Hemodialysis Vascular Access

How we started

Where we are

How we got here

Where we're going

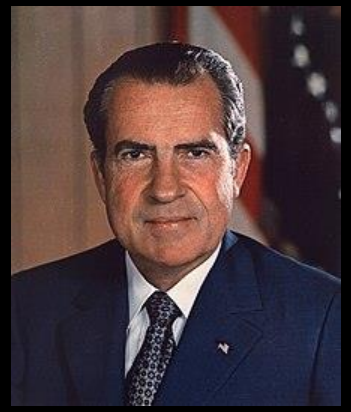
Theodore F. Saad, MD, FASDIN
Nephrology Associates, P.A.
Chief, Section of Renal & Hypertensive Diseases
Christiana Care Heath System, Newark DE
tsaad@delawarekidney.com
www.delawarekidney.com

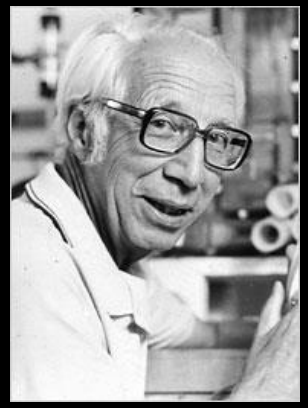
Dialysis Access "Potpourri"

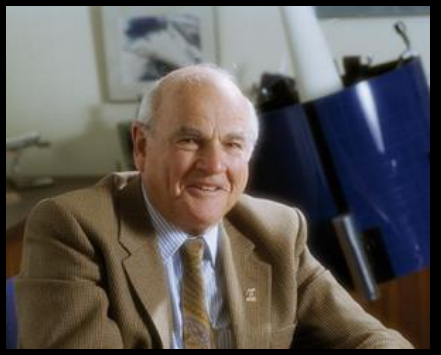
- History
- Medical economics
- Ethics
- Policy/politics
- Clinical science
- New technologies

Highlight areas that our practice and/or Christiana Care colleagues have studied

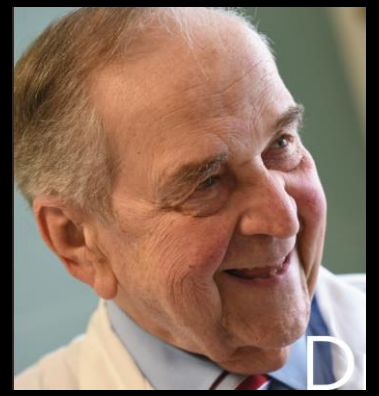
Heroes of this Story

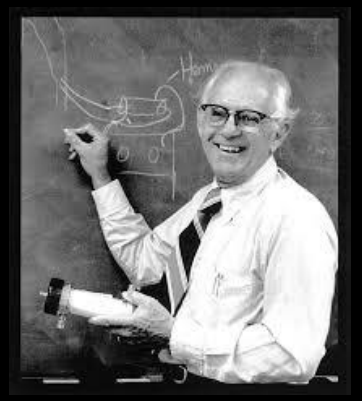






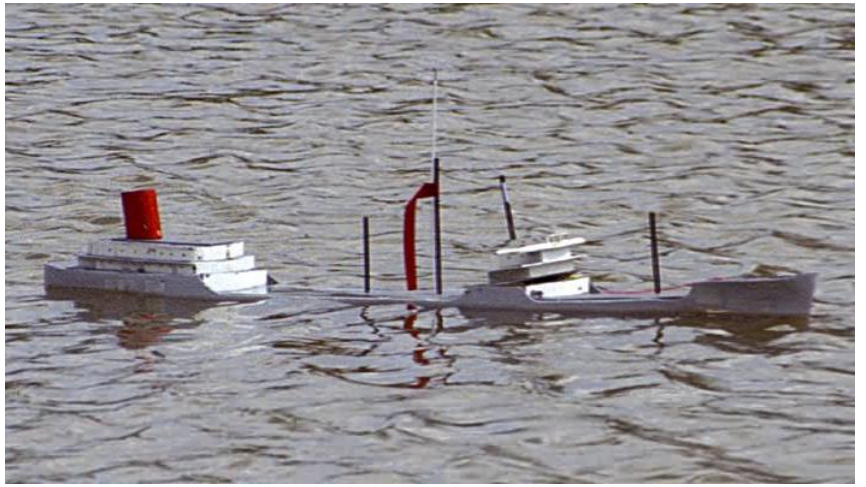
- Patients
- Families
- Advocates
- Caretakers
- Pioneers
- Politicians



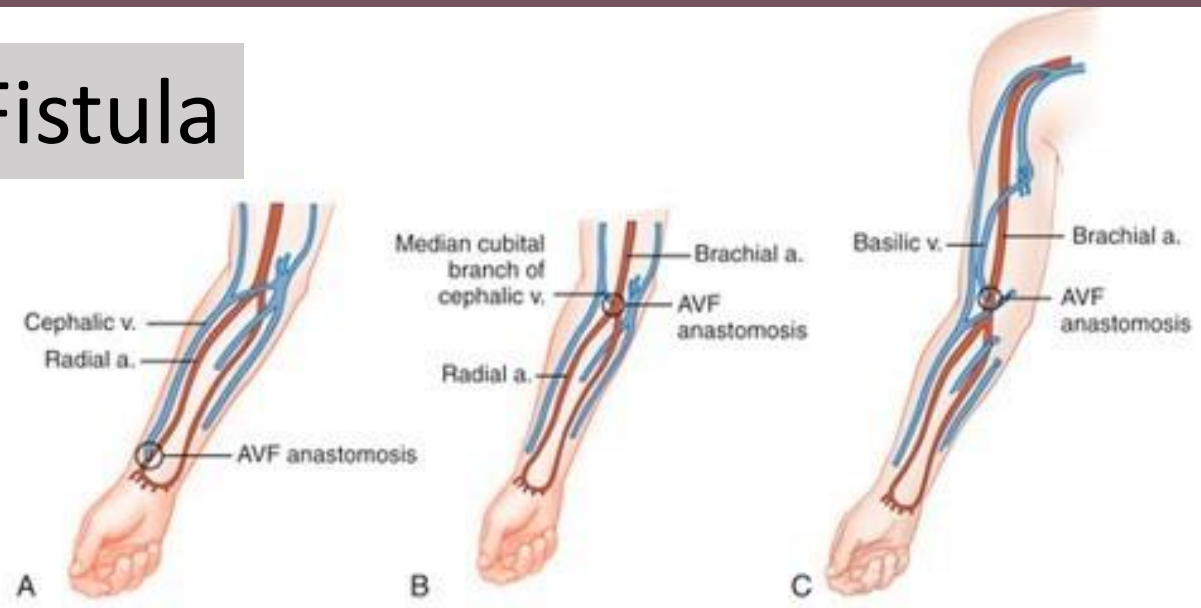


Hemodialysis Vascular Access:

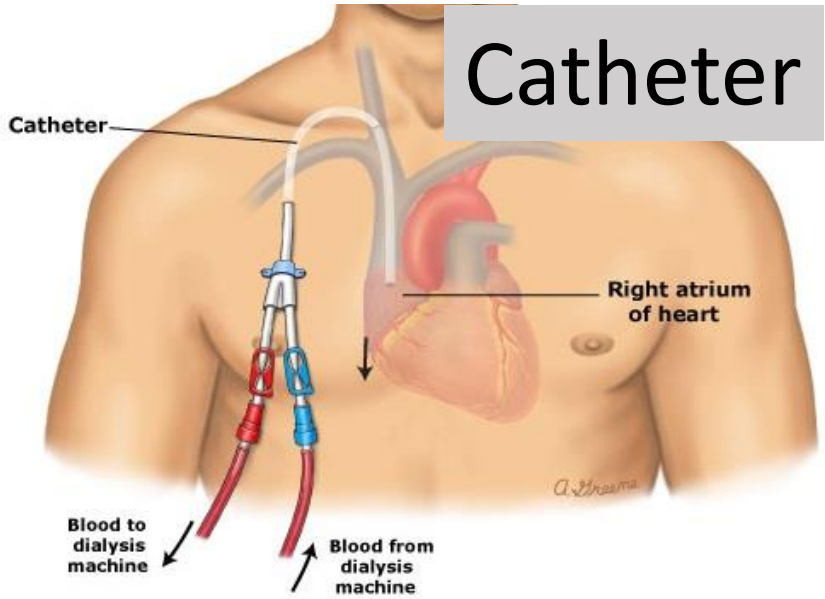
- Essential for everything we do with dialysis
  - Clearance of uremic toxins & electrolytes
  - Volume & BP control
  - Anemia & iron management
  - Phosphorous and bone-mineral management
- Reliable
- Safe
- Comfortable
- Durable
- Cost-effective



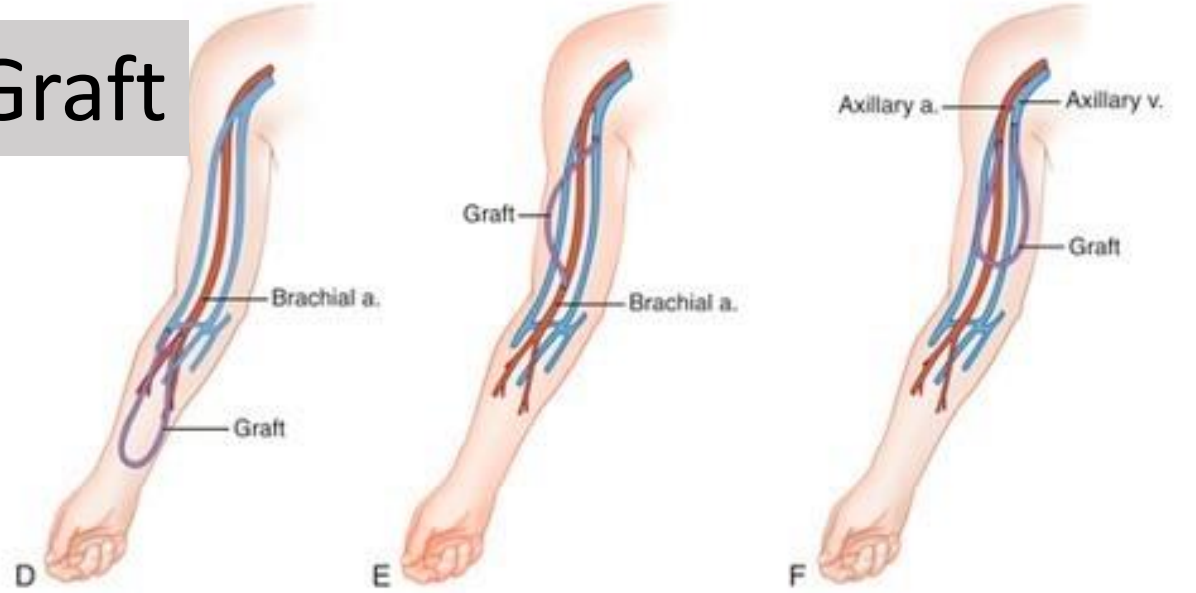
Fistula

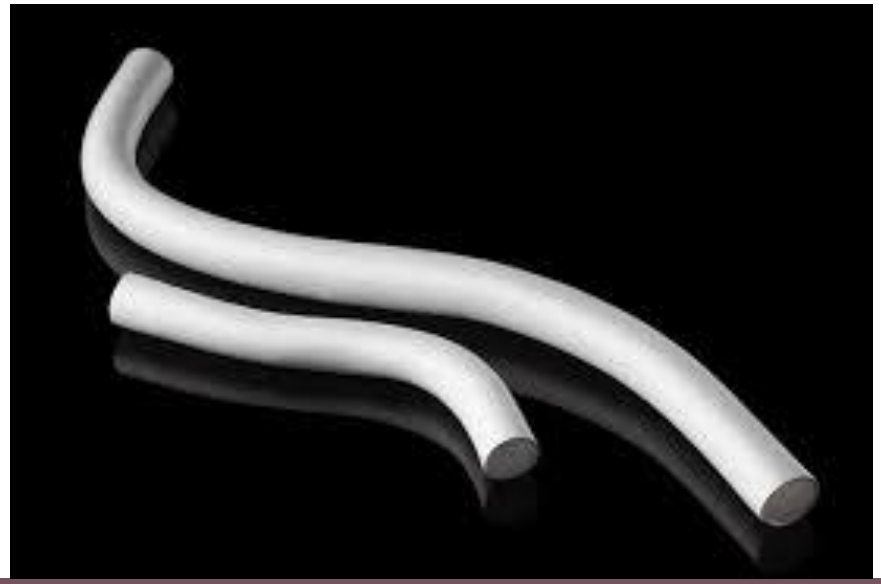


Catheter



Graft





United States Renal Data System
https://www.usrds.org

- National data system that collects, analyzes, and distributes information about chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States.
- All US patients with ESRD included
- Funded by NIH Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)
  - Centers for Medicare & Medicaid Services (CMS)
  - United Network for Organ Sharing (UNOS)
  - ESRD networks
- All data open and publicly available

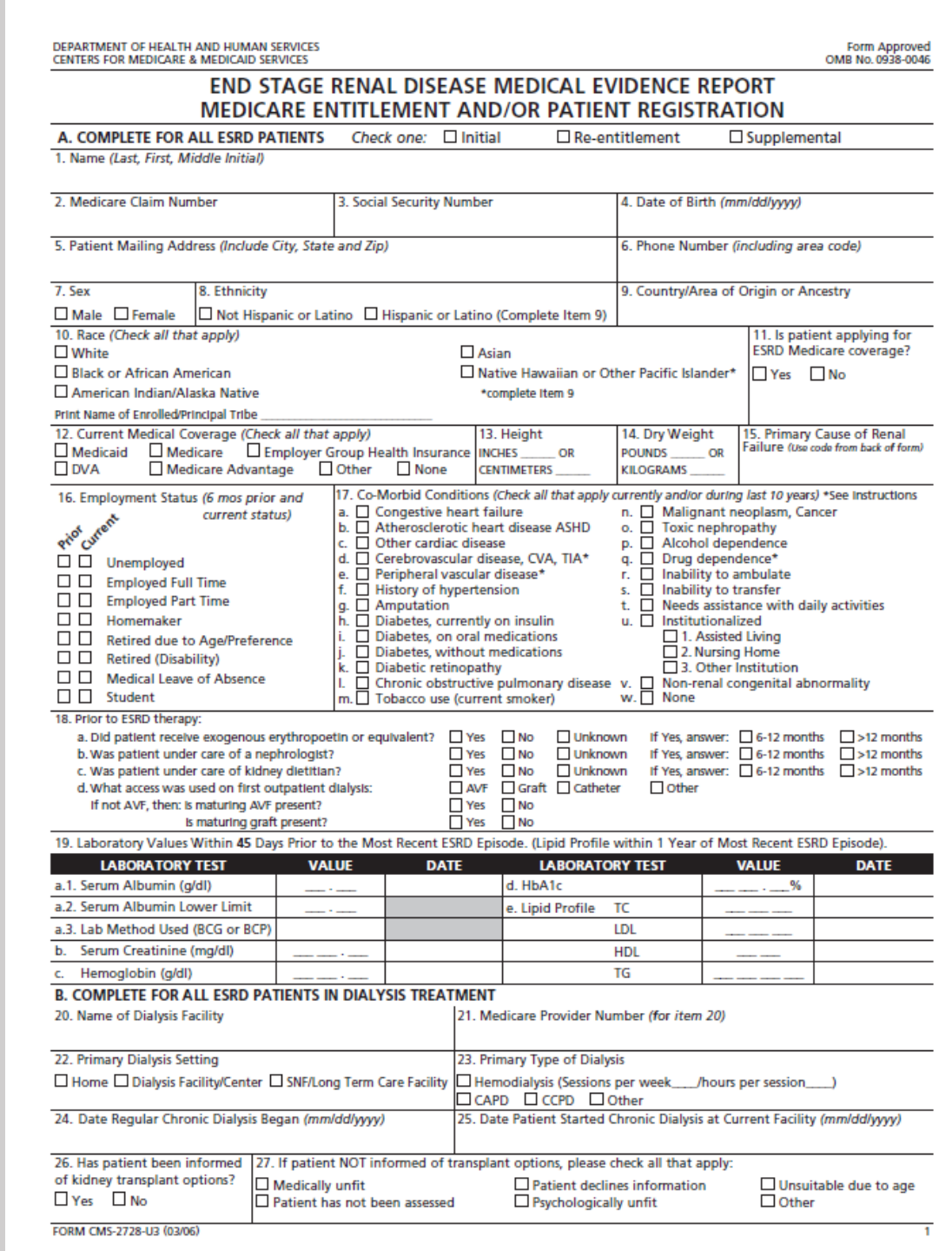
University of Michigan Kidney Epidemiology and Cost Center

United States Renal Data System
Six Central Goals of USRDS

1. Characterize the ESRD population
2. Describe the prevalence and incidence of ESRD along with trends in mortality and disease rates
3. Investigate relationships among patient demographics, treatment modalities, and morbidity
4. Report the costs of ESRD treatments and total burden of ESRD program in the United States
5. Identify new areas for special renal studies and support investigator-initiated research
6. Provide data sets and samples of national data to support research by the Special Studies Centers

CMS Form 2728 Declaration of ESRD

- Required by CMS for all new ESRD patients
  - Demographics
  - Pre-dialysis care
  - Co-morbidities
  - Dialysis Access
  - Treatment modality



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0046

END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS *Check one:* ☐ Initial ☐ Re-entitlement ☐ Supplemental

1. Name *(Last, First, Middle Initial)*

2. Medicare Claim Number | 3. Social Security Number | 4. Date of Birth *(mm/dd/yyyy)*

5. Patient Mailing Address *(Include City, State and Zip)* | 6. Phone Number *(including area code)*

7. Sex ☐ Male ☐ Female | 8. Ethnicity ☐ Not Hispanic or Latino ☐ Hispanic or Latino (Complete Item 9) | 9. Country/Area of Origin or Ancestry

10. Race *(Check all that apply)*
☐ White ☐ Asian
☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander*
☐ American Indian/Alaska Native *complete item 9
Print Name of Enrolled/Principal Tribe _____

11. Is patient applying for ESRD Medicare coverage? ☐ Yes ☐ No

12. Current Medical Coverage *(Check all that apply)*
☐ Medicaid ☐ Medicare ☐ Employer Group Health Insurance ☐ DVA ☐ Medicare Advantage ☐ Other ☐ None

13. Height INCHES _____ OR CENTIMETERS _____

14. Dry Weight POUNDS _____ OR KILOGRAMS _____

15. Primary Cause of Renal Failure *(Use code from back of form)*

16. Employment Status *(6 mos prior and current status)*

Prior	Current	
☐	☐	Unemployed
☐	☐	Employed Full Time
☐	☐	Employed Part Time
☐	☐	Homemaker
☐	☐	Retired due to Age/Preference
☐	☐	Retired (Disability)
☐	☐	Medical Leave of Absence
☐	☐	Student

17. Co-Morbid Conditions *(Check all that apply currently and/or during last 10 years)* *See Instructions

a. ☐ Congestive heart failure
b. ☐ Atherosclerotic heart disease ASHD
c. ☐ Other cardiac disease
d. ☐ Cerebrovascular disease, CVA, TIA*
e. ☐ Peripheral vascular disease*
f. ☐ History of hypertension
g. ☐ Amputation
h. ☐ Diabetes, currently on insulin
i. ☐ Diabetes, on oral medications
j. ☐ Diabetes, without medications
k. ☐ Diabetic retinopathy
l. ☐ Chronic obstructive pulmonary disease
m. ☐ Tobacco use (current smoker)
n. ☐ Malignant neoplasm, Cancer
o. ☐ Toxic nephropathy
p. ☐ Alcohol dependence
q. ☐ Drug dependence*
r. ☐ Inability to ambulate
s. ☐ Inability to transfer
t. ☐ Needs assistance with daily activities
u. ☐ Institutionalized
☐ 1. Assisted Living
☐ 2. Nursing Home
☐ 3. Other Institution
v. ☐ Non-renal congenital abnormality
w. ☐ None

18. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
b. Was patient under care of a nephrologist?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
c. Was patient under care of kidney dietitian?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
d. What access was used on first outpatient dialysis:	☐ AVF	☐ Graft	☐ Catheter		☐ Other	
If not AVF, then: is maturing AVF present?	☐ Yes	☐ No				
is maturing graft present?	☐ Yes	☐ No				

19. Laboratory Values Within **45** Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a.1. Serum Albumin (g/dl)	___ . ___		d. HbA1c	___ ___ . ___ %	
a.2. Serum Albumin Lower Limit	___ . ___		e. Lipid Profile TC	___ ___ ___	
a.3. Lab Method Used (BCG or BCP)			LDL	___ ___ ___	
b. Serum Creatinine (mg/dl)	___ ___ . ___		HDL	___ ___	
c. Hemoglobin (g/dl)	___ ___ . ___		TG	___ ___ ___ ___	

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility | 21. Medicare Provider Number *(for item 20)*

22. Primary Dialysis Setting ☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

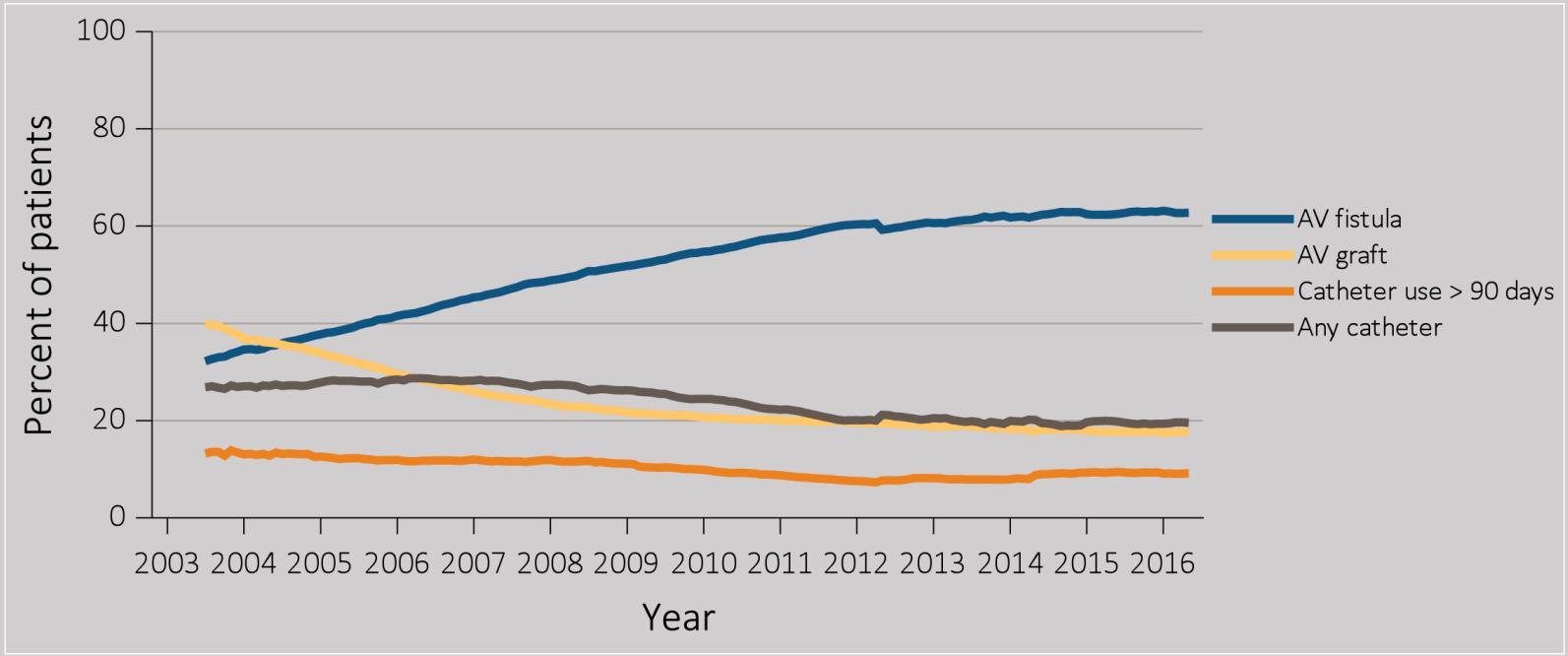
23. Primary Type of Dialysis ☐ Hemodialysis (Sessions per week____/hours per session____) ☐ CAPD ☐ CCPD ☐ Other

24. Date Regular Chronic Dialysis Began *(mm/dd/yyyy)* | 25. Date Patient Started Chronic Dialysis at Current Facility *(mm/dd/yyyy)*

26. Has patient been informed of kidney transplant options? ☐ Yes ☐ No

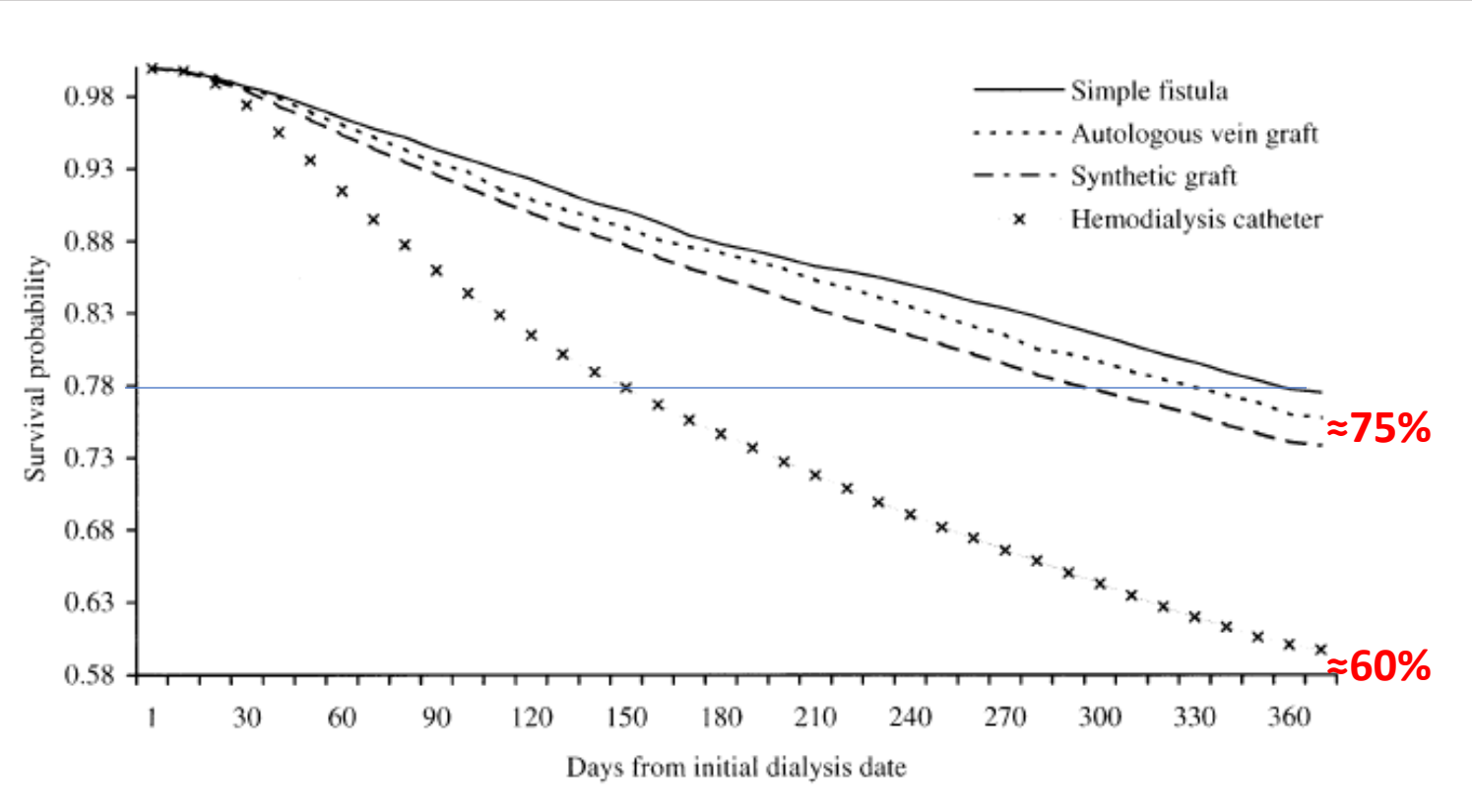
27. If patient NOT informed of transplant options, please check all that apply:
☐ Medically unfit ☐ Patient declines information ☐ Unsuitable due to age
☐ Patient has not been assessed ☐ Psychologically unfit ☐ Other

vol 2 Figure 3.6 Trends in vascular access type use among ESRD prevalent patients, 2003-2016



Data Source: Special analyses, USRDS ESRD Database and Fistula First data. Fistula First data reported from July 2003 through April 2012, CROWNWeb data are reported from June 2012 through May 2016. Abbreviations: AV, arteriovenous; CROWNWeb, Consolidated Renal Operations in a Web-enabled Network; ESRD, end-stage renal disease.

Survival & Vascular Access Type:
66,595 US Medicare HD Patients, 1995-1997

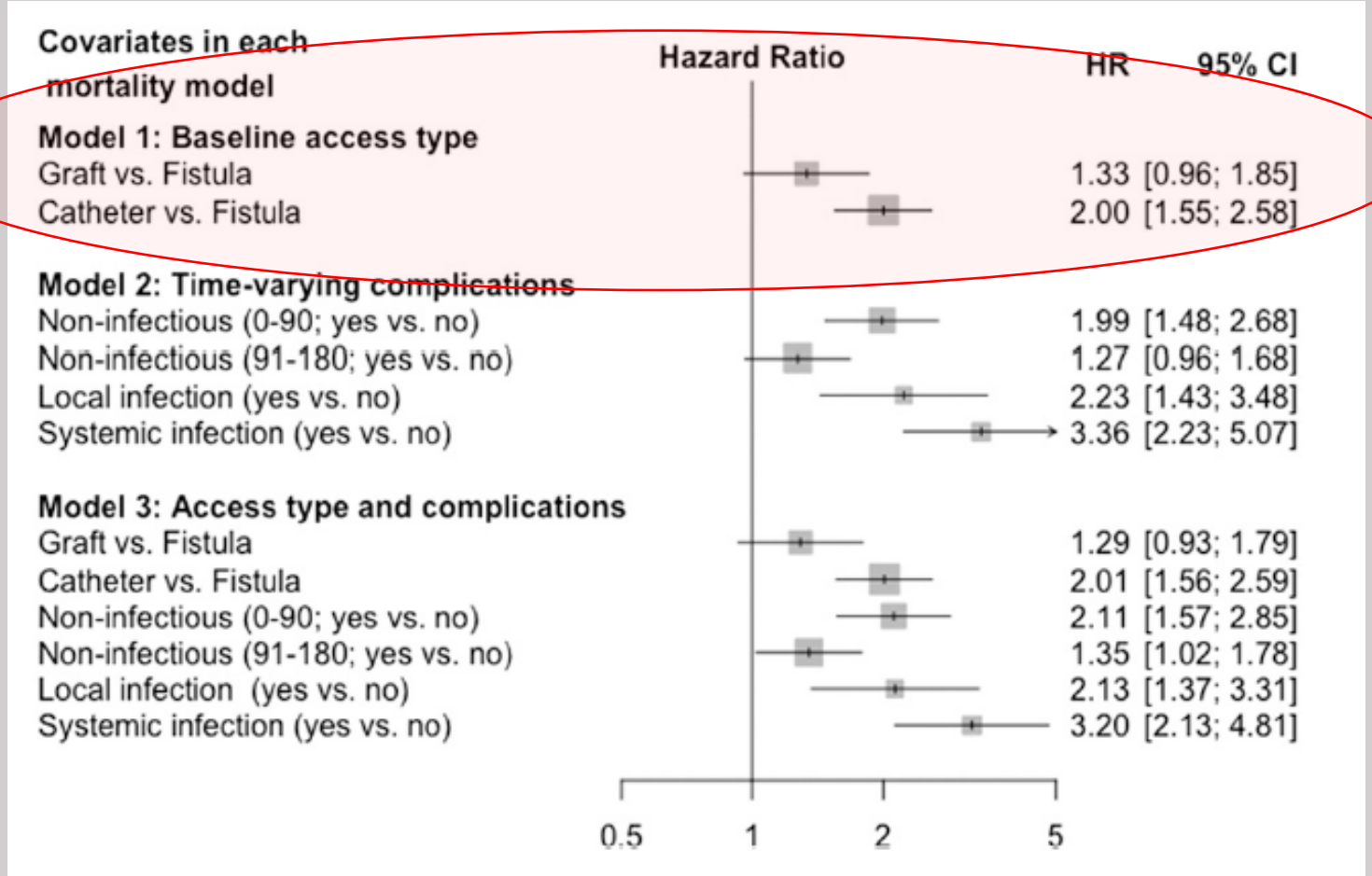


The Association of Initial Hemodialysis Access Type With Mortality Outcomes in Elderly Medicare ESRD Patients

Jay L. Xue, DVM, PhD, David Dahl, MD, James P. Ebben, BS, and Allan J. Collins, MD

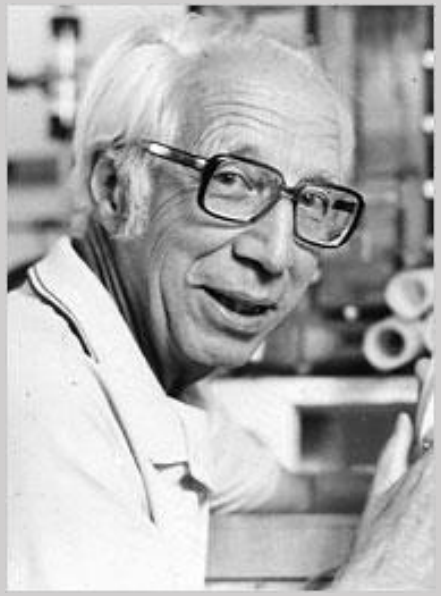
American Journal of Kidney Diseases, Vol 42, No 5 (November), 2003: pp 1013-1019

Mortality Associated with Access Type



Ravani, et al., CJASN 12:955-964, 2017

Willem J. Kolff, MD: 1911-2009
"Father of Dialysis"



- Visionary in biomedical technology
- Acute renal failure from GN, sulfa drugs
- 1st successful human dialysis 1945
  - After 14 failures
- Nobel nominee 2003
- Fascinating life & professional history

https://www.rsnhope.org/health-library/know-willem-j-kolff-md-father-dialysis-dialyzer/

Kollf Dialysis Machine 1945
WWII in Occupied Netherlands


Alfred Fishman

- **Frame:** Downed German bomber
- **Tank:** Repurposed bathtub
- **Drum:** Wooden fence slats
- **Dialysis membrane:** 25-30 meters cellophane sausage casing
- **Dialysate:** 75-100L NaCl + glucose
- **Anticoagulation:** Heparin*
- **Power:** Sewing machine motor
- **Access:** Metal needles or glass tubes in artery and/or vein
  - 150-300 ml aliquots drained, dialyzed then returned to patient by gravity

* Newly available since 1930's; hirudin from leeches proved to be too toxic/difficult

The Artificial Kidney: a dialyser with a great area.

By

W. J. KOLFF, Specialist for internal diseases at the Municipal Hospital of Kampen (The Netherlands);

H. TH. J. BERK, Managing Director of the Kampen Enamel Works. with the collaboration of

NURSE M. ter WELLE; Miss **A. J. W. van der LEY;** Messrs. **E. C. van DIJK** and **J. van NOORDWIJK.**

(Submitted for publication October 6, 1943).

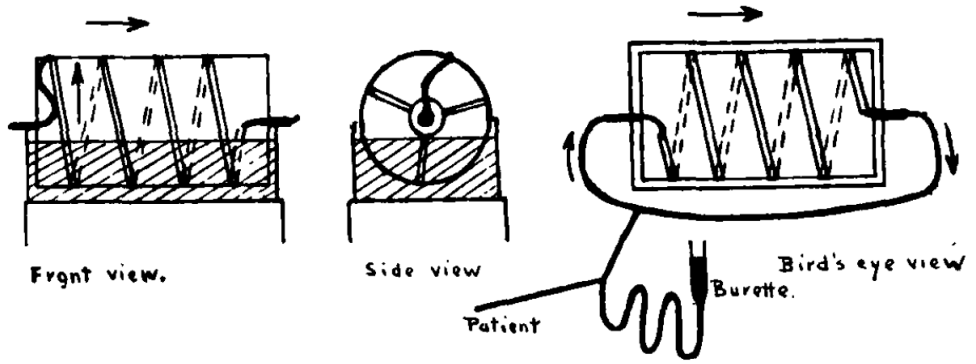


Fig. 1. A cellophane tube has been wound spirally round an aluminium cylinder. The blood within the cellophane always sinks to the lowest point. When the drum is rotating the blood moves from left to right.

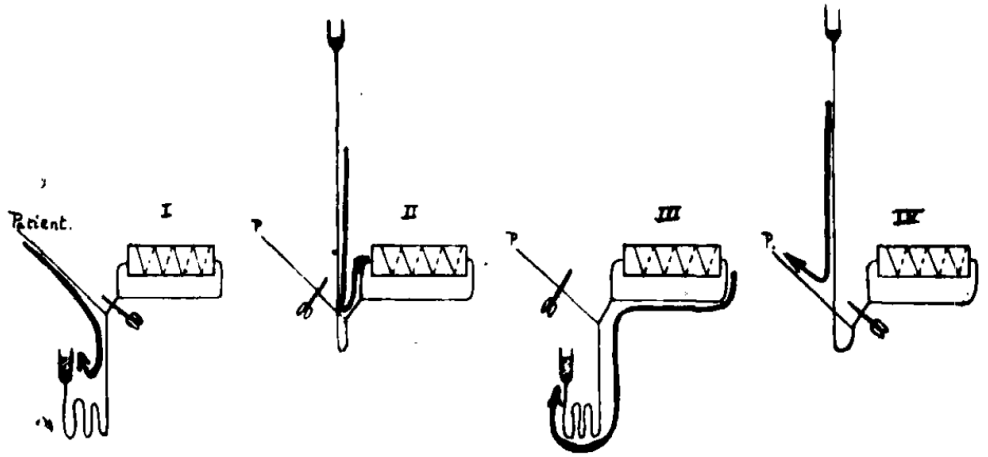
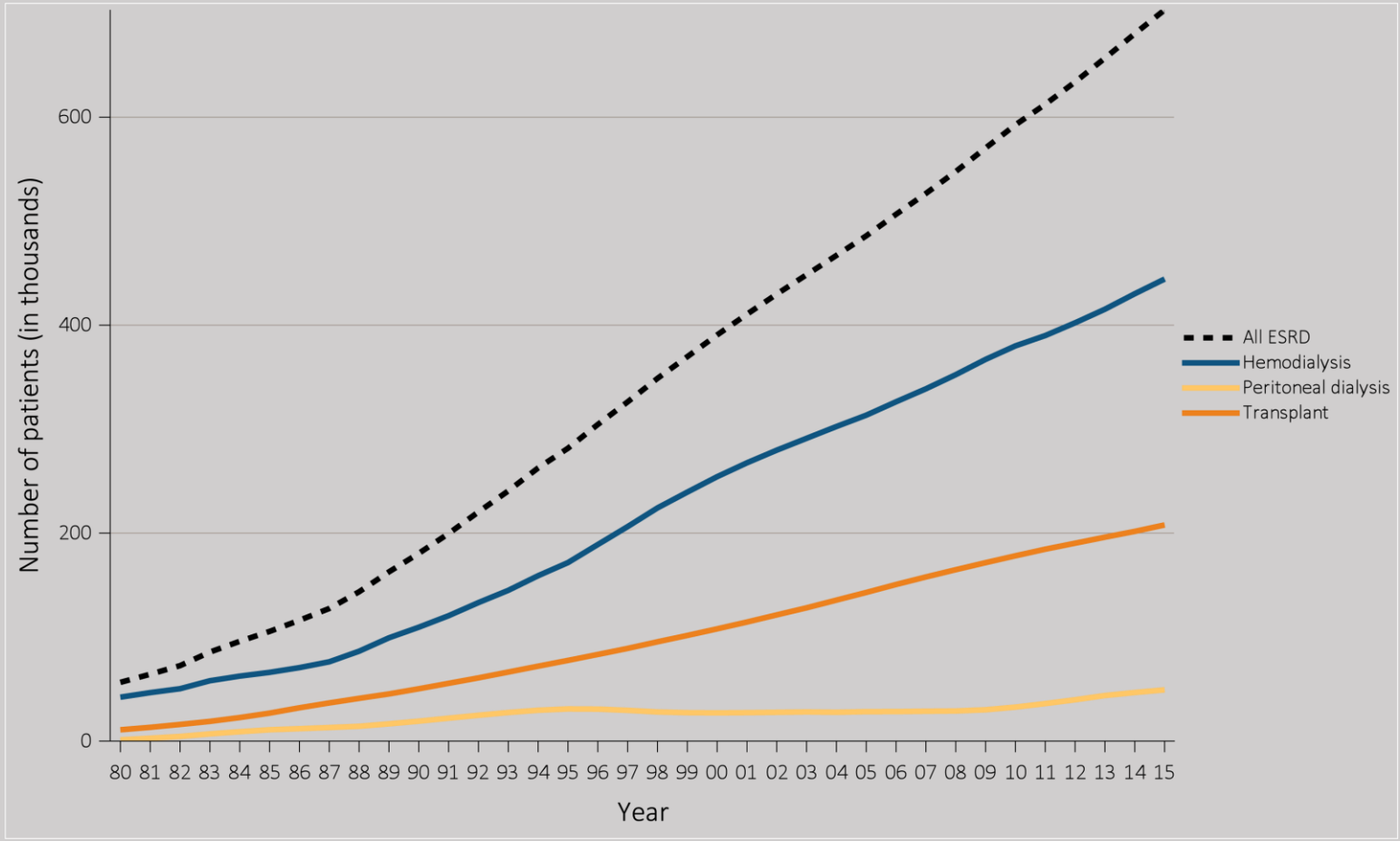


Fig. 2. I. Connection with dialyser shut off. Burette low: impure blood is flowing from the patient's body into the burette.
II. Tube to patient shut off. Burette high: impure blood is flowing from the burette into the dialyser.
III. Tube to patient shut off. Burette low: purified blood is flowing from the dialyser into the burette.
IV. Connection with dialyser shut off. Burette high: purified blood is flowing from the burette into the patient's body.

Acta Medica Scandinavica 1944; CXVII:121-134

70-years After Kolff's 1st Hemodialysis

Trends in the number of ESRD prevalent cases, by modality, in the U.S.,1980-2015

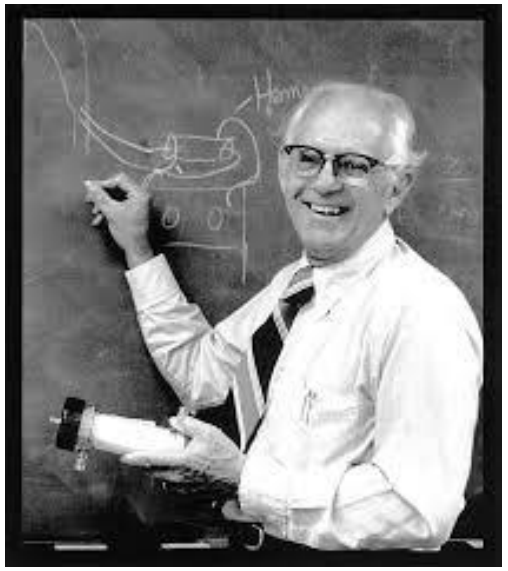


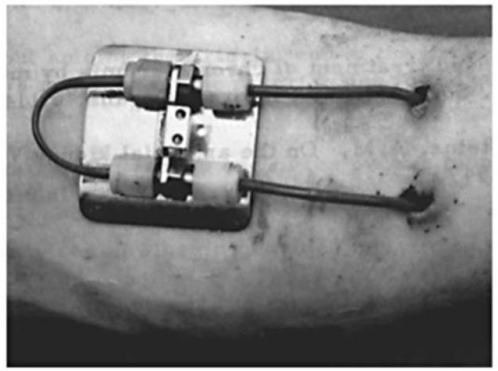
Data Source: Reference Table D.1. Abbreviation: ESRD, end-stage renal disease.

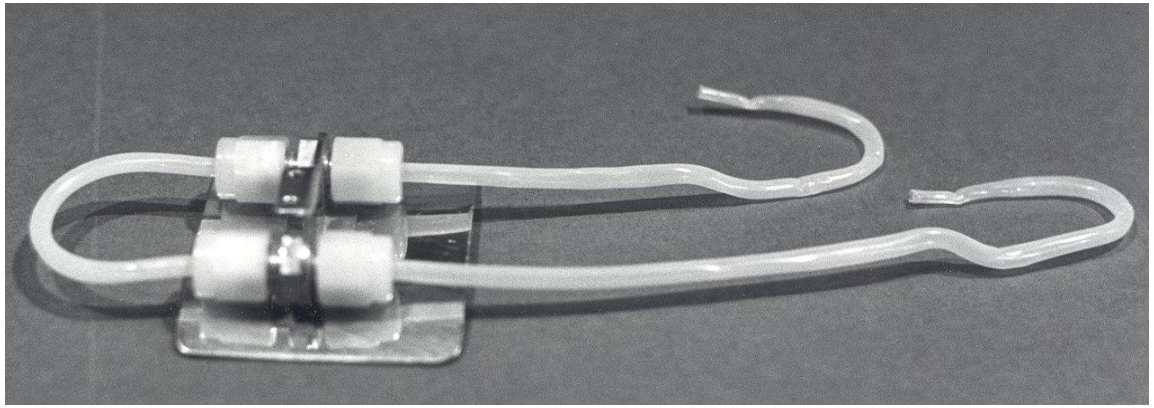
https://www.usrds.org/2017/view/Default.aspx

Scribner Shunt
Belding Scribner, M.D.

- 1960: Seattle, University of Washington
- Cannulae inserted into peripheral artery and vein, connected with Teflon tube
- Semi-permanent exteriorized A-V shunt
- Allowed for long-term hemodialysis
  - Cumbersome and difficult to use
  - Prone to separate between dialyses
  - Infection & thrombosis
  - Destructive to veins & arteries

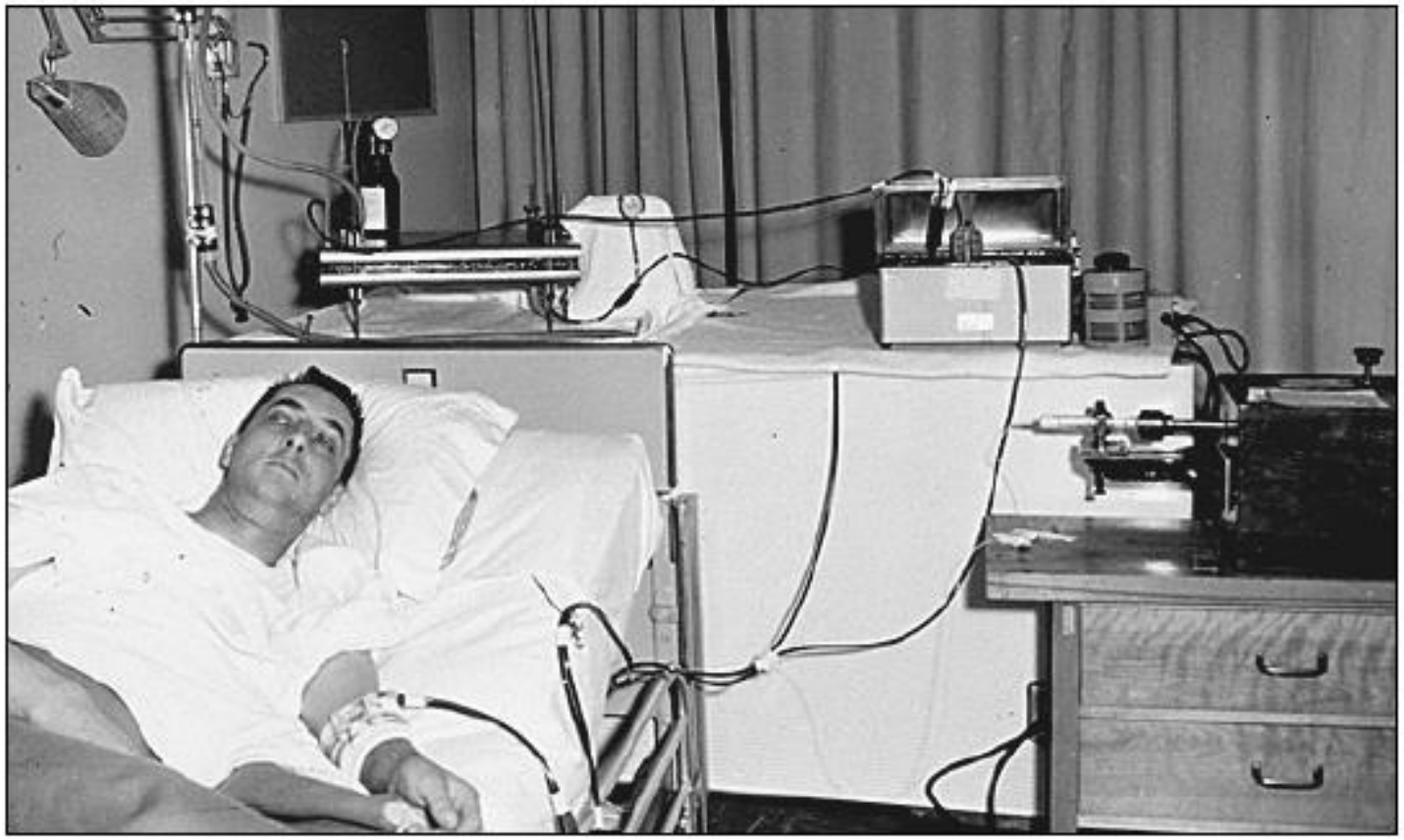






Clyde Shields
First “Chronic” Hemodialysis Patient

- 39 year-old machinist
- Hemodialysis 1960-71



Clyde Shields, the First Patient with Chronic Kidney Disease to Undergo Dialysis, University of Washington, 1960.


Christiana Hospital, August 2018

Infection Control: Hepatitis B & C

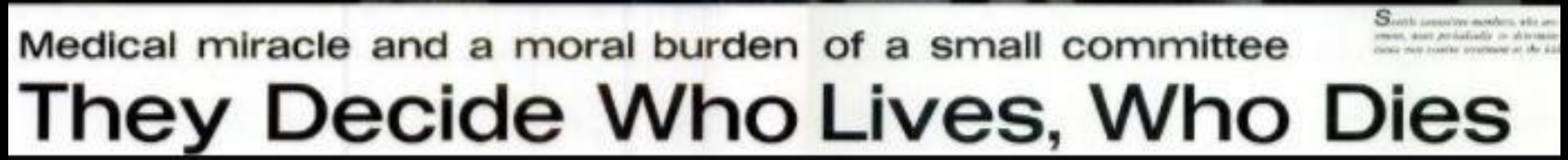
- Transfusion dependence pre-erythropoietin
  - 1989 Epogen® approved
- Blood borne diseases, hepatitis
  - 1963: “Australia antigen”
    - Hepatitis B Surface Antigen
  - 1969: Hepatitis B vaccine
  - “Non-A, Non-B” hepatitis
  - 1989: HCV
- 1972 European Renal Registry
  - 499 staff contracted hepatitis across 568 renal units in Europe
  - 12 deaths (2.4%)
- Dr. Baruch Blumberg
  - 1976 Nobel Prize in Medicine

“Death Panels” were not part of the ACA

Very real in early days of dialysis

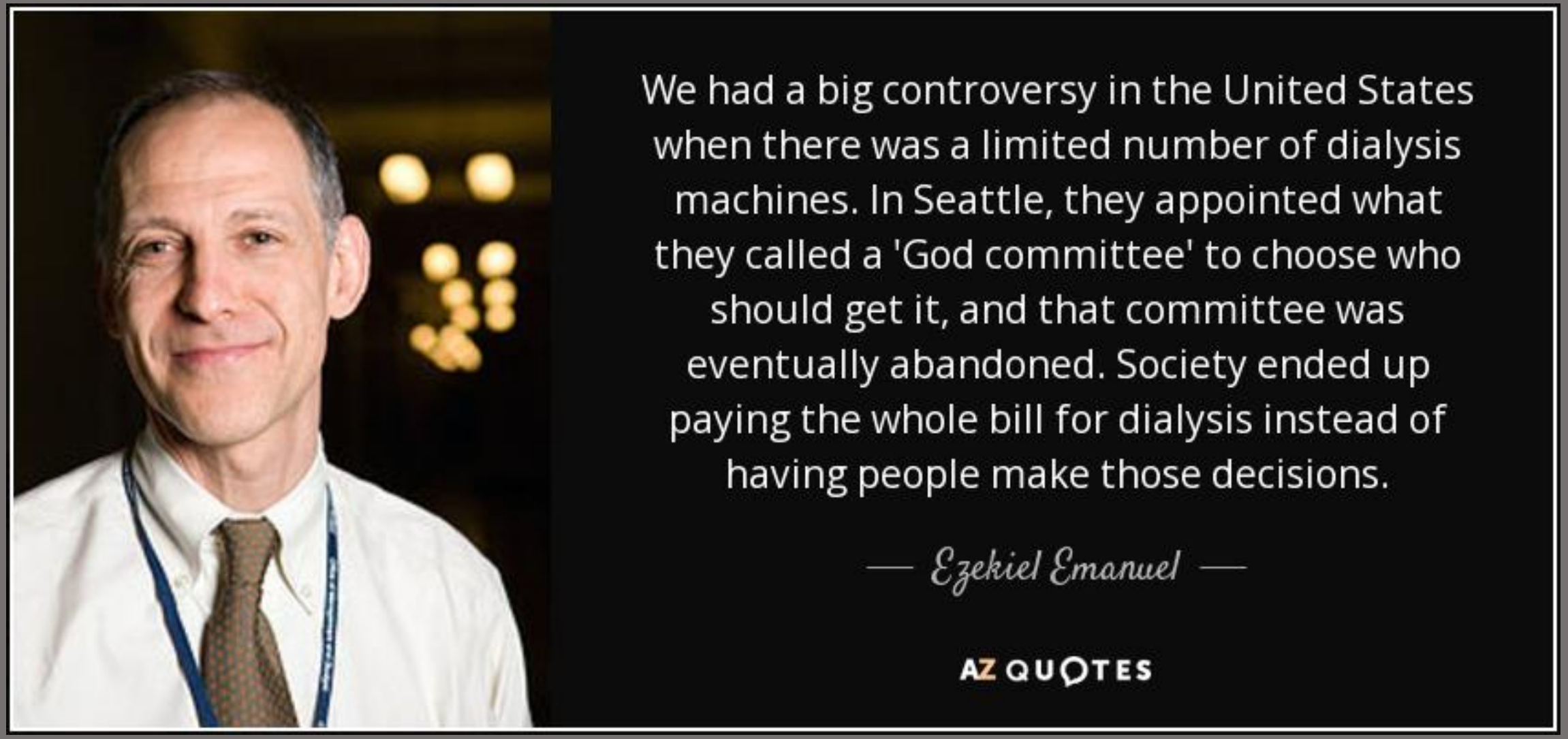
- The Scribner Shunt expanded the number of patients who could benefit from hemodialysis, far beyond the limited capacity at Swedish Hospital.
- The “Admissions and Policies Committee” of the Seattle Artificial Kidney Center was formed in 1961 to choose which patients would receive hemodialysis
- The “God Committee” consisted of seven citizens:
  - Lawyer, minister, banker, housewife, state govt. official, labor-leader, & surgeon
  - Selected by the King County Medical Society

https://www.healthaffairs.org/do/10.1377/hblog20091130.002998/full/

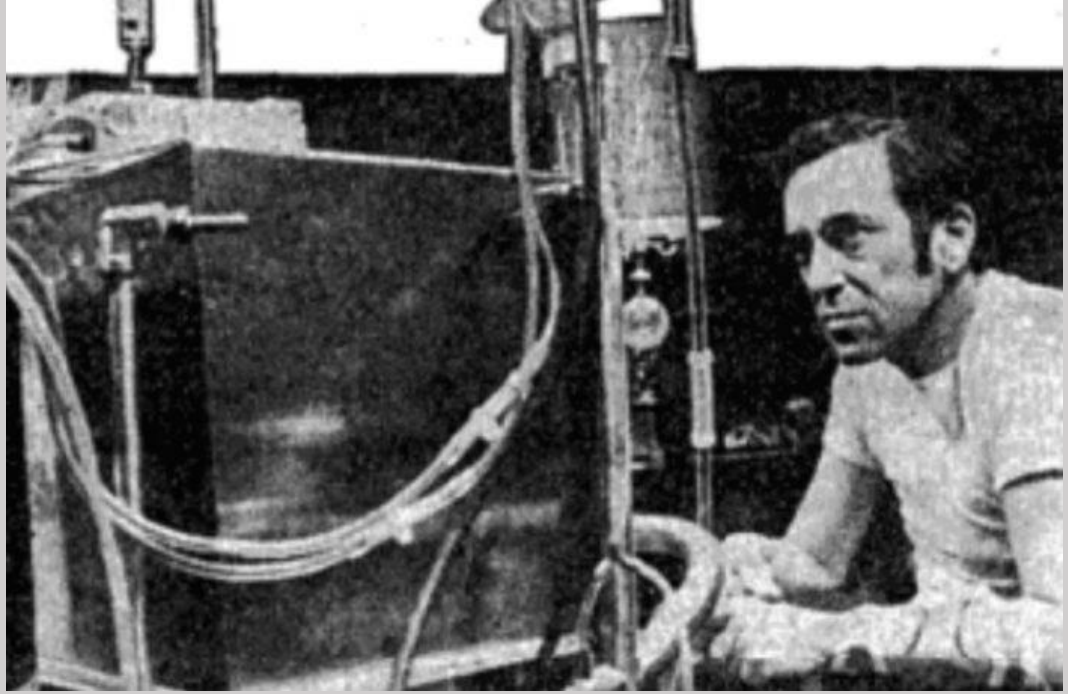


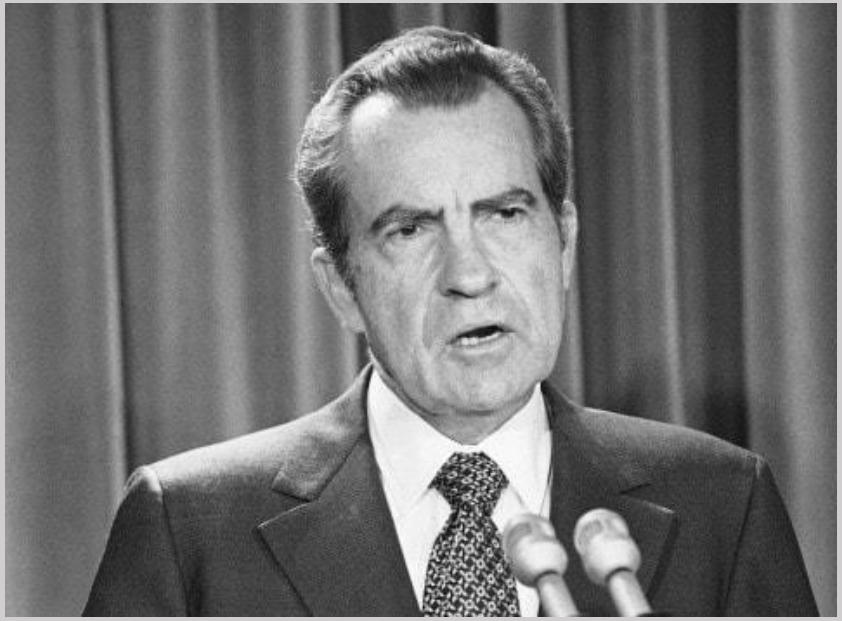
Medical miracle and a moral burden of a small committee

They Decide Who Lives, Who Dies



http://www.ezekielemanuel.com/





Social Security Amendments of 1972 Public Law 92-603, section 299I

Shep Glazer to US House Ways & Means Comm. Nov. 1971, Chaired by Wilbur Mills (D-AK)

"I am 43 years old, married for 20 years, with two children ages 14 and 10.

I was a salesman until a couple of months ago until it became necessary for me to supplement my income to pay for the dialysis supplies. I tried to sell a non-competitive line, was found out, and was fired.

Gentlemen, what should I do? End it all and die? Sell my house for which I worked so hard, and go on welfare? Should I go into the hospital under my hospitalization policy, then I cannot work?

Please tell me. If your kidneys failed tomorrow, wouldn't you want the opportunity to live? Wouldn't you want to see your children grow up?"

Patient advocacy group "American Association of Patients on Hemodialysis" which later became the **American Association of Kidney Patients**

VP of AAPH, **Shep Glazer underwent hemodialysis in the Ways & Means Committee meeting room**

Senate kidney amendment was added to H.R. 1 on the Senate floor, with no prior hearings, on a Saturday morning, September 30, 1972.

The joint House-Senate conference committee agreed to the Senate amendment barely two weeks later. **On October 30, 1971** the brief kidney provision was included in the 300-page bill signed by then **President Nixon.**

https://www.nap.edu/read/1793/chapter/6#187
https://aakp.org/our-history
https://www.youtube.com/watch?v=njvGCYrHjfk

ESRD: The first & only disease-specific entitlement to Medicare benefits

"A person with ESRD is entitled to Medicare if he/she is fully or currently insured for benefits under Social Security, or is a spouse or dependent of an insured person"

- 92 percent of all persons with ESRD qualify for Medicare coverage
- Since 1973, the Medicare-ESRD program has functioned as a *de facto* single-payer national health system
- From the inception of Medicare in 1965 through the creation of the ESRD program in 1972, there was expectation that Medicare expand into a full national health coverage system

"Both liberals and conservatives took for granted that some form of national health insurance would be enacted in the next few years, obviating the need for special funding for patients like Glazer."

http://pensandneedles.org/the-man-hooked-up-to-the-machine/

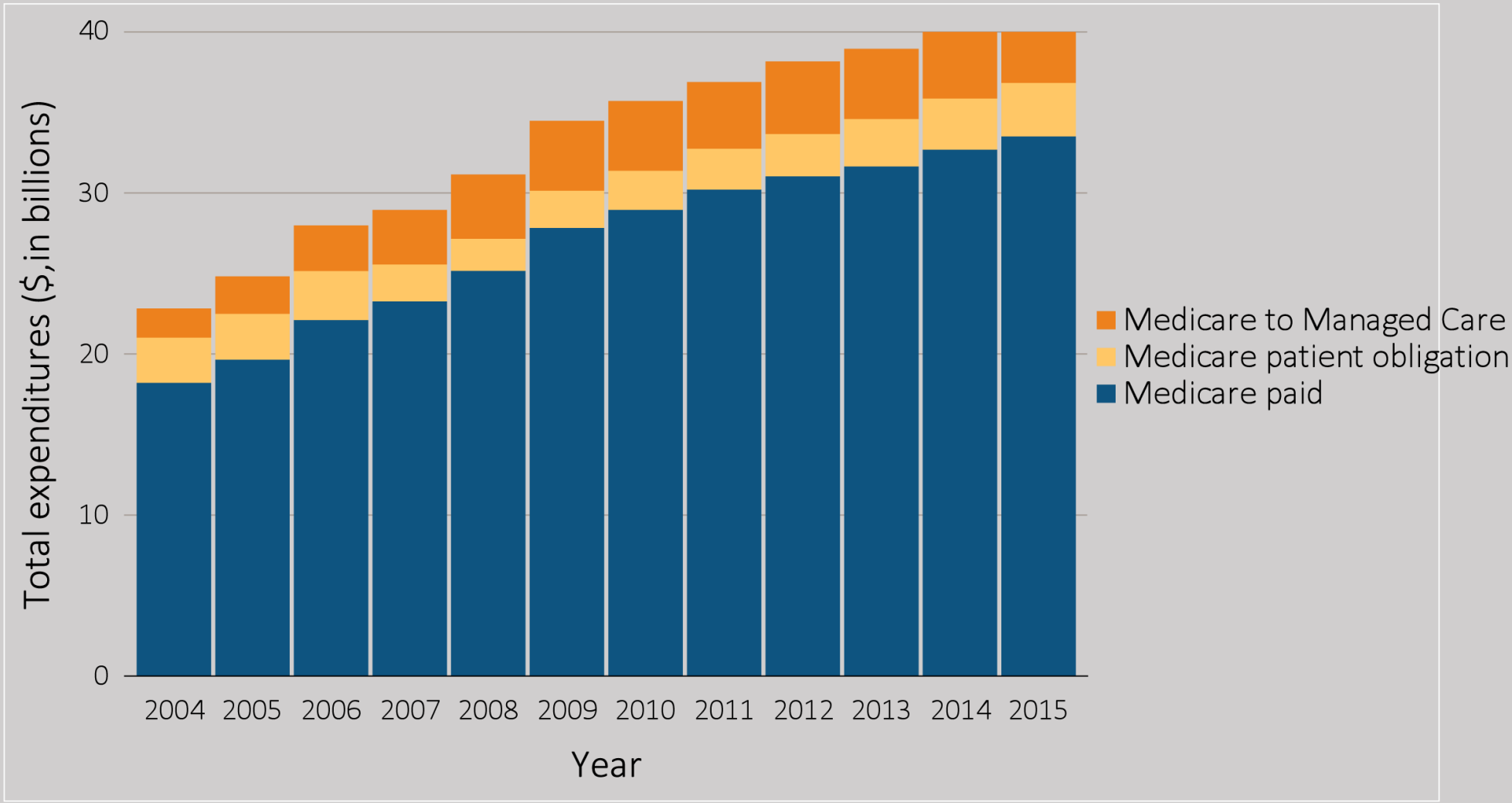
Beware of “Experts!”

Experts agreed that the End-Stage Renal Dialysis program might ultimately serve 10,000 people with kidney failure and would cost Medicare about $135 million dollars. They expected many of those on dialysis would return to work — paying taxes that would help cover the costs involved.

The experts were wrong!

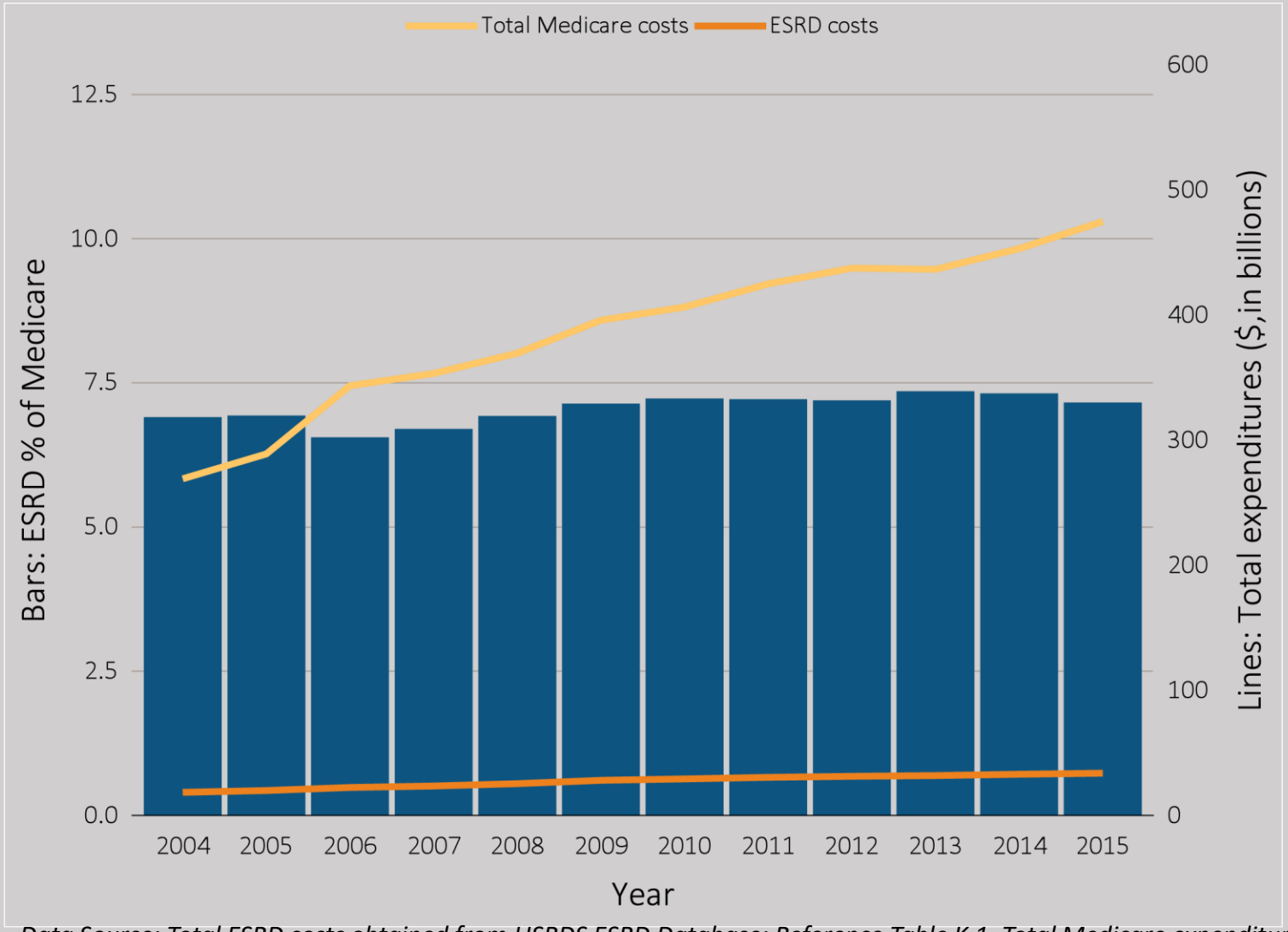
12/30/2010: Arthur Caplan, Ph.D., Director of the Center for Bioethics at the University of Pennsylvania.

vol 2 Figure 9.1 Trends in ESRD expenditures, 2004-2015



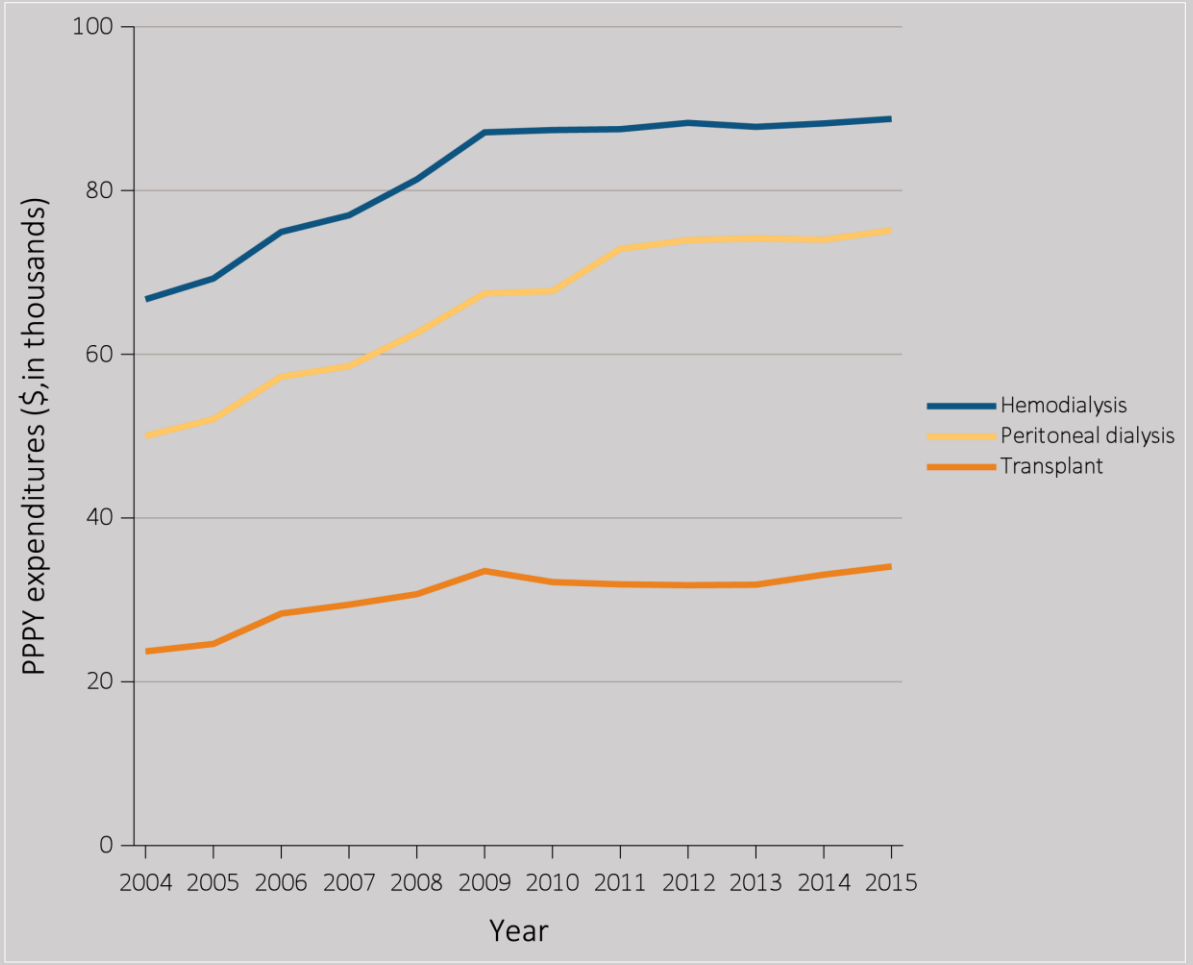
Data Source: USRDS ESRD Database; Reference Table K.1. Abbreviation: ESRD, end-stage renal disease.

vol 2 Figure 9.2 Trends in costs of the Medicare & ESRD programs, 2004-2015



Data Source: Total ESRD costs obtained from USRDS ESRD Database; Reference Table K.1. Total Medicare expenditures obtained from Trustees Report, Table II.B1 https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/TrusteesReports.html. Abbreviation: ESRD, end-stage renal disease.

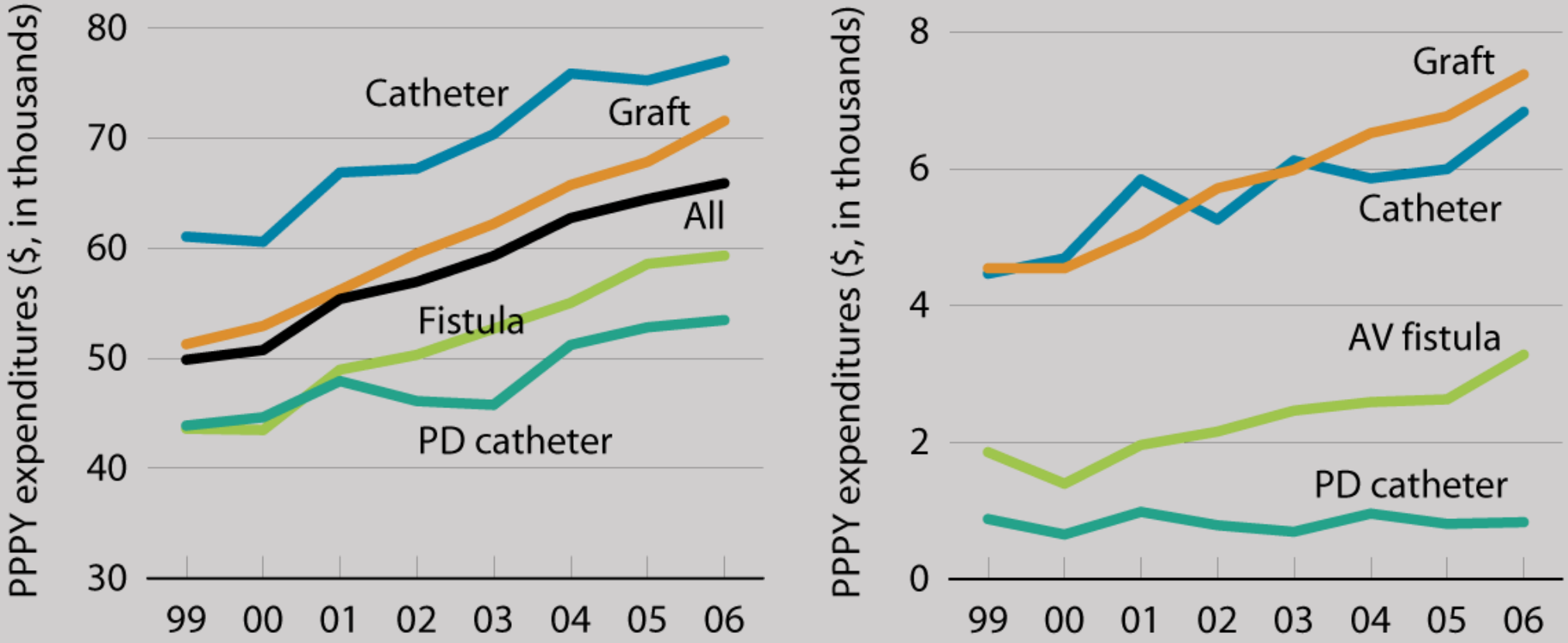
vol 2 Figure 9.8 Total Medicare ESRD expenditures per person per year, by modality, 2004-2015



Data Source: USRDS ESRD Database; Reference Tables K.7, K.8, & K.9. Period prevalent ESRD patients; includes all claims with Medicare as primary payer only. Abbreviation: ESRD, end-stage renal disease.

Per person per year total expenditures, by access type

Figure 11.22 (Volume 2)



https://www.usrds.org/2008/pdf/V2_11_2008.pdf

Cost of HD Vascular Access Management

- $2.8 billion dollars/year for pure Medicare patients
- ≈$5 billion dollars/year for all ESRD, commercial, Medicare managed care, & co-pays
- ≈12% of cost for ESRD patient care

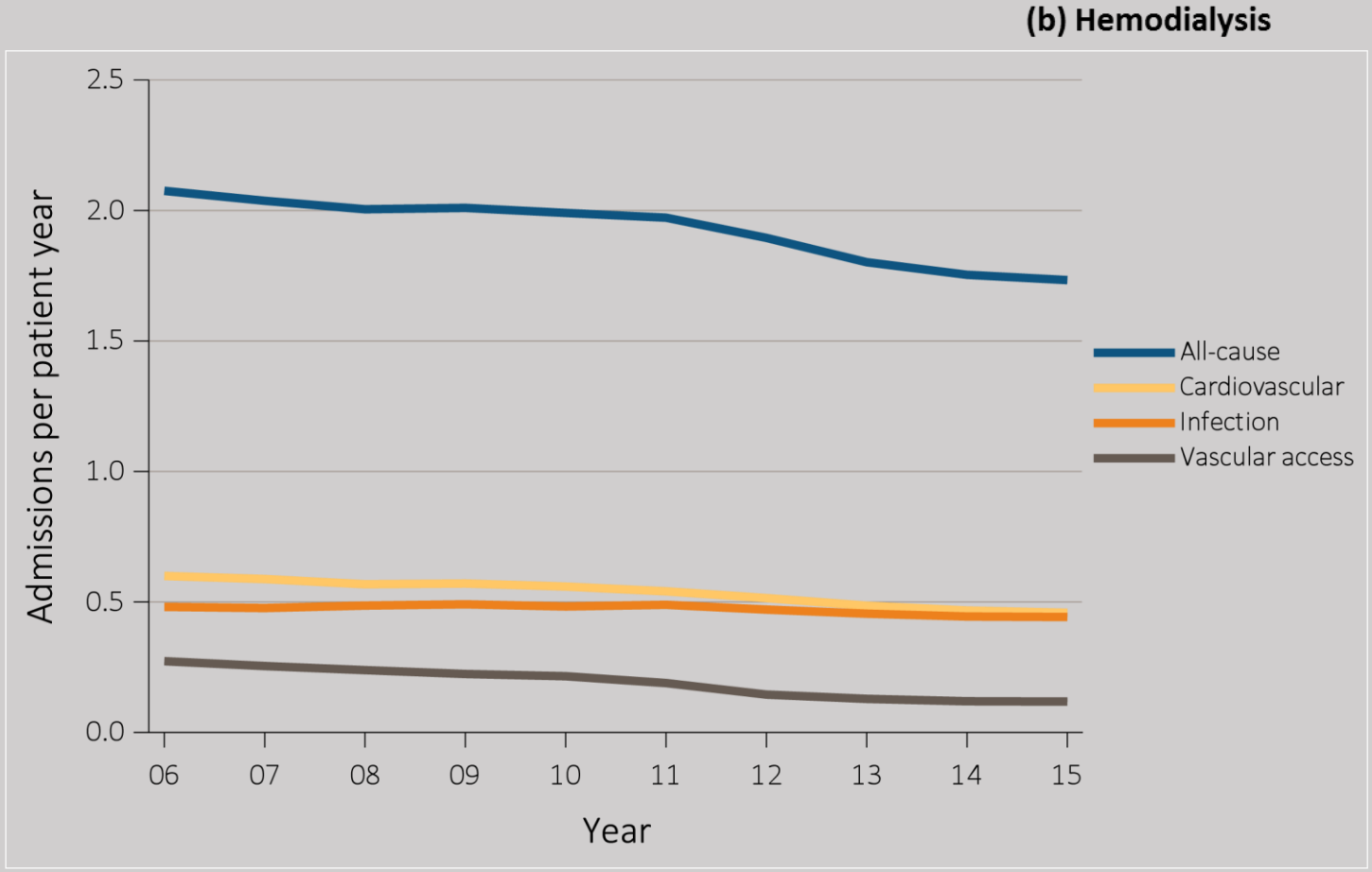
Thamer M, Lee T, Wasse H, Glickman M, Qian J, Gottlieb D, Toner S, Pflederer T: Medicare costs associated with arteriovenous fistulas among US hemodialysis patients. AJKD 2018; 72:10-18

Table 4. Medicare Payments for Vascular Access Management in the ESRD Population

Selected Vascular Access Payments	2011	2012	2013
Noninvasive diagnostic imaging procedures	$15.0	$11.8	$16.8
Open surgical procedures	$260.8	$223.3	$246.0
Invasive imaging and endovascular procedures	$1,038.2	$1,157.2	$1,127.9
Inpatient admissions	$1,519.2	$1,403.2	$1,425.9
Anesthesia associated with VA procedures	$35.0	$29.7	$30.1
Total	$2,868.2	$2,825.2	$2,846.7

Note: Amounts given in millions. See Item S1 for a complete list of all vascular access–related procedures, diagnoses, and codes for each category of payments. Costs include all Medicare payments (primary and secondary) for Parts A and B (institutional and physician supplier claims) for both incident and prevalent dialysis patients in each calendar year associated with vascular access creations, interventions, and ancillary costs, including related hospitalizations. Dialysis patients of all ages are included. Costs do not include Medicare payments for vascular access management for predialysis patients or dialysis patients enrolled in health maintenance organizations.
Abbreviations: ESRD, end-stage renal disease; VA, vascular access.

vol 2 Figure 4.2 Adjusted all-cause & cause-specific hospitalization rates for ESRD patients, by treatment modality, 2006-2015



Michael Brescia, James Cimino, Kenneth Appel

CHRONIC HEMODIALYSIS USING VENIPUNCTURE AND A SURGICALLY CREATED ARTERIOVENOUS FISTULA*

MICHAEL J. BRESCIA, M.D.,† JAMES E. CIMINO, M.D.,‡ KENNETH APPEL, M.D.,§ AND BARUCH J. HURWICH, M.D.†

BRONX, NEW YORK

- Radial artery to cephalic vein
- 14/16 procedures successful
- Unlocked potential for long-term chronic hemodialysis
  - Freed patients from the Scribner shunt

New England Journal of Medicine 275:1089-1092, 1966

http://www.sistersoflife.org/wp-content/uploads/2017/04/SV-Imprint-Spring-2017.pdf

- Origins of hemodialysis access connect with palliative care
- Before the AV fistula, patients with ESRD were often destined to die in weeks to months
- French-fry & ketchup story
- Fear of cardiac complications from AV fistula
- Altruism over profit

CALVARY HOSPITAL
Bronx, New York

We're different; we're mission driven, Gospel driven. We come across a symptom that is unacceptable, and we treat the symptom until there is relief. Our doctrine is succor, compassion, love, gentleness.

-Dr. Michael J. Brescia, Co-founder of Calvary Hospital

Dr. Brescia

An Interview with Sr. Mary Margaret Hope, SV

The Place we call THE VESTIBULE OF HEAVEN

We sat down with Dr. Michael J. Brescia, Executive Medical Director and co-founder of Calvary Hospital, to talk about his experiences at the Catholic palliative care facility and hospice in the Bronx. His friendly banter, warmth, and the twinkle in his eye belied the awe he is held in by the medical field as the co-inventor of the revolutionary Brescia Arterial Fistula in 1966. But what struck us most in our conversation with Dr. Brescia was his clear sense of a call to love God through his patients and the incredible sacrifices he made to uphold the value of the lives of the persons in his care.

How did you get started in palliative care?
I had no intentions of being in palliative care. I did the early work on organ transplant and dialysis. Before 1966, people with kidney failure could only live from three weeks to three months. Everyone was trying to find the method that would allow us to keep repeating the dialysis long-term until a suitable kidney became available.

I heard that you were responsible for a famous invention.
I joined the VA hospital in the Bronx because they had a lot of soldiers coming back from Vietnam who were dying of kidney disease. One day I was feeling very desperate; I had about ten men upstairs in the VA. These were all young folks, but they were all going to die.

I'm down in the lunch shop with my colleague, thinking about the problem. There are two french fries lined up side by side on my plate. I take a bite out of my hamburger and a blob of ketchup falls down perfectly in between the french fries. It was like Gabriel whispering in my ear. "Don't move it! Don't move it! Not yet! There's the answer." I looked at my plate and I thought, "It's like a vein and an artery in the wrist. I wonder...if I connect this vein and artery with a fistula, would this vein, and all the other veins, actually change and become like arteries? Then we wouldn't just have one artery; we'd have 200 arteries! We could keep putting the people on the blood-cleansing machine indefinitely!" I ran upstairs and said, "We're going to do a fistula." Would you believe it – it worked! That was 50 years ago, and they are still using it.

Dr. Michael Brescia

Lifetime Achievement Award
American Society of Diagnostic & Interventional Nephrology, Salt Lake City 2008

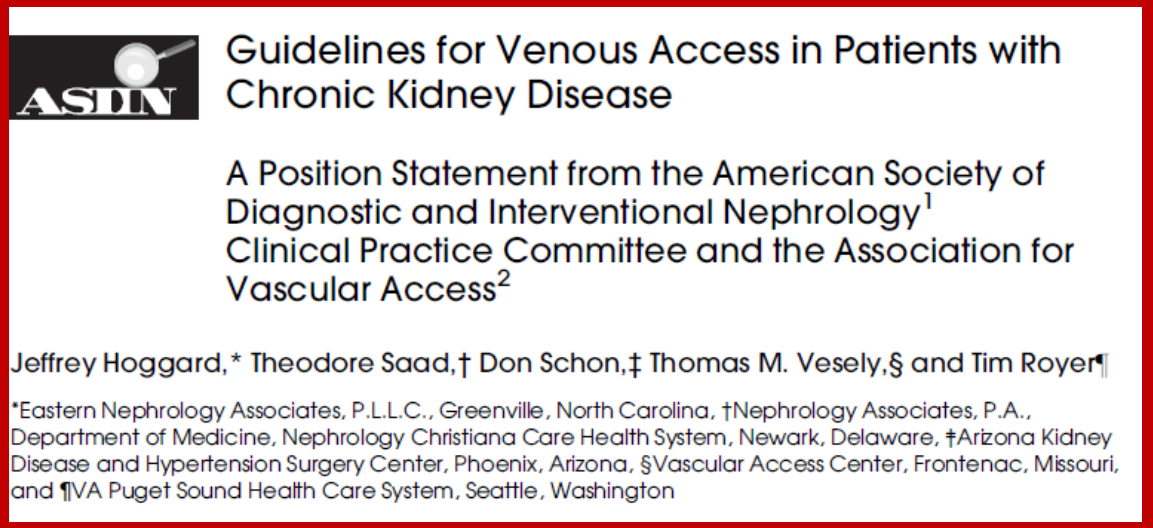
Vein Preservation Publications:
PICC Avoidance in CKD Patients at CCHS

Venous Access for Patients with Chronic Kidney Disease

Theodore F. Saad, MD, and Thomas M. Vesely, MD

J Vasc Interv Radiol 2004; 15:1041–1045

Abbreviation: PICC = peripherally inserted central catheters



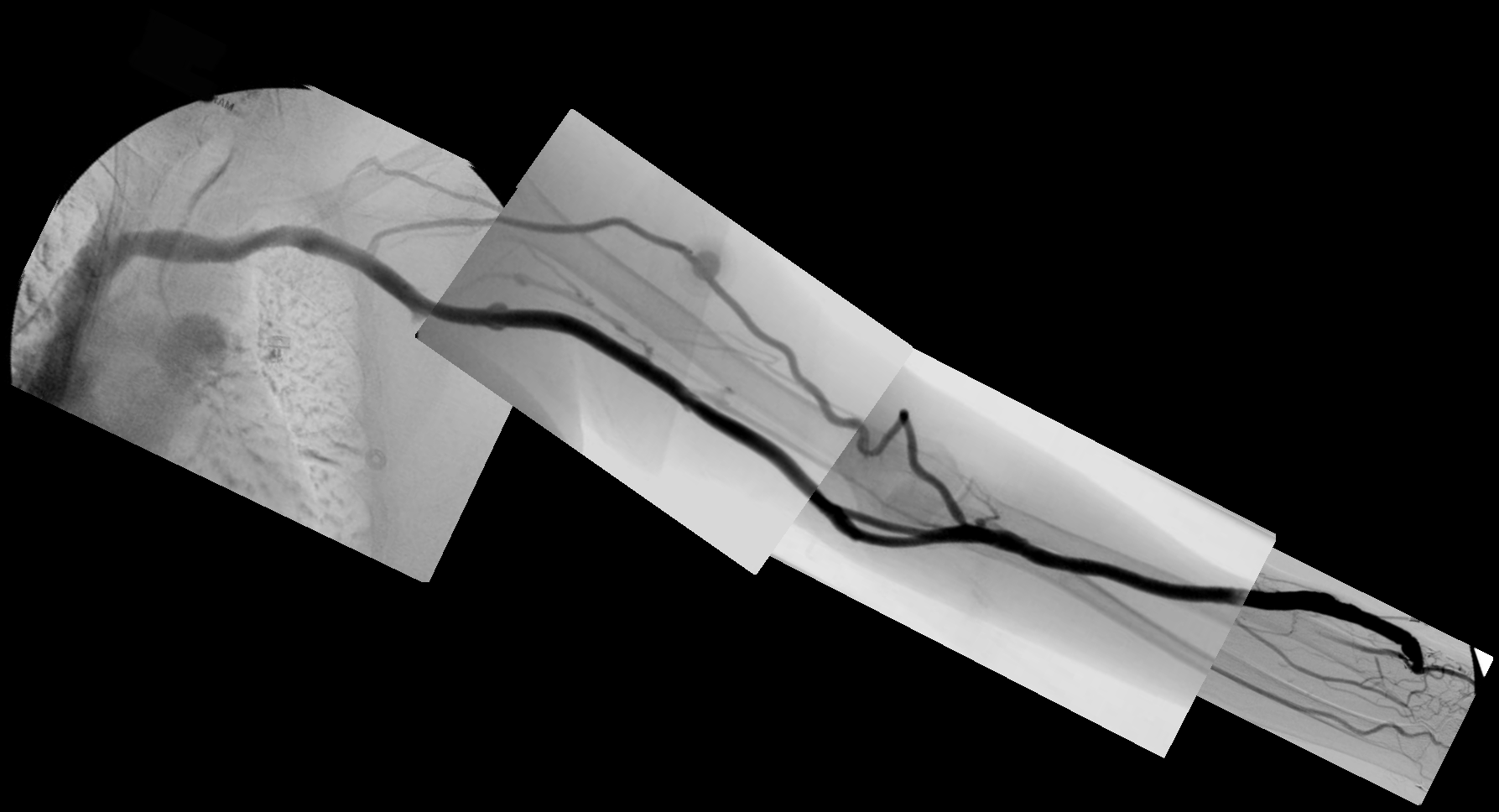
ASDIN

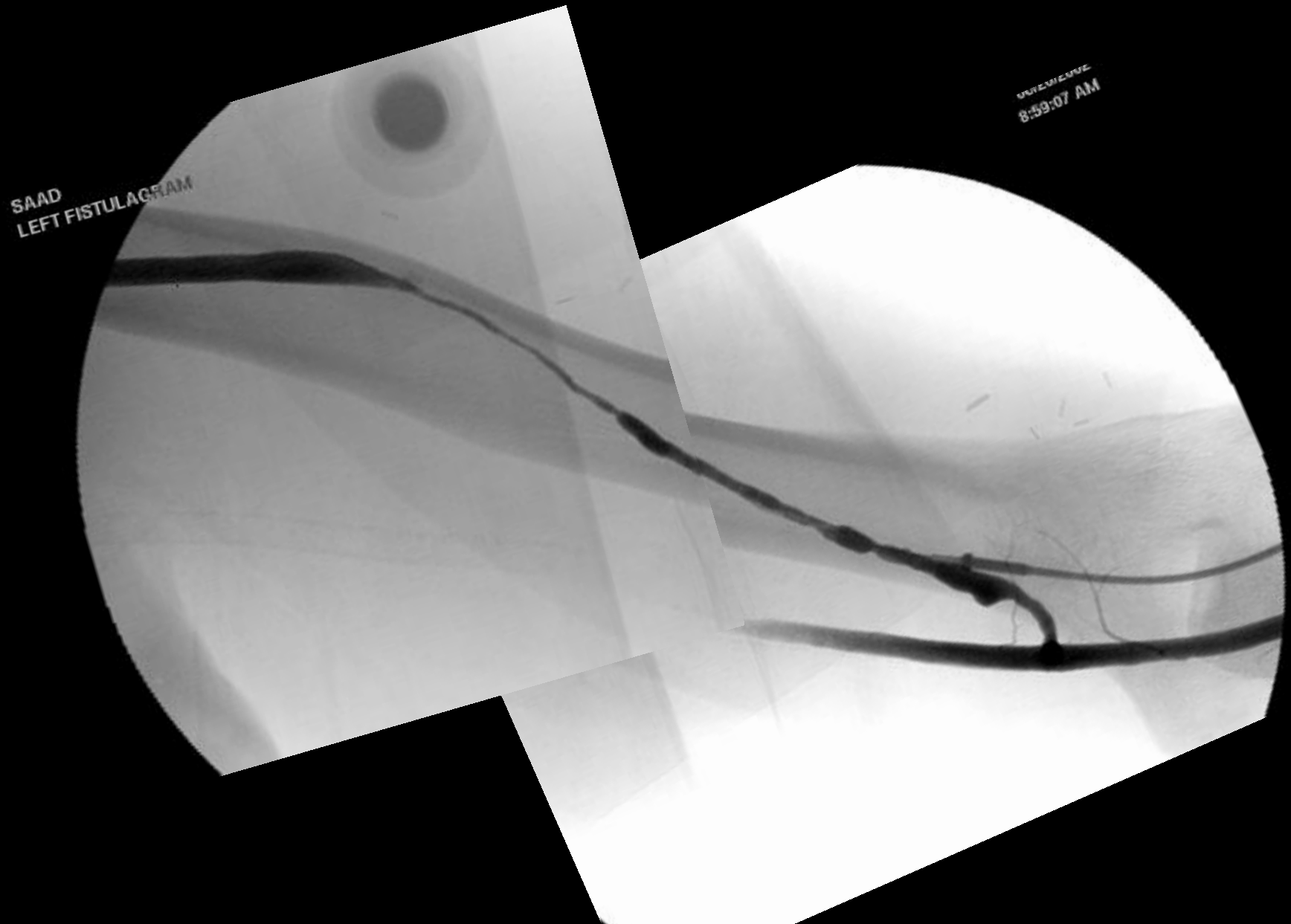
Guidelines for Venous Access in Patients with Chronic Kidney Disease

A Position Statement from the American Society of Diagnostic and Interventional Nephrology[1] Clinical Practice Committee and the Association for Vascular Access[2]

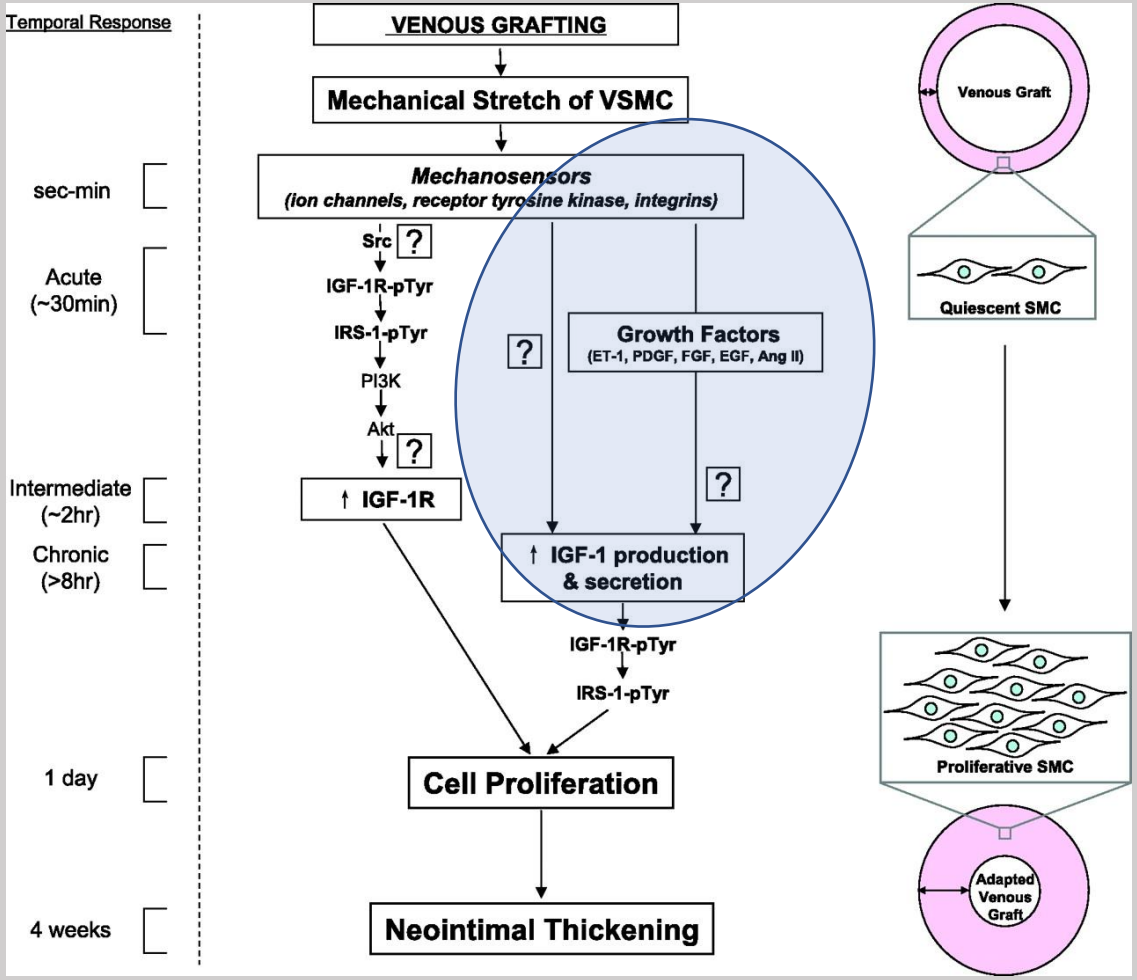
Jeffrey Hoggard,* Theodore Saad,† Don Schon,‡ Thomas M. Vesely,§ and Tim Royer¶

*Eastern Nephrology Associates, P.L.L.C., Greenville, North Carolina, †Nephrology Associates, P.A., Department of Medicine, Nephrology Christiana Care Health System, Newark, Delaware, ‡Arizona Kidney Disease and Hypertension Surgery Center, Phoenix, Arizona, §Vascular Access Center, Frontenac, Missouri, and ¶VA Puget Sound Health Care System, Seattle, Washington




SAAD
LEFT FISTULAGRAM
8:59:07 AM

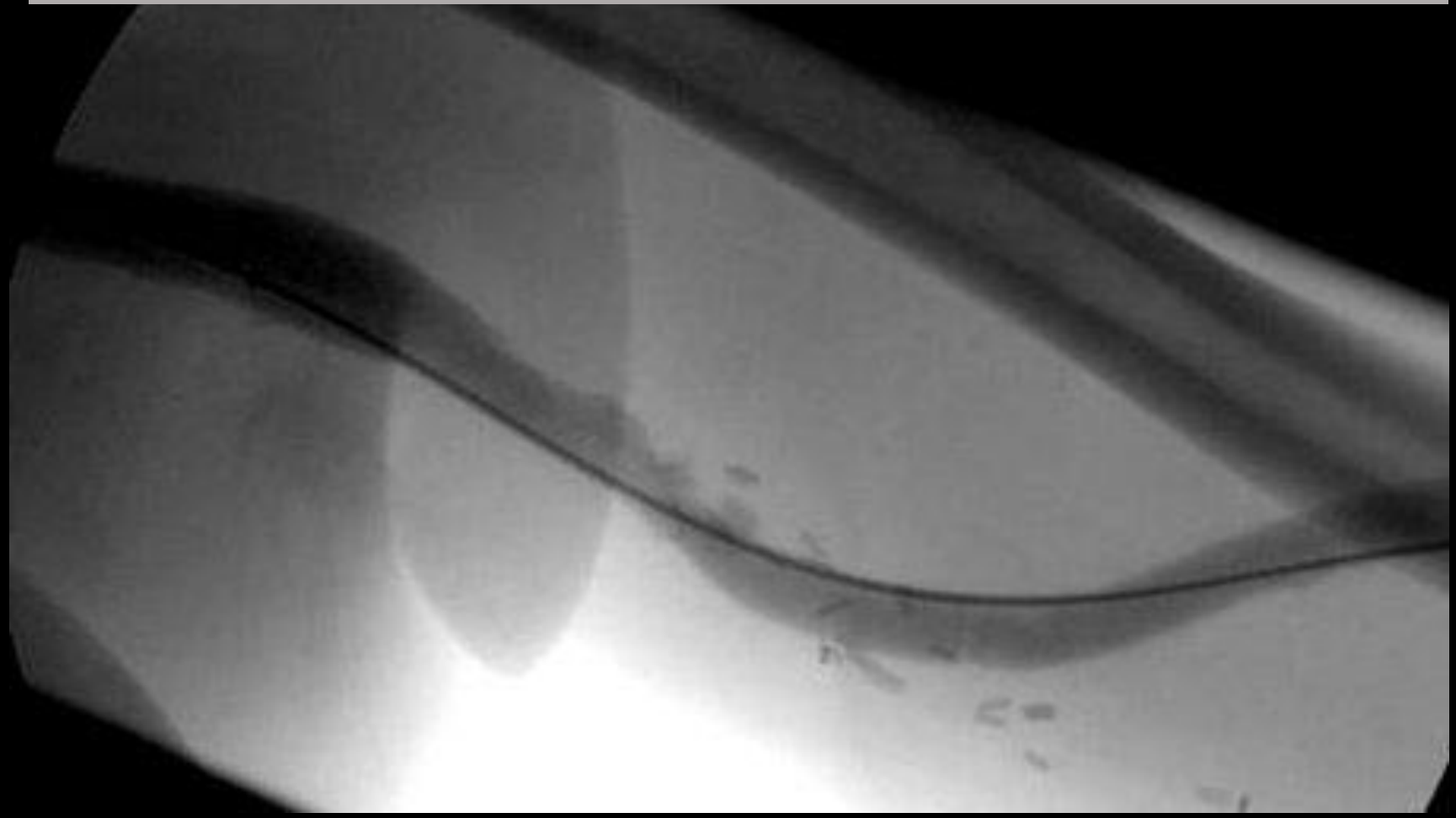
Smooth Muscle Proliferation & Neointimal Thickening Of Arteriovenous Grafts & Fistulae



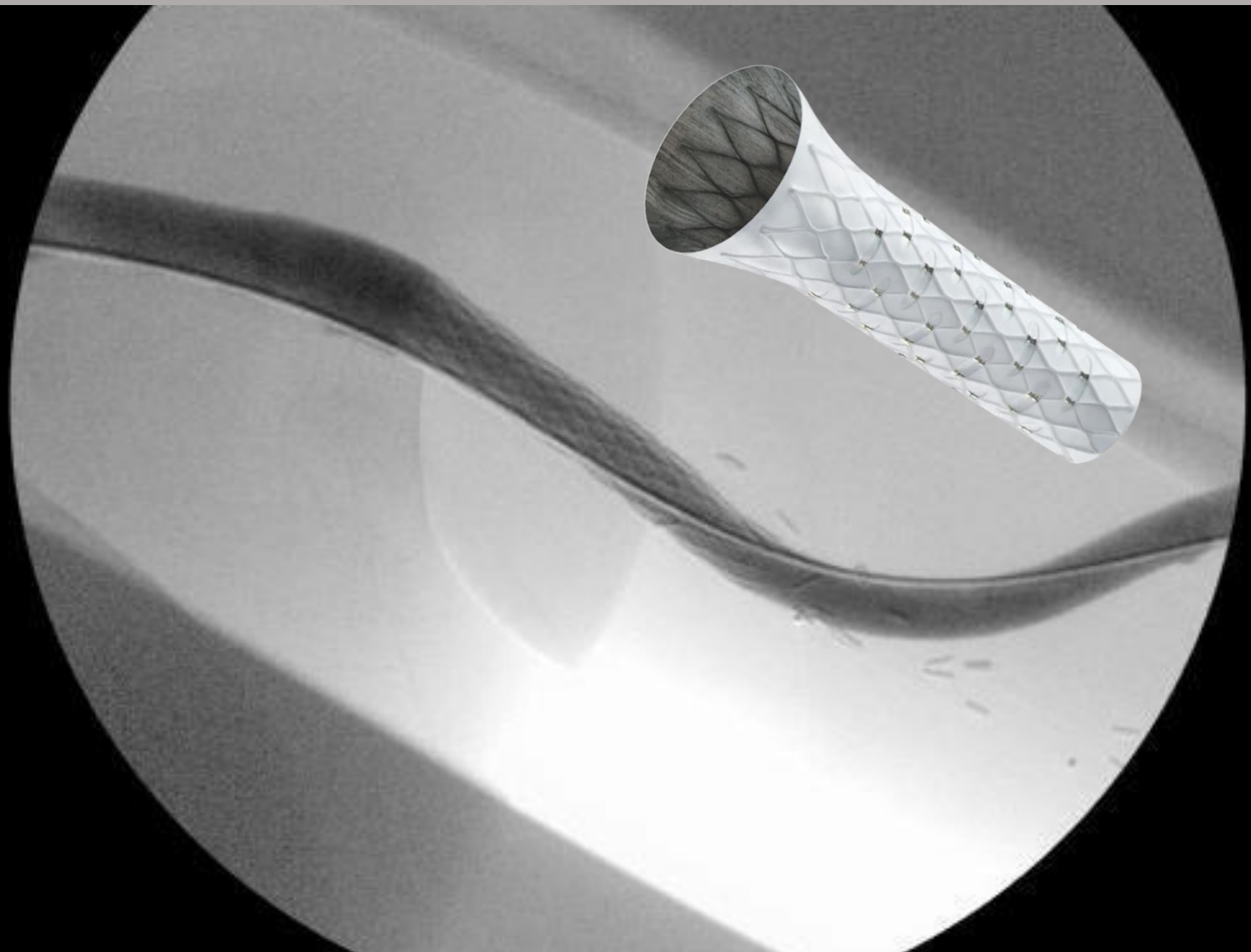
Hannah Song et al. Arterioscler Thromb Vasc Biol. 2007;27:1679-1681

PTFE Graft Venous Anastomosis Typical Stenosis

Post-PTA 8 mm



8 x 50 mm
FLAIR® Stent Graft



3 Years Post-Stent Graft
No thrombosis, 1-intervention

Stent-Grafts for AV Graft Venous Anastomotic Stenosis
Journal of Vascular & Interventional Radiology 27: 1105-1114, 2016

CLINICAL STUDY

Prospective, Randomized, Concurrently-Controlled Study of a Stent Graft versus Balloon Angioplasty for Treatment of Arteriovenous Access Graft Stenosis: 2-Year Results of the RENOVA Study

Ziv J Haskal, MD, FSIR, Theodore F. Saad, MD, Jeffery G. Hoggard, MD, Randy I. Cooper, MD, George S. Lipkowitz, MD, Anwar Gerges, MD, John R. Ross, MD, Timothy A. Pflederer, MD, and Samuel W. Mietling, MD

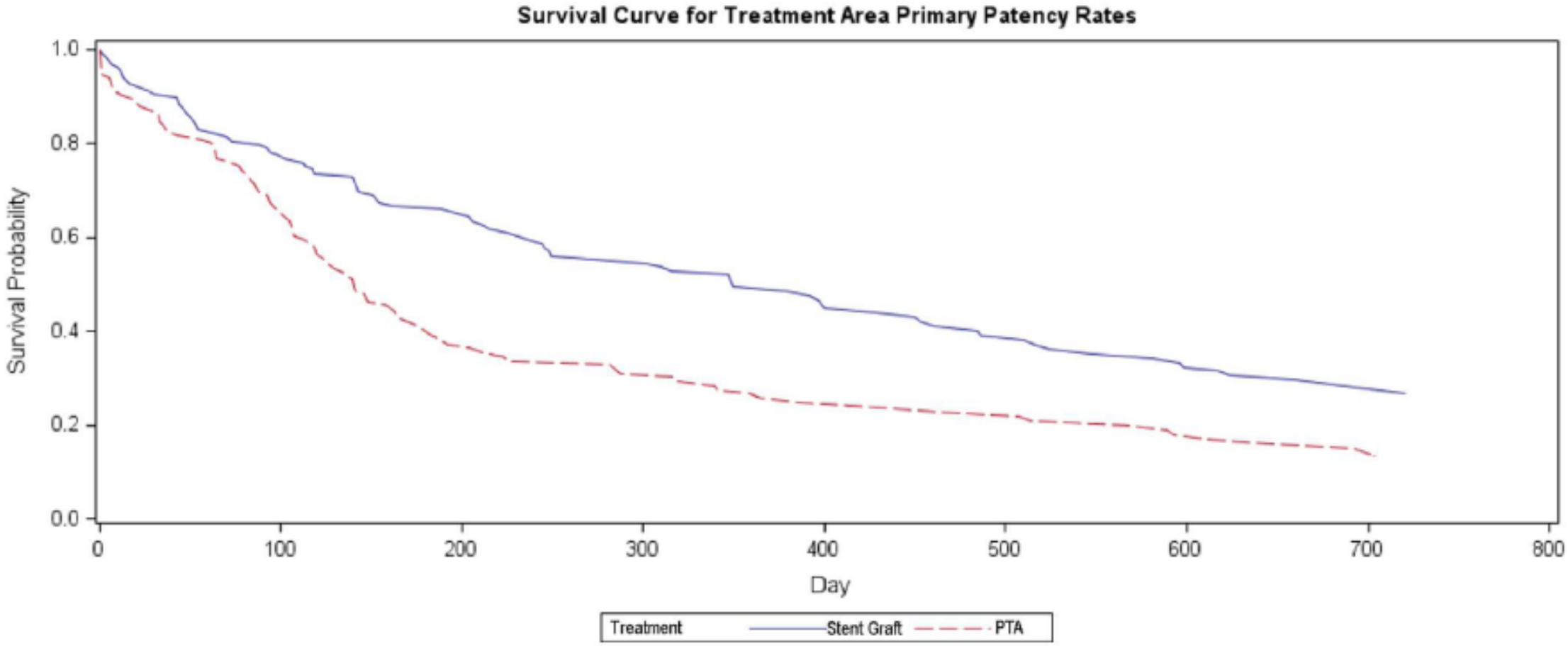
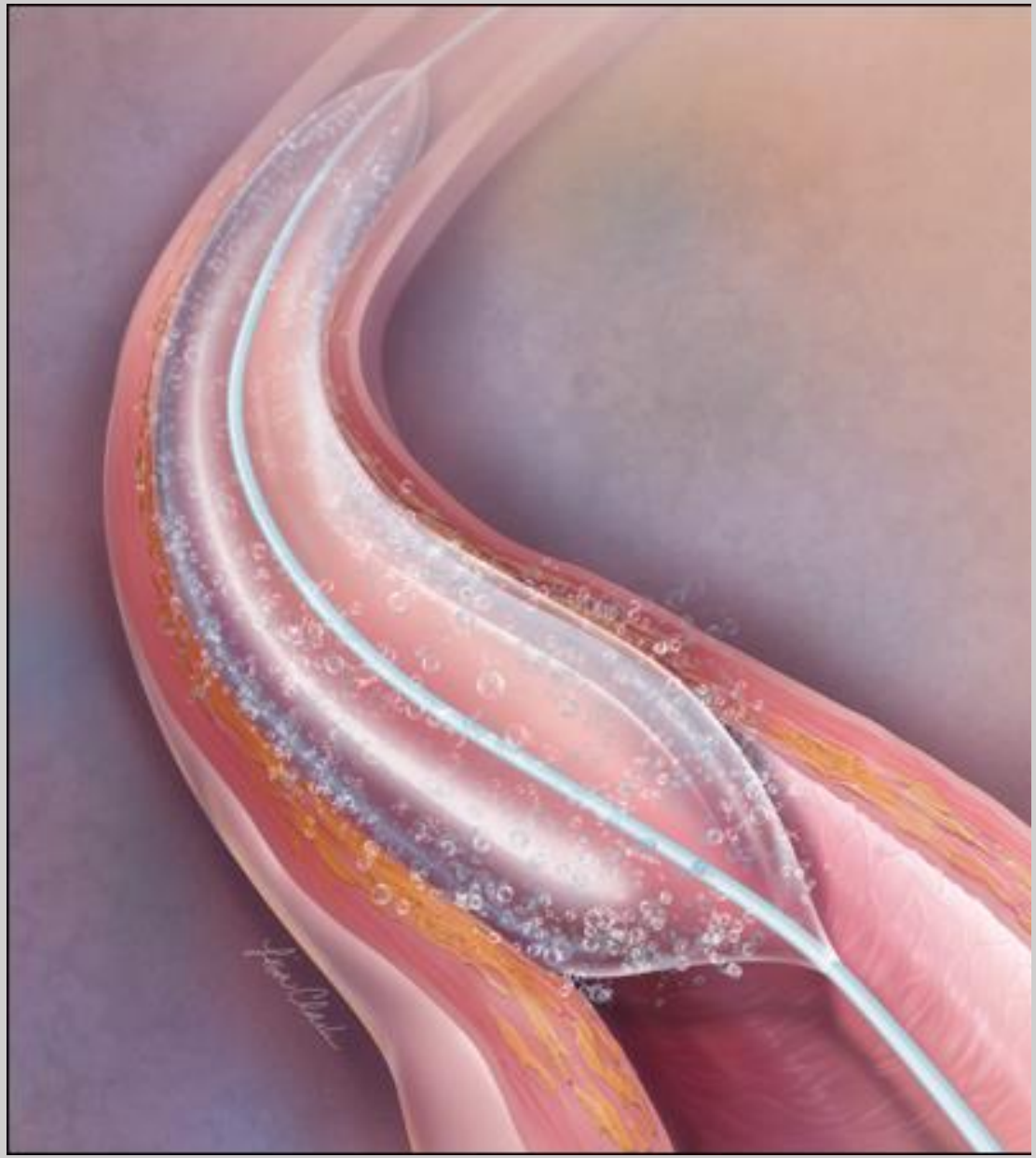


Figure 3. Survival curve of TAPP.

Drug-Eluting Balloons in Dialysis Access



A Prospective, Multicenter, Randomized, Controlled Study Comparing *Lutonix® AV* Paclitaxil-coated Balloon PTA Catheter vs. Standard Balloon PTA Catheter for the Treatment of Dysfunctional AV Fistulae

- Study team
  - Scott Trerotola, MD, PI
    - University of PA, Radiology
  - Jeff Lawson, MD
    - Duke University, Vascular Surgery
  - Prabir Roy-Chaudhury, MD
    - University of AZ, Nephrology
  - Theodore Saad, MD
    - Nephrology Associates, P.A.
- 285 patients in 25 centers
  - USA & Canada
- Primary endpoints
  - Target-lesion primary patency @ 6 months
  - Safety: Freedom of access circuit AE @ 30 days
- Secondary endpoints
  - TL Primary patency at 12 months
  - Access circuit PP at 6 & 12 months
  - Number of interventions at TL in 12 months

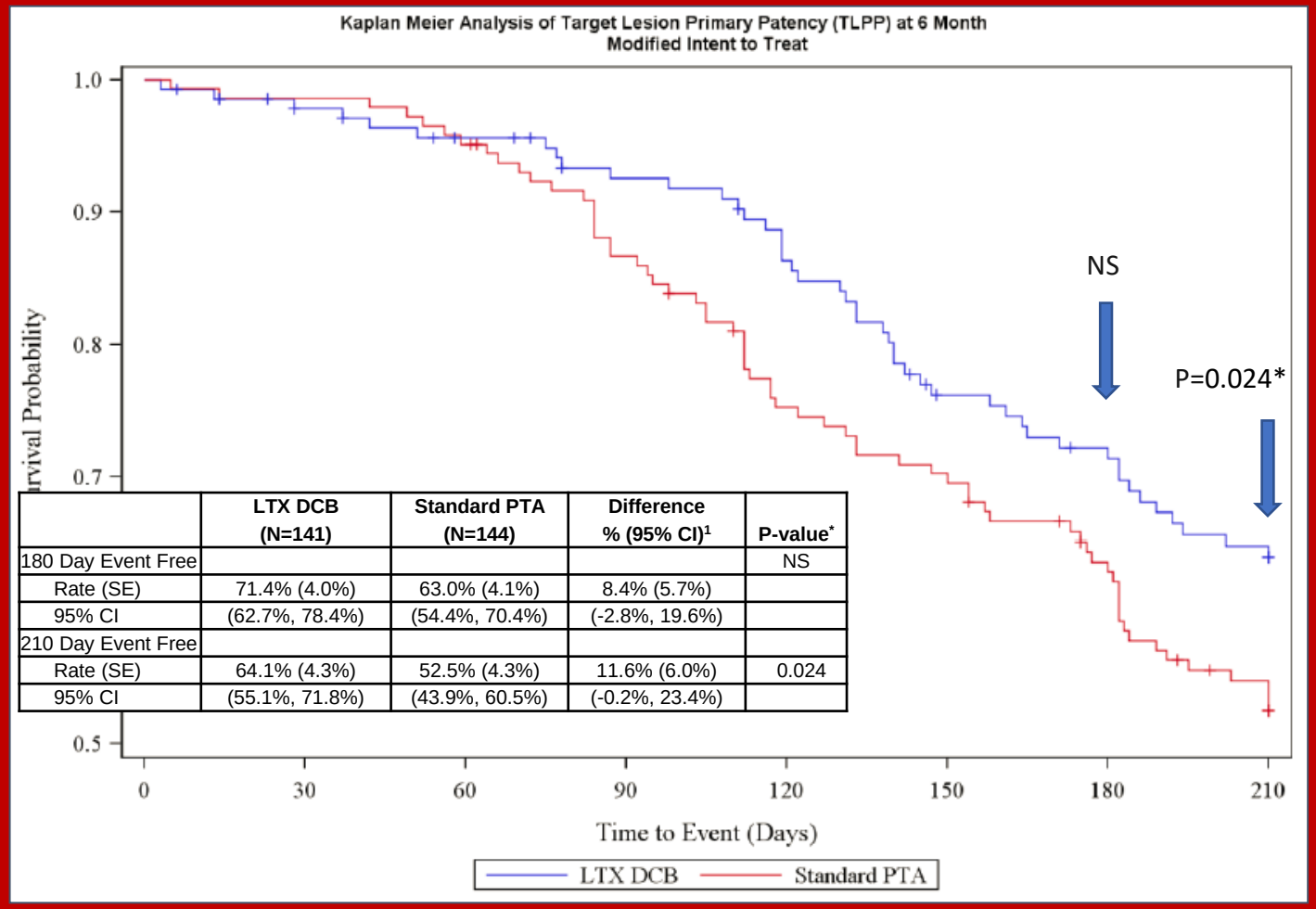
Paclitaxil-Coated Balloons for Treatment of Native AVF Stenosis
Clinical Journal of the American Society of Nephrology 13:1215-1224, 2018

Drug Coated Balloon Angioplasty in Failing AV Fistulas

A Randomized Controlled Trial

Scott O. Trerotola,[1] Jeffrey Lawson,[2,3] Prabir Roy-Chaudhury,[4] and Theodore F. Saad,[5] for the Lutonix AV Clinical Trial Investigators

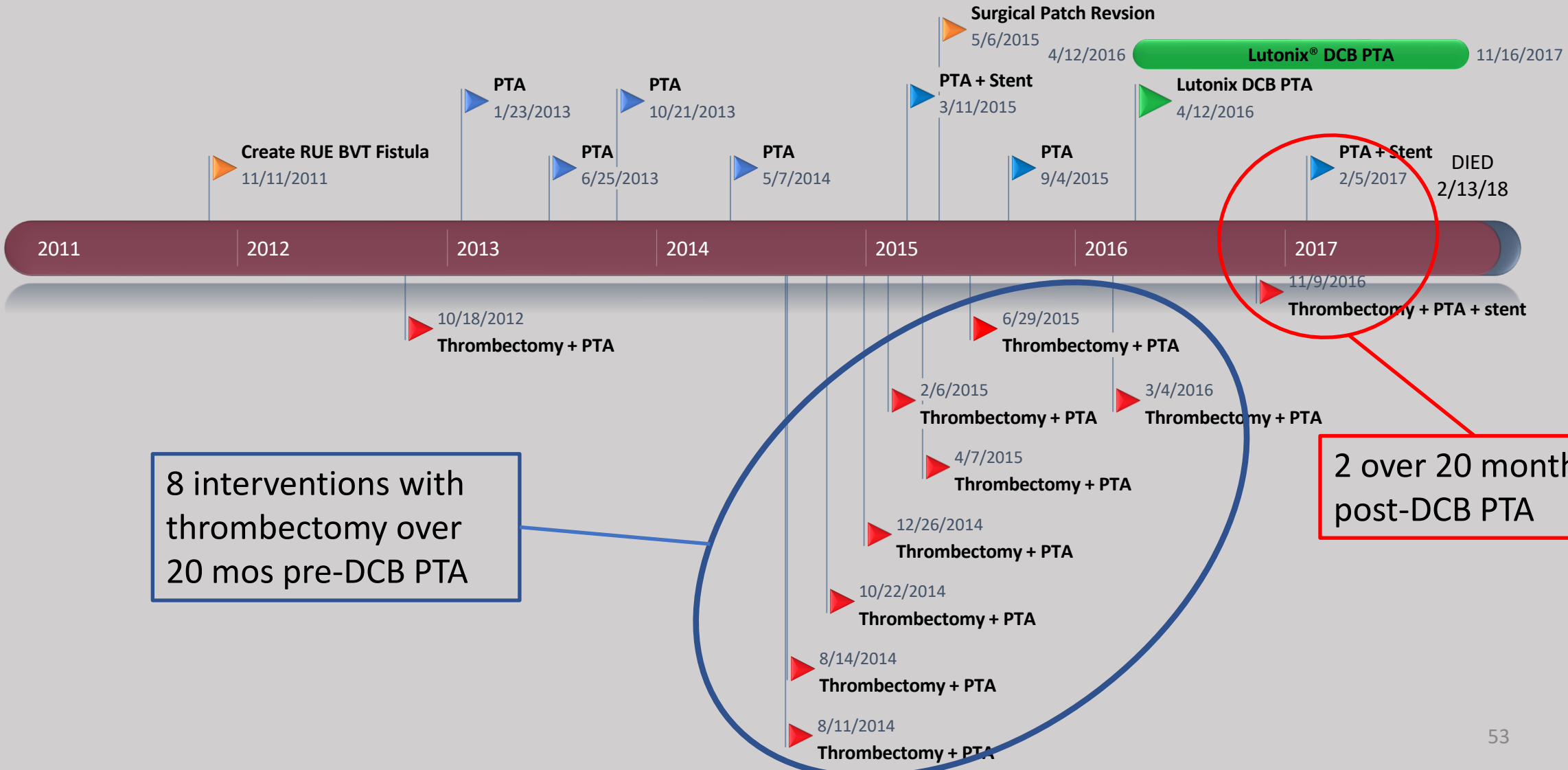
Lutonix® AV IDE Clinical Trial
Primary Efficacy Endpoint: TLPP @ 180 days

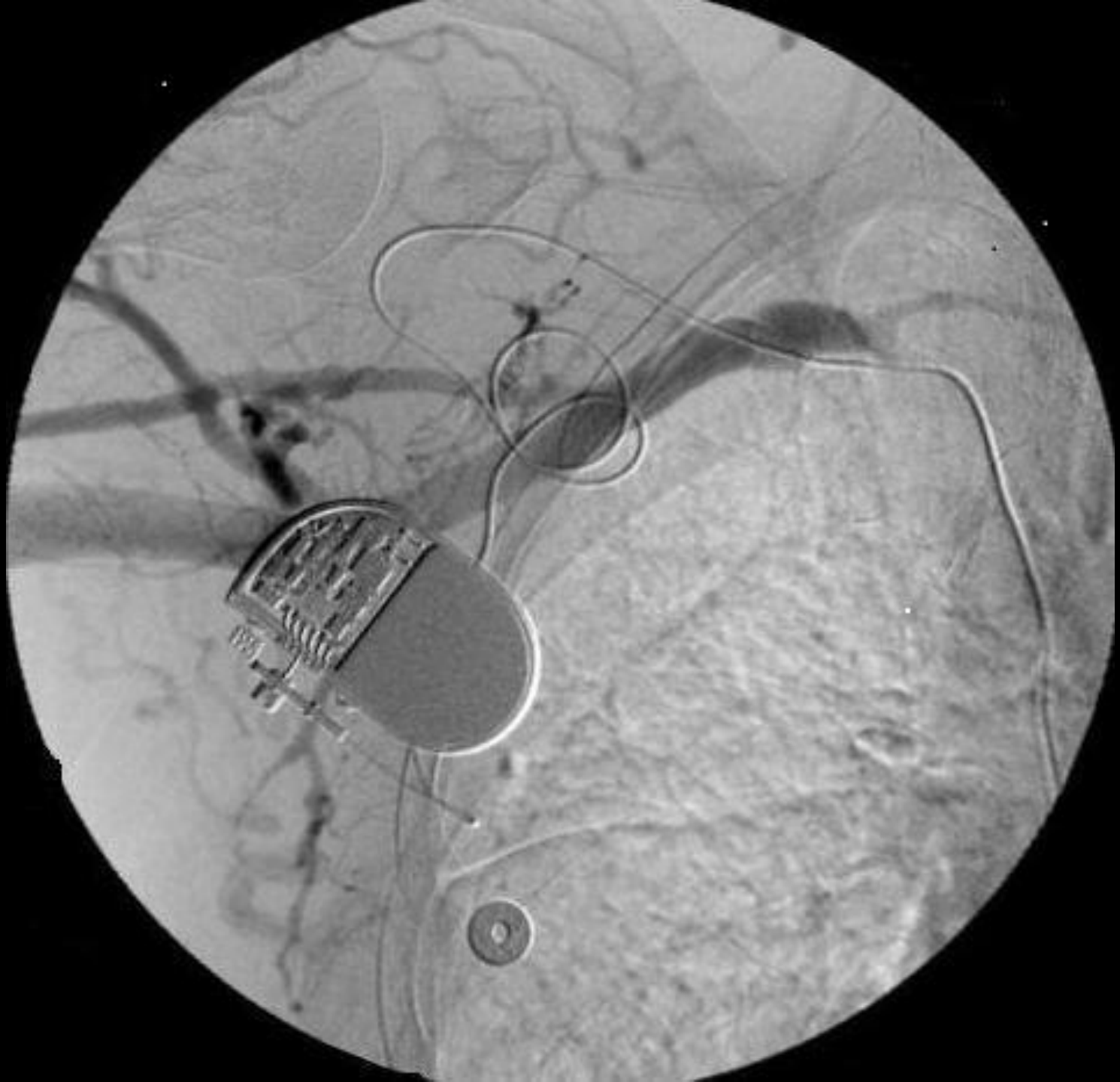


	LTX DCB (N=141)	Standard PTA (N=144)	Difference % (95% CI)[1]	P-value*
180 Day Event Free				NS
Rate (SE)	71.4% (4.0%)	63.0% (4.1%)	8.4% (5.7%)	
95% CI	(62.7%, 78.4%)	(54.4%, 70.4%)	(-2.8%, 19.6%)	
210 Day Event Free				
Rate (SE)	64.1% (4.3%)	52.5% (4.3%)	11.6% (6.0%)	0.024
95% CI	(55.1%, 71.8%)	(43.9%, 60.5%)	(-0.2%, 23.4%)	

“High-maintenance” AVF

Reduced frequency of intervention post-DCB PTA





Cardiovascular Implantable Electronic Devices in Hemodialysis Patients: Prevalence and Implications for Arteriovenous Hemodialysis Access Interventions

Theodore F. Saad,*† Waqas Ahmed,*† Karen Davis,* and Claudine Jurkovitz‡
*Nephrology Associates, PA, Vascular Access Center, Newark, DE, †Section of Renal & Hypertensive Diseases, Department of Medicine, Christiana Care Health System, Newark, DE, and ‡Value Institute Christiana Care Health System, John H. Ammon Education Center, Newark, DE

Seminars in Dialysis 2015; 28:94-100

TABLE 1. CIED in hemodialysis patients

CIED	Number	Percent
ICD	75	6.1%
Pacemaker	54	4.4%
Total CIED	129	10.5%
None	1103	89.3%
Undetermined	3	0.2%
Total	1235	100%

Seminars in Dialysis 2015; 28:94-100.

CIED & AV Access

TABLE 2. Instances of CIED and AV access

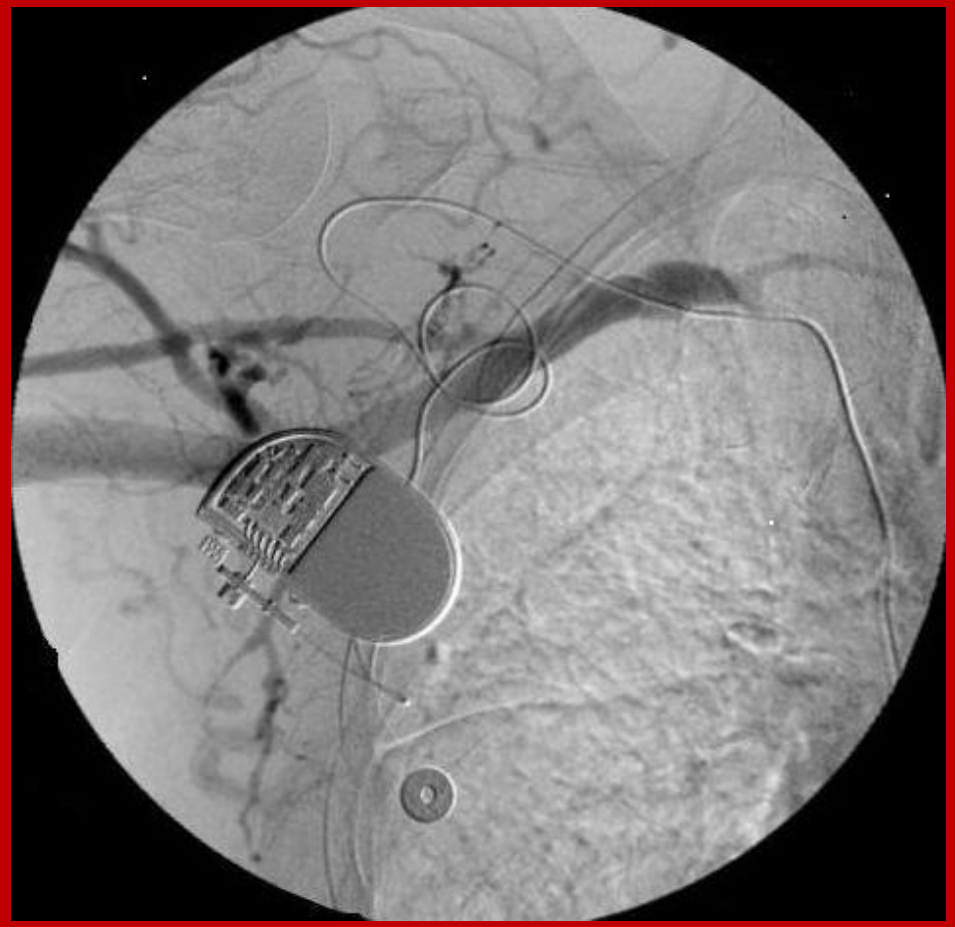
	CIED and AV Access		
	All	Contralateral	Ipsilateral
Instances	137	78	59
CIED left-sided	101 (74%)	45 (58%)	56 (95%)
CIED right-sided	36 (26%)	33 (42%)	3 (5%)
CIED prior to AV access	82 (60%)	34 (44%)	48 (81%)
AV access prior to CIED	54 (39%)	44 (56%)	10 (17%)
Unknown	1		1

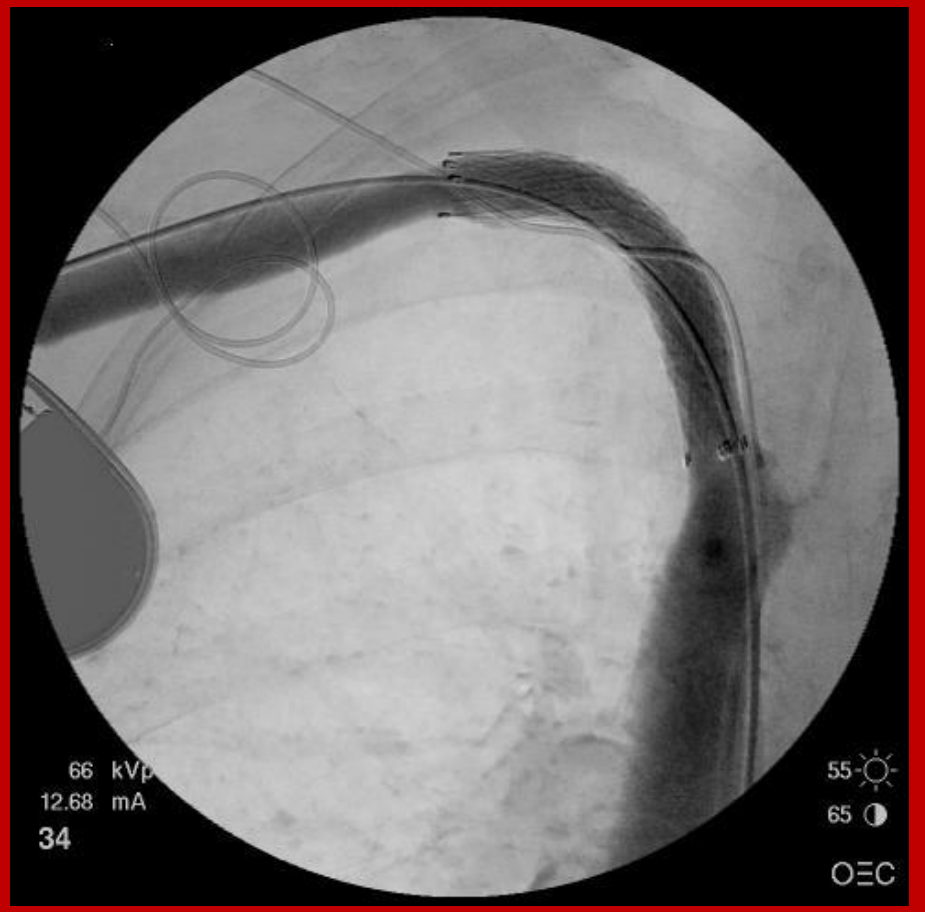
TABLE 3. Intervention rates

	All	Contralateral	Ipsilateral
Number of access circuit interventions (access circuit rate per AY)	506 (1.48)	261 (1.44*)	245 (1.53)
Number of central venous interventions (central	145 (0.43)	50 (0.28†)	95 (0.59)

Seminars in Dialysis 2015; 28:94-100.

Stents for pacemaker or defibrillator lead-associated stenosis





Outcome of stenting central vein stenosis

Saad TF, Myers GR, Cicone JS. *Journal of Vascular Access* 2010; 11: 293-302

JVasc Access 2010; 11 (4): 293-302
DOI: 10.5301/JVA.2010.1064

ORIGINAL ARTICLE

Central vein stenosis or occlusion associated with cardiac rhythm management device leads in hemodialysis patients with ipsilateral arteriovenous access: A retrospective study of treatment using stents or stent-grafts

Theodore F. Saad[1], G. Robert Myers[2], Jeffrey Cicone[1]

[1]Nephrology Associates, PA, Newark, DE - USA; Vascular Access Center, Newark, DE - USA; Nephrology, Christiana Care Health System Department of Medicine, Newark, DE - USA
[2]Cardiology, Christiana Care Health System Department of Medicine, Newark, DE - USA

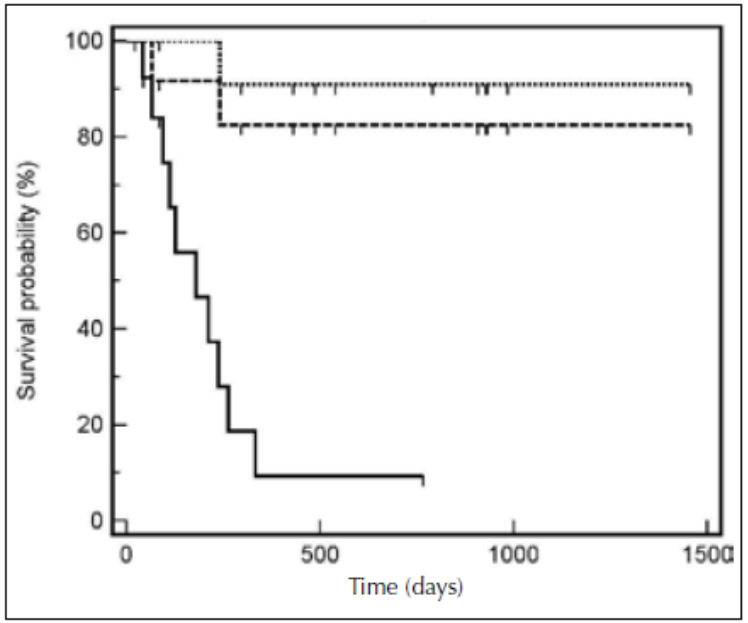


Fig. 2 - *Kaplan-Meier graph of post-intervention patency following initial stent or stent-graft placement for treatment of CRMD lead-associated central vein stenosis.*
Primary Patency: ———————
Primary Assisted Patency: – – – – – – – – – – –
Secondary Patency: .....

Position Papers re. Cardiac Implantable Rhythm Devices in ESRD Patients

ASDIN

Review

Cardiovascular Implantable Electronic Device Leads in CKD and ESRD Patients: Review and Recommendations for Practice

Theodore F. Saad,* Dirk M. Hentschel,† Bruce Koplan,‡ Haimanot Wasse,§ Arif Asif,¶ Daniel V. Patel,** Loay Salman,¶ Roger Carrillo†† and Jeff Hoggard,‡‡
ASDIN Clinical Practice Committee Workgroup
*Department of Medicine, Section of Renal and Hypertensive Diseases, Christiana Care Health System, Newark, Delaware, †Interventional Nephrology, Renal Division, Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts, ‡Cardiac Arrhythmia Section, Brigham and Women's Hospital, Boston, Massachusetts, §Department of Medicine, Renal Division, Emory University School of Medicine, Atlanta, Georgia, ¶Department of Medicine, Division of Nephrology and Hypertension, University of Miami Miller School of Medicine, Miami, Florida, **Volusia-Flagler Vascular Center, Daytona Beach, Florida, ††Division of Thoracic Surgery (Cardiothoracic Vascular Surgery), Department of Surgery, University of Miami Miller School of Medicine, Miami, Florida, and ‡‡Capital Nephrology Associates, Raleigh, North Carolina

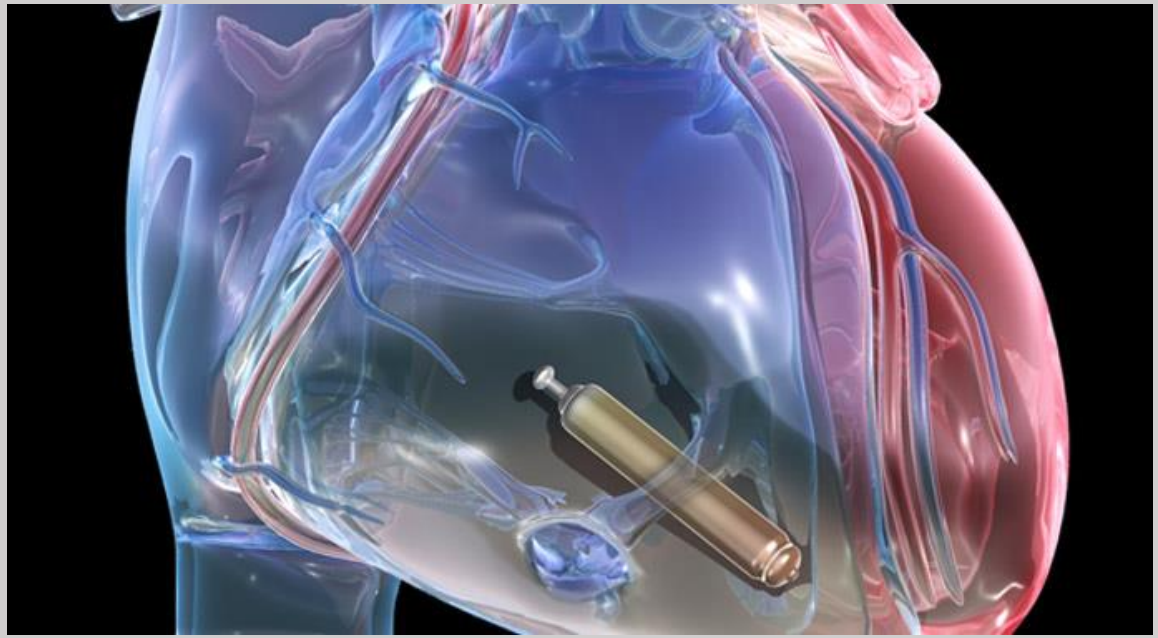
Seminars in Dialysis 2008; 21: 186-191

Venous Hemodialysis Catheters and Cardiac Implantable Electronic Devices: Avoiding a High-Risk Combination

Theodore F. Saad* and Henry L. Weiner†
*Section of Renal and Hypertensive Diseases, Christiana Care Health System, Newark, Delaware, and †Section of Cardiology, Christiana Care Health System, Newark, Delaware

Seminars in Dialysis 2017; 30:187-192

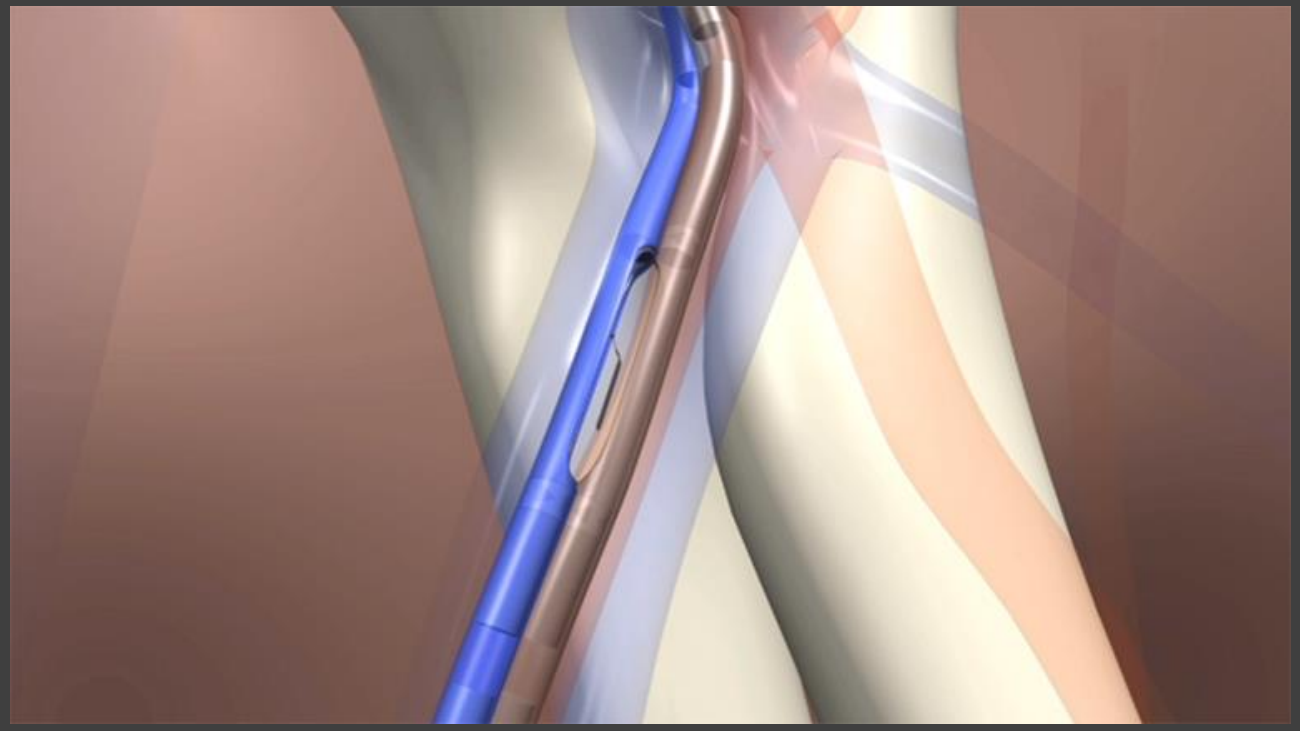
Alternative Devices:
Subcutaneous Defibrillator Leadless Pacemaker

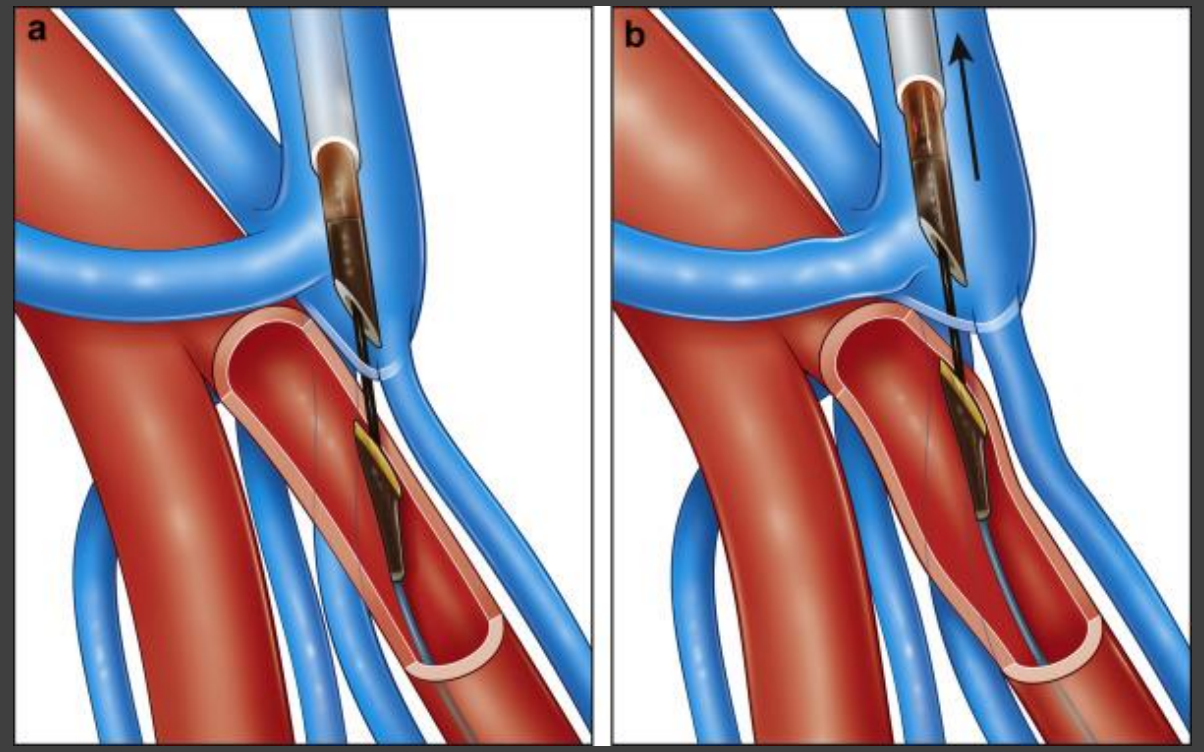


Percutaneous Arteriovenous Fistula Creation
Two Newly FDA-Approved Devices

TVA Medical: everlinQ®
https://www.youtube.com/watch?v=tAV9JV8-GxE

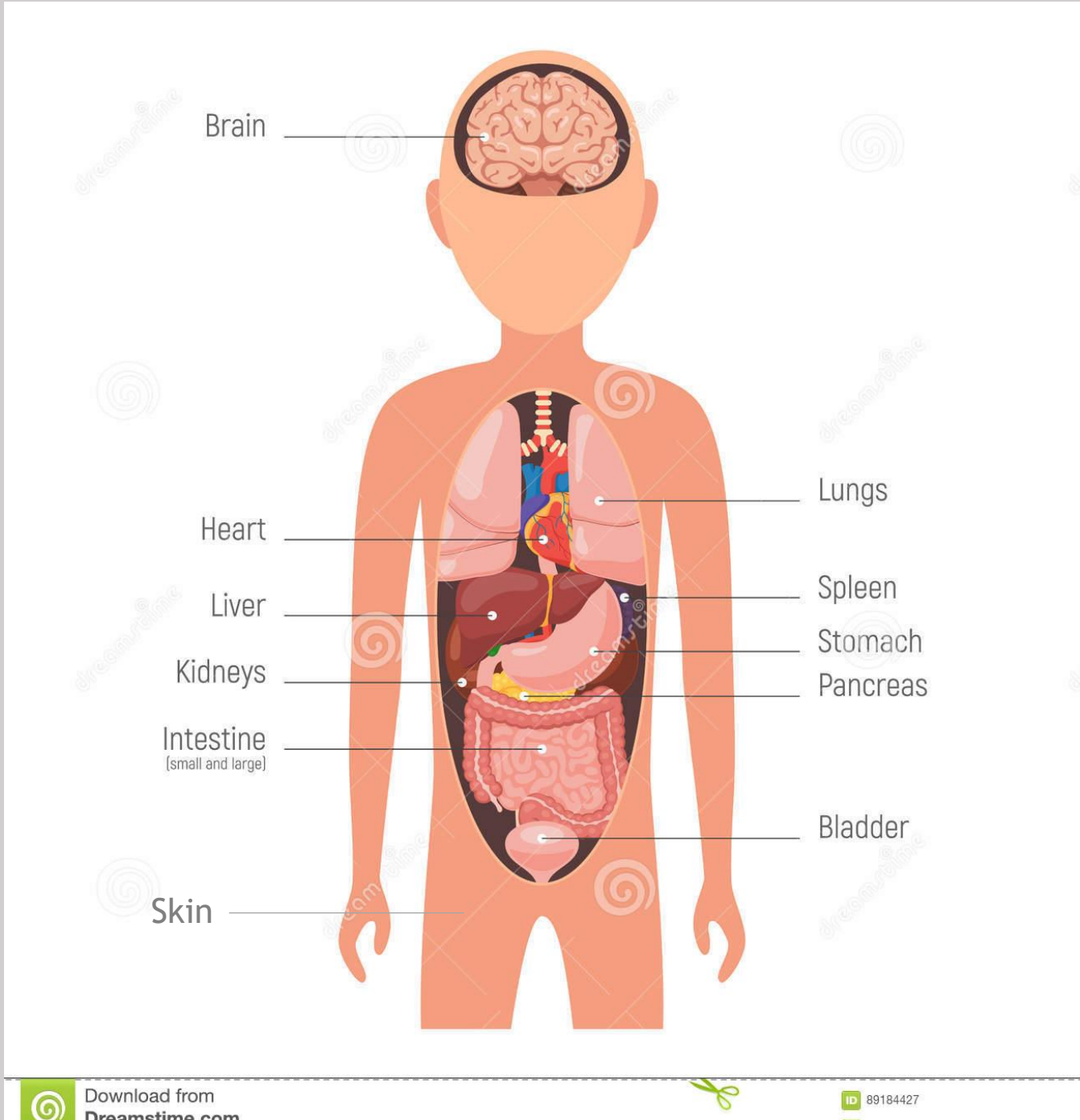
Avenu Medical: Ellispsys®
https://www.youtube.com/watch?v=VoRR7LzyPGM





Dialysis is a Medical Miracle:
Replicate function of critical organ

- Quality of life
  - Employment
  - School
  - Travel
  - Family
- Cost-effective
  - Covered condition
- Widely available
  - USA & worldwide
- Sustainable
  - Years-decades



Selected References

- Blagg C: **The Early History of Dialysis for Chronic Renal Failure in the United States: A View From Seattle.** *American Journal of Kidney Disease,* 2007: 49:482-496 https://www.ncbi.nlm.nih.gov/pubmed/17336711
- Brescia M, Cimino J, Appel K, Hurwich B**: Chronic hemodialysis using venipuncture and a surgically created arteriovenous fistula**. New England Journal of Medicine 275:1089-1092, 1966 https://www.nejm.org/doi/full/10.1056/NEJM196611172752002
- Eggers P: **Medicare's End Stage Renal Disease Program**. Health care financing review 2**000;** 22:55-60
- Haskal Z, Saad TF, Hoggard J, Cooper RI, Lipkowitz G, Gerges A, Ross J, Pflederer TA, Mietling S**: Prospective, Randomized, Concurrently-Controlled Study of** a Stent Graft vs. Balloon Angioplasty for Treatment of Arteriovenous Access Graft Stenosis: Two-Year Results of the RENOVA Study. *J Vasc Interv Radiol* 2016; 8:1105-1114. https://www.ncbi.nlm.nih.gov/pubmed/27388566
- Hoggard J, Saad T, Schon D, Vesely T, Royer T**: Guidelines for venous access in patients with chronic kidney disease.** A position statement from the American Society of Diagnostic and Interventional Nephrology Clinical Practice Committee and the Association for Vascular Access. *Seminars in Dialysis* 2008; 21: 186-191. http://www.ncbi.nlm.nih.gov/pubmed/18364015
- Ing T, SKjellstrand C, Rahman M: Dialysis: History, Development And Promise August 29, 2012 World Scientific. https://play.google.com/store/books/details?id=7KDFCgAAQBAJ
- Kathi E. Hanna, Editor; **Biomedical Politics.** National Academy Press, Washington, D.C. 1991. https://www.nap.edu/catalog/1793/biomedical-politics
- Kolff WJ, Berk H TH J, NURSE M ter Welle, Miss A J W van der Ley, Mssrs E C van Dijk, J van Noordwijk: The artificial kidney: a dialyzer with a great area. Acta Medica Scandinavica 1944; CXVII:121-134. http://jasn.asnjournals.org/content/8/12/1959
- Lockridge J, Chandran S**: The Scribner shunt: 50 years later.** Kidney International 2012; 81:120. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4124935

- Raviani P, Quinn R, Oliver M, et al.: **Examining the association between hemodialysis access type and mortality: The role of access complications.** Clin J Am Soc Nephrol 2017; 12:955–964
- Rettig R: **Special Treatment: The Story of Medicare's ESRD Entitlement. NEJM 2011;** 364:596-598. https://www.nejm.org/doi/10.1056/NEJMp1014193
- Saad TF, Weiner H: **Venous Hemodialysis Catheters and Cardiac Implantable Electronic Devices: Avoiding a High-Risk Combination.** *Seminars in Dialysis* 2017; 30:187-192 https://www.ncbi.nlm.nih.gov/pubmed/28229483
- Saad TF, Ahmed W, Davis K, Jurkowitz C: **Cardiovascular Implantable Electronic Devices in Hemodialysis Patients: Prevalence and Implications for Arteriovenous Hemodialysis Access Interventions.** *Seminars in Dialysis* 2015; 28:94-100. http://www.ncbi.nlm.nih.gov/pubmed/24863543
- Saad TF, Hentschel D, Koplan B, Wasse H, Asif A, Patel DV, Salman L, Carrillo R, Hoggard J: **Cardiovascular Implantable Electronic Device Leads in Chronic Kidney Disease and End-Stage Renal Disease Patients: Review and Recommendations for Practice.** *Seminars in Dialysis 2012;* 26: 114-123. http://www.ncbi.nlm.nih.gov/pubmed/22891983
- Saad TF, Myers GR, Cicone JS**: Central vein stenosis or occlusion associated with cardiac rhythm management device leads in hemodialysis patients with ipsilateral arteriovenous access: A retrospective study of treatment using stents or stent-grafts.** *Journal of Vascular Access* 2010; 11: 293-302. http://www.ncbi.nlm.nih.gov/pubmed/20658455
- Thamer M, Lee T, Wasse H, Glickman M, Qian J, Gottlieb D, Toner S, Pflederer T: Medicare costs associated with arteriovenous fistulas among US hemodialysis patients. AJKD 2018; 72:10-18. https://www.ncbi.nlm.nih.gov/pubmed/29602630
- Trerotola S, Roy-Chaudhury P, Lawson J, Saad T: **Randomized trial of drug coated balloon angioplasty in failing AV fistulae**. *Clinical J of American Society of Nephrology* 2018; 13: 1215-1224 https://www.ncbi.nlm.nih.gov/pubmed/30042225
- https://www.davita.com/treatment-services/dialysis/the-history-of-dialysis
- https://www.davita.com/treatment-services/dialysis/on-dialysis/political-advocacy-and-chronic-kidney-disease


11' 3"