Management of Failing Renal Allograft

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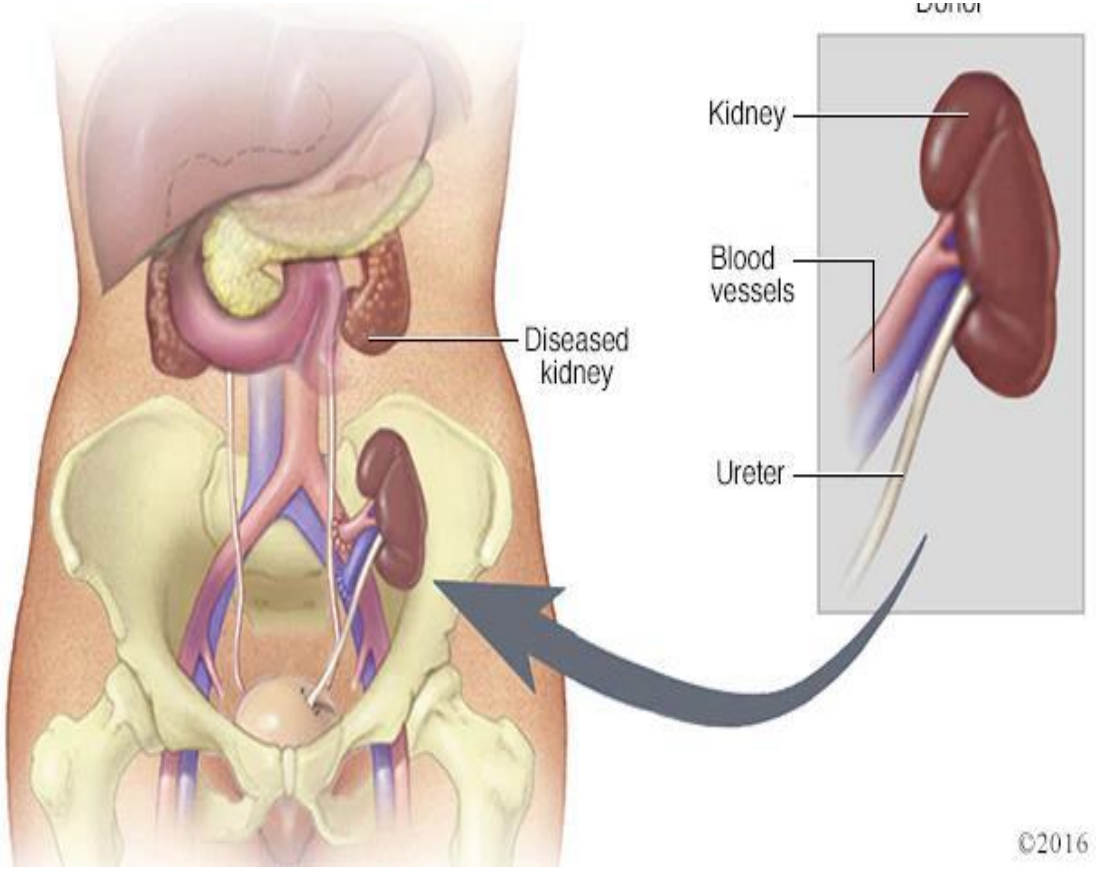
Vice President of the Arab society of nephrology and renal transplantation

Agenda

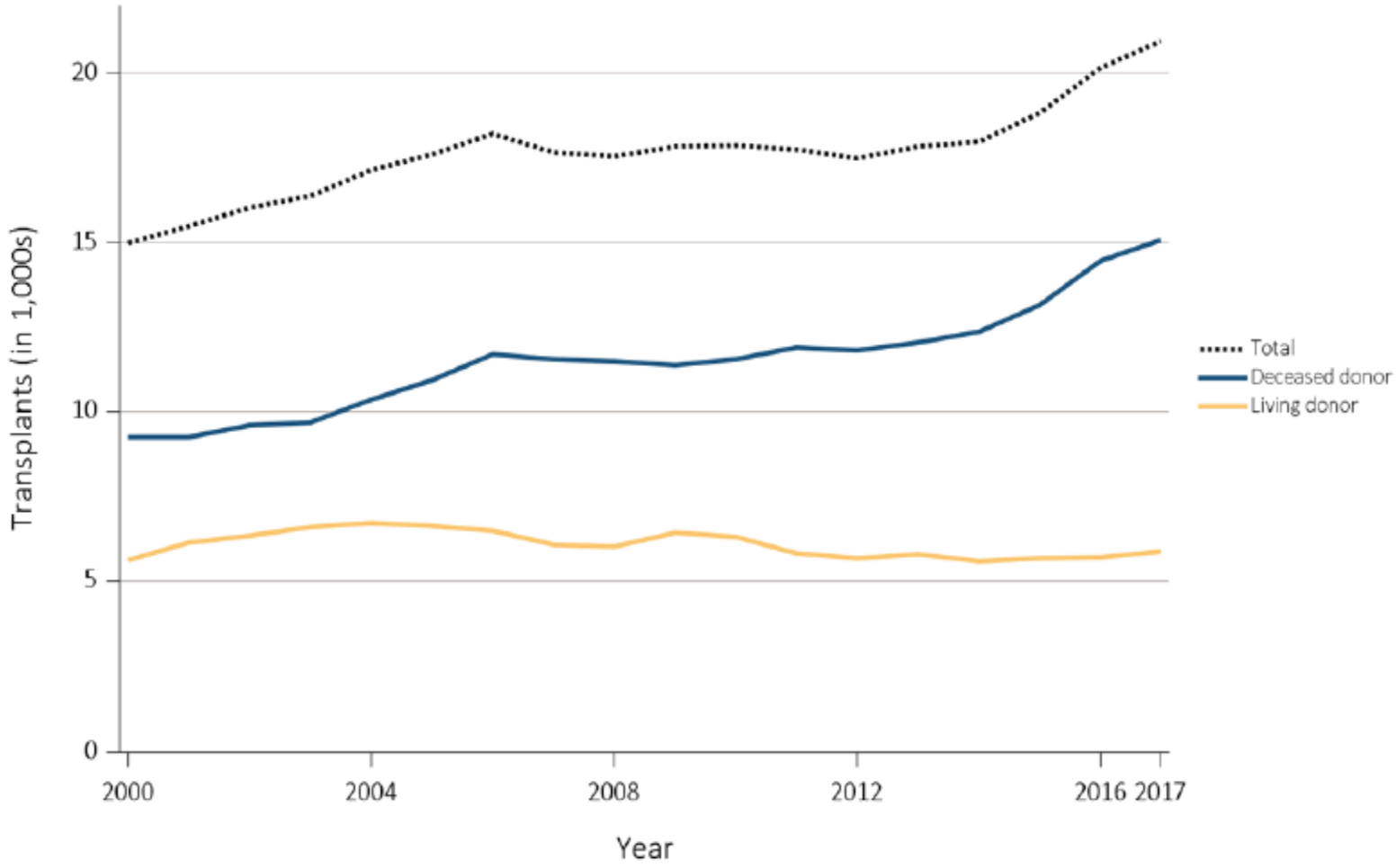
- **Introduction**
- **Mortality in patient with failed renal allograft returning to dialysis**
- **Dialysis after graft loss (DAGL)**
  - Time of initiation
  - Modality (PD vs. HD)
- **Management of immunosuppression**
- **Transplant Nephrectomy**
  - Outcome (sensitization / re-transplantation)
  - Surgical vs. Embolization

Introduction

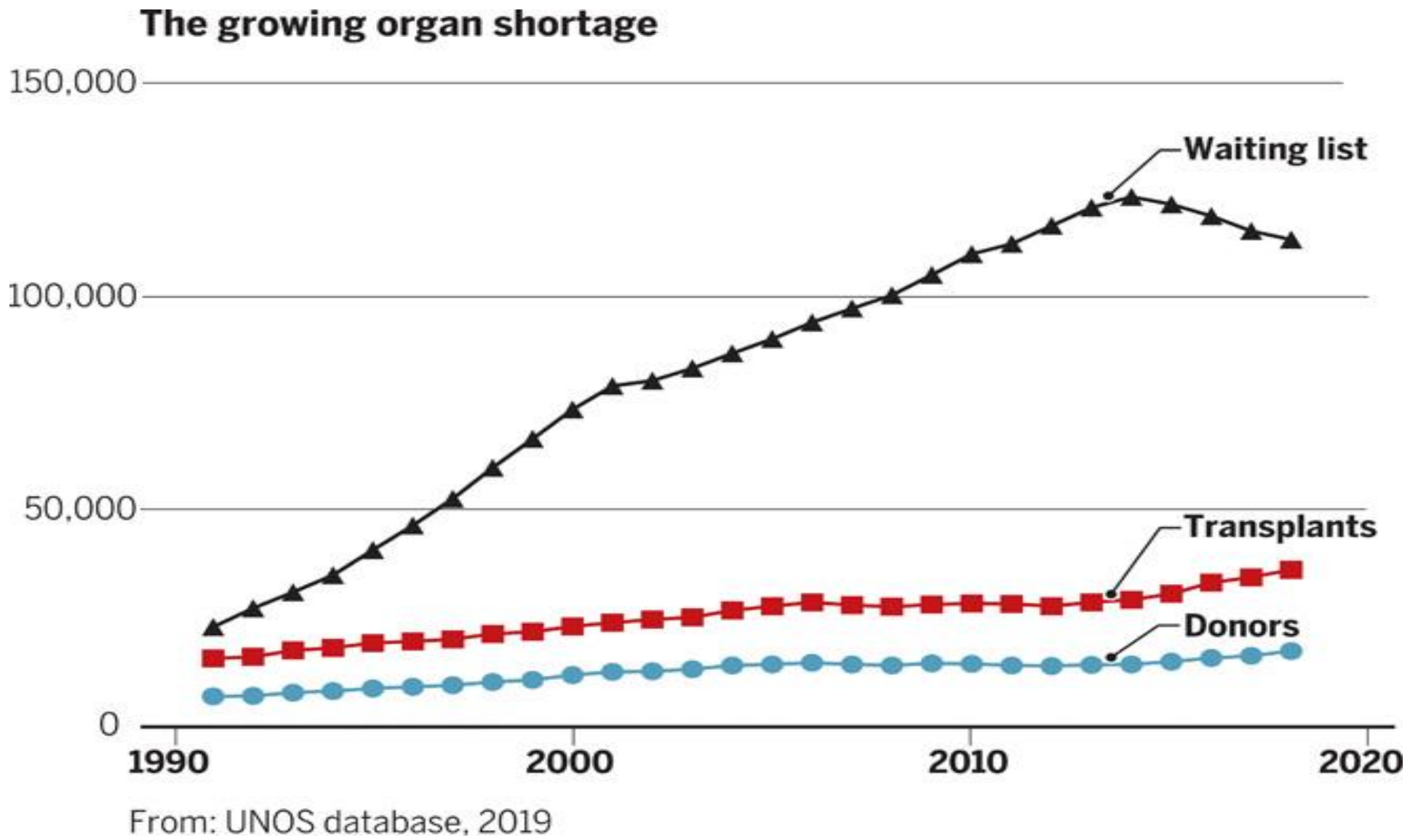


- The number of ESKD undergoing renal transplant both cadaveric and living donor continues to rise.

Number of kidney transplants 1999-2017 in USA



2019 Annual Data Report


The growing organ shortage
150,000
100,000
50,000
0
1990
2000
2010
2020
Waiting list
Transplants
Donors
From: UNOS database, 2019

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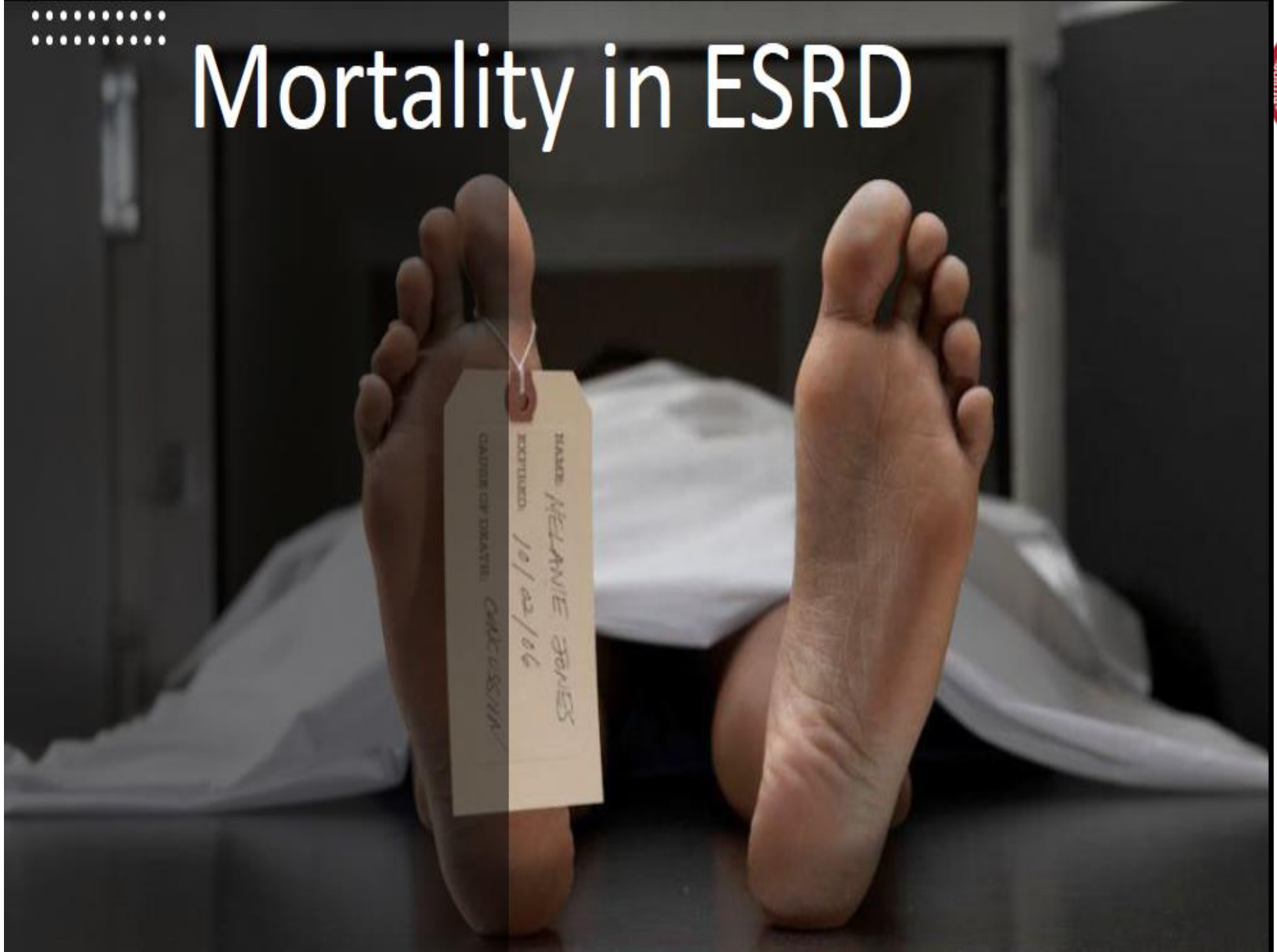
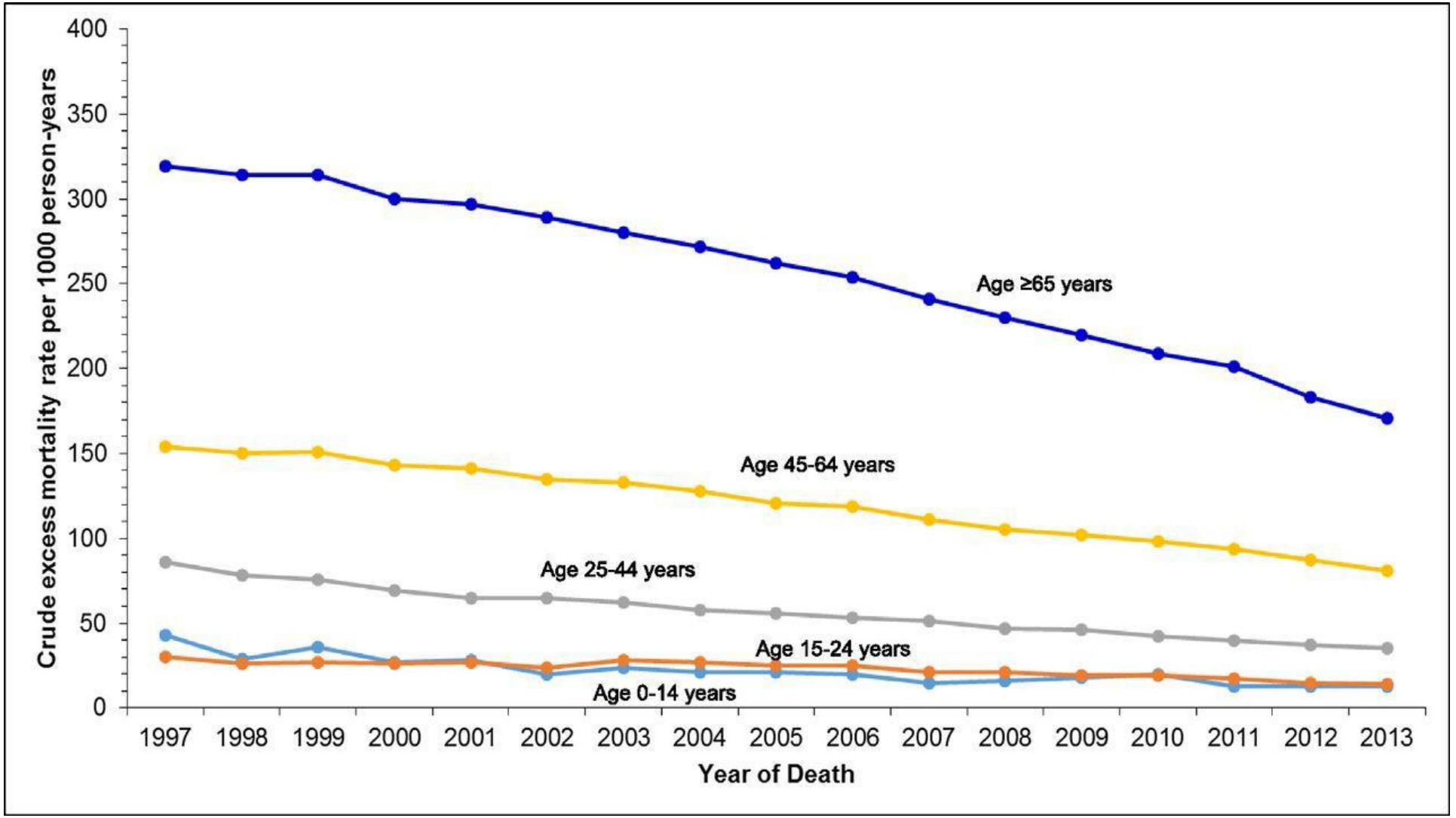
Mortality in ESRD



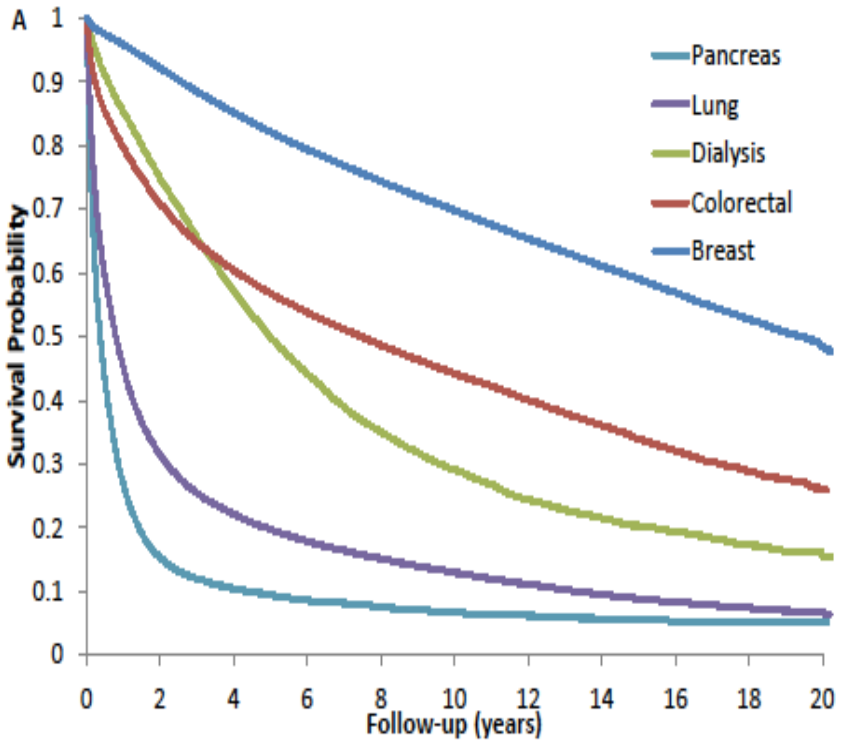
Crude excess mortality rates decreased over calendar time, for all ages, in people with ESRD



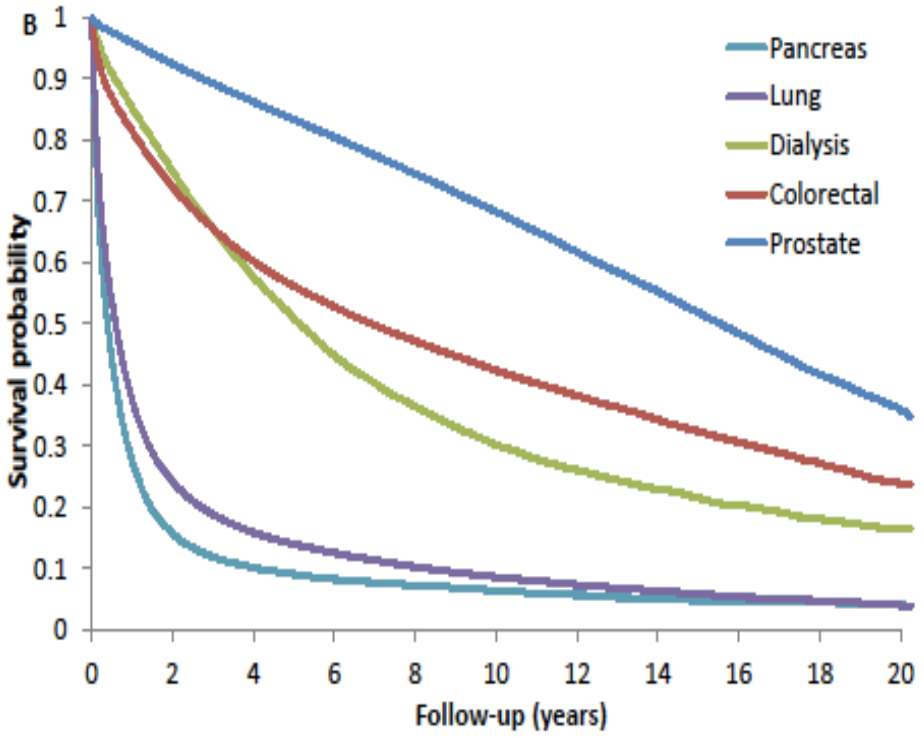
Bethany J. Foster et al. CJASN 2018;13:91-99.

Mortality in Incident Maintenance Dialysis Patients Versus Incident Solid Organ Cancer Patients

Females



Males



Naylor KL et al . Am J Kidney Dis. 2019 Jun;73(6):765-776

Risk of Death Among Renal Transplant Recipients

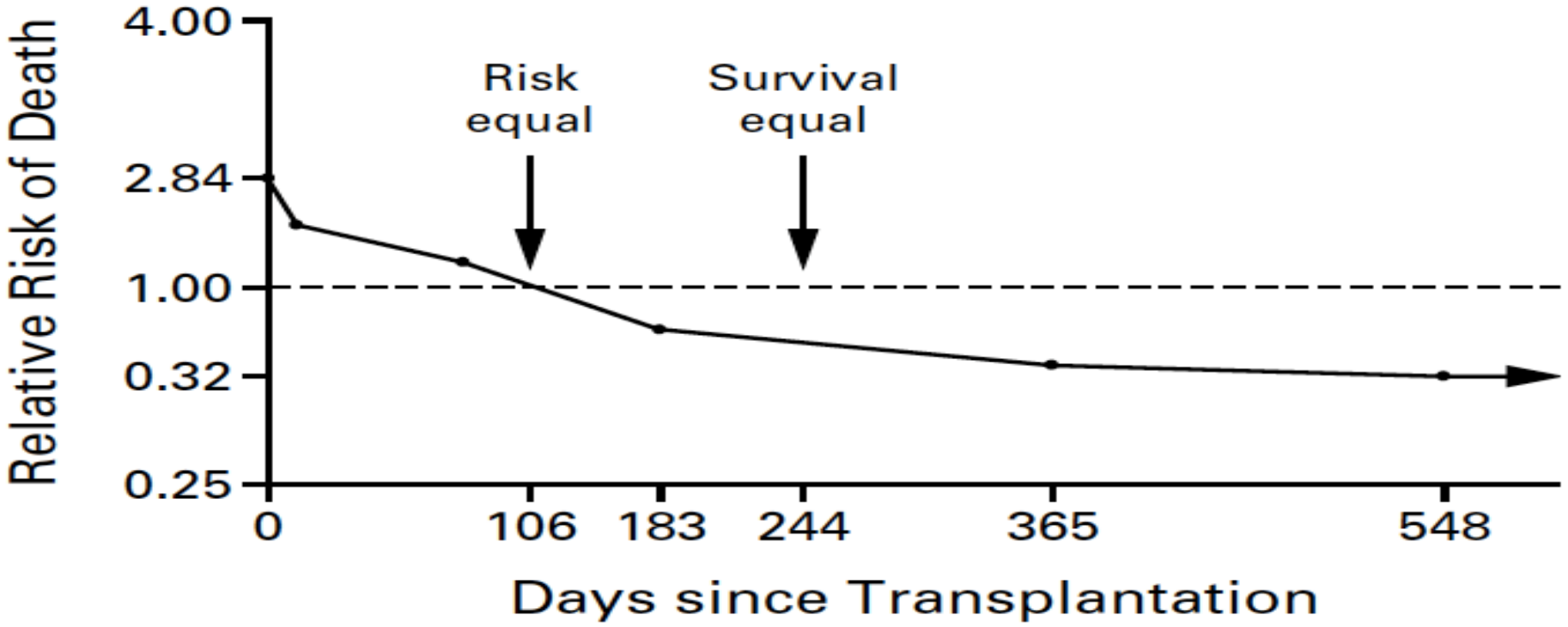


Figure 2. Adjusted Relative Risk of Death among 23,275 Recipients of a First Cadaveric Transplant.

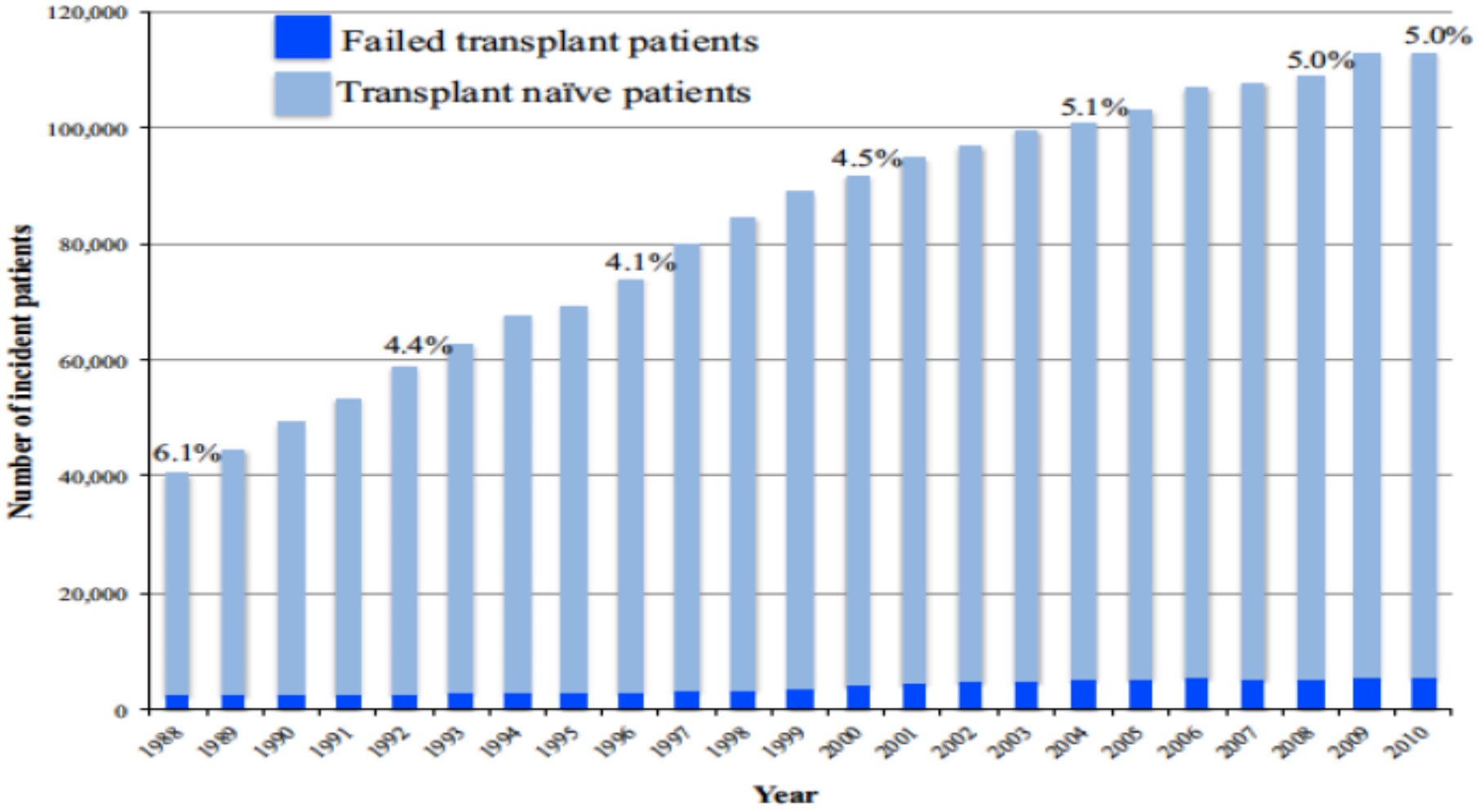
Wolfe RA et al. N EnglJ Med. 1999 Dec 2;341(23):1725-30

Dialysis After Graft Loss (DAGL)

In the same time ,over the past decade, patients returning to dialysis after a failed transplant comprised of 5–10% of the annual number of dialysis initiations in the United States

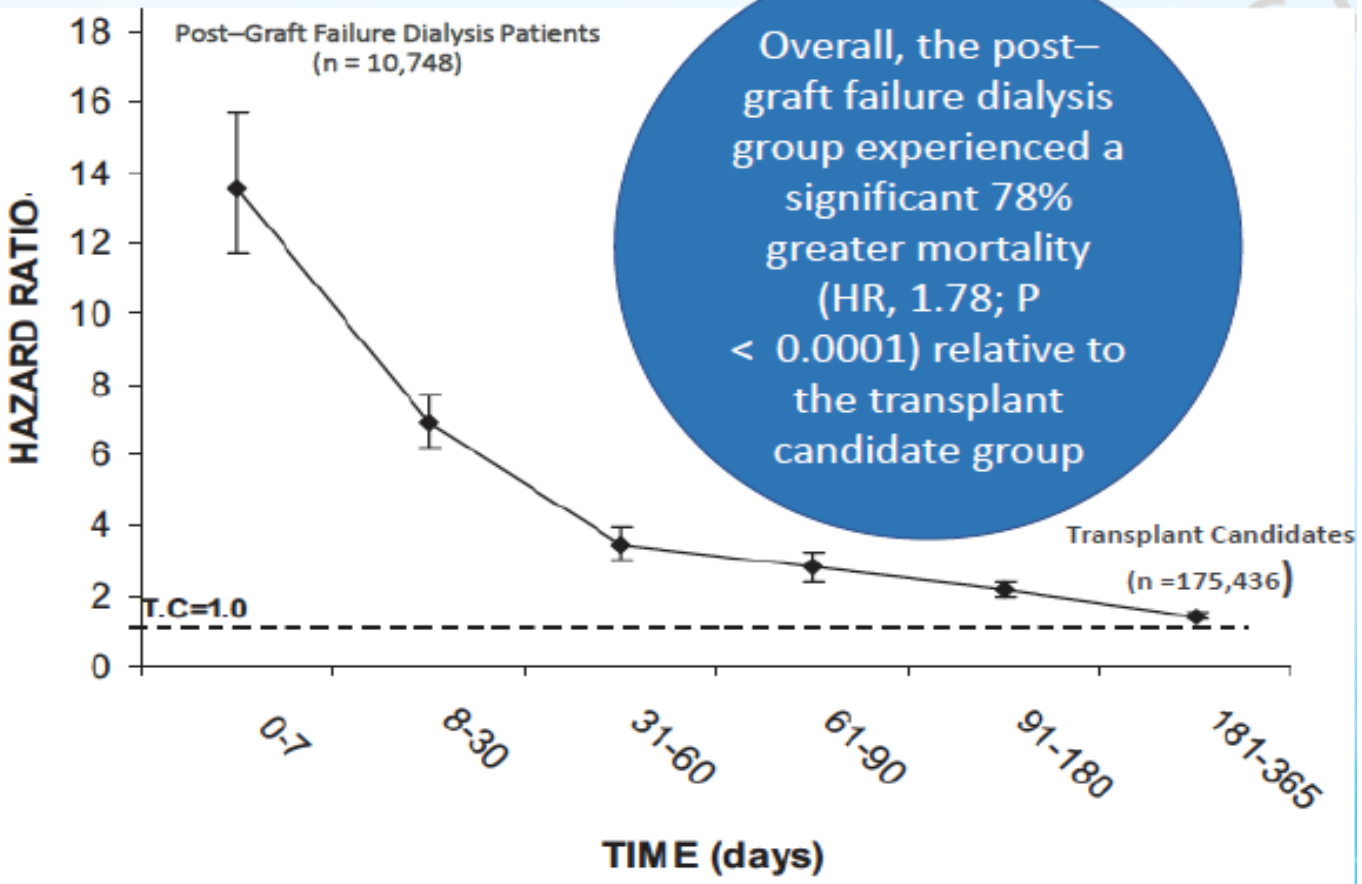
The re-transplant candidates account for only 5.0–13% of the annual deceased donor wait-list additions .

Dialysis After Graft Loss (DAGL)



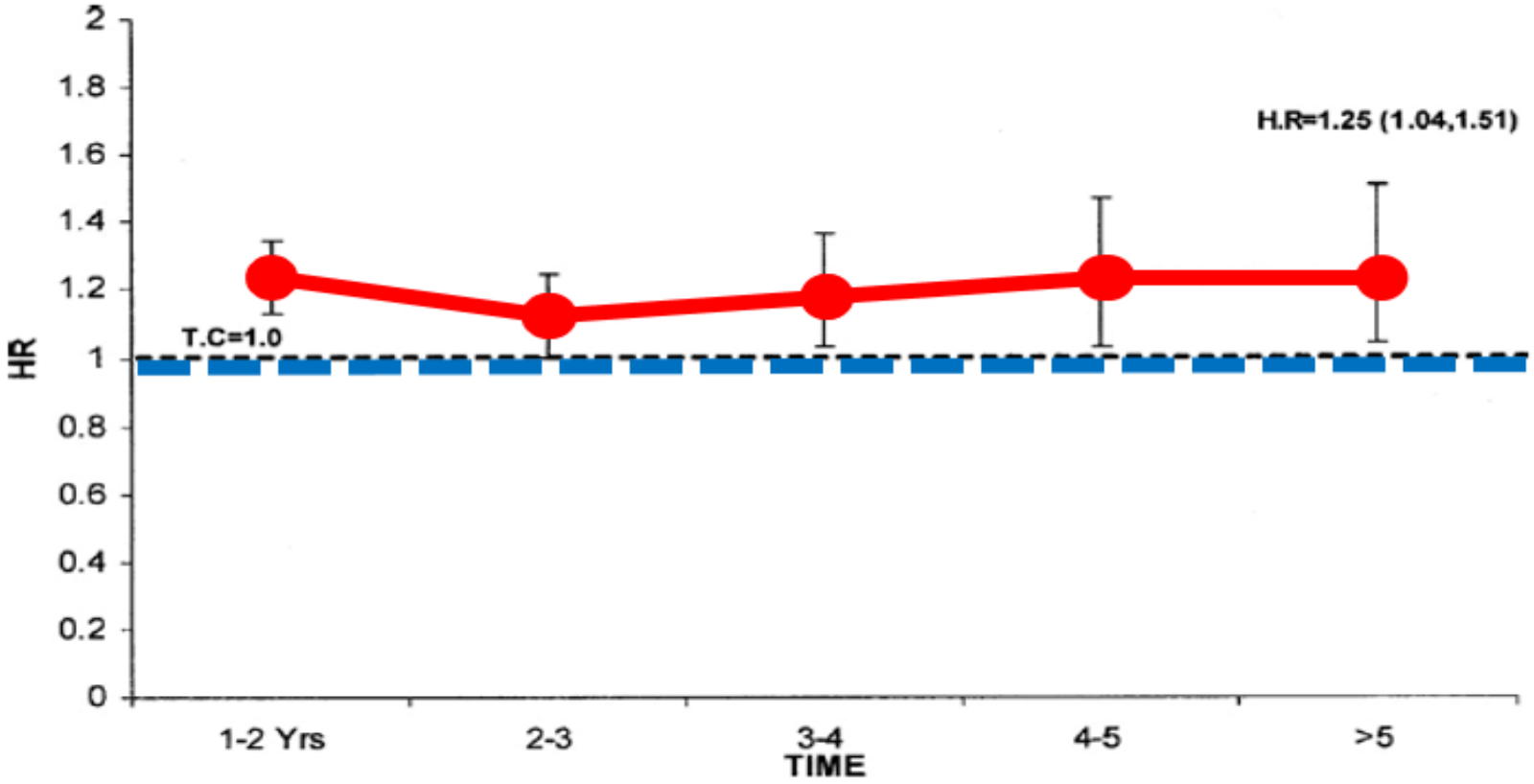
Mortality on Dialysis Post–Kidney Transplant Failure

Figure 1. Mortality HRs (post–graft failure dialysis relative to transplant candidates [TC]) in the first year after graft failure. The horizontal axis is time since graft failure; vertical axis is HR (bars indicate 95% CIs). Each HR is plotted against the midpoint of the post–graft failure interval to which it pertains. Results are based on a Cox nonproportional hazards model, a generalization of the Cox model that allows the HR to depend on time since graft failure. Note that the post–graft failure dialysis/transplant candidate HR in Table 2 (HR, 1.78) averages across HRs shown in Figs 1 and 2. HRs in Figs 1 and 2 are from the same nonproportional hazards model and are shown separately for presentation purposes.



Rao PS et al. Am J Kidney Dis. 2007 Feb;49(2):294-300

Mortality on Dialysis Post–Kidney Transplant Failure



Rao PS et al. Am J Kidney Dis. 2007 Feb;49(2):294-300

Cause of death in patient with DAGL

Table 2: Annual adjusted death rates per 100 patient years based on 10- year follow up by cause of death

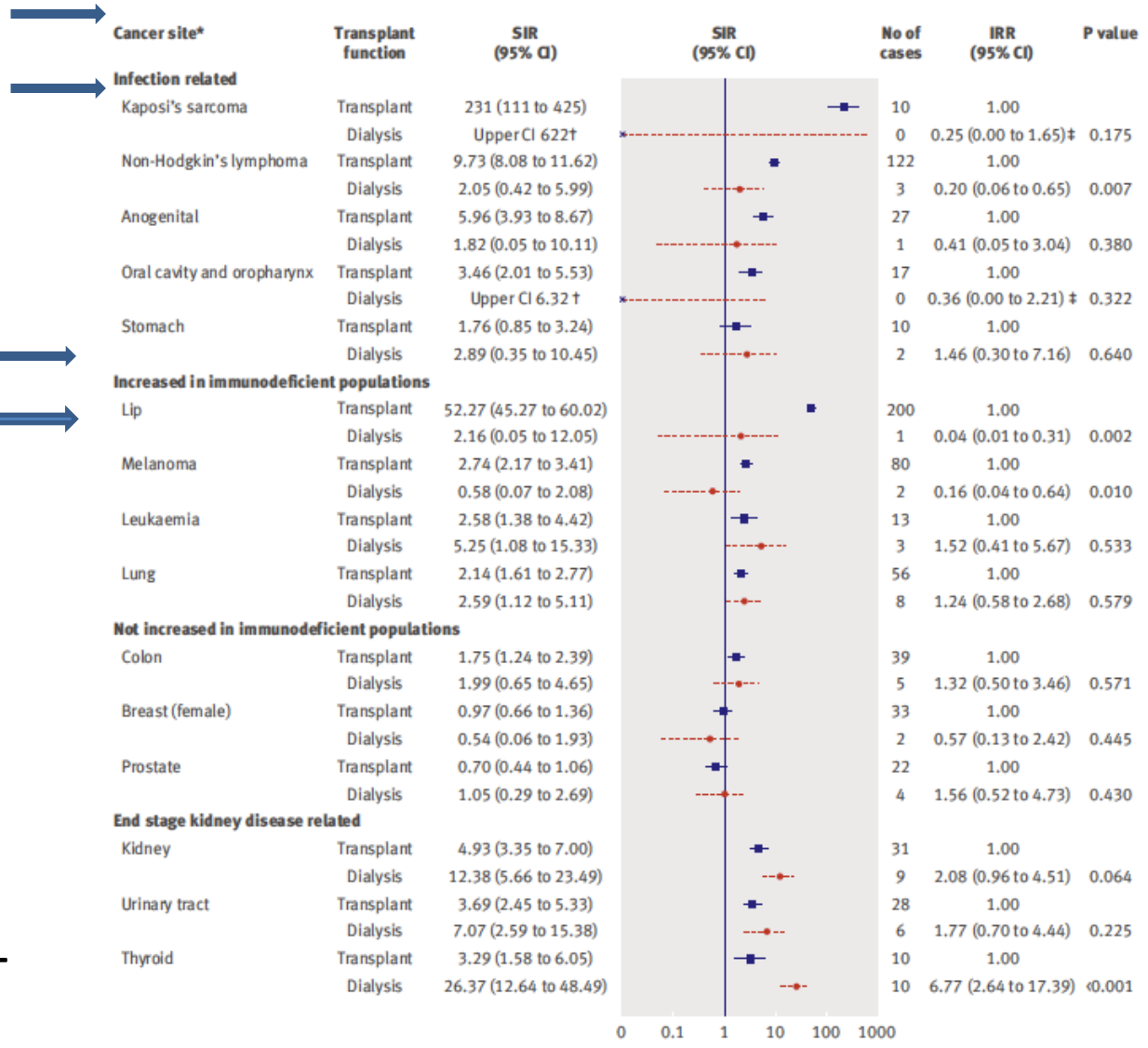
	Death during transplant		Death after graft loss	
	N	Annual rate percentage	N	Annual rate percentage
Overall	10816	2.81	4712	9.42
Cardiovascular	3402	0.69	2252	4.31
Infectious	1856	0.37	879	1.63
Malignancy	808	0.19	122	0.11

Calculated from the Cox model adjusted for covariates as described in methods.

Kaplan B et al. Am J Transplant. 2002 Nov;2(10):970-4

Cancer In DAGL Patients

- Retrospective cohort study of 8173 Australian kidney transplant recipients who received Tx during1982-2003
- Main out come measures Cancer-specific standardized incidence ratios for periods of transplant function and for DAGL



Cancer site*	Transplant function	SIR (95% CI)	No of cases	IRR (95% CI)	P value
Infection related					
Kaposi's sarcoma	Transplant	231 (111 to 425)	10	1.00	
	Dialysis	Upper CI 622†	0	0.25 (0.00 to 1.65)‡	0.175
Non-Hodgkin's lymphoma	Transplant	9.73 (8.08 to 11.62)	122	1.00	
	Dialysis	2.05 (0.42 to 5.99)	3	0.20 (0.06 to 0.65)	0.007
Anogenital	Transplant	5.96 (3.93 to 8.67)	27	1.00	
	Dialysis	1.82 (0.05 to 10.11)	1	0.41 (0.05 to 3.04)	0.380
Oral cavity and oropharynx	Transplant	3.46 (2.01 to 5.53)	17	1.00	
	Dialysis	Upper CI 6.32 †	0	0.36 (0.00 to 2.21) ‡	0.322
Stomach	Transplant	1.76 (0.85 to 3.24)	10	1.00	
	Dialysis	2.89 (0.35 to 10.45)	2	1.46 (0.30 to 7.16)	0.640
Increased in immunodeficient populations					
Lip	Transplant	52.27 (45.27 to 60.02)	200	1.00	
	Dialysis	2.16 (0.05 to 12.05)	1	0.04 (0.01 to 0.31)	0.002
Melanoma	Transplant	2.74 (2.17 to 3.41)	80	1.00	
	Dialysis	0.58 (0.07 to 2.08)	2	0.16 (0.04 to 0.64)	0.010
Leukaemia	Transplant	2.58 (1.38 to 4.42)	13	1.00	
	Dialysis	5.25 (1.08 to 15.33)	3	1.52 (0.41 to 5.67)	0.533
Lung	Transplant	2.14 (1.61 to 2.77)	56	1.00	
	Dialysis	2.59 (1.12 to 5.11)	8	1.24 (0.58 to 2.68)	0.579
Not increased in immunodeficient populations					
Colon	Transplant	1.75 (1.24 to 2.39)	39	1.00	
	Dialysis	1.99 (0.65 to 4.65)	5	1.32 (0.50 to 3.46)	0.571
Breast (female)	Transplant	0.97 (0.66 to 1.36)	33	1.00	
	Dialysis	0.54 (0.06 to 1.93)	2	0.57 (0.13 to 2.42)	0.445
Prostate	Transplant	0.70 (0.44 to 1.06)	22	1.00	
	Dialysis	1.05 (0.29 to 2.69)	4	1.56 (0.52 to 4.73)	0.430
End stage kidney disease related					
Kidney	Transplant	4.93 (3.35 to 7.00)	31	1.00	
	Dialysis	12.38 (5.66 to 23.49)	9	2.08 (0.96 to 4.51)	0.064
Urinary tract	Transplant	3.69 (2.45 to 5.33)	28	1.00	
	Dialysis	7.07 (2.59 to 15.38)	6	1.77 (0.70 to 4.44)	0.225
Thyroid	Transplant	3.29 (1.58 to 6.05)	10	1.00	
	Dialysis	26.37 (12.64 to 48.49)	10	6.77 (2.64 to 17.39)	<0.001

van LeeuwenMT et al . BMJ. 2010 Feb 11; 340: c570

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Dialysis After Graft Loss (DAGL)

Clinical Practice Guidelines for Hemodialysis Adequacy 2006

1.3 Timing of therapy:

When patients reach stage 5 CKD (estimated GFR < 15 mL/min/1.73 m2), nephrologists should evaluate the benefits, risks, and disadvantages of beginning kidney replacement therapy. Particular clinical considerations and certain characteristic complications of kidney failure may prompt initiation of therapy before stage 5. (B)

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 12, 2010 VOL. 363 NO. 7

A Randomized, Controlled Trial of Early versus Late Initiation of Dialysis

Bruce A. Cooper, M.B., B.S., Ph.D., Pauline Branley, B.Med., Ph.D., Liliana Bulfone, B.Pharm., M.B.A., John F. Collins, M.B., Ch.B., Jonathan C. Craig, M.B., Ch.B., Ph.D., Margaret B. Fraenkel, B.M., B.S., Ph.D., Anthony Harris, M.A., M.Sc., David W. Johnson, M.B., B.S., Ph.D., Joan Kesselhut, Jing Jing Li, B.Pharm., B.Com., Grant Luxton, M.B., B.S., Andrew Pilmore, B.Sc., David J. Tiller, M.B., B.S., David C. Harris, M.B., B.S., M.D., and Carol A. Pollock, M.B., B.S., Ph.D., for the IDEAL Study*

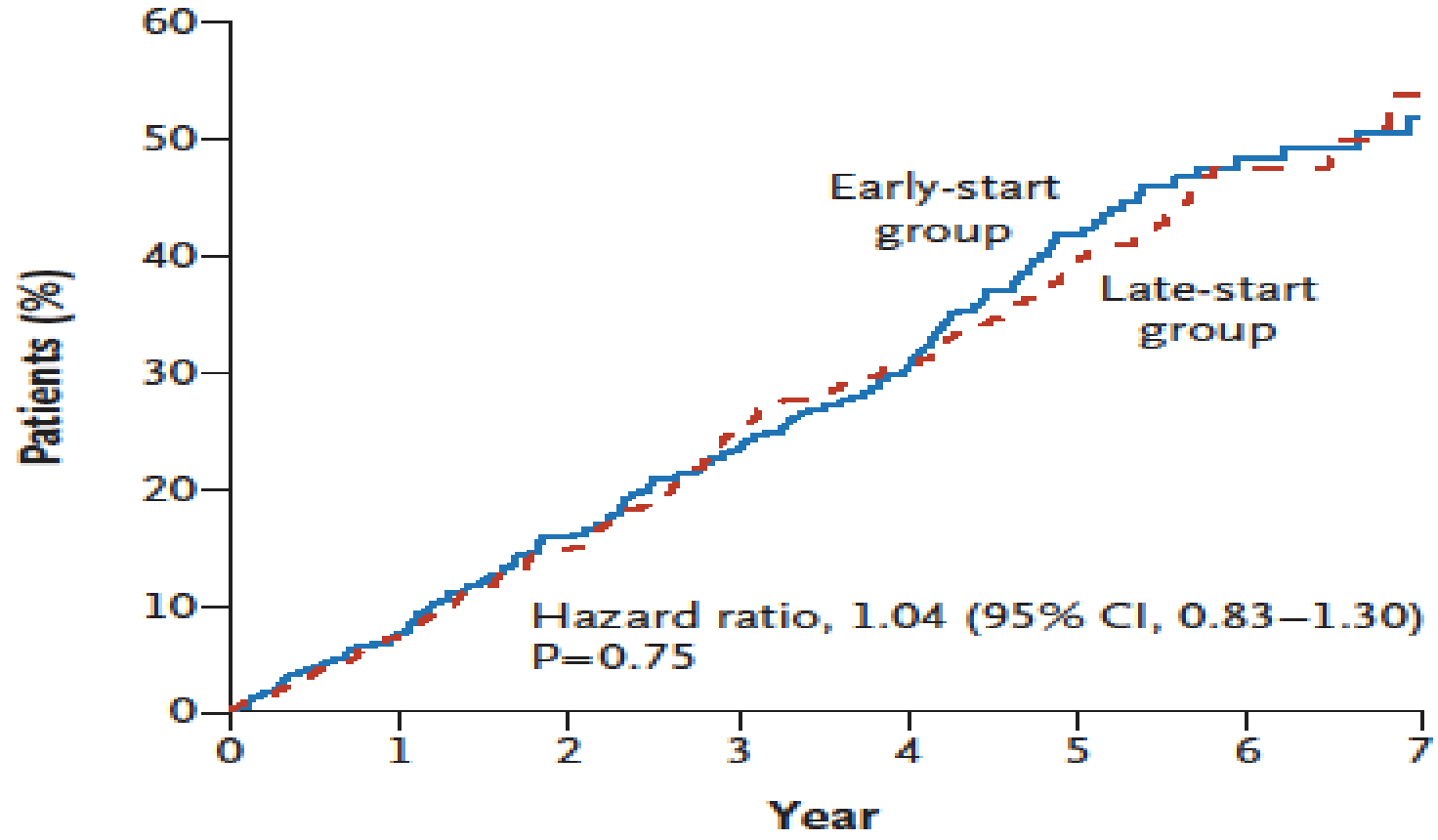
IDEAL study

Multicenter randomized control trial

- Patients > 18 years of age
- CKD with eGFR between 10 -15 ml/min
- Total of 828 patients randomized to initiate dialysis at eGFR of 10.0 to 14.0 ml per minute (early start) or when eGFR was 5.0 to 7.0 ml per minute (late start)
- The primary outcome was death from any cause

3.2 % DAGL in (early start)
3.5 % DAGL in (late start)

Time to Death



No. at Risk

Early start	404	358	305	249	177	99	59	32
Late start	424	385	333	254	187	115	60	32

What about timing of re-initiation of dialysis in failed renal allograft ?

Timing of re-initiation of dialysis in failed renal allograft

The USRDS registry study (n = 4741 patients followed for a median of 15 ±11 months after dialysis re-initiation) demonstrated that non survivors had a significantly higher eGFR at dialysis initiation than their survivor counterparts (9.7 ±4.8 vs. 8.0 ±3.7 mL/min per 1.73 m2, respectively).

Timing of re-initiation of dialysis in failed renal allograft
Gill JS et al. Kidney Int 2002; 62: 1875-1883

- For each 1 mL/min per m2 higher eGFR at the time of dialysis re-initiation was found to be associated with a 4% higher mortality risk after dialysis re-initiation (P < 0.01)

Gill JS et al. Kidney Int 2002; 62: 1875-1883

KDOQI Clinical Practice Guideline for Hemodialysis Adequacy 2015

1.1 Patients who reach CKD stage 4 (GFR,30mL/min/1.73m2), including those who have imminent need for maintenance dialysis at the time of initial assessment, should receive education about kidney failure and options for its treatment, including kidney transplantation ,PD,HD in the home or in center ,and conservative treatment. Patients' family members and caregivers also should be educated about treatment choices for kidney failure(Not Graded)

- **1.2 The decision to initiate maintenance dialysis in patients who choose to do so should be based primarily upon an assessment of signs and/or symptoms associated with uremia, evidence of protein-energy wasting, and the ability to safely manage metabolic abnormalities and/or volume overload with medical therapy rather than on a specific level of kidney function in the absence of such signs and symptoms.(Not Graded)**

Is There an Optimal Dialysis Modality for DAGL Patients?

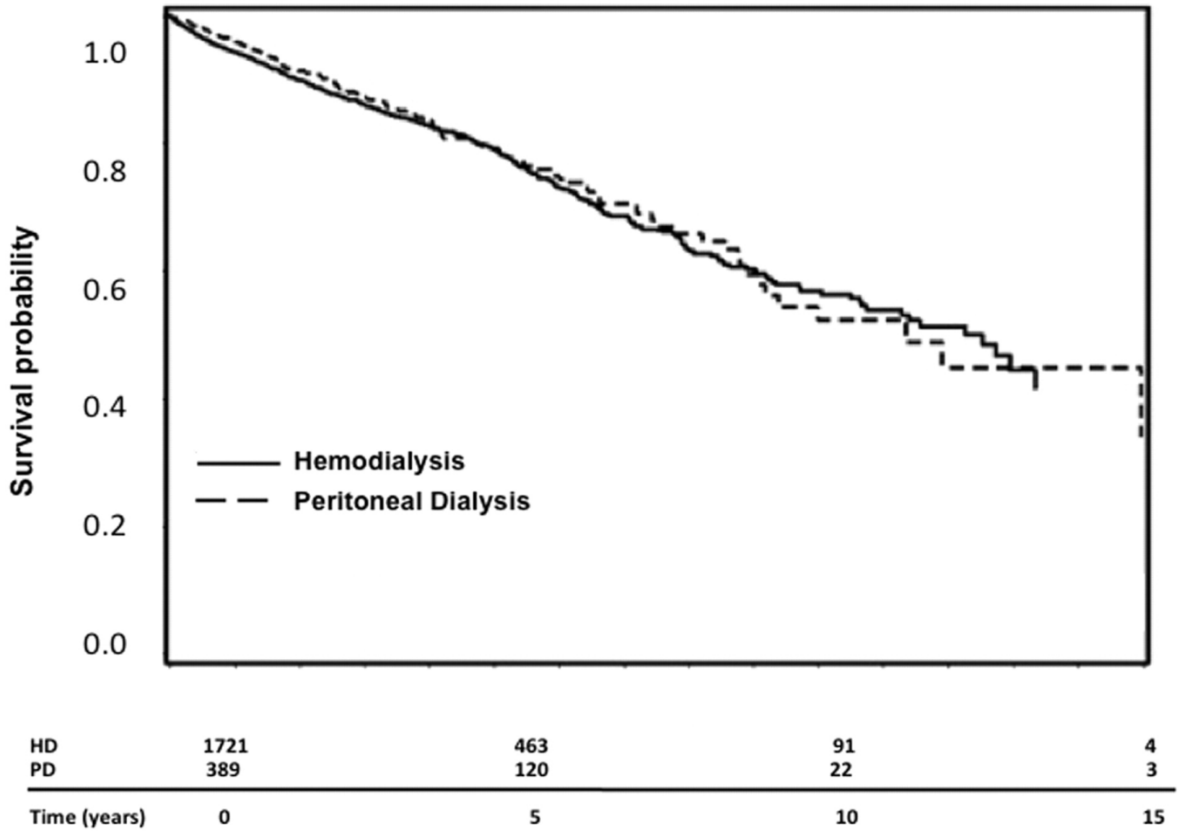
Studies comparing outcome of different modalities in failed kidney transplant patients

Authors	Year	Cohort size	Groups	Follow-up time	Results
Davies[1]	2001	45	PD compared to HD	Up to 125 months	PD and HD groups had similar outcome
Sasal[2]	2001	85 (42 failed kidney Tx patients)	Kidney failed PD compared to Tx naive PD	Up to 100 months	Failed kidney transplant patients reported higher mortality and complication risk
Duman[3]	2004	116 (34 failed kidney Tx patients)	Kidney failed PD compared to Tx naive PD	Up to 5 years	Similar patients and technique survival
Rao[4]	2005	25,362 (675 failed kidney Tx patients)	Compared transplant naïve dialysis, deceased/living kidney transplant, failed kidney transplant dialysis and re-transplant	Up to 8 years	The transplant naive and failed kidney transplant dialysis patients have equivalent mortality risk and that mortality is significantly reduced upon Re-transplantation
De Jonge[5]	2006	60	PD compared to HD	Up to 60 months	PD and HD groups had similar outcome
Mujais[6]	2006	1464 (494 failed kidney Tx patients)	Failed kidney transplant patients on PD compared to new dialysis initiation or transfer from HD	Up to 4 years	Similar outcome between the groups; however, the re-transplant rate was lower in failed kidney transplant group

1.Davies SJ et al .PeritDial Int 21(Suppl 3):S280–S284, 2001 , 2.SasalJ et al . PeritDial Int 21:405–410, 2001 ,3.DumanS et al. Int UrolNephrol36:249–252, 2004
4.Rao PS et al . NephrolDial Transplant 20:387–391, 2005 , 5.de JongeH et al . NephrolDial Transplant 21:1669–1674, 2006 ,6.MujaisS et al . Kidney Int Suppl (103):S133–S137, 2006

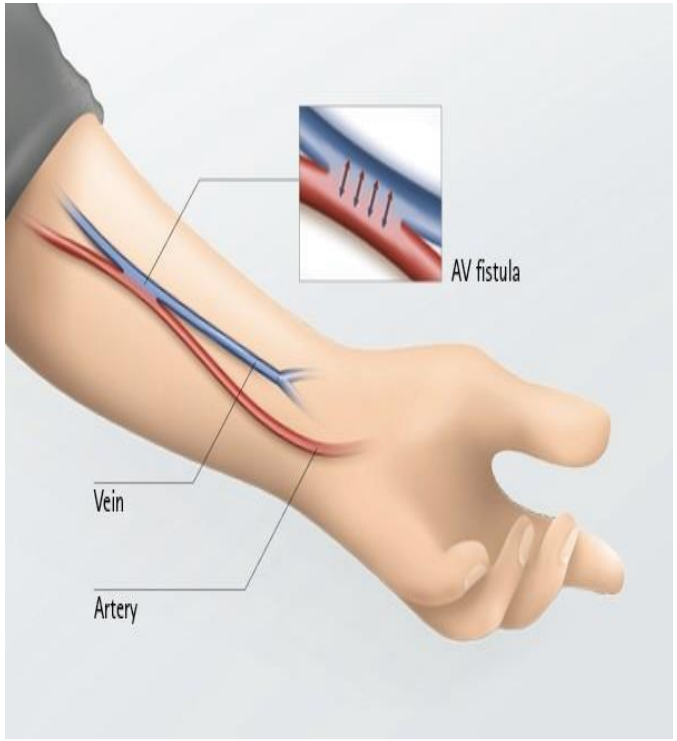
Adjusted survival curves for patients returning to PD (dashed line) and HD (solid line)

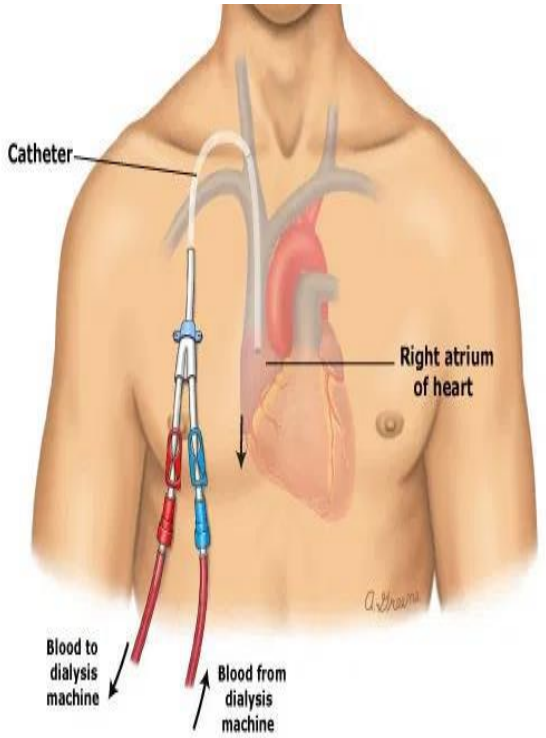
2110 adult patients who initiated dialysis after renal transplant failure between 1991 and 2005 from The Canadian Organ Replacement Register

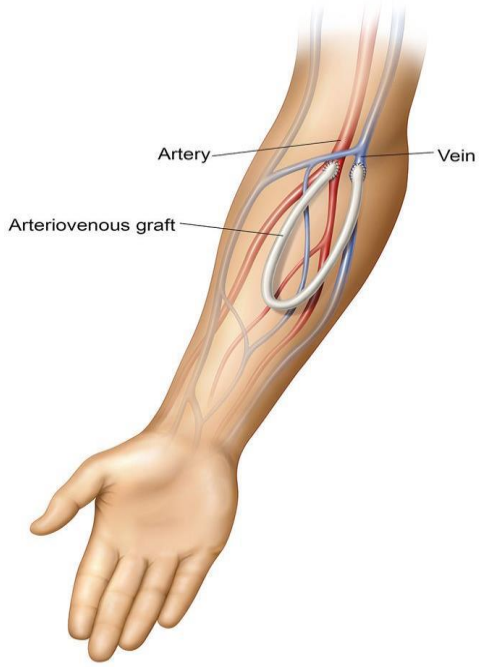


Jeffrey Perl et al. CJASN 2011;6:582-590.

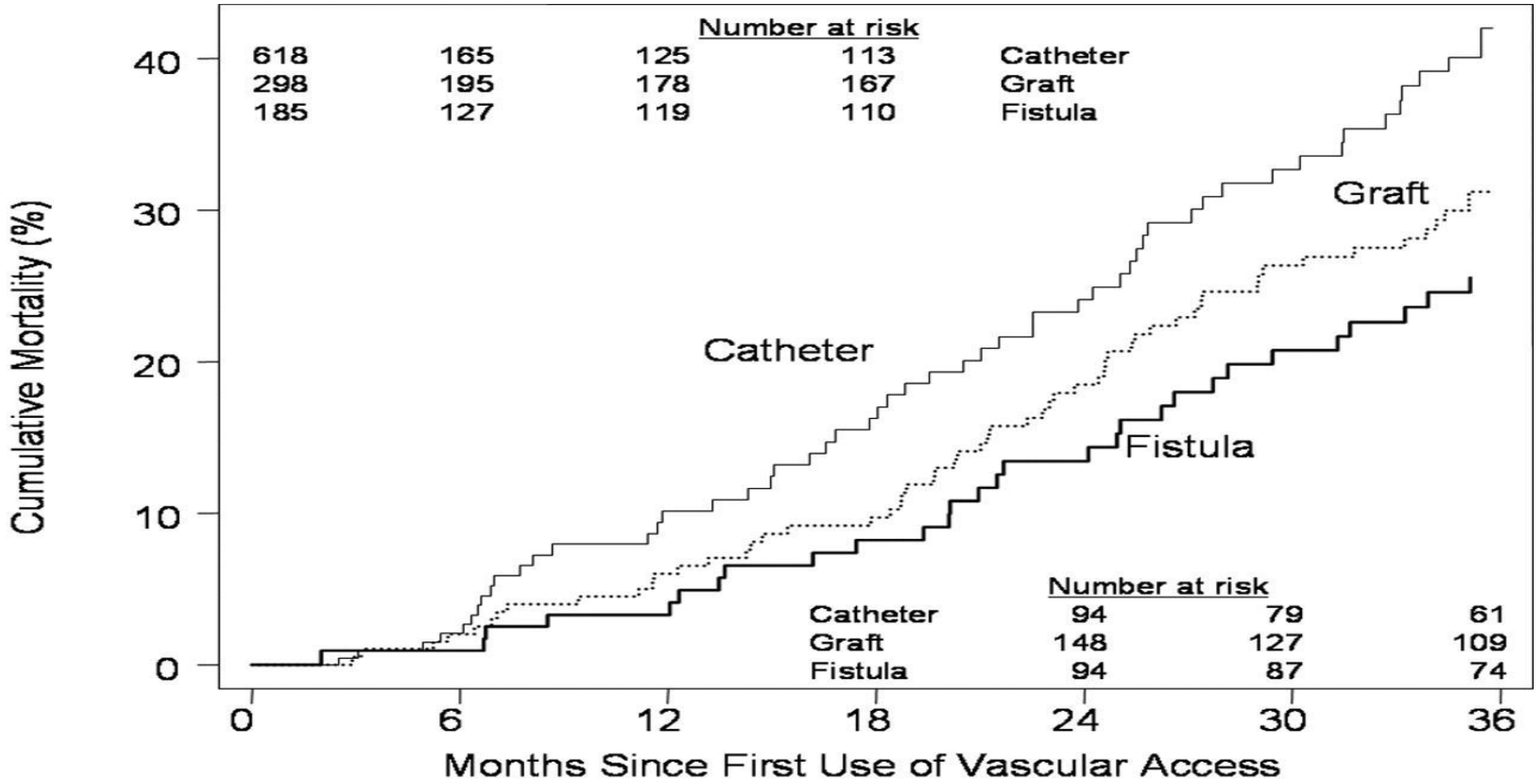
The Impact of Initial Vascular Access







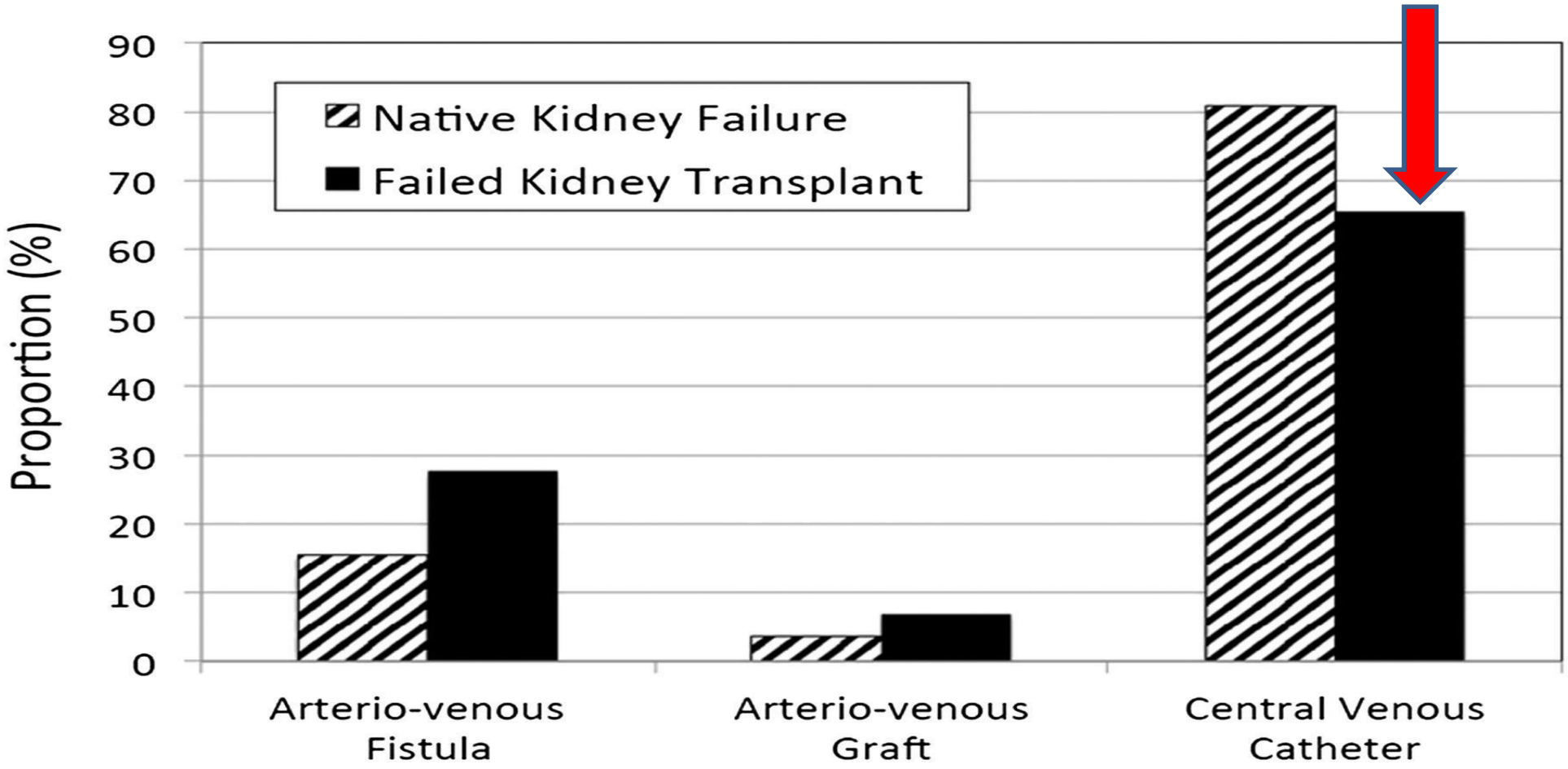
Kaplan-Meier cumulative mortality curve, by type of vascular access in use among 616 participants in the Choices for Healthy Outcomes in Caring for End-Stage Renal Disease (CHOICE) Study



Brad C. Astor et al. JASN 2005;16:1449-1455.

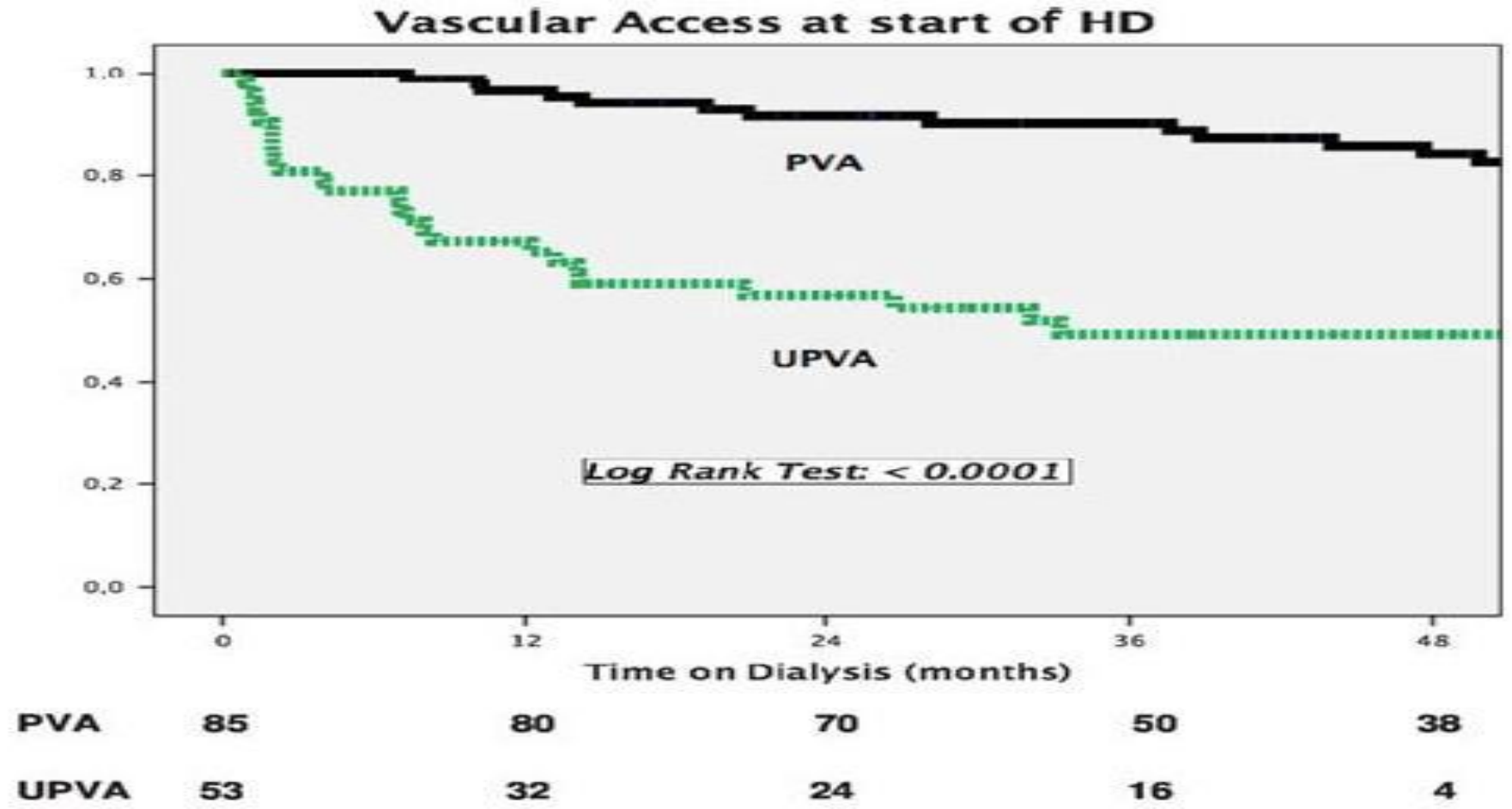
Initial Vascular Access Type In Patient with a Failed Renal Transplant

The proportion of vascular access use between native kidney failure and failed kidneys transplants.



Micah R. Chan et al. CJASN 2014;9:1225-1231

Unplanned Vascular Access Is Associated With Greater Mortality in Patients Who Return to Hemodialysis With a Failing Renal Graft



Kaplan-Meier plots of survival curves: the effect upon survival of VA type at the start of HD (PVA vs UPVA) LahamG et al . Transplantation. 2017 Oct;101(10):2606-2611

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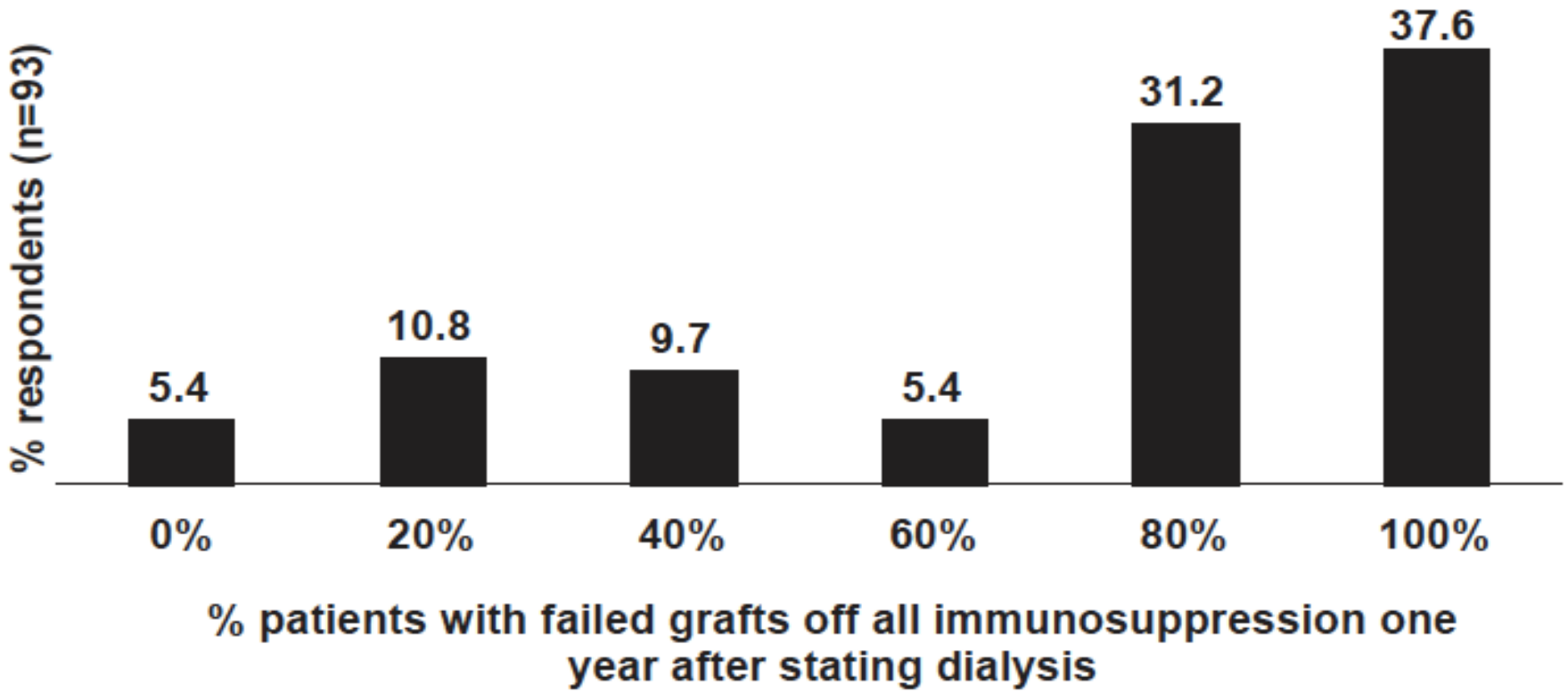
What percentage of your centers' patients with failed grafts is off all immunosuppression one year after starting on dialysis?



Bayliss et al . Clin Transplant. 2013 Nov-Dec;27(6):895-900

Immunosuppression regimens related questions ?

	MMF/AZA %	Tacro/CSA%	Sirolimus %	Prednisone %	None %
What drugs do you use in your standard immunosuppression regimen? n = 93	95.7/8.6	95.7/17.2	15.1	74.2	NA
If a patient's transplant fails, which drug do you wean off first? n = 92	57.6	38.0	0.0	4.3	0
Which drug do you usually wean next? n = 93	35.5	55.9	2.2	6.5	0
Which drugs do you leave patients on indefinitely after graft failure and return to dialysis? n = 93[a]	5.4	5.4	0.0	21.5	71.0

AZA, azathioprine; CSA, cyclosporine; MMF, mycophenolate mofetil; Tacro, tacrolimus.

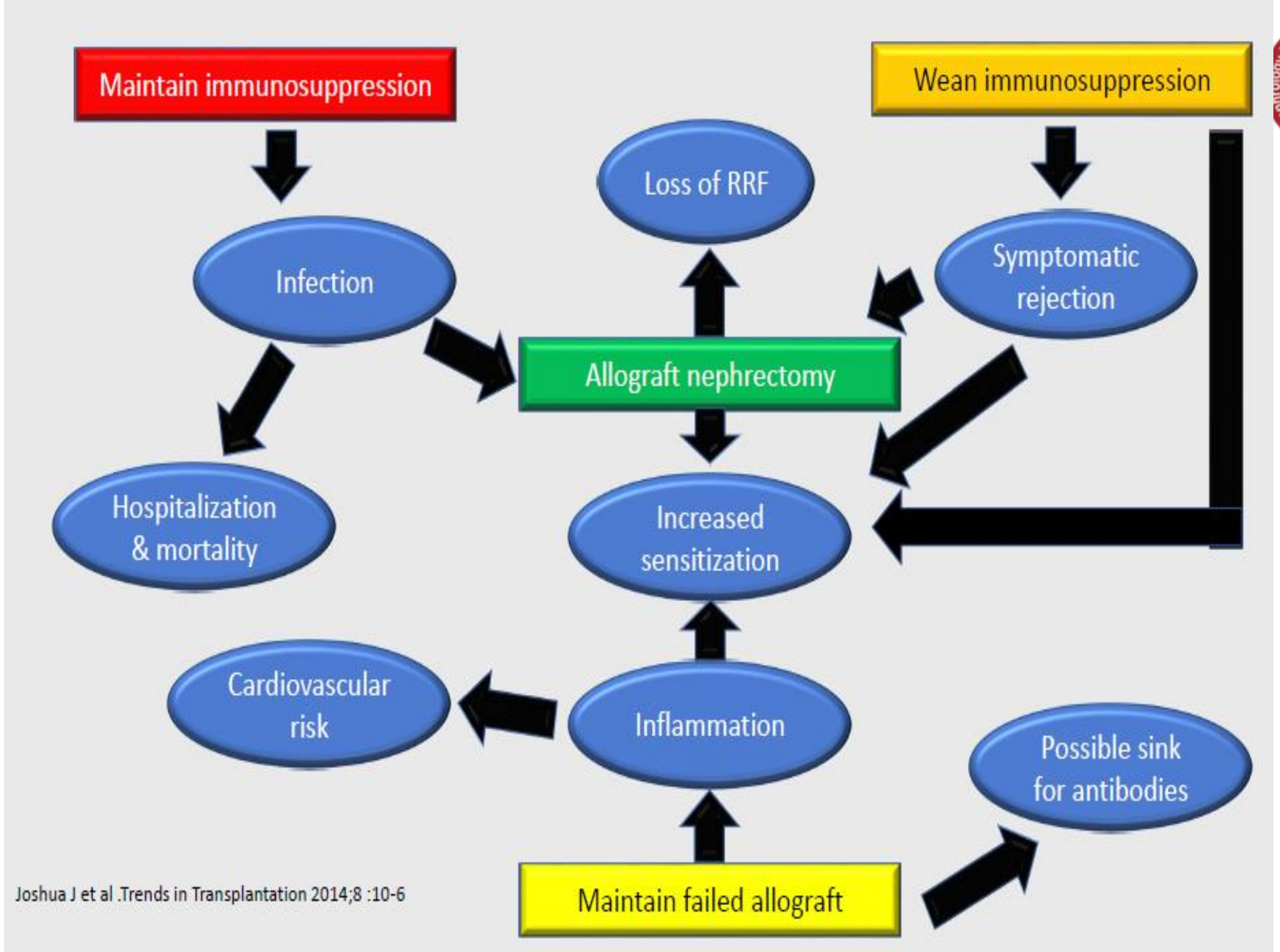
[a]Three respondents said they leave patients on both prednisone and an antimetabolite, so the percentages add up to over 100%.

Factors considered in stopping vs. continuing immunosuppression

Factors	% responding it is the single most important factor (n = 92)
Ongoing signs and symptoms of rejection	37
Plans to re-transplant	40.2
History of infections	5.4
History of BK nephropathy	2.2
Urine output	2.2
History of rejection	2.2
Cost of the medications	2.2
Others	8.7

Arguments for and against continuing immunosuppression in the setting of transplant failure

In favour of continuing immunosuppression	Against continuing immunosuppression
Minimization of allosensitization ahead of possible re-transplantation	Increased risk of infection
Decreased incidence of graft intolerance syndrome and the need for allograft nephrectomy	Increased risk of cancer
Reduced risk of overt acute rejection	Increased risk of cardiovascular disease
Prevention of adrenal insufficiency	Metabolic complications (diabetes, hypertension, dyslipidemia)
Potential to preserve residual transplant	Steroid-associated adverse effects
Prevention of reactivation of systemic disease (e.g., SLE, vasculitis)	Cost



Joshua J et al .Trends in Transplantation 2014;8 :10-6

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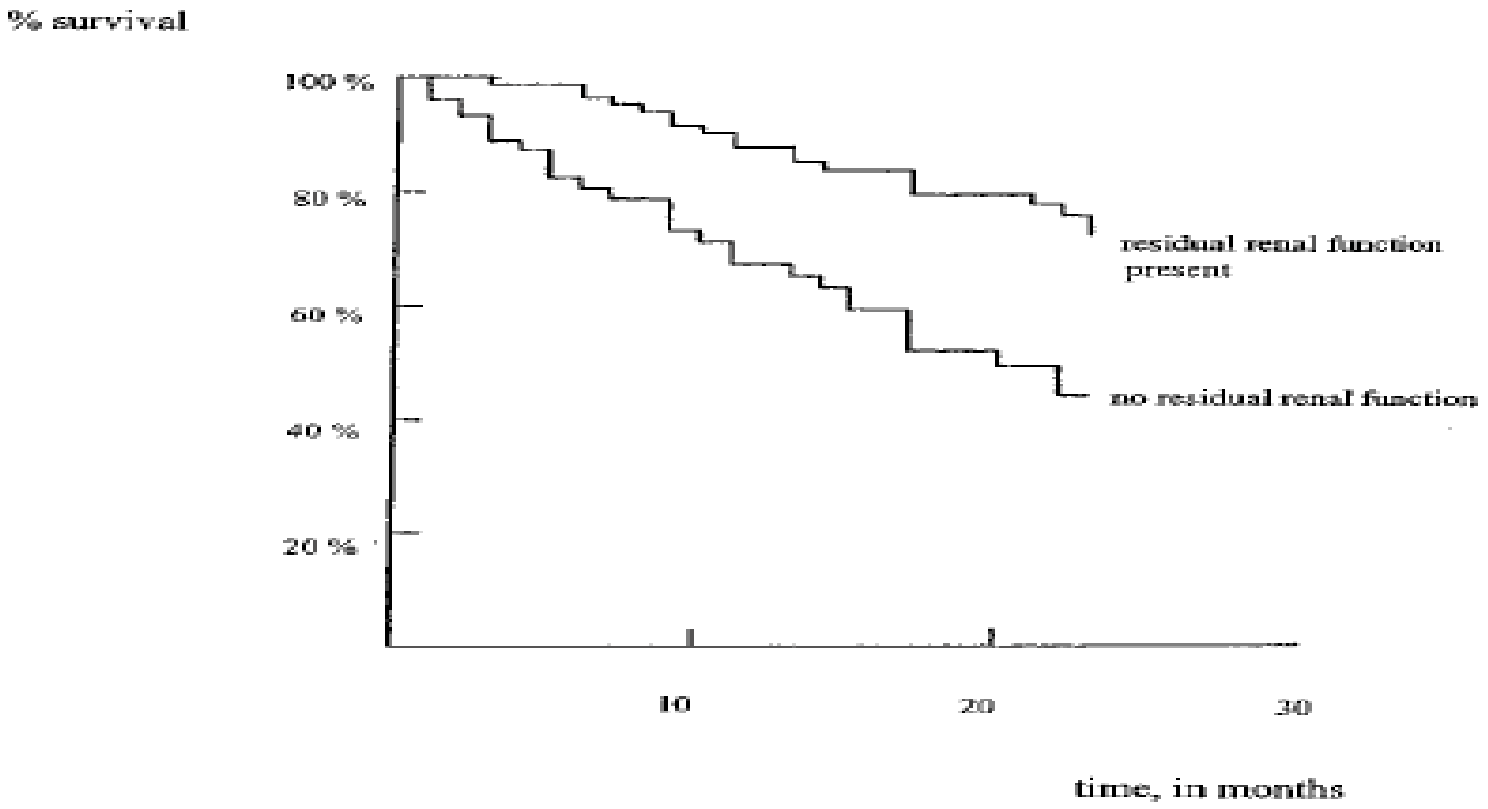
Residual Renal Function and Mortality Risk in Hemodialysis Patients



SheminD et al . Am J Kidney Dis. 2001 Jul;38(1):85-90

J Am Soc Nephrol 12: 2158–2162, 2001

Relative Contribution of Residual Renal Function and Peritoneal Clearance to Adequacy of Dialysis: A Reanalysis of the CANUSA Study

JOANNE M. BARGMAN,* KEVIN E. THORPE,† and DAVID N. CHURCHILL,‡ for the CANUSA Peritoneal Dialysis Study Group

**Division of Nephrology, Toronto General Hospital, University of Toronto, Toronto; and †Department of Clinical Epidemiology and Biostatistics, and ‡Father Sean O'Sullivan Research Center, St. Joseph's Hospital, Division of Nephrology, McMaster University, Hamilton, Ontario, Canada.*

Table 2. Cox model of relative risk of death with time-dependent Ccr divided into peritoneal clearance and GFR and entered as time-dependent covariates[a]

Variable	Relative Risk	95% Confidence Limit
Age	1.02	1.005–1.044
CVD	2.42	1.499–3.904
Diabetes mellitus	1.25	0.769–2.036
Serum albumin	0.96	0.912–1.000
LA transport	1.66	0.379–7.218
HA transport	2.33	0.554–9.801
H transport	2.01	0.430–9.357
SGA	0.74	0.647–0.842
Ccrp (5 L/wk per 1.73 m^2 greater)	1.00	0.898–1.105
GFR (5 L/wk per 1.73 m^2 greater)	0.88	0.829–0.943

[a] CVD, cardiovascular disease; LA, low average; HA, high average; H, high; SGA, subjective global assessment.

Table 3. Cox model of relative risk for death with urine volume forced in as a time-dependent covariate

Variable	Relative Risk	95% Confidence Limits
Age (1 yr older)	1.02	1.002–1.041
CVD	2.37	1.465–3.821
Diabetes mellitus	1.31	0.807–2.134
Serum albumin (1 g/L increase)	0.96	0.914–1.003
LA transport	1.84	0.418–8.075
HA transport	2.71	0.631–11.623
H transport	2.46	0.523–11.590
SGA (1 unit greater)	0.78	0.672–0.876
Ccrp (5 L/wk per 1.73 m^2 greater)	0.93	0.795–1.079
GFR (5 L/wk per 1.73 m^2 greater)	0.99	0.943–1.044
Urine volume (250 ml daily greater)	0.64	0.508–0.800

For each 5 L/wk per 1.73 m2 increment in GFR, there was a 12% decrease in the relative risk (RR) of death. & for a 250-ml increment in urine volume, there was a 36% decrease in the RR of death

What Are the Risks and Benefits of Allograft Nephrectomy ?

In favor of transplantectomy

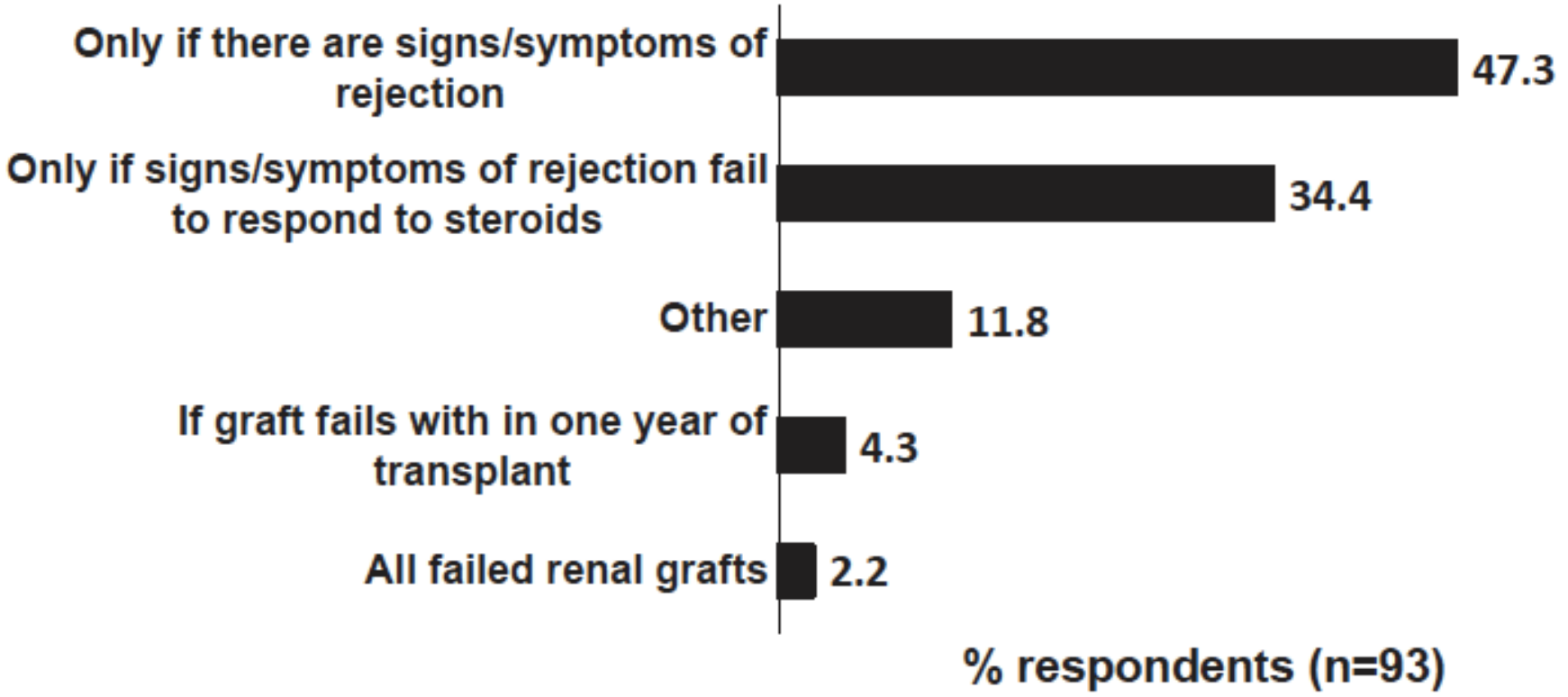
- A failing graft is a focus of a chronic inflammatory state
- May reduce mortality rates as IS can be stopped directly

Against continuing transplantectomy

- Residual kidney function may allow less stringent fluid restriction and may improve survival
- Allo-sensitization and the potential for future prolonged wait-times for a compatible crossmatch kidney
- Surgery-related morbidity and mortality.

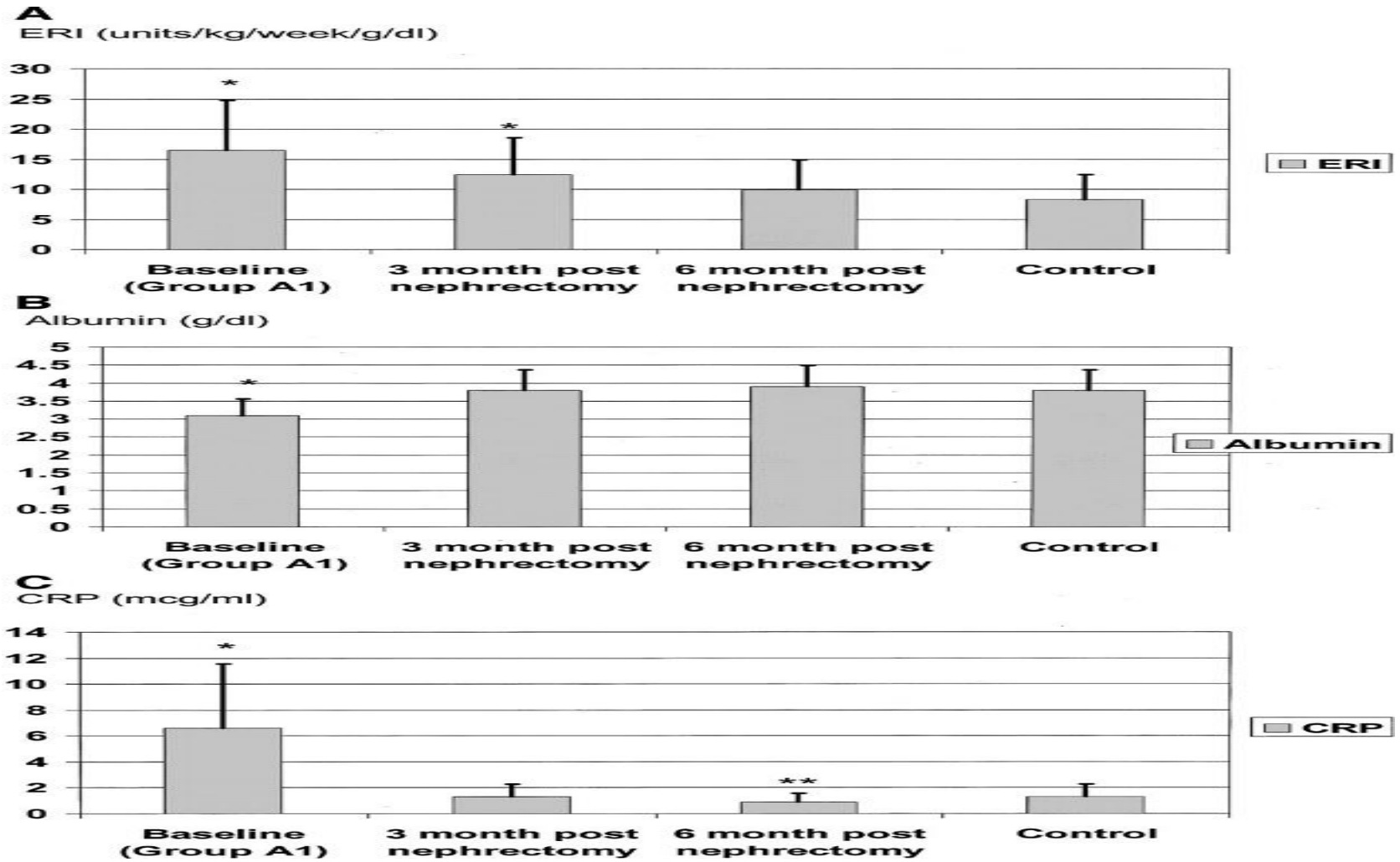
Pham PT et al . World J Nephrol. 2015 May 6;4(2):148-59

When does your program perform a nephrectomy of a failed renal graft?



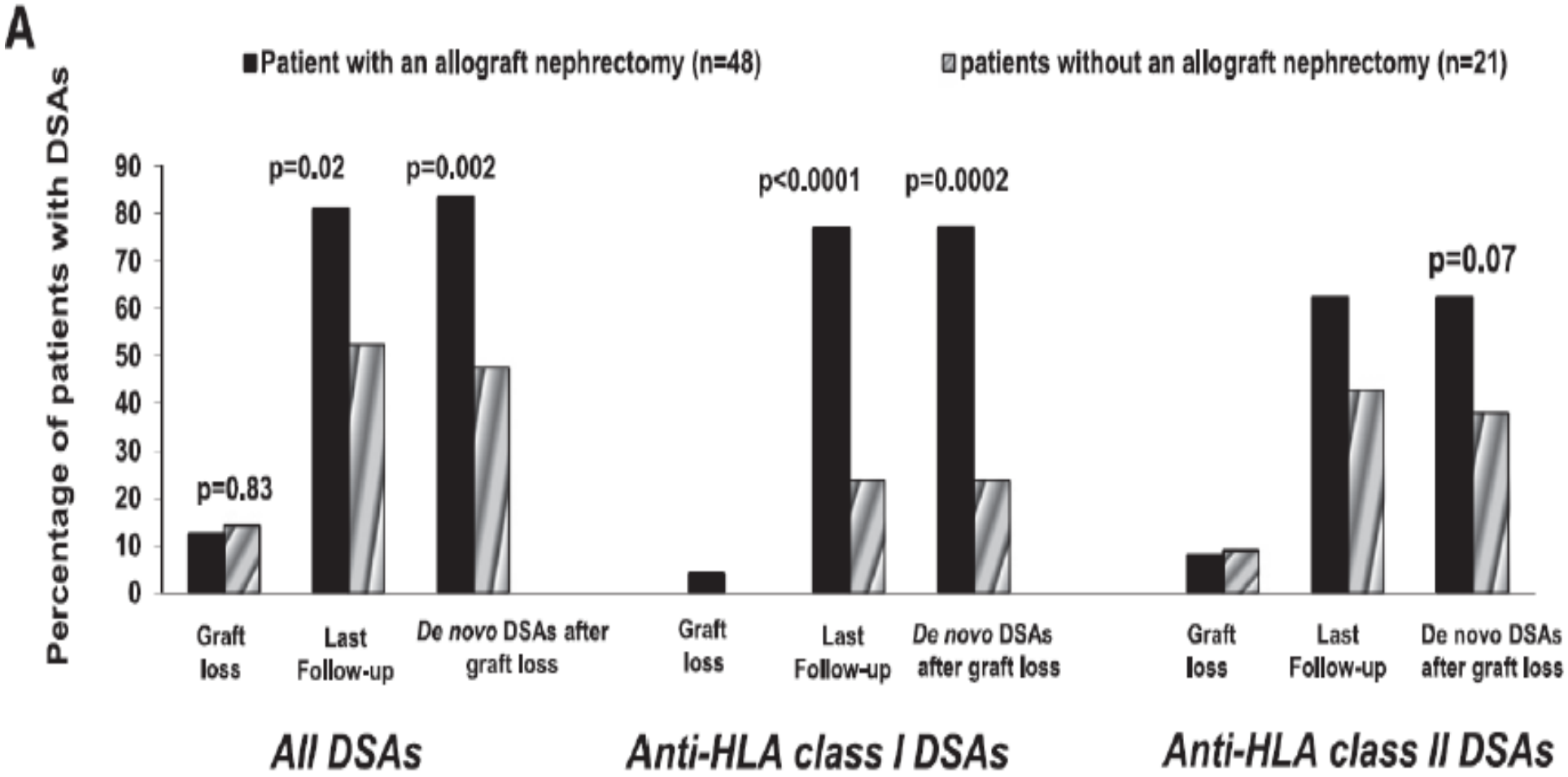
Bayliss et al . Clin Transplant. 2013 Nov-Dec;27(6):895-900

Prospective follow-up of erythropoietin resistance index (ERI; A), serum albumin levels (B), and C-reactive protein (CRP) in group A1 (C).



Juan M. López-Gómez et al. JASN 2004;15:2494-2501

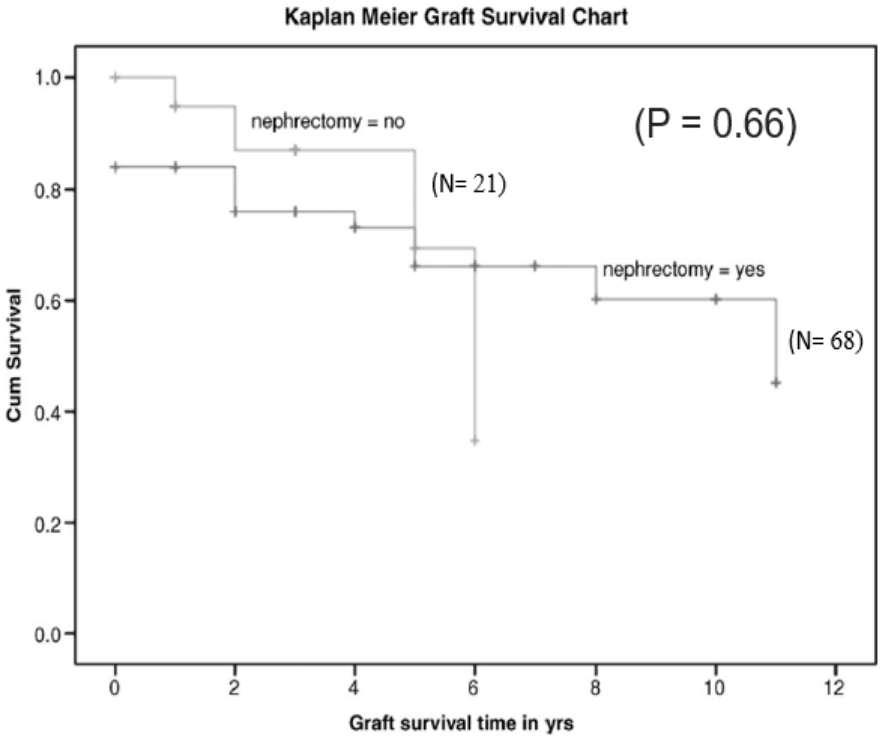
DSA with/without allograft nephrectomy

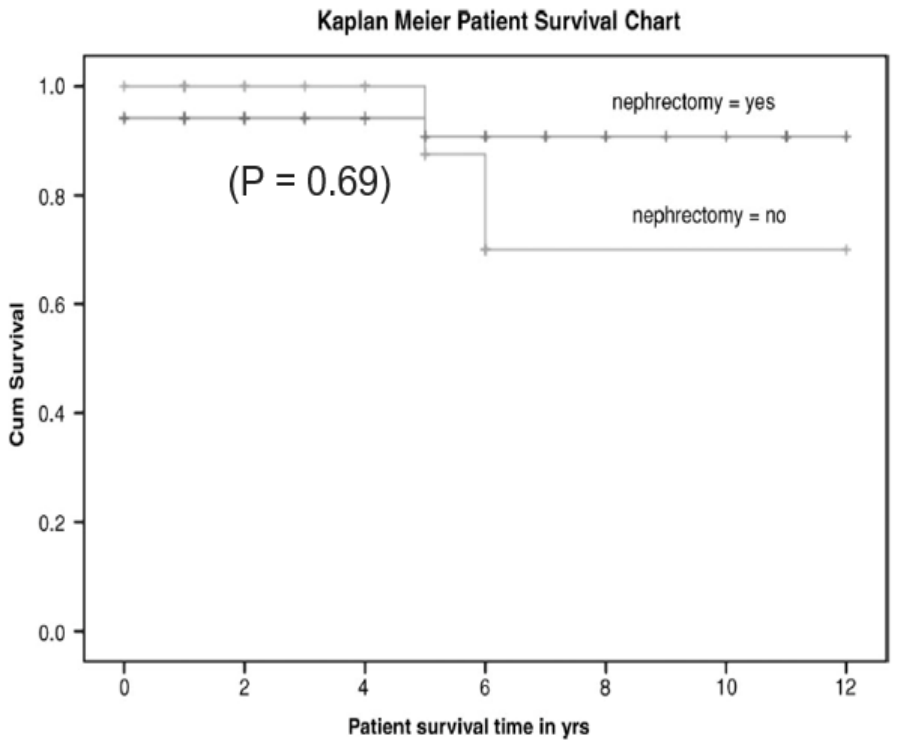


Del Bello A et al . Clin J Am Soc Nephrol. 2012 Aug;7(8):1310-19.

Impact of Failed Allograft Nephrectomy on Initial Function and Graft Survival After Kidney Re-transplantation

Does nephrectomy of failed allograft influence graft survival after re-transplantation?



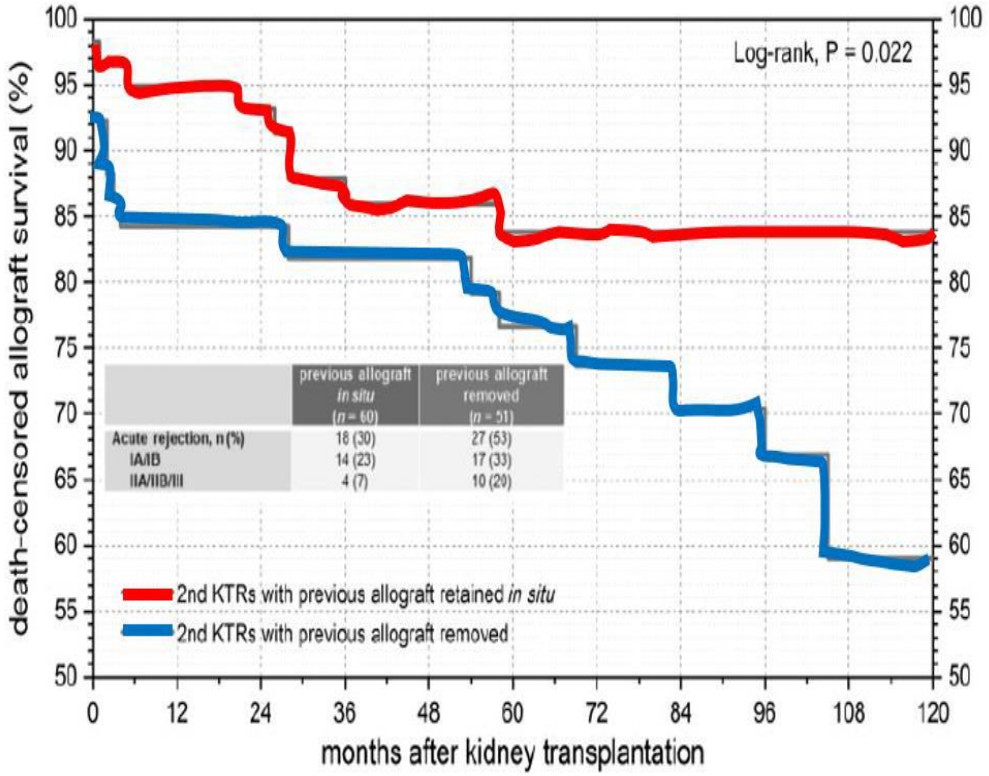


PRA level at the time of re-transplantation (Neph 37% versus No Neph 29%)

Ahmad N et al . Nephrol Dial Transplant. 2009 Feb;24(2):639-42

111 KTRs who underwent their second kidney transplantation from 1998 to 2015.

- In 51/111 KTRs (46%) the failed allograft was removed and in 60/111 (54%) the failed allograft was retained.



Schachtner T et al . Nephrol Dial Transplant. 2018 May 1;33(5):889-896.

Nephrol Dial Transplant (2018) 33: 700–708
doi: 10.1093/ndt/gfx360
Advance Access publication 12 February 2018

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Impact of renal allograft nephrectomy on graft and patient survival following retransplantation: a systematic review and meta-analysis

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*These authors contributed equally to this work.

Conclusion

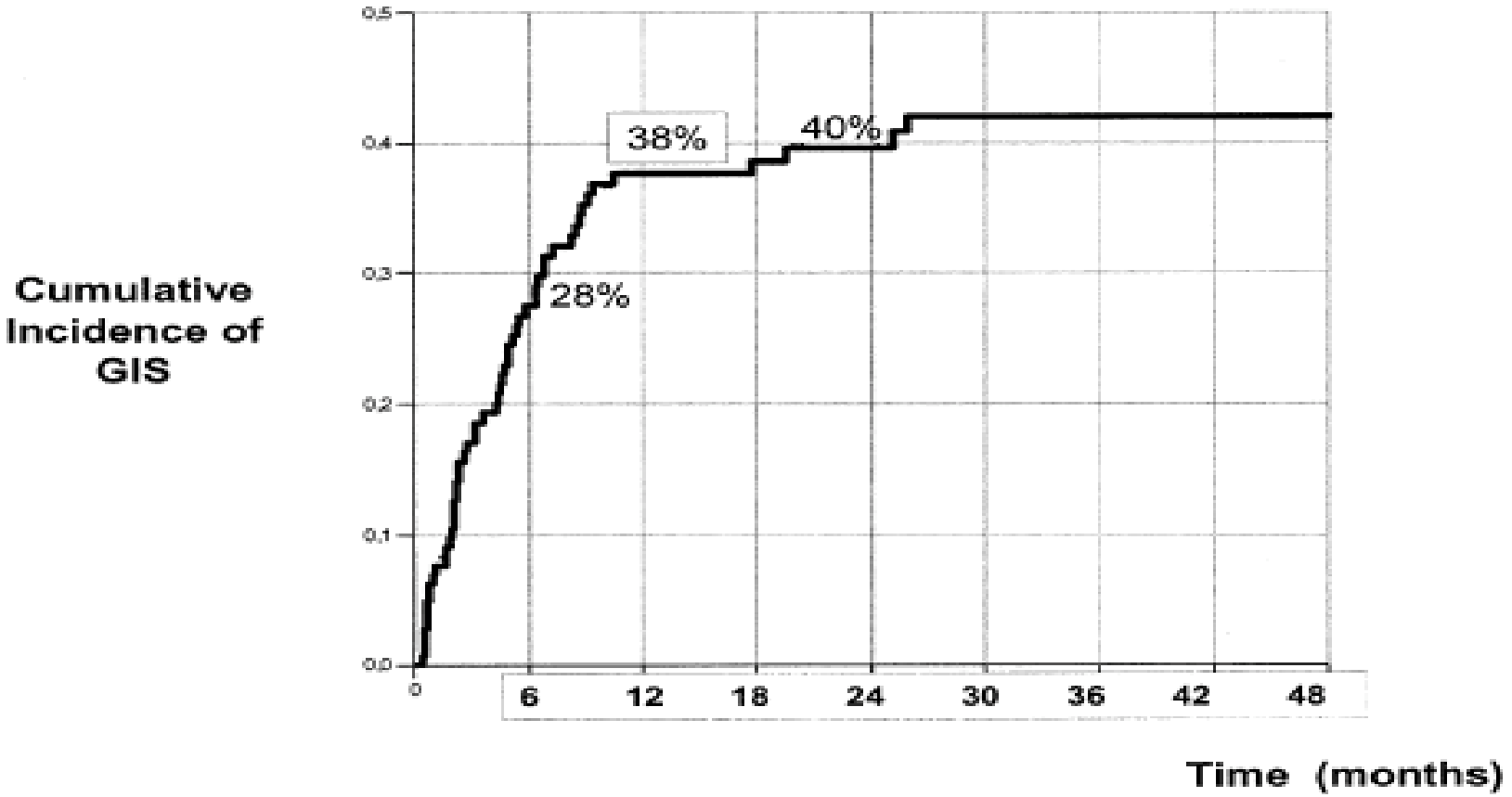
The rate of 1-year graft survival and 10-year graft survival, serum creatinine levels at 1year after re-transplantation were similar between the AN and No-AN groups.

- We recommend allowing the failed graft to remain unless symptoms dictate the need for surgery.
- We also suggest donor-specific antibody dynamic monitoring and better human leukocyte antigen matching for improved long-term outcome of re-transplantation.

Graft Intolerance Syndrome

- Graft intolerance syndrome refers to a constellation of signs and symptoms that occur in patients with a retained failed allograft.
- Graft intolerance syndrome commonly occurs within the first year of returning to dialysis .
- Incidence is 30–50%.
- Related to rapid discontinuation of immunosuppression

Cumulative incidence of graft intolerance syndrome



Delgado P et al . Am J Kidney Dis. 2005 Aug;46(2):339-44

Symptoms & Signs of Graft Intolerance Syndrome

Symptoms	%
• Fever	88
• Local pain	53
• Hematuria	39
• Flu-like, malaise	33
• Increased graft size	31
• Nausea, vomiting	6

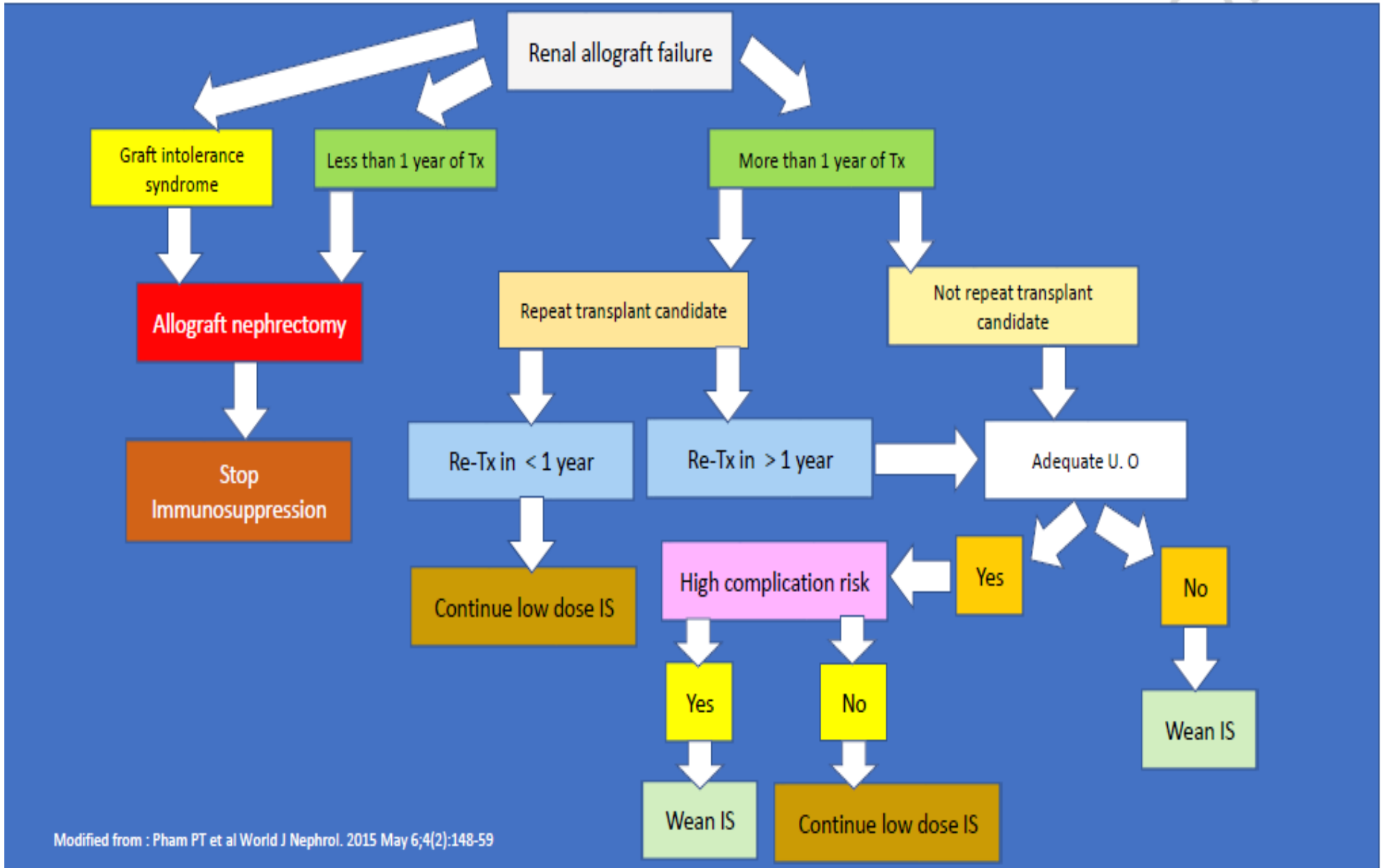
Embolization vs. Surgical Nephrectomy

Complications	Embolization of graft (N = 32)	Surgical nephrectomy of graft (N = 40)	P value
All complications	2 (06.25)	14 (35.00)	0.0035
≥2 g drop in post-op Hb: n (%)	0 (0.00)	8 (20.00)	0.0073
Need for post-op transfusion: n (%)	0 (0.00)	9 (22.50)	0.0041
Number of hospitalization days: mean ± SD	3.22 ± 1.64	8.37 ± 7.65	0.0001

The overall success rate of embolization in complete resolution of graft intolerance syndrome and ultimately avoidance of surgical removal was 84.37%.

Al Badaai G et al . Transpl Int. 2017 May;30(5):484-493

Suggested algorithm for management of IS in patient with DAGL



Suggested immunosuppression withdrawal protocol

Table 4 Suggested immunosuppression withdrawal protocols based on maintenance therapy

CNI + antimetabolite[a] + prednisone	CNI + mTOR inh + prednisone	mTOR inh + prednisone
Discontinue antimetabolite at initiation of dialysis	Discontinue mTOR inh at initiation of dialysis	Taper mTOR inh over 4-6 wk[b]
Taper CNI over 4-6 wk[b] Maintain same steroid dose at initiation of dialysis x 2-4 wk, then taper by 1 mg/mo (starting from 5 mg daily) until off	Taper CNI over 4-6 wk[b] Maintain same steroid dose at initiation of dialysis x 2-4 wk, then taper by 1 mg/mo (starting from 5 mg daily) until off	Maintain same steroid dose at initiation of dialysis x 2-4 wk, then taper by 1 mg/mo (starting from 5 mg daily) until off

[a]Mycophenolate Mofetil (Cellcept®) or Mycophenolic Acid (Myfortic®) or Azathioprine (Imuran®); [b]Taper can be done over a shorter period in slow chronic progressive graft failure but over a longer period when graft failure occurred following recent acute rejection episodes. CNI: Calcineurin inhibitor; mTOR inh: Mammalian target of rapamycin inhibitor.

Pham PT et al World J Nephrol. 2015 May 6;4(2):148-59

Indications for Transplantectomy

Table 5 Absolute and relative indications for transplantectomy

Absolute indications (commonly accepted)	Relative indications (controversial)
Primary nonfunction	The presence of hematologic or biochemical markers of the chronic inflammatory state
Hyperacute rejection	Erythropoietin resistance anemia
Early recalcitrant acute rejection	Elevated ferritin level
Early graft loss (generally defined as graft loss within the first year)	Elevated C reactive protein
Arterial or venous thrombosis	Elevated erythrocyte sedimentation rate
Graft intolerance syndrome	Low prealbumin/albumin
Recurrent urinary tract infections or sepsis/urosepsis	Graft loss due to BK nephropathy and high level BK viremia (see text)
Multiple retained failed transplants prior to a repeat transplant	

Pham PT et al World J Nephrol. 2015 May 6;4(2):148-59

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