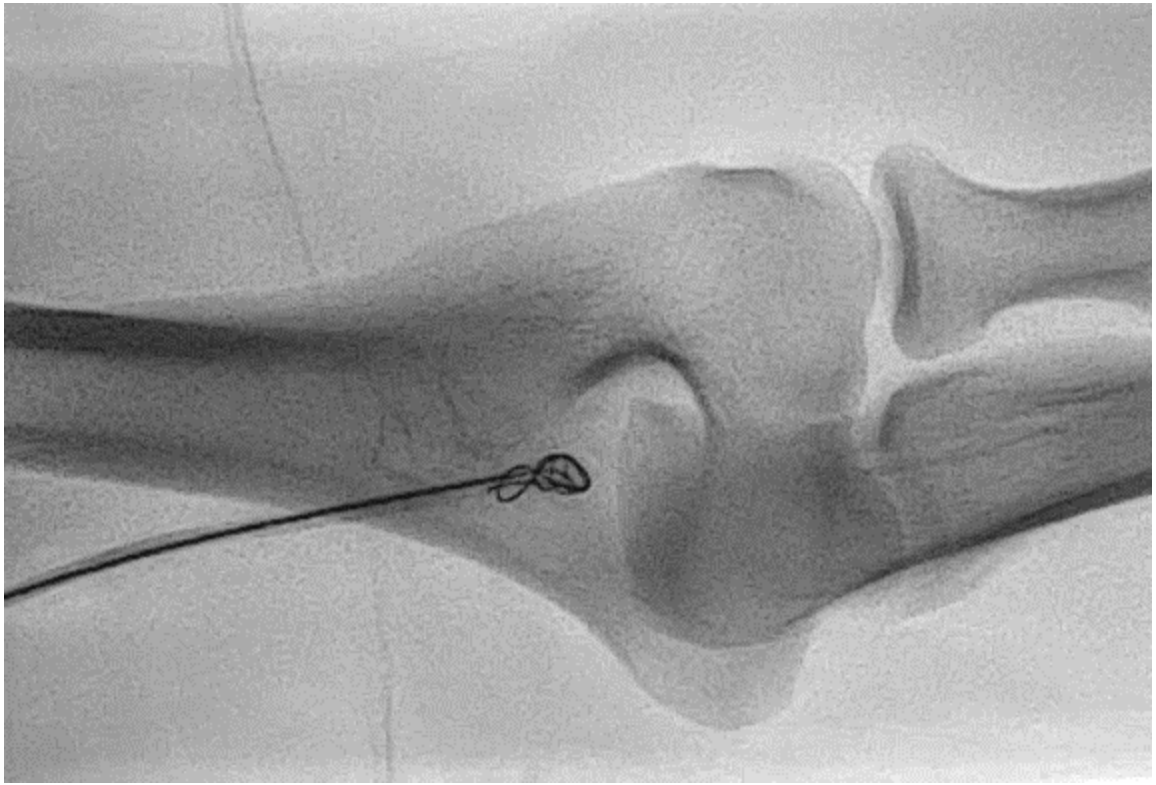
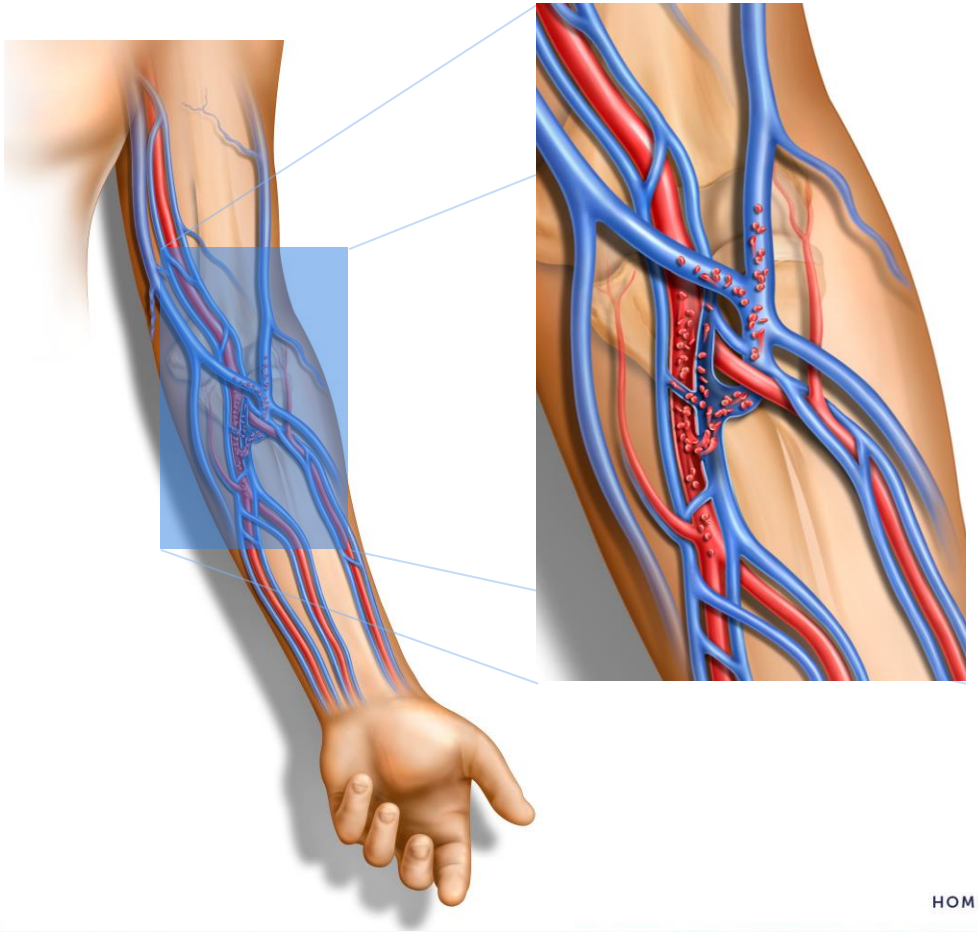
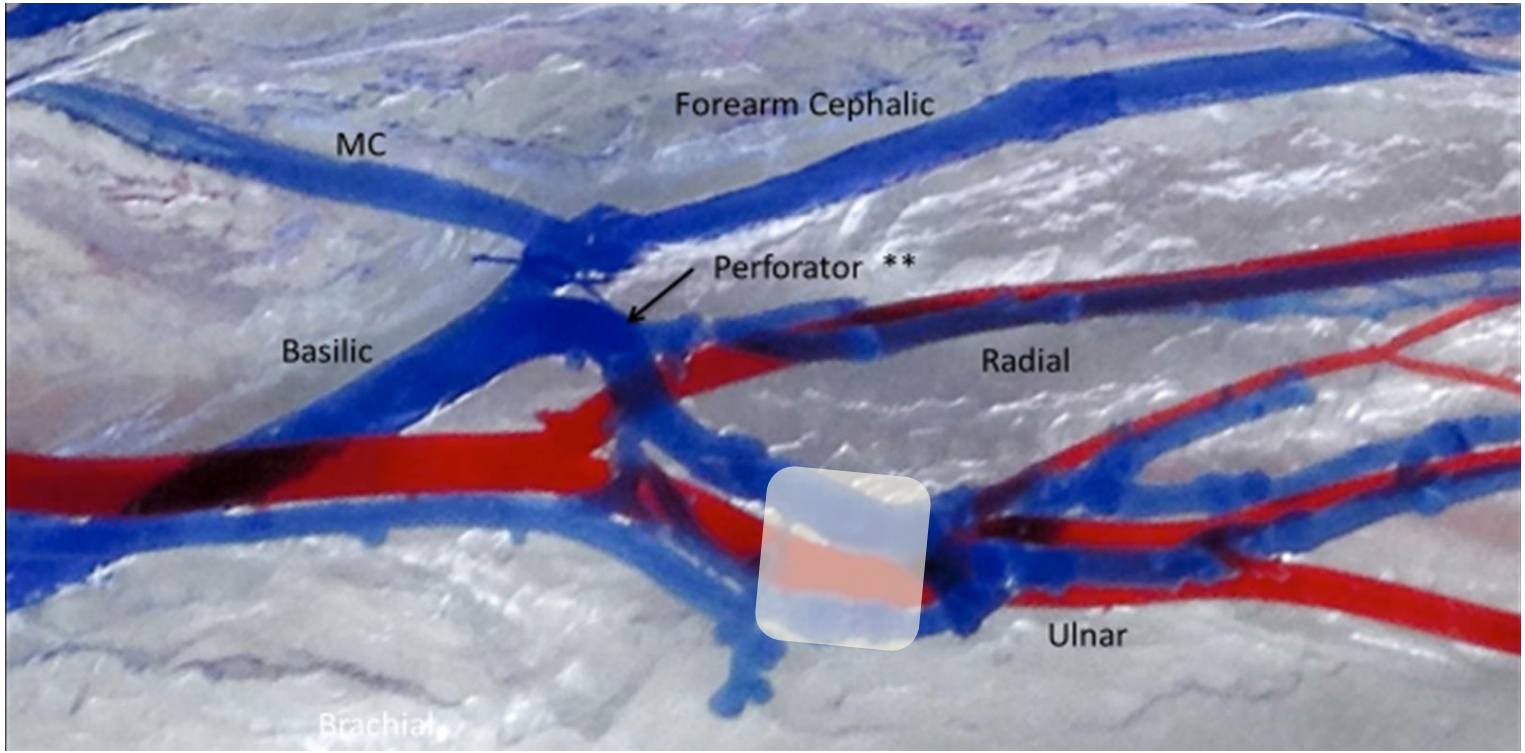


Post AVF creation

Percutaneous AVF devices

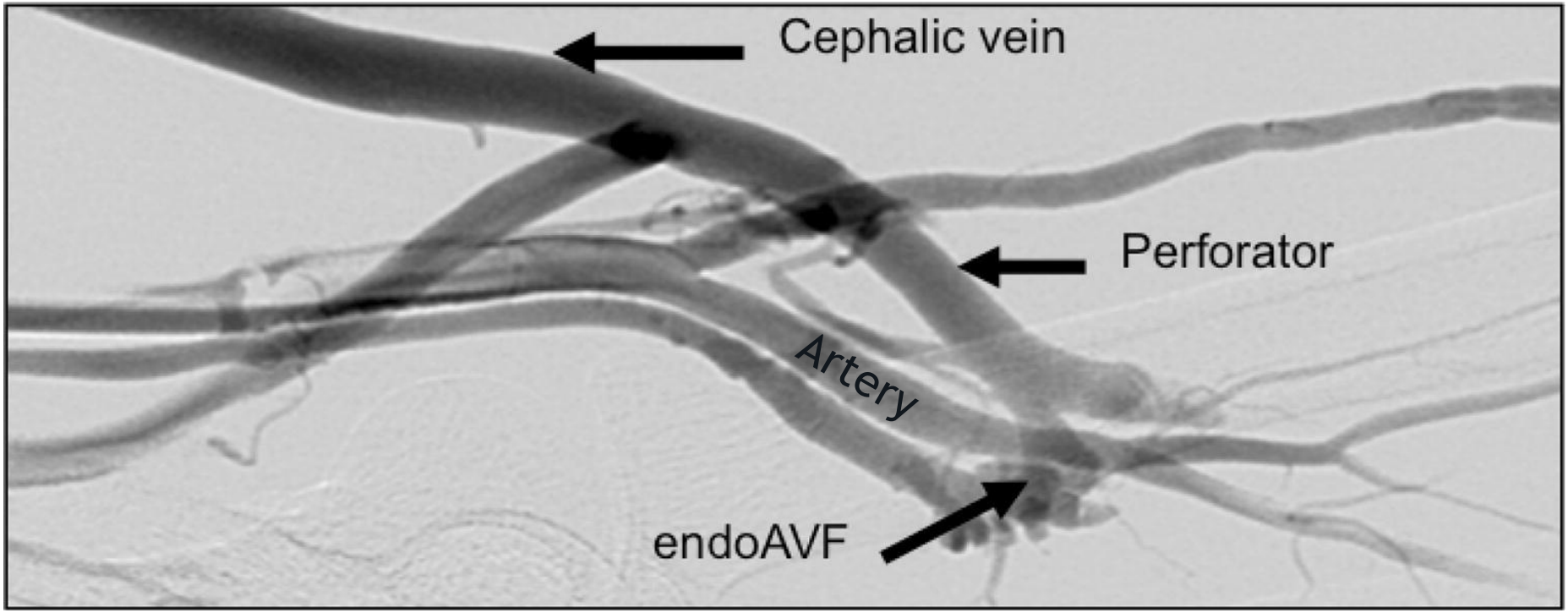


Percutaneous AVF devices - WavelinQ



Pre AVF creation

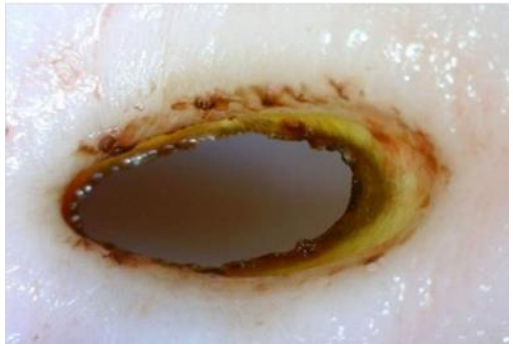
Percutaneous AVF devices



Post AVF creation

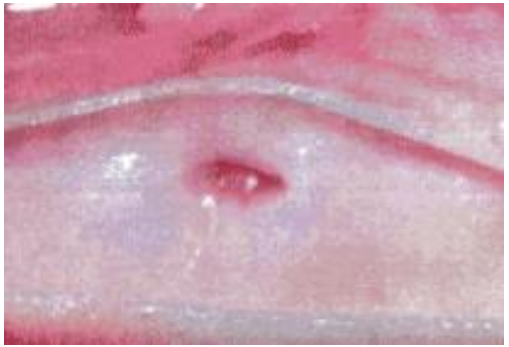
Percutaneous AVF devices - Comparison

ELLIPSYS



- Post balloon angioplasty to 5 mm
- Immediate tissue fusion

WAVELINQ™ | 4F
EndoAVF System



- Coil 1 brachial vein
- Endothelialized tract ~30d (48h)

Percutaneous AVF devices - WavelinQ

Author (Year)	Device	# pts	Technical success	Maturation 90d	Median time to maturation	Mean time to 2 needle cann	Patency	Use for ≥75% of sessions
Rajan (2015)	W	33	97%	96%	58 d (37-168 d)	--	96% $_{6m}$	100%
Lok (2017)	W	60	98%	87%	--	111.8 d $_{HD}$ 32.4 d $_{nonHD}$	84% $_{12m, cum}$	--
Radosa (2017)	W	8	100%	86%	63 d (26-137 d)	--	100% $_{6m}$	100%
Berland (2019)	W	32	100%	91%	--	43 ± 14 d	87% $_{6m, cum}$	74%
Hull (2017)	E	107	95%	86%		114.3 d	86.7% $_{24m, cum}$	
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Beathard (2019)	E	105	Unkwn	100%			92.7% $_{24m, cum}$	

Author (Year)	Device	# pts	Intervention rate (ppy)	Major adverse event rate	Adverse events
Rajan (2015)	W	33	0.1-0.6	3% (1)	brachial artery PSA
Lok (2017)	W	60	0.46	8% (5)	closure device embo, brach art dissection and thrombus, PSA (access site, endoAVF site), steal syndrome
Radosa (2017)	W	8	0.12	0%	--
Berland (2019)	W	32	0.21	3% (1)	guidewire perf tx'd w/ stenting
Hull (2017)	E	107	2.7	many	thrombosis, anast stenosis, steal, ven HTN, coil mig, vein rupture, neuropathy
Hebibi (2019)	E	34	35%	--	--
Mallios (2019)	E	34	2.9%	**0%**	--
Beathard (2019)	E	105	--	**--**	--

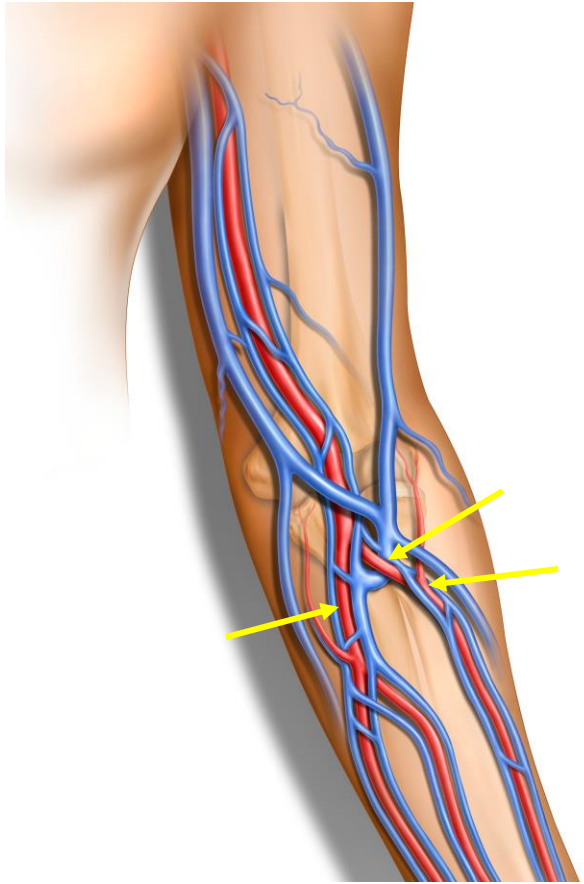
- Wee IJY, et al. J Vasc Surg (2020)
  - Meta analysis
  - WavelinQ and Ellipsys
  - 300 patients

Maturation →
Diameter ≥4 mm
Flow rate: ≥500 mL/min

	WavelinQ	Ellipsys
Technical success	99.45%	95.19%
90 d maturation	89.27%	89.35%
6 mo patency	85.71%	90.98%
Procedure AE	8.59%	2.48%

Percutaneous AVF devices

Candidates for pAVF
+ Perforator vein
No prior upper arm AVF creation
No flow limiting central stenosis
Vessel size at target creation site ≥ 2 mm
No significant arterial calcification
Conscious sedation candidate



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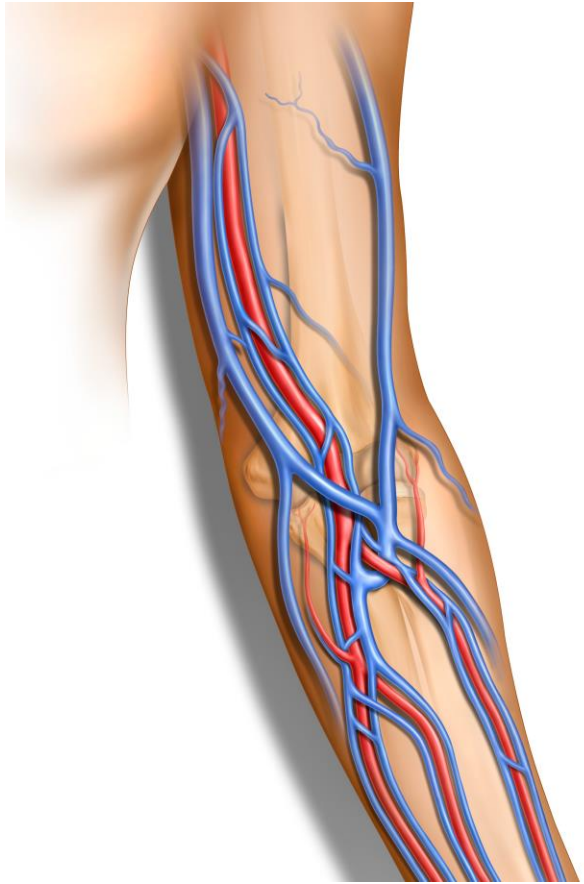
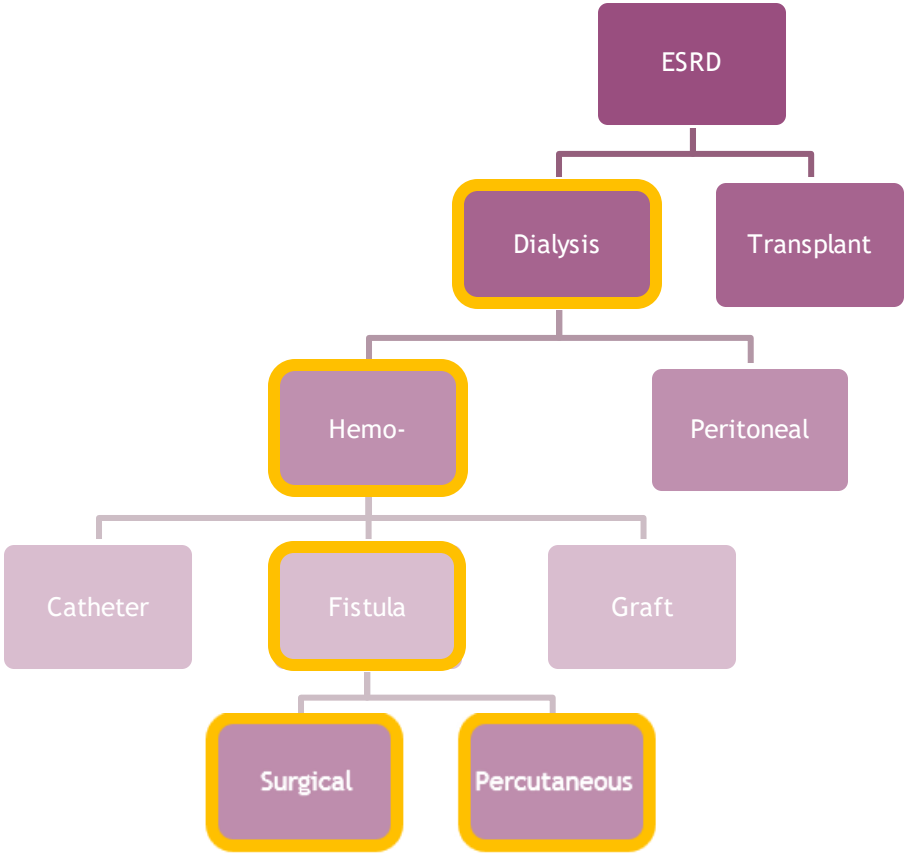


Renal replacement therapy



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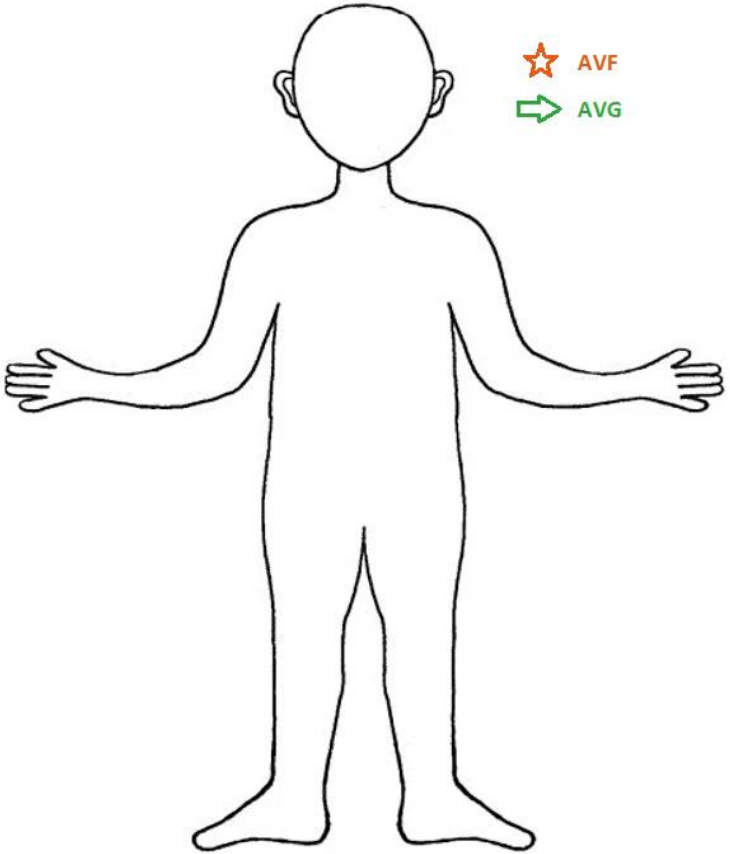
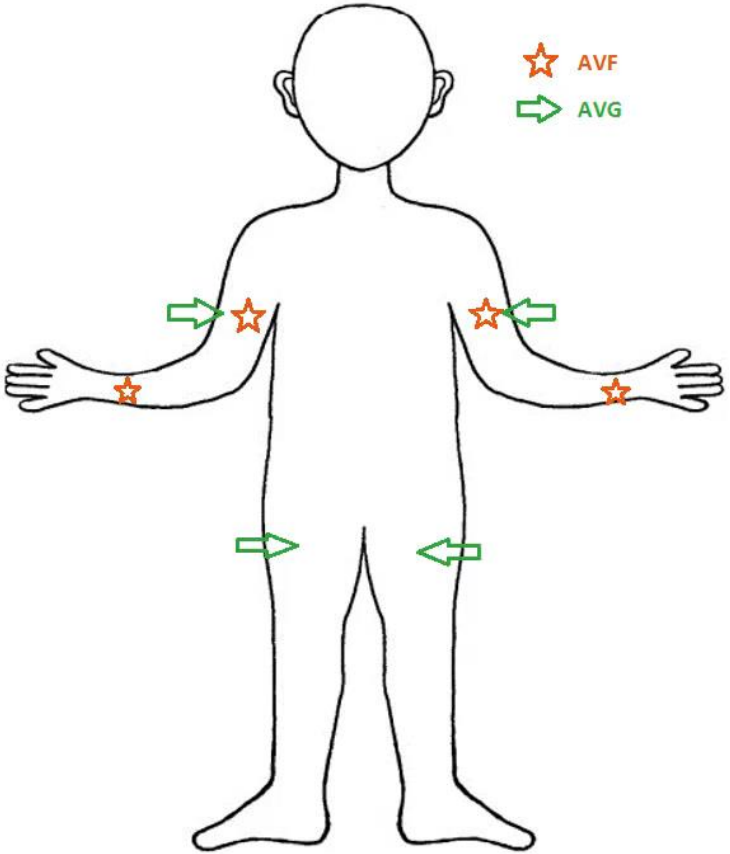
Rajan (2015)	33	97%	96%	58 d (37-168 d)	--	96% 6m	100%
Lok (2017)	60	98%	87%	--	111.8 d HD 32.4 d nonHD	69% 12m, primary 84% 12m, cum	--
Radosa (2017)	8	100%	86%	63 d (26-137 d)	--	100% 6m	100%
Berland (2019)	32	100%	91%	--	43 ± 14 d	87% 6m, cum	74%
Surgical AVFs	--	93%	40-80%	159 d (77-285 d)		60% 12m, primary 71% 12m, cum	

Author (Year)	# pts	Major adverse event rate	Intervention rate (ppy)	Interventions needed
Rajan (2015)	33	3% (1)	0.1-0.6	Brachial artery PSA
Lok (2017)	60	8% (5)	0.46	Closure device embo, brach art dissection and thrombus, PSA (access site, endoAVF site), Steal Syndrome
Radosa (2017)	8	0%	0.12	--
Berland (2019)	32	3% (1)	0.21	Guidewire perf tx'd w/ stenting
Surgical AVFs	--	--	1.5-3.3	Superficialization, angioplasty, stenting, revision, conversion to AVG, Steal syndrome, tributary ligation, thrombectomy, etc


AVF
AVG


AVF
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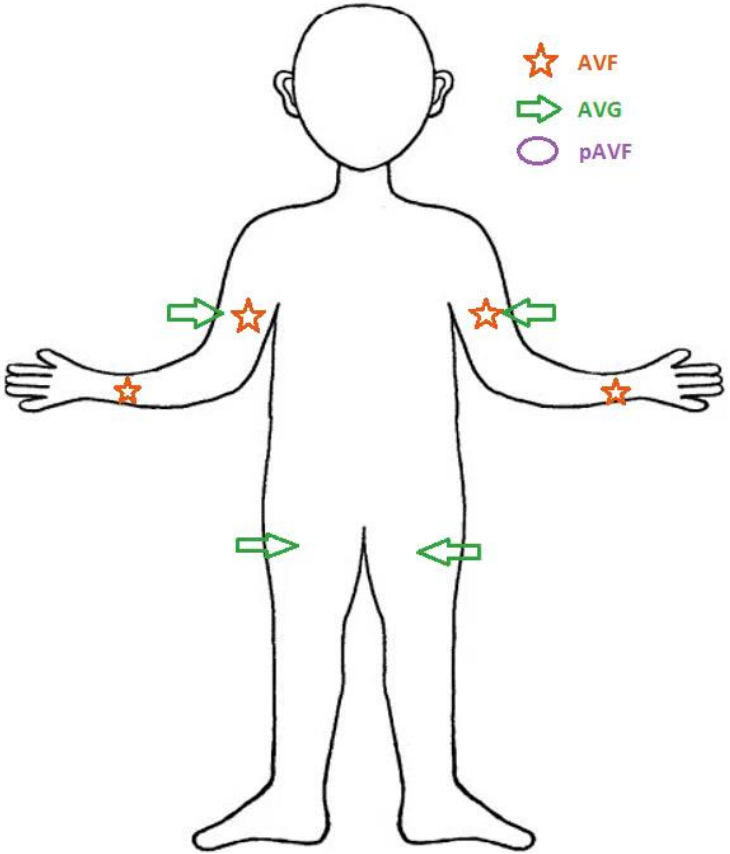
AVF
AVG
pAVF


Jefferson
Philadelphia University +
Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE