Vascular Access

Technical Expert Panel

April 22 and 23, 2015

SCHOOL OF PUBLIC HEALTH
KECC
UNIVERSITY OF MICHIGAN

Agenda: April 22, 2015

9:00 – 9:30	Introductions and Conflict of Interest
9:30 – 10:30	Review of literature
10:30 – 10:45	Break
10:45 – 11:45	Preliminary KECC Analyses
11:45 – 12:00	Review existing Vascular Access measures
12:00 – 1:00	*LUNCH*
1:00 – 3:00	Evaluation and Revision of current Vascular Access measures
	Consideration of risk adjustment strategies
3:00 - 3:15	*BREAK*
3:15 – 5:00	Revision of current measures and draft measure specifications

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Agenda: April 23, 2015

9:00 – 10:45	Draft measure specifications (continued)
10:45 – 11:00	*BREAK*
11:00 – 12:00	Draft measure specifications (continued)
12:00 – 1:00	*LUNCH*
1:00 – 2:20	Recommendations from TEP for future direction
2:20 – 2:30	Wrap-up
2:30 – 3:00	Public Comment Period

Disclosures of potential conflicts of interest – TEP members

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Monet Carnahan, RN, BSN, CDN	Renal Care Coordinator Program Manager Fresenius Medical Center (FMC), Franklin, TN American Nephrology Nurses Association	None
Lynn Poole, FNP-BC, CNN	NCC Fistula First Catheter Last Project Clinical Lead ESRD National Coordinating Center Lake Success, NY	None
Joseph Vassalotti, MD, FASN, FNKF	Chief Medical Officer, National Kidney Foundation Associate Professor of Medicine, Division of Nephrology Mount Sinai Medical Center, New York, NY	None

Disclosures of potential conflicts of interest – TEP members (Continued)

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Charmaine Lok, MD, MSc, FRCPC (C)	Medical Director of Hemodialysis and Renal Management Clinics University Health Network Professor of Medicine University of Toronto, Toronto, ON	None
Daniel Weiner, MD, MS	Nephrologist, Tufts Medical Center Associate Medical Director, DCI Boston Associate Professor of Medicine Tufts University School of Medicine, Boston, MA	Receives salary support from DCI as a medical director. Receives some salary support for DCI for research work within DCI (10% salary support). Member of the American Society of Nephrology Public Policy Board, and as such participates in some KCP calls. There is a $2,000 per year honorarium for service on the ASN Public Policy Board. Member of the NKF KDOQI Hemodialysis Adequacy Guideline Workgroup.
Rudy Valentini, MD	Chief Medical Officer Children's Hospital of Michigan (CHM) Professor of Pediatrics, Division of Nephrology Wayne State University School of Medicine	Former consultant for Gambro (2013)

Disclosures of potential conflicts of interest – TEP members (Continued)

Name and Credentials	Organizational Affiliation	Conflicts of Interest
Lee Kirskey, MD	Attending staff, Department of Vascular Surgery Cleveland Clinic Foundation, Cleveland, OH	None
Derek Forfang	Patient Leadership Committee Chair ESRD Network 17 Board Member Intermountain End State Renal Disease Network Inc. Beneficiary Advisory Council (Vice Chair) The National Forum of ESRD Networks Board Member The National Forum of ERSD Networks San Pablo, CA	None
Nance Lehman	Board Member Dialysis Patient Citizens (DPC) Billings, MT	None

Disclosures of potential conflicts of interest – UM-KECC

Name	Title & Organization	Conflicts of Interest
Jonathan Segal, MD, MS	Nephrologist/Clinical Associate Professor, Internal Medicine	None
Joe Messana, MD	Collegiate Professor of Nephrology and Professor of Internal Medicine	None
Sehee Kim, PhD	Research Assistant Professor, Biostatistics	None
Claudia Dahlerus, PhD, MA	Principal Scientist	None
Shu Chen	Research Analyst	None
Jie Tang	Research Analyst	None
Casey Parrotte	Research Analyst	None
Jennifer Sardone	Research Analyst	None

Review of Literature

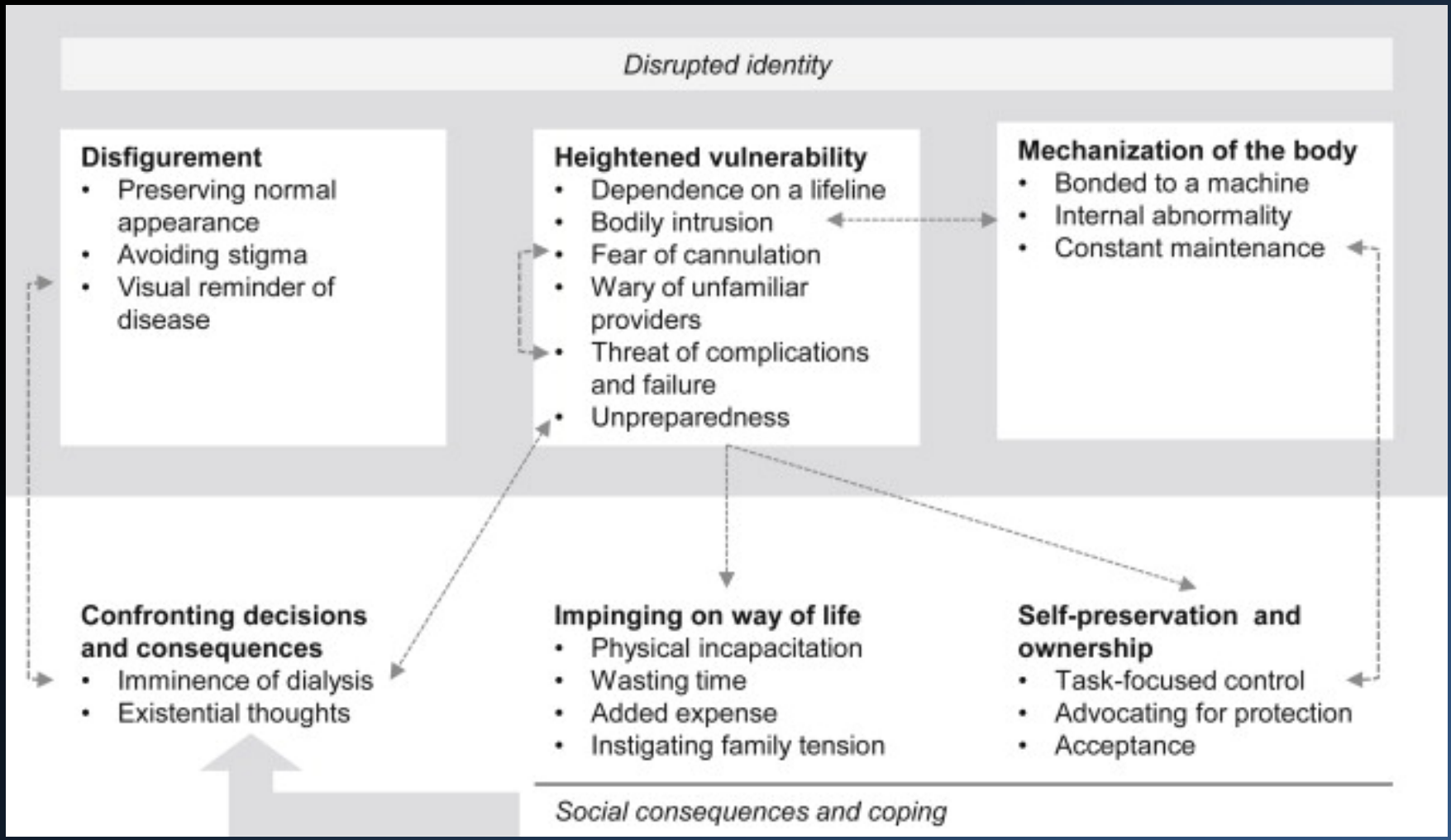
UM-KECC Literature Review

- PubMed Search: January 2010 to April 2014
  - 705 abstracted
  - 26 selected for relevance
- PubMed Search: January 2014 to January 2015
  - 337 abstracted
  - 10 selected for relevance

Literature Review Summary

- Confirmatory Studies – Vascular Access is Actionable
- Pros and Cons of Fistula First Initiatives and ESRD QIP Measures
- AVG and AVF Comparisons
  - Usable or Mature AVF is generally superior to AVG
  - AVF time to Maturation and high Primary Failure rate attenuate advantage
  - Overall AVG vs. AVF differences are less prominent than either vs. catheters
- Individualize Approach especially by age and co-morbidities – risk adjustment?
- Miscellaneous
- Future Directions
  - Hemodialysis Fistula Maturation (HFM) Study Observational Study
  - Randomized Trials AVG versus AVF - proposed to guide decision making

Patient's Perspective on Hemodialysis Vascular Access: A Systematic Review of Quantitative Analysis



American Journal of Kidney Diseases, Volume 64, Issue 6, 2014, 937 - 953

Patient's Perspective on Hemodialysis Vascular Access: Selected Quotations from the 6 Themes

"The only thing that reminded me of my sickness was my arm."

Disfigurement

"My biggest fear is the clogging."

Heightened vulnerability

"In this way the machine and body become an interwoven unit."

Mechanization of the body

American Journal of Kidney Diseases, Volume 64, Issue 6, 2014, 937 - 953

Patient's Perspective on Hemodialysis Vascular Access: Selected Quotations from the 6 Themes

"I did not have the operation at that time because I told myself that I could resist [dialysis]."

Confronting Decisions and Consequences

"Sometimes I get a little angry. It's hard to get my needle in place and my dialysis takes 4.5 hours."

Impinging on Way of Life

"I scrub my arm and take care of my graft"

Self-Preservation & Ownership

American Journal of Kidney Diseases, Volume 64, Issue 6, 2014, 937 - 953

Patient's Perspective on Hemodialysis Vascular Access: Conclusion

Timely education and counseling about vascular access and building patients' trust in health care professionals may improve the quality of dialysis and lead to better outcomes for patients with chronic kidney disease requiring hemodialysis.

This unique article describes the patient's perspective and experience, emphasizing the importance of vascular access.

American Journal of Kidney Diseases, Volume 64, Issue 6, 2014, 937 - 953

Table 1. Advantages and disadvantages of different vascular access types

Access Type	Advantages	Disadvantages
Tunneled hemodialysis catheter	Universally applicable Multiple potential sites available Immediately useable Venipuncture not required Minimal patient preparation required Relatively low cost of placement and replacement Provides access over several months Lower burden on cardiac function	Catheter occlusion Highest risk of catheter and systemic infection Vascular thrombosis/stenosis with loss of future potential arteriovenous sites Aesthetic concern Shortest access survival Lower blood flow rates
Prosthetic arteriovenous graft	Minimal to moderate maturation time required May provide years of access Relative ease of cannulation May provide opportunity for development and creation of secondary fistula Low burden on cardiac function Less prone to dialysis access-related distal ischemia (steal)	Prone to higher cost of placement and creation Higher cost of revision or repair May develop pseudoaneurysms and/or aneurysms Moderate risk for infection
Autologous arteriovenous fistula	Provides longest access survival Lowest risk of access thrombosis Lowest risk of access infection	Considerable risk for maturation failure Longest time to mature May require more preoperative evaluation and testing Higher risk for dialysis access-related distal ischemia (steal) May develop aneurysms and megafistula May have higher burden on cardiac function with high-flow arteriovenous fistula

Clin J Am Soc Nephrol 8: 1228–1233, 2013.

Pros and Cons of Fistula First

Pro

- Nephrology ownership
- Elevate the priority of vascular access in medical community
- Surgical Training
- Cannulation Training
- Access Coordinator
- ESRD Network and dialysis clinic staff engagement in QI

Con

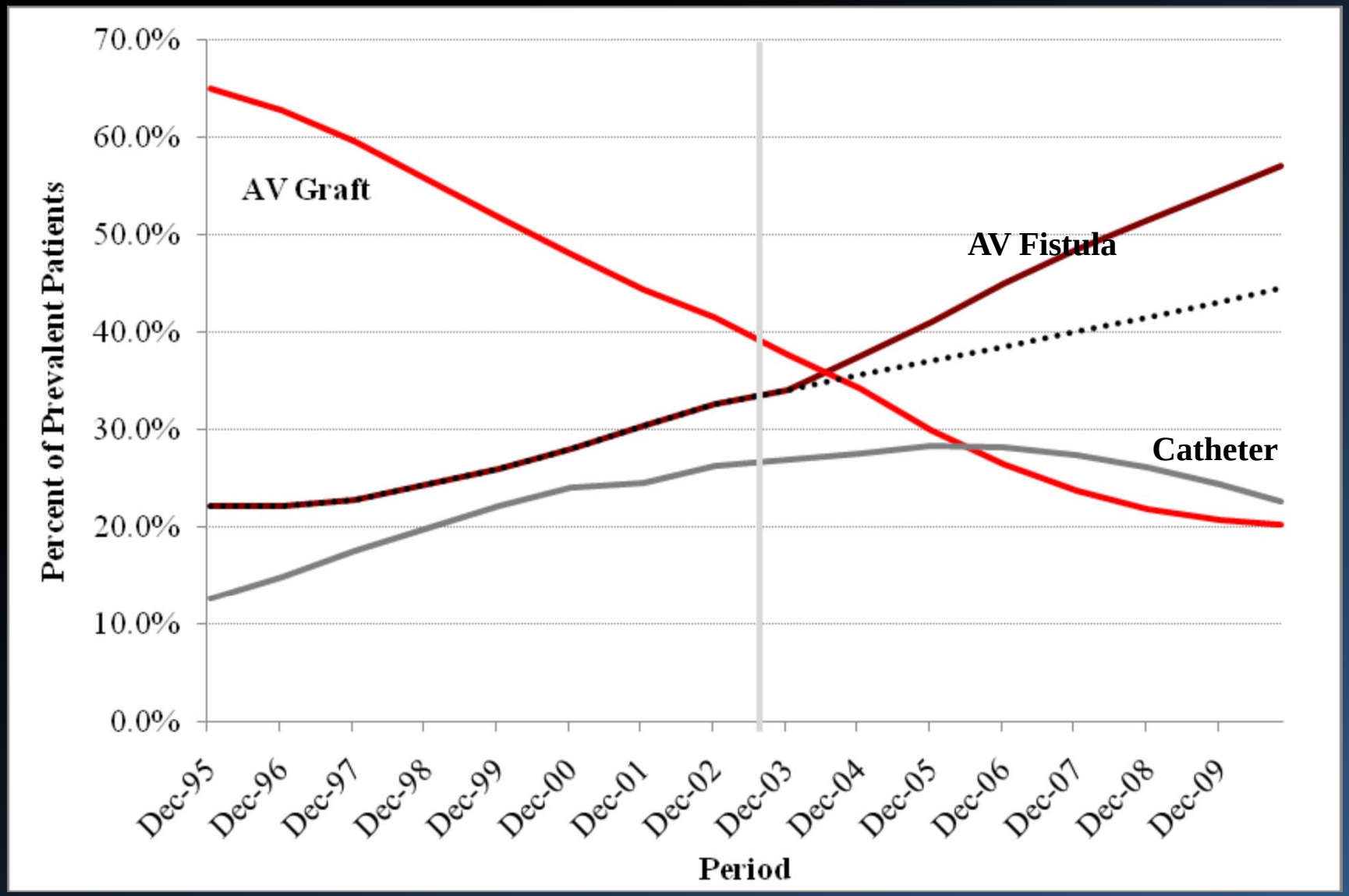
- Perceived as rigid approach to fistula for all, although it was never intended.
- Above is reinforced by the ESRD QIP.
- Role of AVG not clearly defined.
- High primary AVF rate and prolonged time to maturation results in prolonged catheter exposure.

Semin Dial. 25(3):303-310, 2012

Nephrol Dial Transplant 27: 3752–3756, 2012

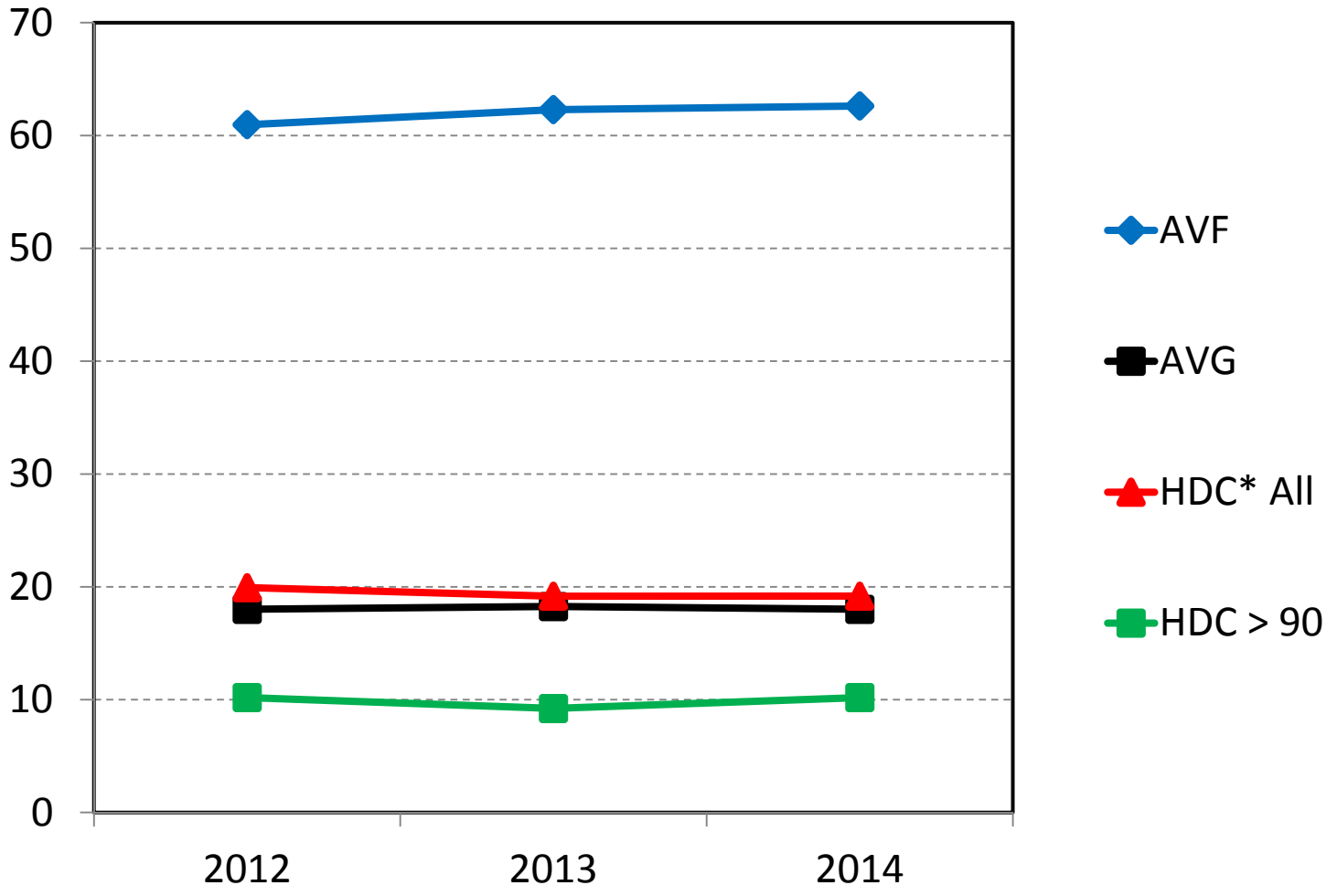
J Am Soc Nephrol 26: 5–7, 2015.

U.S. Vascular Access Prevalence



Seminars in Dialysis 25(3):303-310, 2012

Fistula First Catheter Last Data

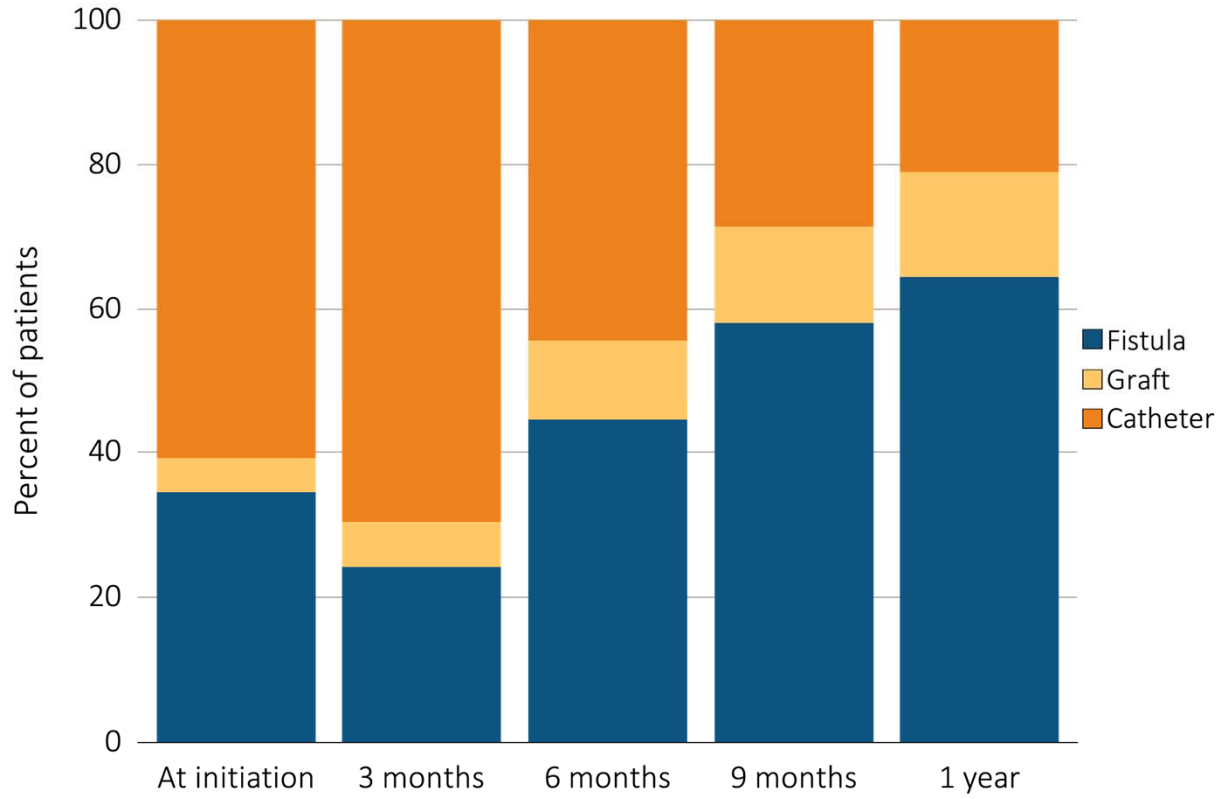


CROWNWeb Data

A ‘patient first, not fistula first,
but avoid a catheter
if at all possible approach
might be the best.

Nephrol Dial Transplant (2012) 27: 3752–3756

vol 2 Figure i.5 VA use during the first year of HD by time since initiation of ESRD treatment, among patients new to HD in 2012, from the ESRD Medical Evidence 2728 Form and CROWNWeb data

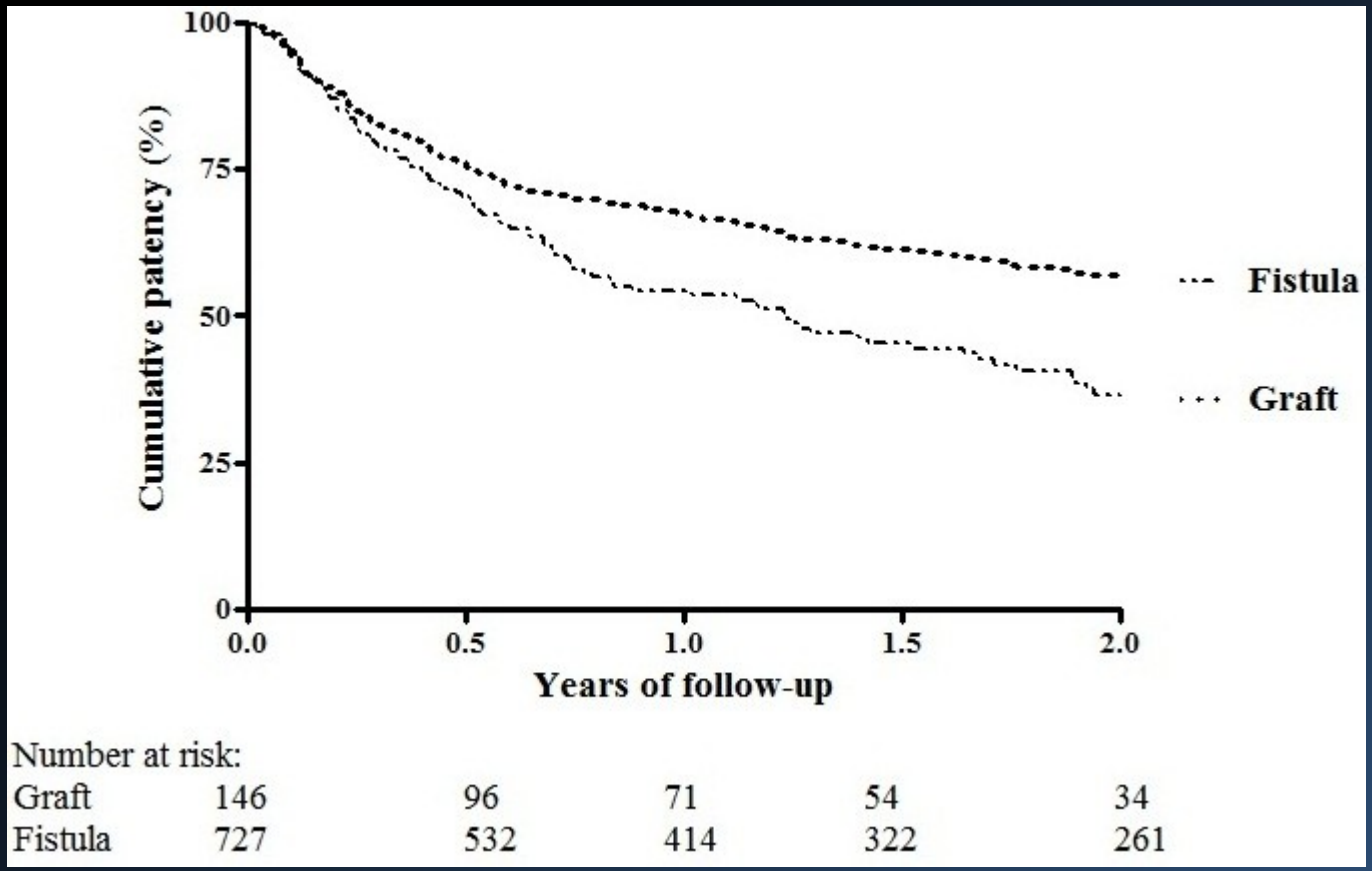


78% of hemodialysis patients start with a dialysis catheter

Literature Review:
AVG and AVF Comparisons

- Usable or Mature AVF is generally superior to AVG
- AVF Time to Maturation and High Primary Failure rate attenuate advantage
- Overall, AVG and AVF differences are less than either compared to catheters

Type of arteriovenous vascular access and association with patency and mortality

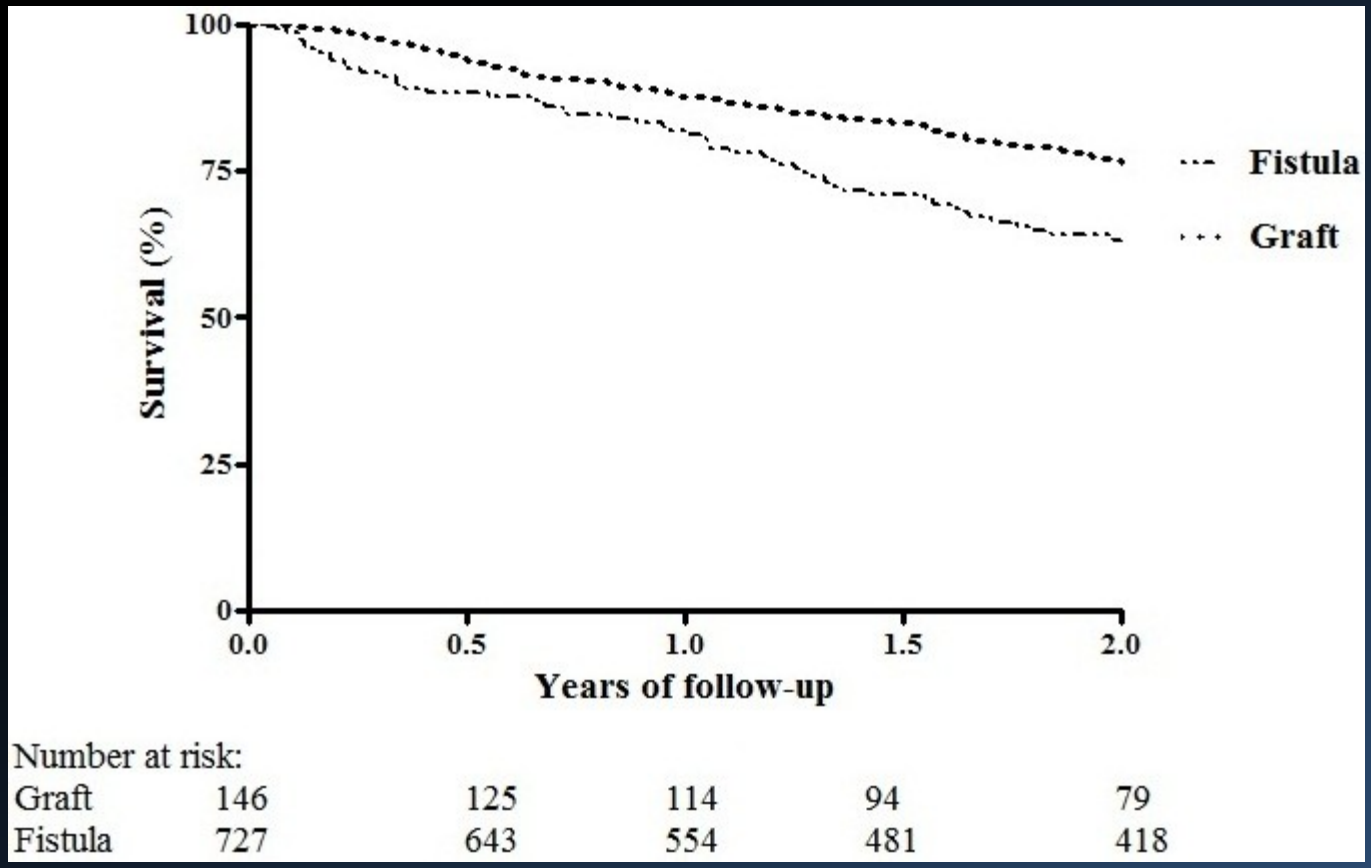


Kaplan-Meier survival curve for two-year mortality.

This is an example of a study that compares usable AVF and AVG. Incident Patients

Ocak et al. BMC Nephrology 2013, 14:79

Type of arteriovenous vascular access and association with patency and mortality



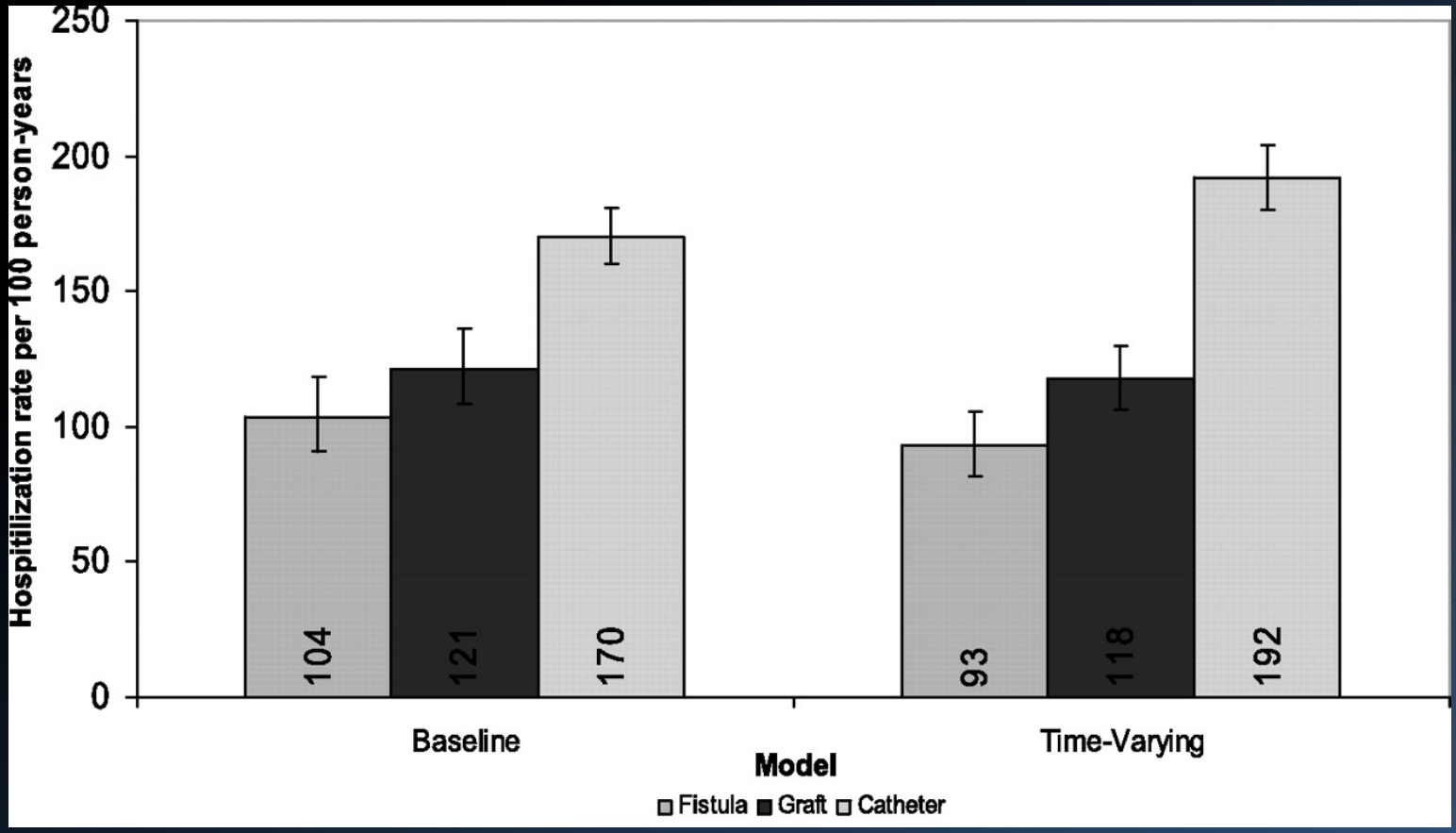
Kaplan-Meier survival curve for two-year primary patency loss after first successful cannulation.

This is an example of a study that compares usable AVF and AVG.

Incident Patients

Ocak et al. BMC Nephrology 2013, 14:79

Hospitalization risks related to vascular access type among incident US hemodialysis patients



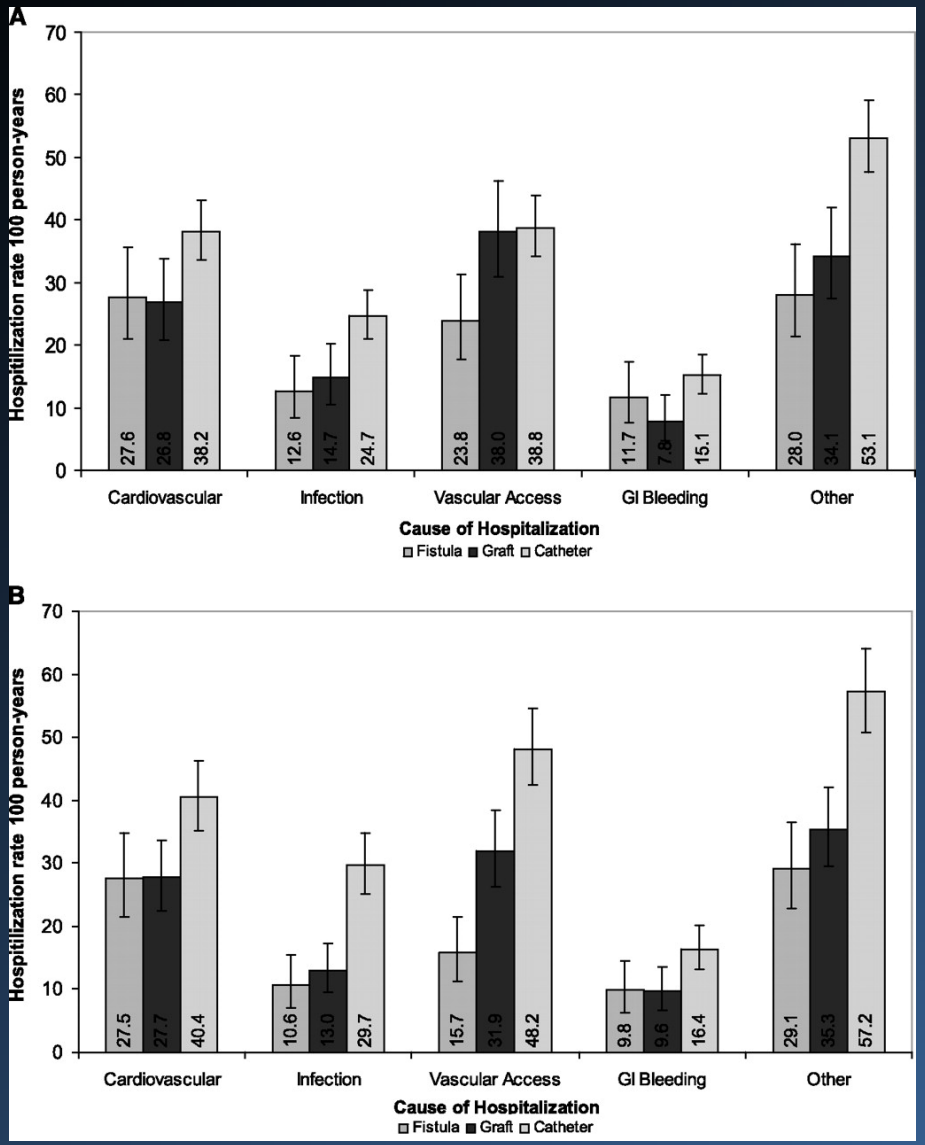
All-cause hospitalization rates and 95% CI according to VA type at baseline and accounting for conversions occurring within the first 6 months of follow-up (time-varying). This is an example of a study that compares usable AVF and AVG.

Leslie J. Ng et al. Nephrol. Dial. Transplant. 2011;26:3659-3666

Hospitalization risks related to vascular access type among incident US hemodialysis patients

Cause-specific hospitalization rates and 95% CI according to VA type among patients: (A) at baseline and (B) accounting for conversions occurring within the first 6 months (time-varying).

This is another example of a study that compares usable AVF and AVG.



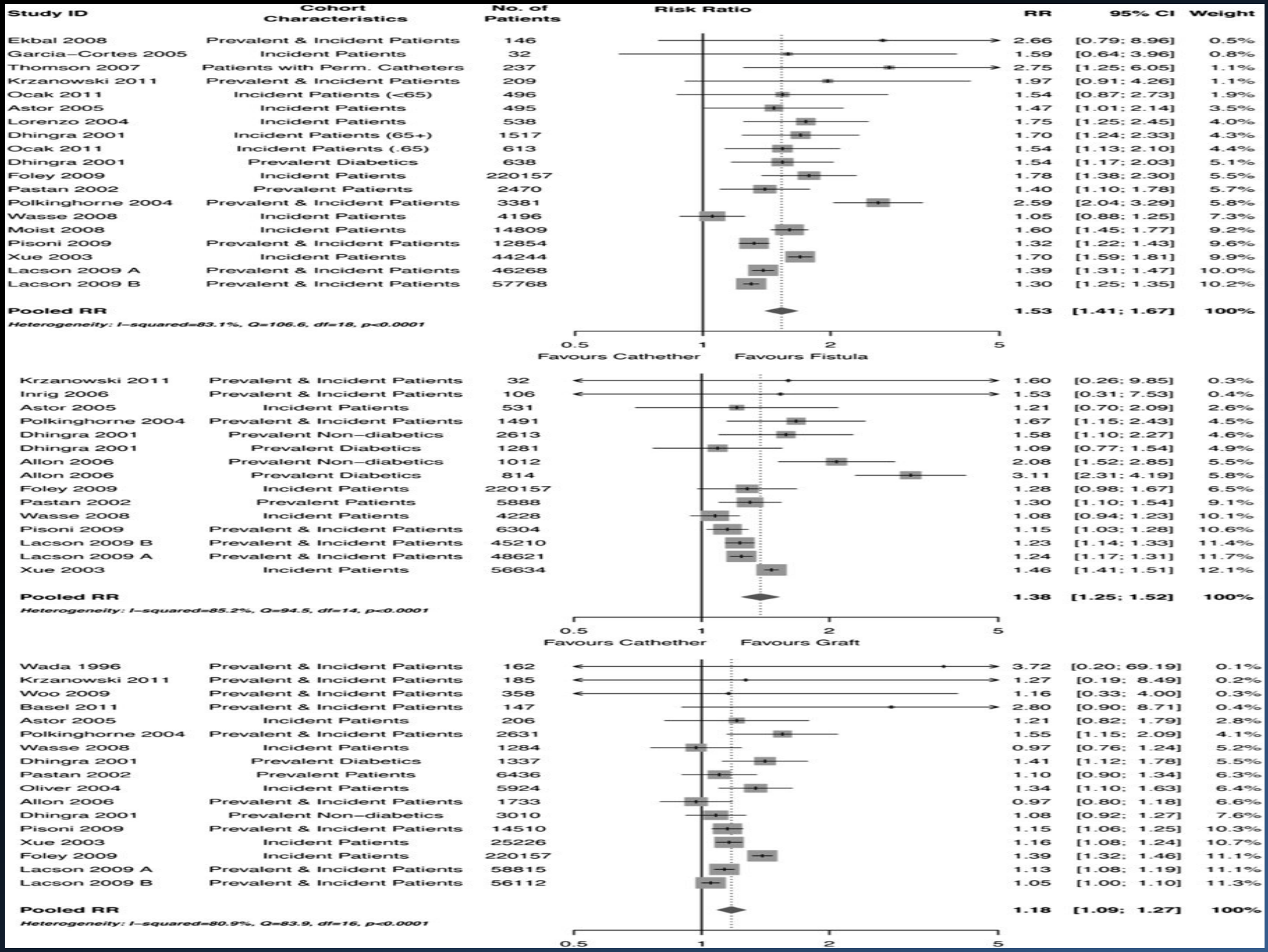
Leslie J. Ng et al. Nephrol. Dial. Transplant. 2011;26:3659-3666

Associations between Hemodialysis Access Type and Clinical Outcomes: A Systematic Review

- Identified 3965 citations, of which 67 (62 cohort studies comprising 586,337 participants) met inclusion criteria

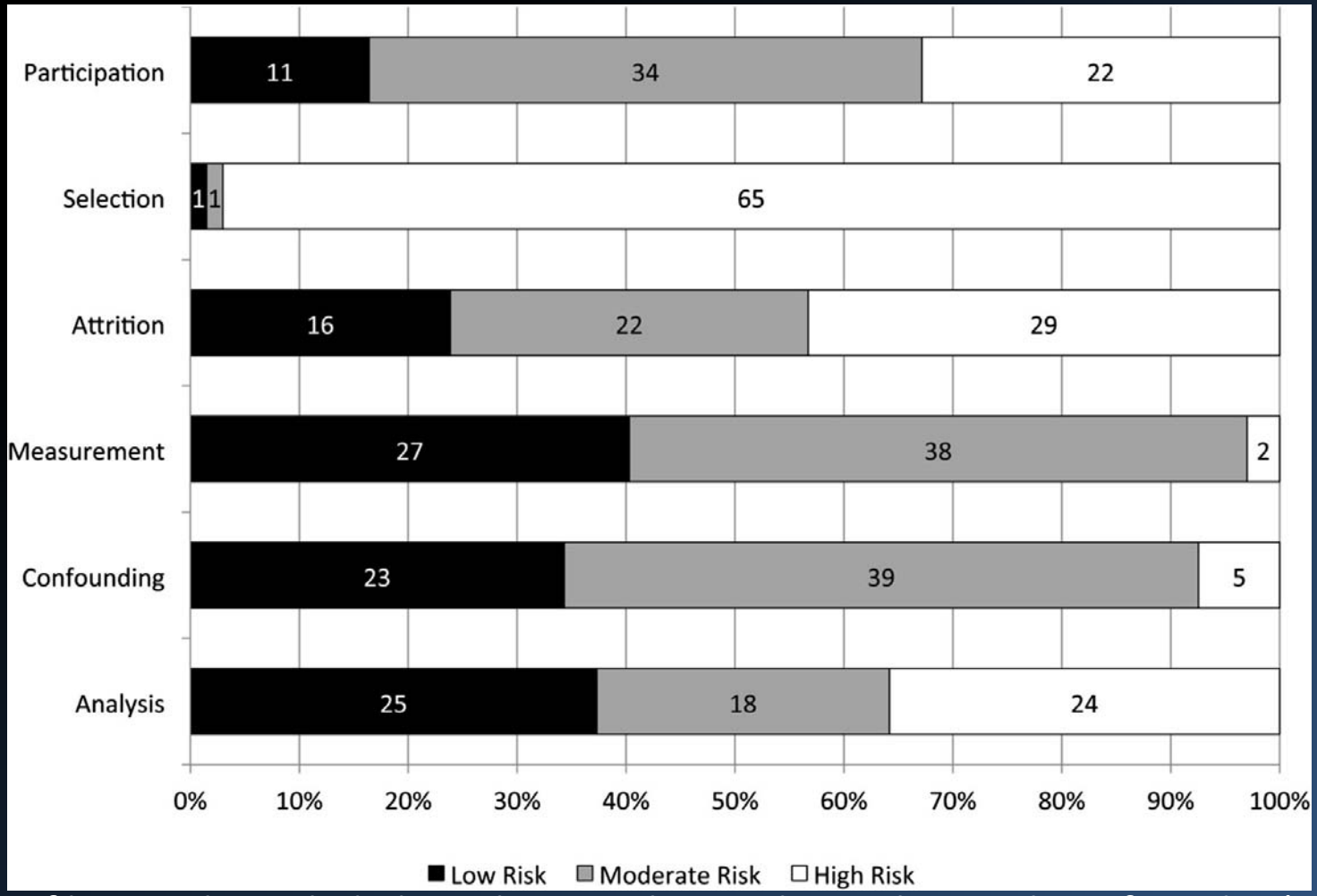
- In conclusion, persons using catheters for hemodialysis seem to have the highest risks for death, infections, and cardiovascular events compared with other vascular access types, and patients with usable fistulas have the lowest risk.

Pietro Ravani et al. JASN 2013;24:465-473



Pietro Ravani et al. JASN 2013;24:465-473

Associations between Hemodialysis Access Type and Clinical Outcomes: A Systematic Review Selection Bias – Suggests Risk Adjustment



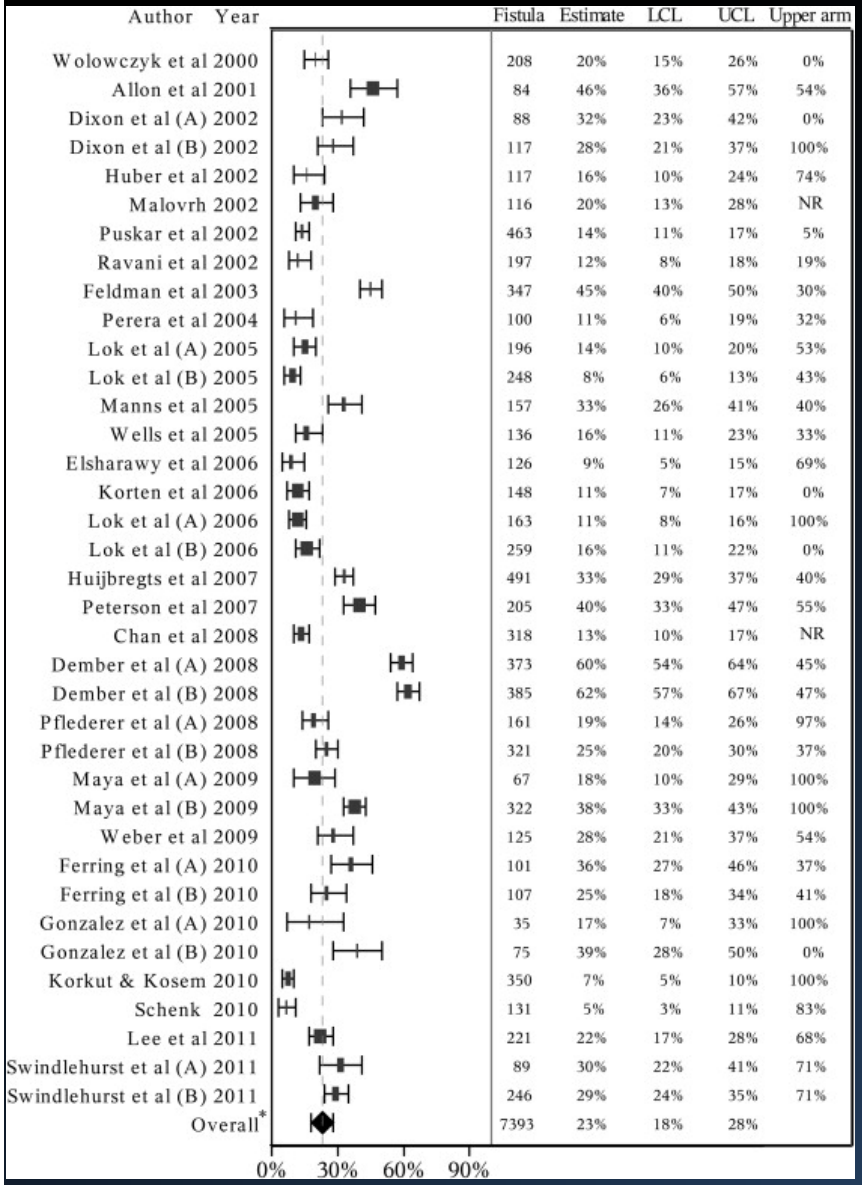
Risk of bias in the included articles. Numbers indicate the number of articles (n=67)

Pietro Ravani et al. JASN 2013;24:465-473

Literature Review:
AVG and AVF Comparisons

- Usable or Mature AVF is generally superior to AVG
- AVF Time to Maturation and High Primary Failure rate attenuate advantage
- Overall, AVG and AVF differences are less than either compared to catheters

Patency Rates of the Arteriovenous Fistula for Hemodialysis: A Systematic Review and Meta-analysis



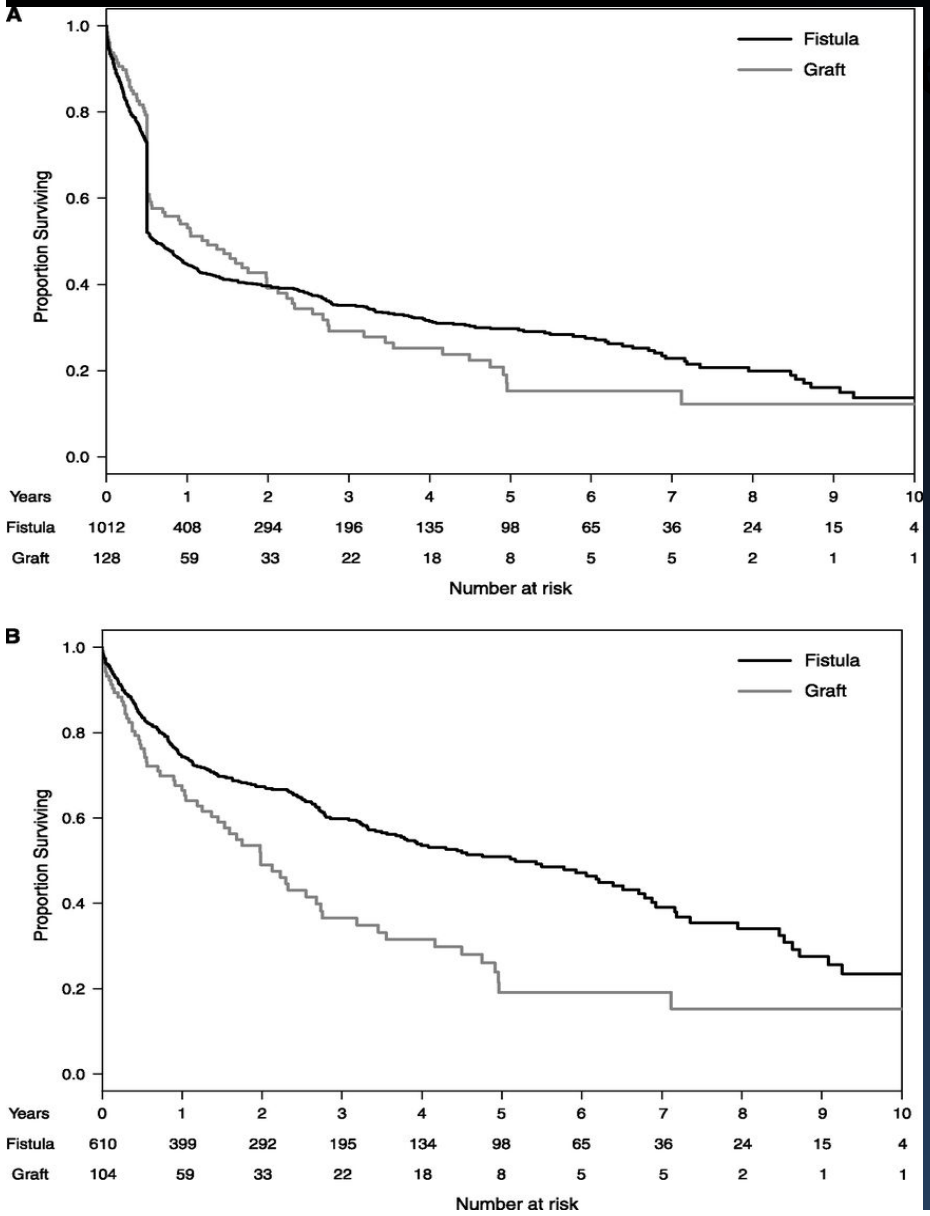
Author Year	Fistula	Estimate	LCL	UCL	Upper arm
Wolowczyk et al 2000	208	20%	15%	26%	0%
Allon et al 2001	84	46%	36%	57%	54%
Dixon et al (A) 2002	88	32%	23%	42%	0%
Dixon et al (B) 2002	117	28%	21%	37%	100%
Huber et al 2002	117	16%	10%	24%	74%
Malovrh 2002	116	20%	13%	28%	NR
Puskar et al 2002	463	14%	11%	17%	5%
Ravani et al 2002	197	12%	8%	18%	19%
Feldman et al 2003	347	45%	40%	50%	30%
Perera et al 2004	100	11%	6%	19%	32%
Lok et al (A) 2005	196	14%	10%	20%	53%
Lok et al (B) 2005	248	8%	6%	13%	43%
Manns et al 2005	157	33%	26%	41%	40%
Wells et al 2005	136	16%	11%	23%	33%
Elsharawy et al 2006	126	9%	5%	15%	69%
Korten et al 2006	148	11%	7%	17%	0%
Lok et al (A) 2006	163	11%	8%	16%	100%
Lok et al (B) 2006	259	16%	11%	22%	0%
Huijbregts et al 2007	491	33%	29%	37%	40%
Peterson et al 2007	205	40%	33%	47%	55%
Chan et al 2008	318	13%	10%	17%	NR
Dember et al (A) 2008	373	60%	54%	64%	45%
Dember et al (B) 2008	385	62%	57%	67%	47%
Pflederer et al (A) 2008	161	19%	14%	26%	97%
Pflederer et al (B) 2008	321	25%	20%	30%	37%
Maya et al (A) 2009	67	18%	10%	29%	100%
Maya et al (B) 2009	322	38%	33%	43%	100%
Weber et al 2009	125	28%	21%	37%	54%
Ferring et al (A) 2010	101	36%	27%	46%	37%
Ferring et al (B) 2010	107	25%	18%	34%	41%
Gonzalez et al (A) 2010	35	17%	7%	33%	100%
Gonzalez et al (B) 2010	75	39%	28%	50%	0%
Korkut & Kosem 2010	350	7%	5%	10%	100%
Schenk 2010	131	5%	3%	11%	83%
Lee et al 2011	221	22%	17%	28%	68%
Swindlehurst et al (A) 2011	89	30%	22%	41%	71%
Swindlehurst et al (B) 2011	246	29%	24%	35%	71%
Overall*	7393	23%	18%	28%	

MEDLINE between 2000 and 2012 using prospectively collected data on 100 or more AVFs.

Conclusion

In recent years, AVFs had a high rate of primary failure and low to moderate primary and secondary patency rates. Consideration of these outcomes is required when choosing a patient's preferred access type.

Cumulative Patency of Contemporary Fistulas versus Grafts (2000–2010)



Survival curves of cumulative patency in hemodialysis patients.

(A) 1140 patients: arteriovenous fistulas versus arteriovenous grafts (hazard ratio [HR], 0.99; 95% confidence interval [CI], 0.79–1.23).

(B) 714 patients after excluding 426 primary failures: arteriovenous fistulas versus arteriovenous grafts (HR, 0.56; 95% CI, 0.43–0.74).

Clin J Am Soc Nephrol 8: 810–818, May, 2013

Cumulative Patency of Contemporary Fistulas versus Grafts (2000–2010)

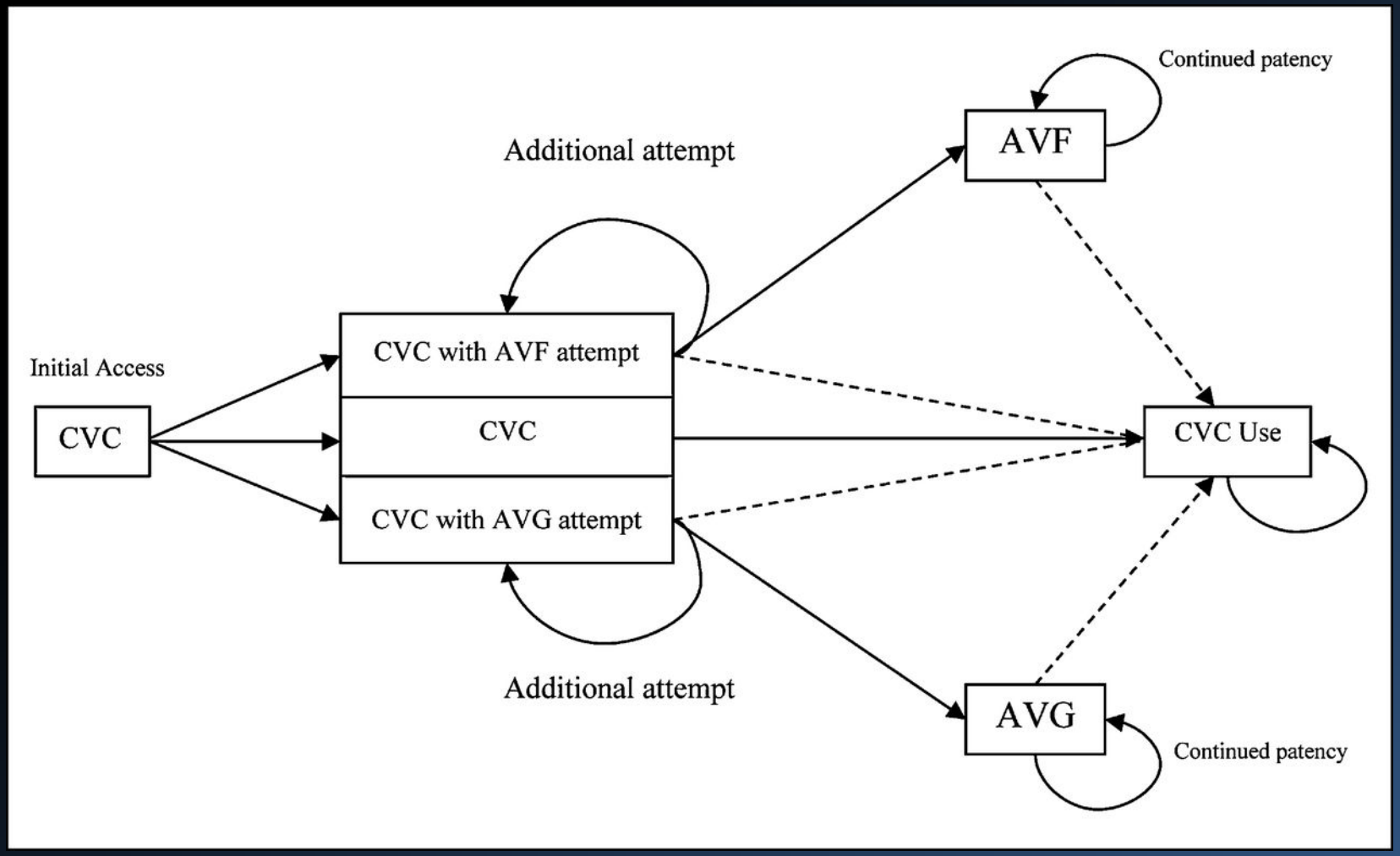
- The primary failure rate was two times greater for fistulas than for grafts: 40% versus 19% (P<0.001).

- For the patients' first access (median, 7.4 versus 15.0 months, respectively [HR, 0.99; 95%CI, 0.7921.23; P=0.85]) or for 600 with a subsequent access (7.0 versus 9.0 months [HR, 0.93; 95% CI, 0.7721.13; P=0.39]).

- Cumulative patency did not differ between fistulas and grafts, however grafts necessitated more interventions to maintain functional patency.

Clin J Am Soc Nephrol 8: 810–818, May, 2013

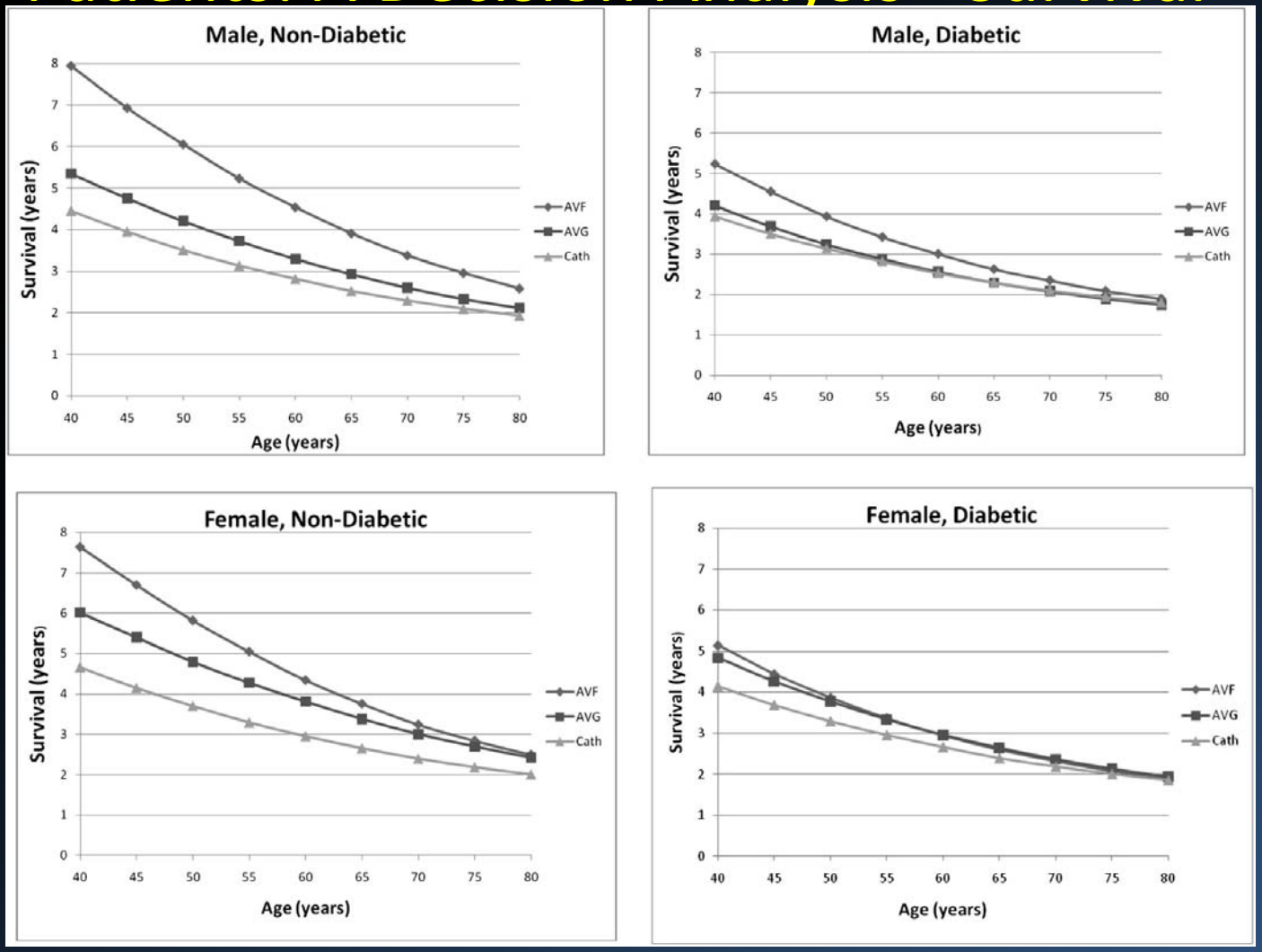
Vascular Access Choice in Incident Hemodialysis Patients: A Decision Analysis - Model



Concept model of simulated progression across vascular access options beginning at hemodialysis initiation. Death can be reached from all states; in all failure states, dialysis persists with a CVC. Dashed lines represent failure to achieve or loss of access patency. AVF, AV fistula; AVG, AV graft.

Drew et al. J Am Soc Nephrol 26: 183–191, 2015

Vascular Access Choice in Incident Hemodialysis Patients: A Decision Analysis - Survival



Patient survival by access attempt strategy. Plots are stratified by sex and diabetes status. The *x* axis represents the age in years of modeled patients. The *y* axis represents the survival in years for modeled patients. Patient survival in years by age stratified by sex and diabetes status. AVF, AV fistula; AVG, AV graft; cath, CVC.

Drew et al. J Am Soc Nephrol 26: 183–191, 2015

Vascular Access Choice in Incident Hemodialysis Patients: A Decision Analysis - Conclusion

Overall, the advantages of an AV fistula attempt strategy lessened considerably among older patients, particularly women with diabetes, reflecting the effect of lower AV fistula success rates and lower life expectancy. These results suggest that vascular access-related outcomes may be optimized by considering individual patient characteristics.

Drew et al. J Am Soc Nephrol 26: 183–191, 2015

Literature Review: The Elderly

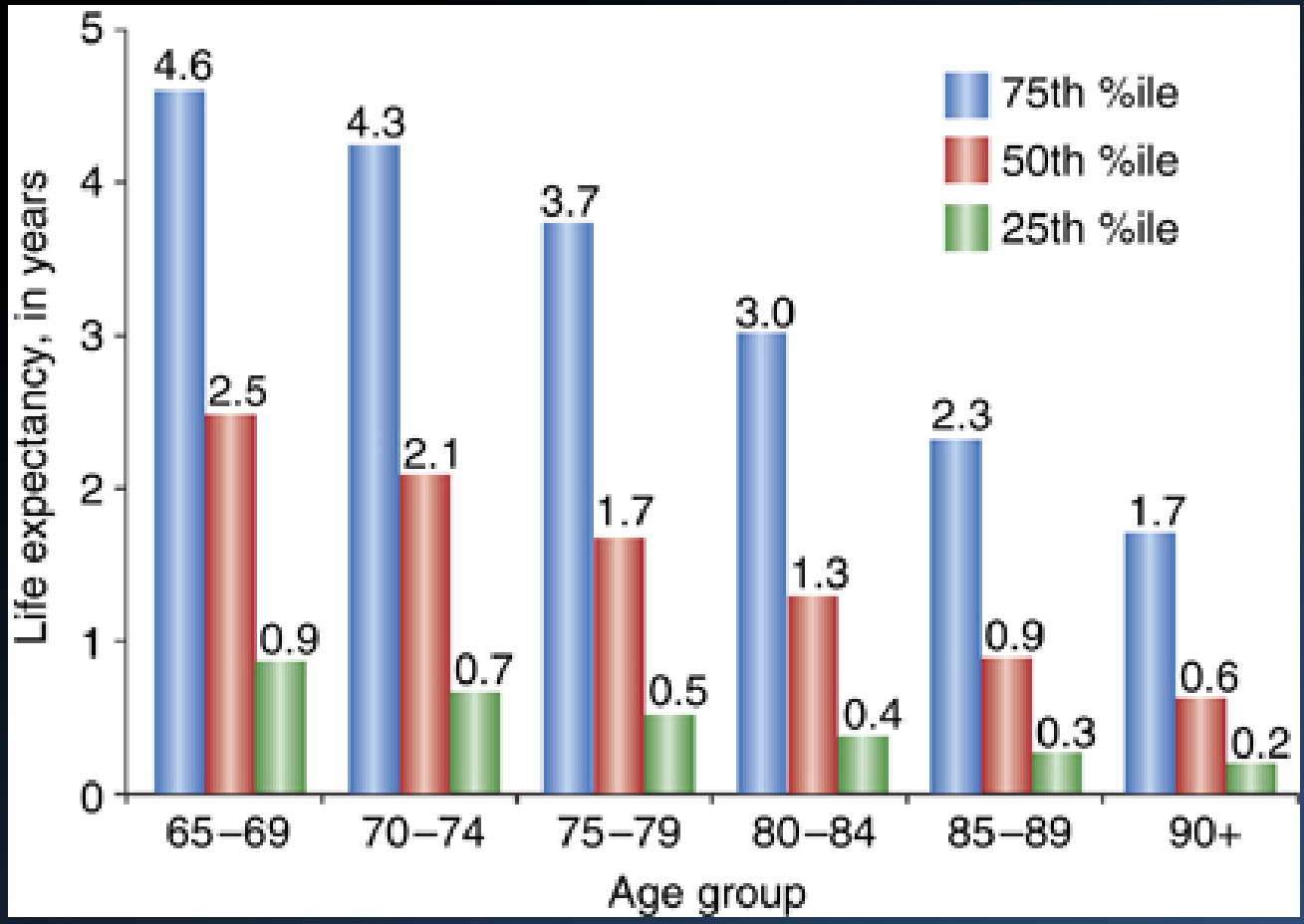
- 6 articles
- Heterogeneous definition of elderly
- Individualized approaches emphasized
  - Life Expectancy
  - Different Risks and Benefits
  - Distinction between pre-dialysis and established on dialysis
  - Personal Preferences

Optimizing Renal Replacement Therapy in Older Adults: A Framework for Individualized Decision Making

- Life Expectancy
- Risks and Benefits of Competing Strategies
- Patient Preferences

Kidney International (2012) 82, 261–269

Optimizing Renal Replacement Therapy in Older Adults: A Framework for Individualized Decision Making



Quartiles of life expectancy after dialysis initiation by age group.

Kidney International (2012) 82, 261–269

Optimizing Renal Replacement Therapy in Older Adults: A Framework for Individualized Decision Making

Vascular Access

- Number Needed to Treat to Prevent one Vascular Access BSI (Table 2 data not shown)
  - AVF vs. AVG - 2 models – modest reduction in BSI
  - AVG vs. Catheter – 2 models – order of magnitude reduction BSI
  - Both of the above differences attenuated with advancing age.

- By combining quantitative estimates of benefits and harms with qualitative assessments of patient preferences, clinicians may be better able to tailor treatment recommendations to individual older patients, thereby improving the overall quality of end-stage renal disease care.

Kidney International (2012) 82, 261–269

Optimizing Vascular Access in the Elderly Patient

Framework

- Likelihood of Disease Progression Before Death
- Life Expectancy
- Risks and Benefits of Vascular Access Type
- Patient Preferences

Semin Dial. 2012 ; 25(6): 640–648.

Optimizing Vascular Access in the Elderly Patient

Pragmatic Approach Considerations

- AVF
  - Minimal co-morbidities
  - Pre-dialysis
  - Life expectancy at least 2 years (implied)
- AVG
  - Moderate co-morbidities
  - Less than 1-2 years life expectancy
- Catheter
  - Severe Co-morbities
  - Minimal life expectancy

Semin Dial. 2012 ; 25(6): 640–648.

Optimizing Vascular Access in the Elderly Patient

…all of these decisions are dependent on the access to care, time to surgical creation, expertise of the surgeon and surgical outcomes, facility practice patterns, availability of procedures to assist with maturation, and the rates of complications including catheter related bacteremia.

Semin Dial. 2012 ; 25(6): 640–648.

Dialysis Patient in Combination With the Quality of Life

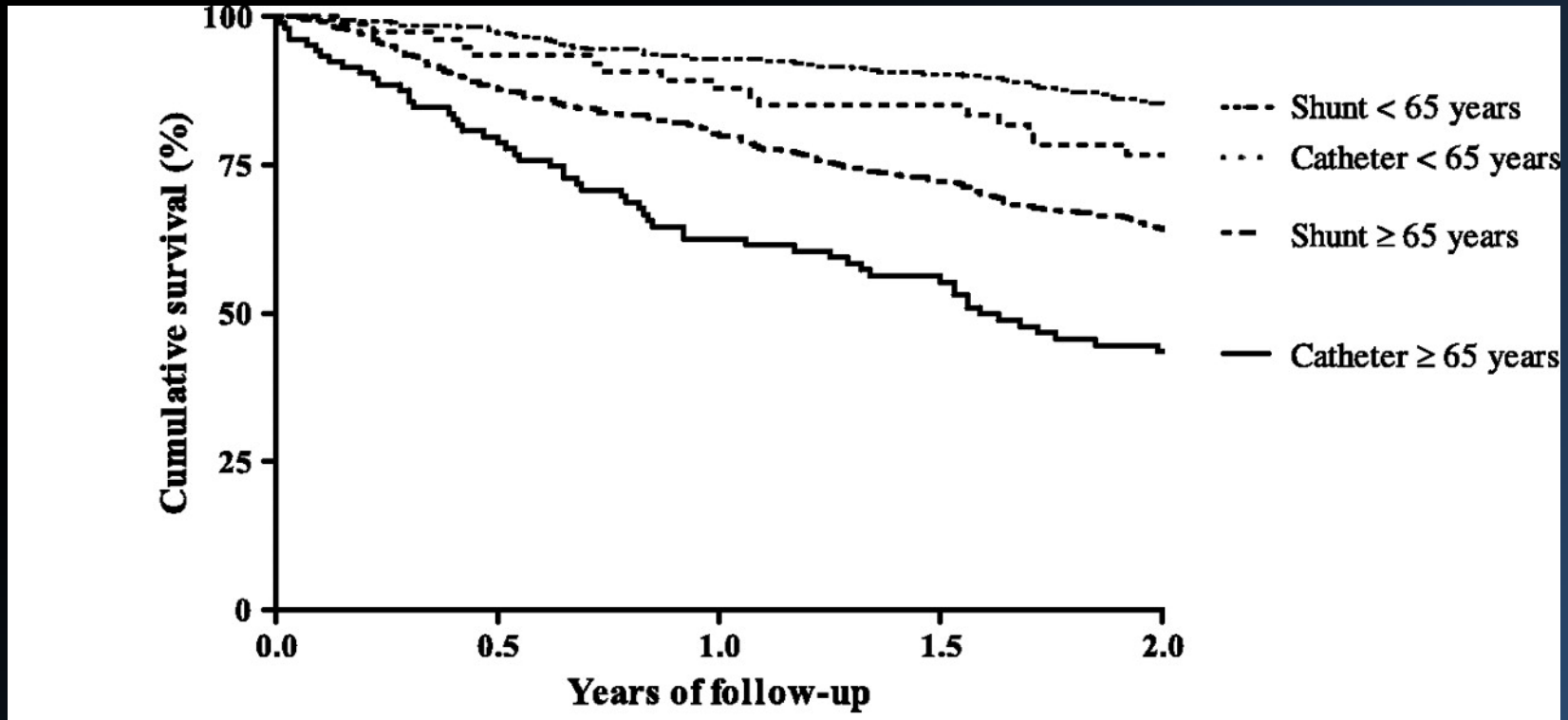
107 AVF in 90 patients aged 75 and older at 2 hospitals in the Netherlands.

Upper arm (Brachiocephalic) had higher primary patency at 1 & 2 years than Forearm (Radiocephalic) AVF. Secondary patency at 2 years was 57 and 50 %, respectively.

Relevant to surgical decision making since all patients had AVF.

Vascular and Endovascular Surgery 2013; 47(6) 444-448

Haemodialysis catheters increase mortality as compared to arteriovenous accesses especially in elderly patients



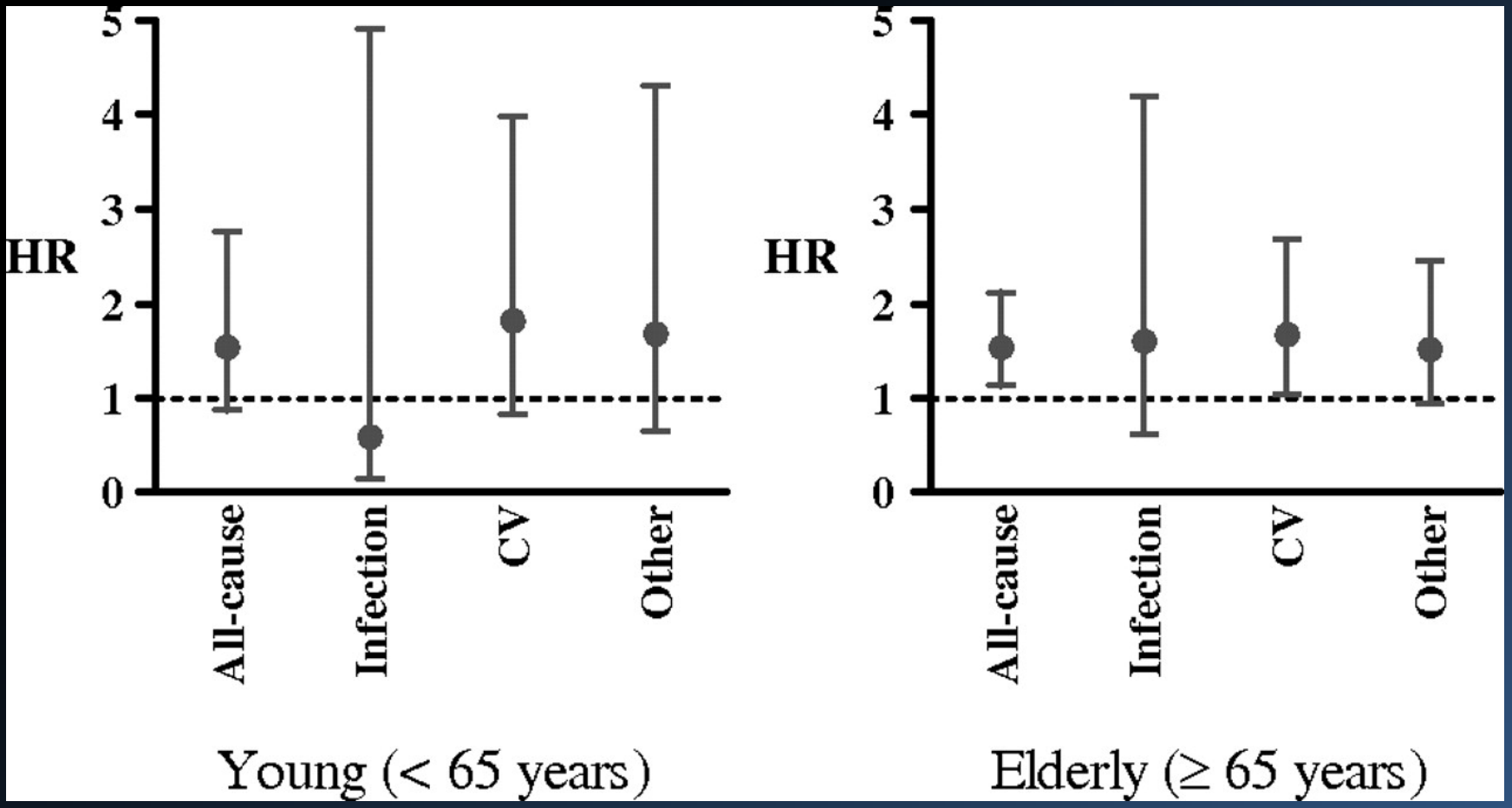
Number at risk:

Shunt < 65 years	412	371	320	273	235
Catheter < 65 years	84	70	62	54	42
Shunt ≥ 65 years	507	424	376	325	282
Catheter ≥ 65 years	106	80	61	53	41

Kaplan–Meier survival curve for arteriovenous access versus catheter in young and elderly haemodialysis patients.

Nephrol Dial Transplant (2011) 26: 2611–2617

Haemodialysis catheters increase mortality as compared to arteriovenous accesses especially in elderly patients



Kaplan–Meier survival curve for arteriovenous access versus catheter in young and elderly haemodialysis patients.

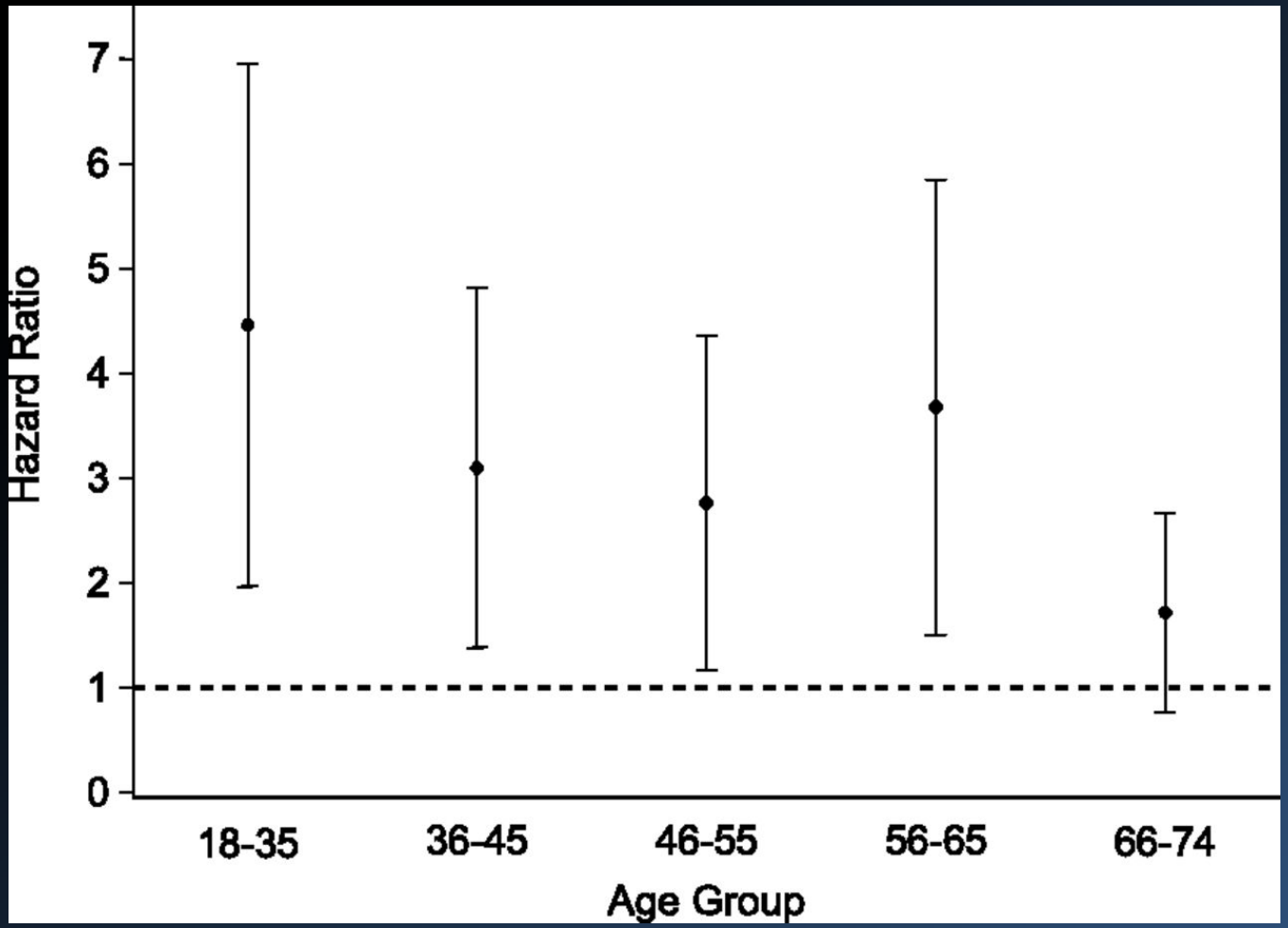
Nephrol Dial Transplant (2011) 26: 2611–2617

Risk of Catheter Related Bloodstream Infection in Elderly Patients on Hemodialysis

- 274 (age 18-74) and 90 (age 75 & older) prevalent hemodialysis catheter treated patients at a single center. Similar mean catheter days.
- BSI 1.97 in younger versus 0.55 in elderly per 1000 catheter days, $P<0.001$.
- Conclusion: Elderly patients using catheters are at lower BSI risk than younger counterparts.

Murea et al. Clin J Am Soc Nephrol 9: 764–770, 2014.

Risk of Catheter Related Bloodstream Infection in Elderly Patients on Hemodialysis



Hazard ratios for catheter-related bloodstream infections across the range of ages. Reference Age 75 and older. Single Center Study of 464 patients with dialysis catheters .

Murea et al. Clin J Am Soc Nephrol 9: 764–770, 2014.

Recalibrating Vascular Access for Elderly Patients

Editorial on Murea et al.

- BSI 0.55 in elderly reflects one event every 5.4 years.

Limitations

- Small single-center study & incident patients not included.

Conclusion

- Individualized approach to vascular access in the elderly. Catheters are appropriate for some patients.

Clin J Am Soc Nephrol 9: 645–647, 2014.

Literature Review Summary

- Confirmatory Studies – Vascular Access is Actionable
- Pros and Cons of Fistula First Initiatives and ESRD QIP Measures
- AVG and AVF Comparisons
  - Usable or Mature AVF is generally superior to AVG
  - AVF time to Maturation and high Primary Failure rate attenuate advantage
  - Overall AVG vs. AVF differences are less prominent than either vs. catheters
- Individualize Approach especially by age and co-morbidities – risk adjustment?
- Miscellaneous
- Future Directions
  - Hemodialysis Fistula Maturation (HFM) Study Observational Study
  - Randomized Trials AVG versus AVF - proposed to guide decision making

Vascular Access Measures
Preliminary Analyses

SCHOOL OF PUBLIC HEALTH
KECC
UNIVERSITY OF MICHIGAN

Goals

- Explore the impact of demographic and comorbidity adjustment on vascular access creation
- Evaluate surgical access success rates when including both AV Fistula and AV graft as a desired outcome

Scenario

- Incident hemodialysis patients who start treatment with a tunneled catheter
- At the end of one year, what type of vascular access is in use?

Process Flow

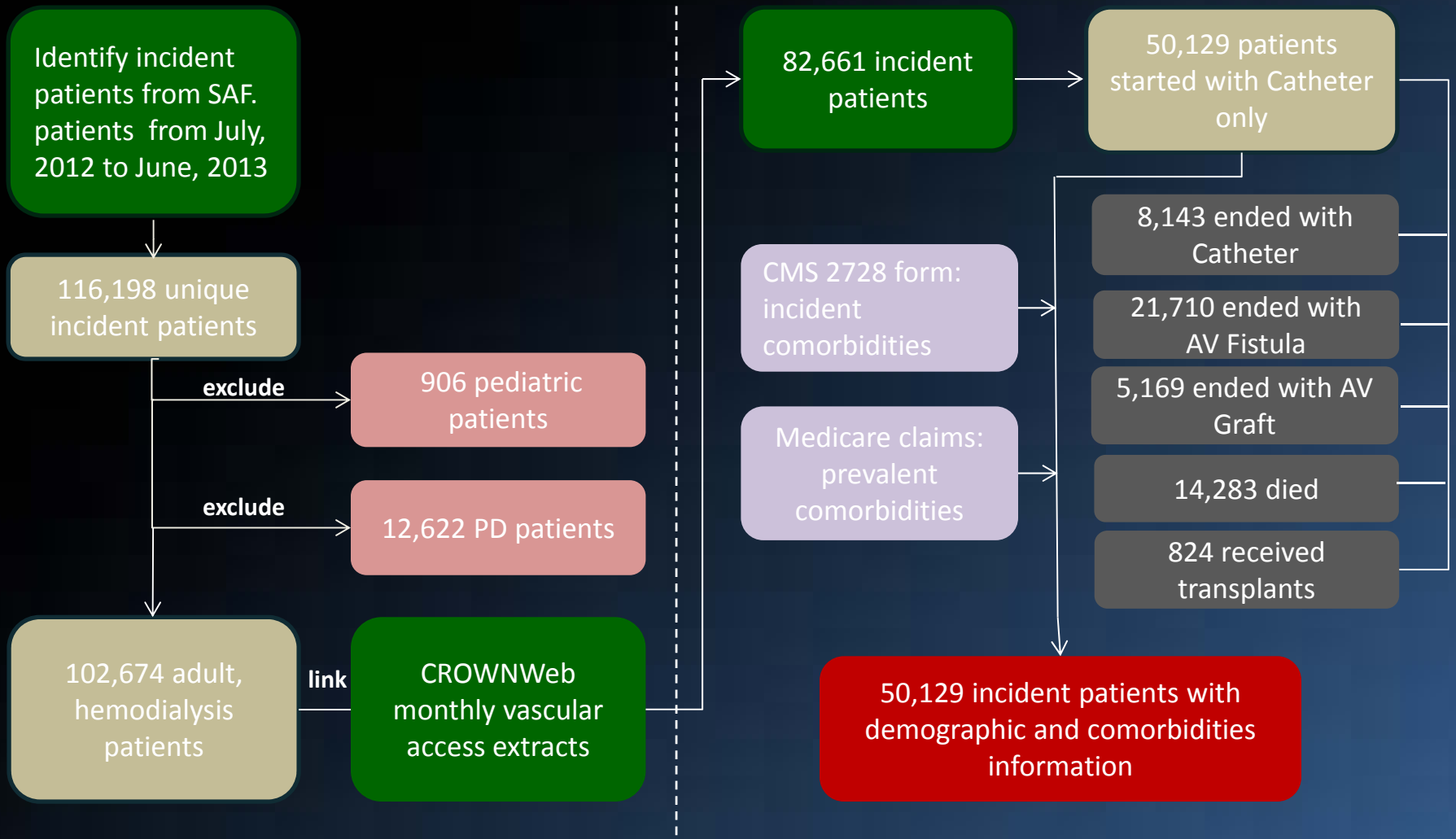


Table 1: Baseline characteristics of study population at ESRD onset and analysis results for **AVF**, compared to Catheter access (N=29,853)

Predictor	Total N (%)	Success in AVF N=21,710 N (%)	Multivariate Analysis Model 1 (Unadjusted by Comorbidities)	
			OR	P
Age				
18-<25	349(1.17)	243(69.63)	0.95(0.75, 1.2)	0.647
25-<45	3546(11.88)	2650(74.73)	1.12(1.03, 1.23)	0.010
45-<60	8640(28.94)	6474(74.93)	1.09(1.03, 1.17)	0.007
60-<75	11109(37.21)	8105(72.96)	Ref	
75+	6209(20.8)	4238(68.26)	0.82(0.77, 0.88)	<.001
Sex				
Female	12518(41.93)	8349(66.70)	0.60(0.57, 0.63)	<.001
Male	17335(58.07)	13361(77.08)	Ref	
Race				
White	19188(64.27)	14037(73.16)	Ref	
Black	8643(28.95)	6053(70.03)	0.87(0.82, 0.92)	<.001
Other	2022(6.77)	1620(80.12)	1.52(1.36, 1.71)	<.001
BMI				
underweight(< 18.5)	841(2.82)	546(64.92)	0.83(0.72, 0.97)	0.019
normal(18.5 - 24.9)	8024(26.88)	5676(70.74)	Ref	
overweight(24.9 – 29.9)	8351(27.97)	6162(73.79)	1.14(1.06, 1.22)	<.001
obesity(> 29.9)	12637(42.33)	9326(73.80)	1.18(1.10, 1.26)	<.001
Nursing home status				
Yes	462(1.55)	254(54.98)	0.52(0.43, 0.63)	<.001
No	29391(98.45)	21456(73.00)	Ref	
Primary Cause of ESRD				
Diabetes	15112(50.62)	11181(73.99)	1.06(1.00, 1.12)	0.041
Other	14741(49.38)	10529(71.43)	Ref	
Nephrologist's Care prior to ESRD				
Yes	16237(54.39)	12231(75.33)	1.35(1.28, 1.43)	<.001
No/Unknown	13616(45.61)	9479(69.62)	Ref	

Table 1: Baseline characteristics of study population at ESRD onset and analysis results for **AVF**, compared to Catheter access (N=29,853)

Predictor	Total N (%)	Success in AVF N=21,710 N (%)	Multivariate Analysis Model 1 (Unadjusted by Comorbidities)		Multivariate Analysis Model 2 (Adjusted by Comorbidities)	
			OR	P	OR	P
Age						
18-<25	349(1.17)	243(69.63)	0.95(0.75, 1.2)	0.647	0.78(0.61, 0.99)	0.045
25-<45	3546(11.88)	2650(74.73)	1.12(1.03, 1.23)	0.010	0.94(0.85, 1.04)	0.212
45-<60	8640(28.94)	6474(74.93)	1.09(1.03, 1.17)	0.007	1.00(0.93, 1.07)	0.920
60-<75	11109(37.21)	8105(72.96)	Ref		Ref	
75+	6209(20.8)	4238(68.26)	0.82(0.77, 0.88)	<.001	0.90(0.84, 0.97)	0.005
Sex						
Female	12518(41.93)	8349(66.70)	0.60(0.57, 0.63)	<.001	0.60(0.57, 0.64)	<.001
Male	17335(58.07)	13361(77.08)	Ref		Ref	
Race						
White	19188(64.27)	14037(73.16)	Ref		Ref	
Black	8643(28.95)	6053(70.03)	0.87(0.82, 0.92)	<.001	0.84(0.80, 0.90)	<.001
Other	2022(6.77)	1620(80.12)	1.52(1.36, 1.71)	<.001	1.43(1.28, 1.61)	<.001
BMI						
underweight(< 18.5)	841(2.82)	546(64.92)	0.83(0.72, 0.97)	0.019	0.85(0.73, 0.99)	0.034
normal(18.5 - 24.9)	8024(26.88)	5676(70.74)	Ref		Ref	
overweight(24.9 – 29.9)	8351(27.97)	6162(73.79)	1.14(1.06, 1.22)	<.001	1.13(1.06, 1.22)	<.001
obesity(> 29.9)	12637(42.33)	9326(73.80)	1.18(1.10, 1.26)	<.001	1.22(1.14, 1.30)	<.001
Nursing home status						
Yes	462(1.55)	254(54.98)	0.52(0.43, 0.63)	<.001	0.70(0.57, 0.85)	<.001
No	29391(98.45)	21456(73.00)	Ref		Ref	
Primary Cause of ESRD						
Diabetes	15112(50.62)	11181(73.99)	1.06(1.00, 1.12)	0.041	1.11(1.04, 1.19)	0.003
Other	14741(49.38)	10529(71.43)	Ref		Ref	
Nephrologist's Care prior to ESRD						
Yes	16237(54.39)	12231(75.33)	1.35(1.28, 1.43)	<.001	1.34(1.27, 1.41)	<.001
No/Unknown	13616(45.61)	9479(69.62)	Ref		Ref	

Table 2: Multivariate analysis establishing 1) AVF and 2) AVF/AVG after 1 year (compared to Catheter)

Predictor	Multivariate Analysis 1) AVF vs Catheter (Adjusted by Comorbidities)		Multivariate Analysis 2) AVF/AVG vs Catheter (Adjusted by Comorbidities)	
	OR	P	OR	P
Age				
18-<25	0.78(0.61, 0.99)	0.045	0.70(0.55, 0.89)	0.003
25-<45	0.94(0.85, 1.04)	0.212	0.88(0.81, 0.97)	0.010
45-<60	1.00(0.93, 1.07)	0.920	0.96(0.90, 1.03)	0.238
60-<75	Ref		Ref	
75+	0.90(0.84, 0.97)	0.005	0.95(0.88, 1.01)	0.116
Sex				
Female	0.60(0.57, 0.64)	<.001	0.70(0.66, 0.73)	<.001
Male	Ref		Ref	
Race				
White	Ref		Ref	
Black	0.84(0.80, 0.90)	<.001	0.98(0.93, 1.04)	0.485
Other	1.43(1.28, 1.61)	<.001	1.41(1.25, 1.58)	<.001
BMI				
underweight(< 18.5)	0.85(0.73, 0.99)	0.034	0.89(0.77, 1.03)	0.124
normal(18.5 - 24.9)	Ref		Ref	
overweight(24.9 – 29.9)	1.13(1.06, 1.22)	<.001	1.12(1.04, 1.20)	0.002
obesity(> 29.9)	1.22(1.14, 1.30)	<.001	1.17(1.10, 1.25)	<.001
Nursing home status				
Yes	0.70(0.57, 0.85)	<.001	0.75(0.63, 0.90)	0.002
No	Ref		Ref	
Primary Cause of ESRD				
Diabetes	1.11(1.04, 1.19)	0.003	1.11(1.04, 1.19)	0.001
Other	Ref		Ref	
Nephrologist's Care prior to ESRD				
Yes	1.34(1.27, 1.41)	<.001	1.32(1.25, 1.39)	<.001
No/Unknown	Ref		Ref	

Review existing Vascular Access measures

NQF #0256

Measure Title	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
Measure Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.
Numerator	Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.
Denominator	Patients on maintenance hemodialysis during the last HD treatment of study period.
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.

NQF #0257

Measure Title	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
Measure Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles
Numerator	Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month
Denominator	Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, AVF and AVG reported, or patients <18 years of age

NQF #0251

Measure Title	Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
Measure Description	Percentage of ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who: (1) have a functional autogenous AVF; (2) have a functional AV graft; or (3) have a catheter but have been seen/evaluated by a surgeon for a functional AVF or AV graft at least once during the 12-month reporting period
Numerator	As listed above
Denominator	All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.
Exclusions	None

NQF #2594

Measure Title	Optimal End Stage Renal Disease (ESRD) Starts
Measure Description	Percentage of new ESRD patients who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis, or by initiating outpatient in-center hemodialysis via AVF or AVG.
Numerator	The number of new ESRD patients who initiate renal replacement therapy in the twelve month measurement period with an optimal ESRD therapy (specific optimal ESRD therapies are defined in section S.6).
Denominator	The number of patients who receive a preemptive kidney transplant or initiate long-term dialysis therapy (do not recover kidney function by 90 days) for the first time in the twelve month measurement period
Exclusions	None

Evaluation of current Vascular Access measures

Draft measure specifications

Measure Evaluation Criteria

- Evidence, Performance Gap, and Priority (Impact)- Importance to Measure and Report
- Reliability and Validity- Scientific Acceptability
- Feasibility
- Usability
- Comparison to Related or Competing Measures (Harmonization)

Measure Specification

- Numerator
- Denominator
- Exclusions
- Risk Adjustments

Data Sources

- CrownWeb
- Claims
- Medical Evidence Form (CMS 2728)

Recommendations from TEP for future direction

Wrap Up

Public Comment

Agenda: April 23, 2015

9:00 – 10:45	Draft measure specifications
10:45 – 11:00	*BREAK*
11:00 – 12:00	Draft measure specifications (continued)
12:00 – 1:00	*LUNCH*
1:00 – 2:20	Recommendations from TEP for future direction
2:20 – 2:30	Wrap-up
2:30 – 3:00	Public Comment Period

Tasks

- Both Measures
  - Determine how to categorize patients with more than one access
  - Recommendation Data Source: CROWNWeb vs. Claims
  - Numerator / Denominator Statements
- Catheter Measure
  - Review exclusion criteria
  - Decide if there is rationale for changing the time frame (e.g. >90 days)
- AVF Measure
  - Review Risk adjustment

Access Type

Category	Access in Use
Cath	Catheter Only
Cath	Catheter with maturing AV Fistula or AV Graft
Cath	AV Fistula with Catheter (using both or AVF only, but catheter still present)
Cath	AV Graft with Catheter (using both or AVG only, but catheter still present)
AVF	AVF (no catheter present)
AVG	AVG (no catheter present)
AVG	AVF + AVG: two separate accesses with one needle in each; if two needles in one access it should be considered as above
	Other

Data Sources

- Medicare Claims:
  - Pro: clear definition of when a catheter is present
  - Con: only Medicare beneficiaries
- CROWNWeb:
  - Pro: All dialysis patients
  - Con: Unable to detect when a catheter is present but not being used

Medicare Claims

- Modifier V5 - Any Vascular Catheter (alone or with any other vascular access),
- Modifier V6 - Arteriovenous Graft Only (2 needles)
- Modifier V7 - Arteriovenous Fistula Only (2 needles)

Instructions: Modifier V5 must be entered if a vascular catheter is present even if it is not being used for the delivery of the hemodialysis. In this instance 2 modifiers should be entered, V5 for the vascular catheter and either V6 or V7 for the access that is being used for the delivery of hemodialysis.

Medicare Claims Reporting

- V5: Catheter (alone or with other vascular access)
- V6: AVG only with 2 needles
- V7: AVF only with 2 needles
- V5 + V6: AVG with catheter
- V5 + V7: AVF with catheter

CROWNWeb

- AVF only (2 needles; no catheter in place)
- AVF with Catheter (1 needle and 1 lumen, *or two needles with catheter still present*)
- AVG only (2 needles)
- AVG with Catheter (1 needle and 1 lumen)
- Catheter only (option to indicate if maturing AVF/AVG is present)

- Note: If catheter is present, but not being used, it is considered AVF or AVG

Data Source Recommendation

- Current: Measure is designed for CROWNWeb, but can be calculated with Claims. Claims data are used to calculate measures for public reporting: (e.g. QIP)
- Recommendation: CROWNWeb.
  - Change instructions

Catheter Denominator

- All patients at least 18 years old who are determined to be maintenance hemodialysis patients (in-center and home HD)
- Exclusions:
  - [Pediatric patients (<18 years old)]
  - ~~Acute hemodialysis (<91 days)~~
  - As previously defined (limited life expectancy etc)

Catheter Exclusion Criteria (appropriate for catheter)

- limited life expectancy (e.g. < 6 months)
  - Hospice care
  - Metastatic Cancer
  - End stage liver
    - Non-transplant candidates
  - End stage heart disease (advanced cardiomyopathy)
  - Other: tbd
- Exhausted anatomic options
  - Attestation: validation issues
  - External documentation? Documentation by IDT and one other qualified professional (surgeon / interventional
- ~~Scheduled Kidney transplant?~~
- ~~Transient modality from PD complications~~
- transient modality < 90 from PD
- ~~Delayed transplant graft function~~

Options

1. Evaluation by qualified external professional (vascular access surgeon/interventional radiologist/neph)

   With documentation

   With reporting option

   Are you in favor of removing anatomic exclusion:

   YES / NO

2. Remove from exclusion

   With consensus statement from group

Re-Vote

- Should “exhausted anatomic options with documentation” be included as an exclusion criteria for catheter measure?
  - **Include**: includes this category as an exclusion criteria for the catheter measure
  - **Don’t Include**: this category will **not** be considered as an exclusion criteria

Catheter Numerator

- Patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.
  - From date of first dialysis for all patients
  - With one or more dialysis catheters for > 90 days without the use of AVF or AVG in the interim

Catheter: Other recommendations

- Date access type for dialysis changed: include explicit instructions not to change date when tunneled catheter exchanged for infection/malfunction?]
- Change instructions to CROWNWeb: AVF only means 2 needles and no catheter; use AVF and catheter category for either one needle and one lumen or AVF with 2 needles but catheter is still present.

AVF Access

- Risk Adjustment for conditions when AVG acceptable:
  - Life expectancy short (age)
  - AVF success rate low
    - Age
    - DM
    - Vascular disease: peripheral, cerebral vascular, cardiovascular
    - BMI low/high
  - Sex/Race: disparity vs. biologic

AVF Numerator

- The numerator will be determined by counting the patient months in the denominator who were on maintenance hemodialysis using an AV fistula with two needles and without dialysis catheter as the means of access at the last treatment of the month.

AVF Denominator

- All patients at least 18 years old who are determined to be maintenance hemodialysis patients (in-center and home HD)
- Exclusions:
  - [Pediatric patients (<18 years old)]
  - ~~Acute hemodialysis (<91 days)~~

Recommendations from TEP for future direction

Wrap Up

Public Comment