2. DACH ANCA VASKULITIS FORUM 2024
22. & 23. NOVEMBER 2024 | MÜNCHEN

CSL Vifor

Was tun, wenn die Niere versagt? - NTX bei AAV

Univ.-Prof. Dr.
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Wien

Was tun, wenn die Niere versagt? NTX bei AAV

Rainer Oberbauer

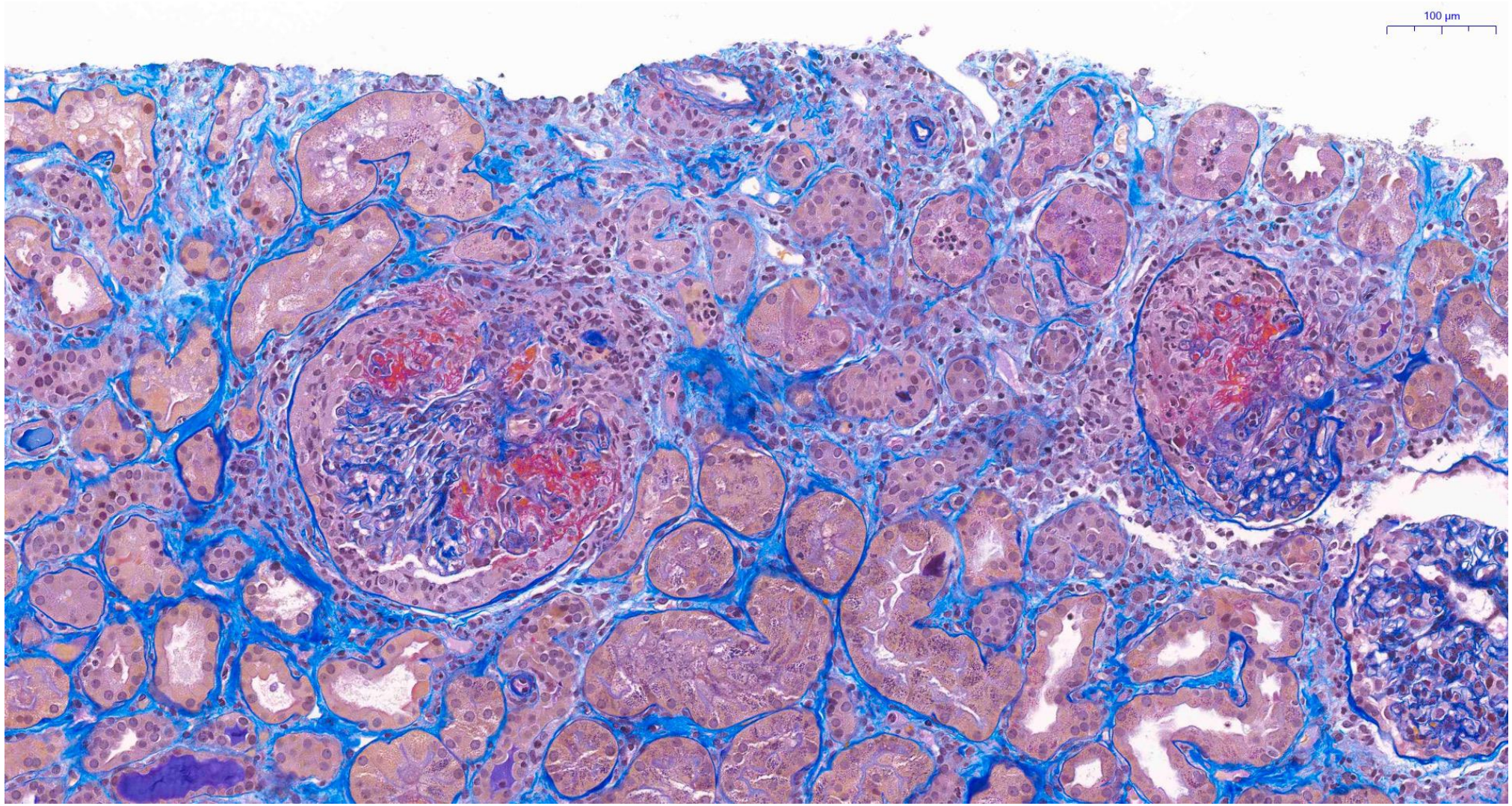
Conflict of interest

Honorarium CSL Vifor

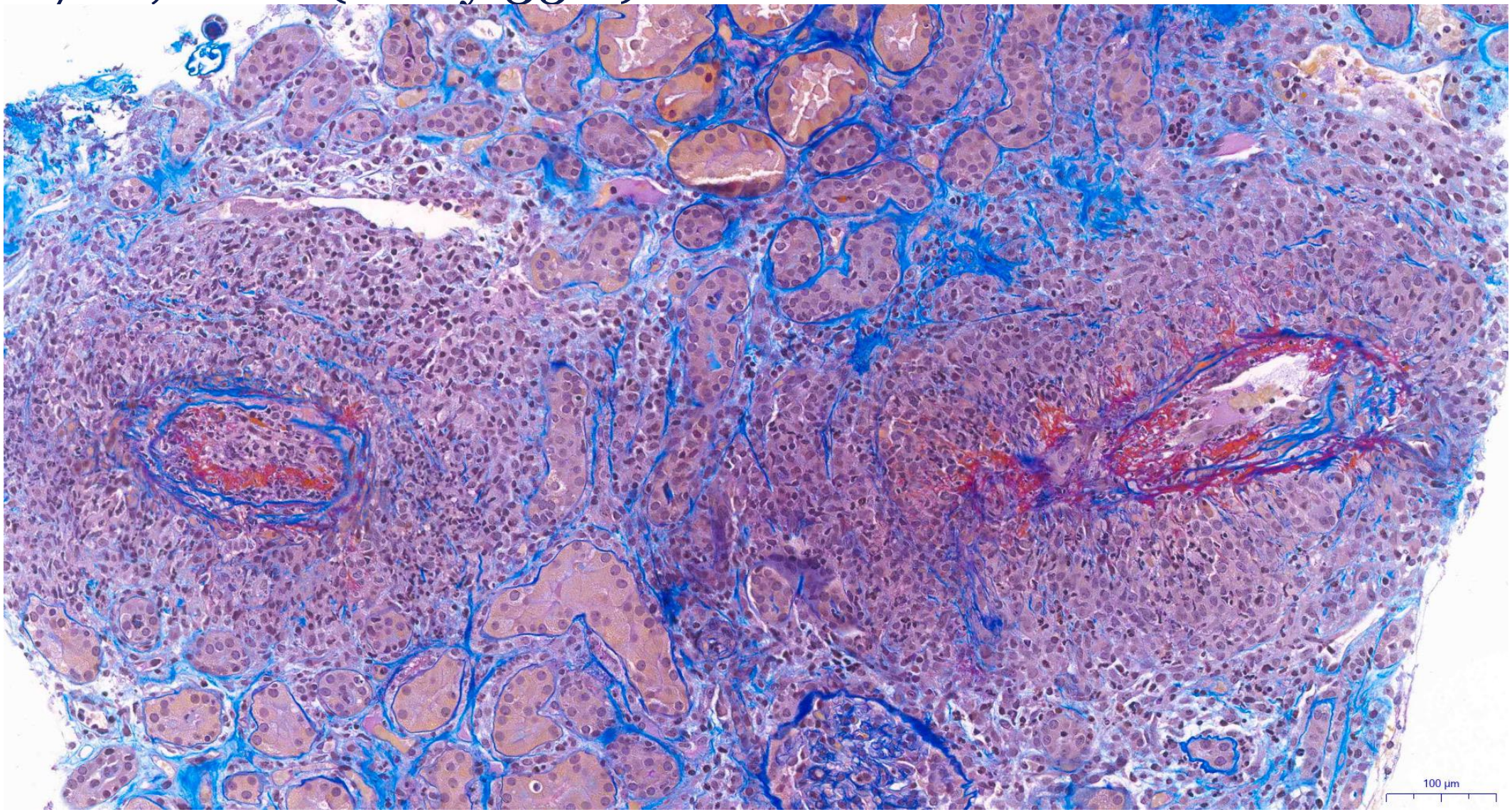
S.J. 70a, male

- Oct 25, – external teaching hospital border Upper/Lower AUT
- 1 wk of prodomi (hemorragic coughing, fever)
- Acute kidney injury (RPGN), Dyspnoe, pulmorenal syndrome (CT-accordingly)
- Anti-GBM neg
- PR3-cANCA pos
- Krea 9.1mg/dl, BUN 92 mg/dl, oliguria
- -> transfer to Bundeshauptstadt ;--)
- Kidney BX at arrival, then iHD

S.J. 70a, male (SFOG)



S.J. 70a, male (lucky 35%)

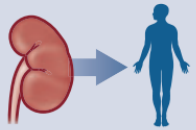


Long-term outcome of kidney function in patients with AAV
(RCTs 1995–2012 (NORAM, CYCAZAREM, CYCLOPS, MEPEX, IMPROVE, RITUXVAS, MYCYC)

End-stage kidney disease incidence

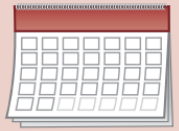
Overall 175/848 (21%)

Dialysis
n = 140 (80%)

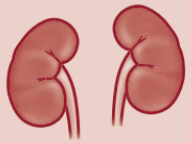


Transplant
n = 35 (20%)

Factors associated with end-stage kidney disease



Age > 65 years
1.68
(1.18–2.41)



eGFR
0.97
(0.93–0.99)

Haemoglobin
0.88
(0.78–0.98)

Hazard ratio
(95% CI)

Sanchez-Alamo B et al. EUVAS Nephrol Dial Transplant 2024 Aug 30;39(9):1483-1493

Prediction models for ESKD in AAV

Prognostic model	HR	95% CI	*P*-value
EUVAS/Berden histologic classification			
Focal	1.00	Reference	Reference
Crescentic	7.21	0.75–69.47	0.087
Mixed	3.47	0.43–28.22	0.245
Sclerotic	11.96	1.62–88.30	0.015
Mayo Clinic Chronicity Score[a]			
Mild	1.00	Reference	Reference
Moderate	1.13	0.42–3.03	0.812
High	4.35	1.84–10.28	0.001
Percentage of ANCA crescentic score (PACS), per each 10%	1.57	1.31–1.88	<0.001
ANCA renal risk score (ARRS)			
Mild risk	1.00	Reference	Reference
Moderate risk	1.42	0.32–6.35	0.646
High risk	7.09	1.66–30.29	0.008
Improved ANCA kidney risk score (AKRiS)			
Low risk	1.00	Reference	Reference
Moderate risk	2.99	1.02–8.78	0.046
High risk	4.61	1.40–15.14	0.012
Very-high risk	17.60	6.23–49.75	<0.001

Sandino-Bermuduez et al. Rheumatology, 2024, 00, 1–8 (Advance access publication)

Kidney transplantation prolongs life?

Journal of Nephrology (2019) 32:919–926
https://doi.org/10.1007/s40620-019-00642-x

REVIEW

Kidney transplantation in ANCA-associated vasculitis

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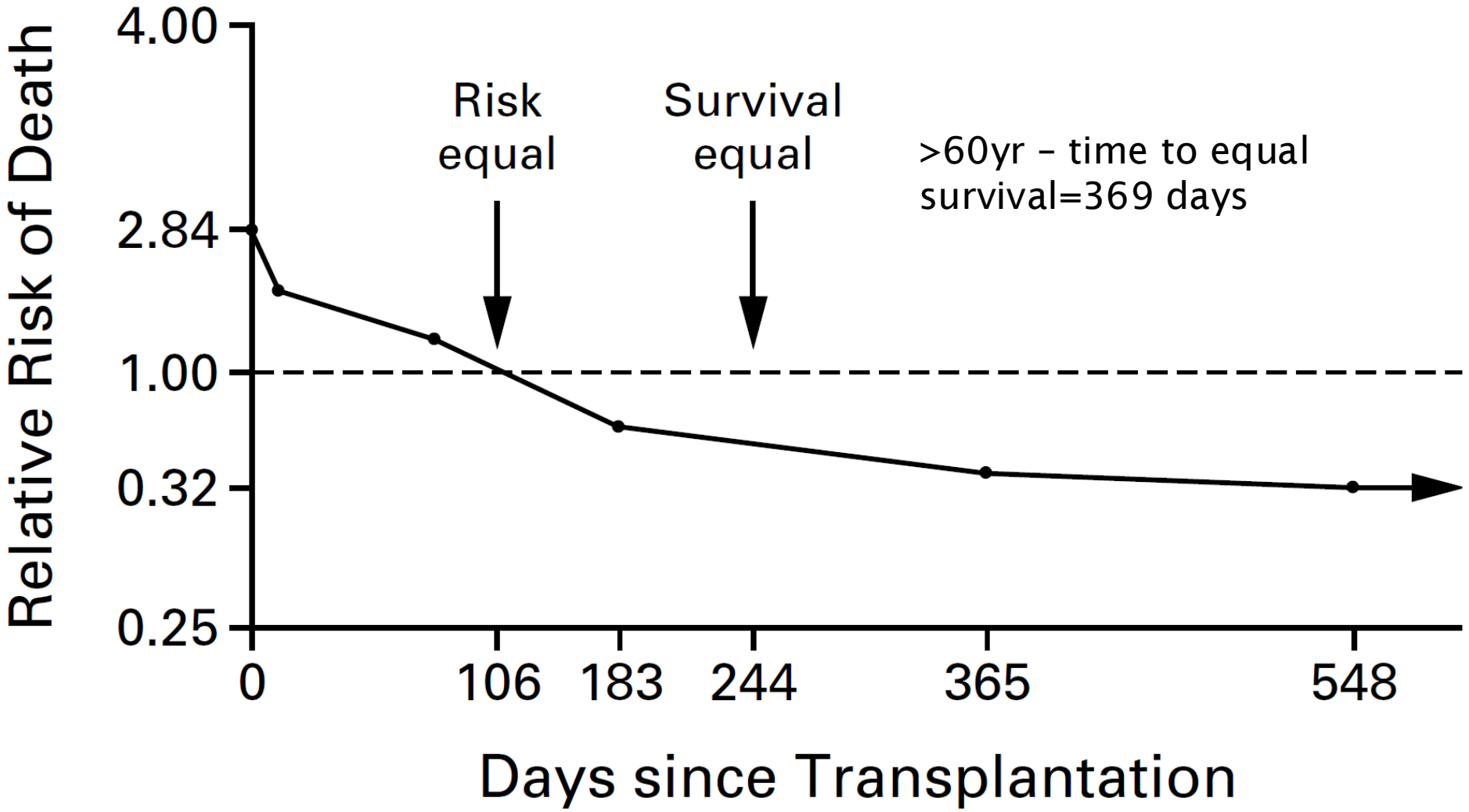
Outcome of kidney transplantation in AAV

As in other patient populations kidney transplantation offers a survival benefit for AAV patients as compared to patients on maintenance dialysis and a better quality of life [9]. A recent national cohort study of patients with ESRD due to GPA attributed the significant survival benefit largely due to a dramatic reduction in the risk of death due to cardiovascular disease [10]. Therefore, kidney transplantation has become the treatment of choice for AAV patients with ESRD.

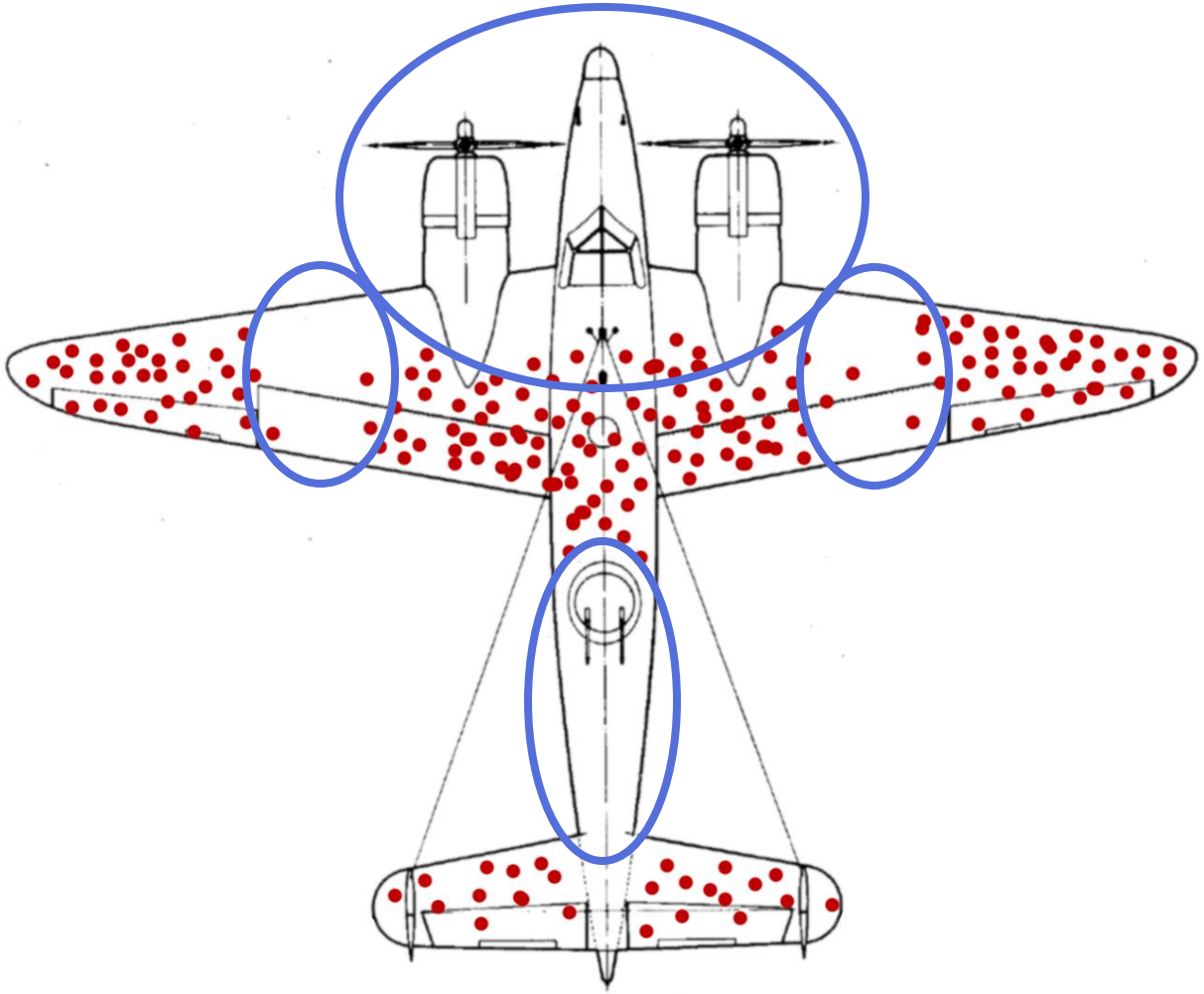
9. Wolfe RA, Ashby VB, Milford EL, Ojo AO, Ettenger RE, Agodoa LY, Held PJ, Port FK (1999) Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant. N Engl J Med 341(23):1725–1730
10. Wallace ZS, Wallwork R, Zhang Y, Lu N, Cortazar F, Niles JL,

aRR of death after 1st kidney transplant



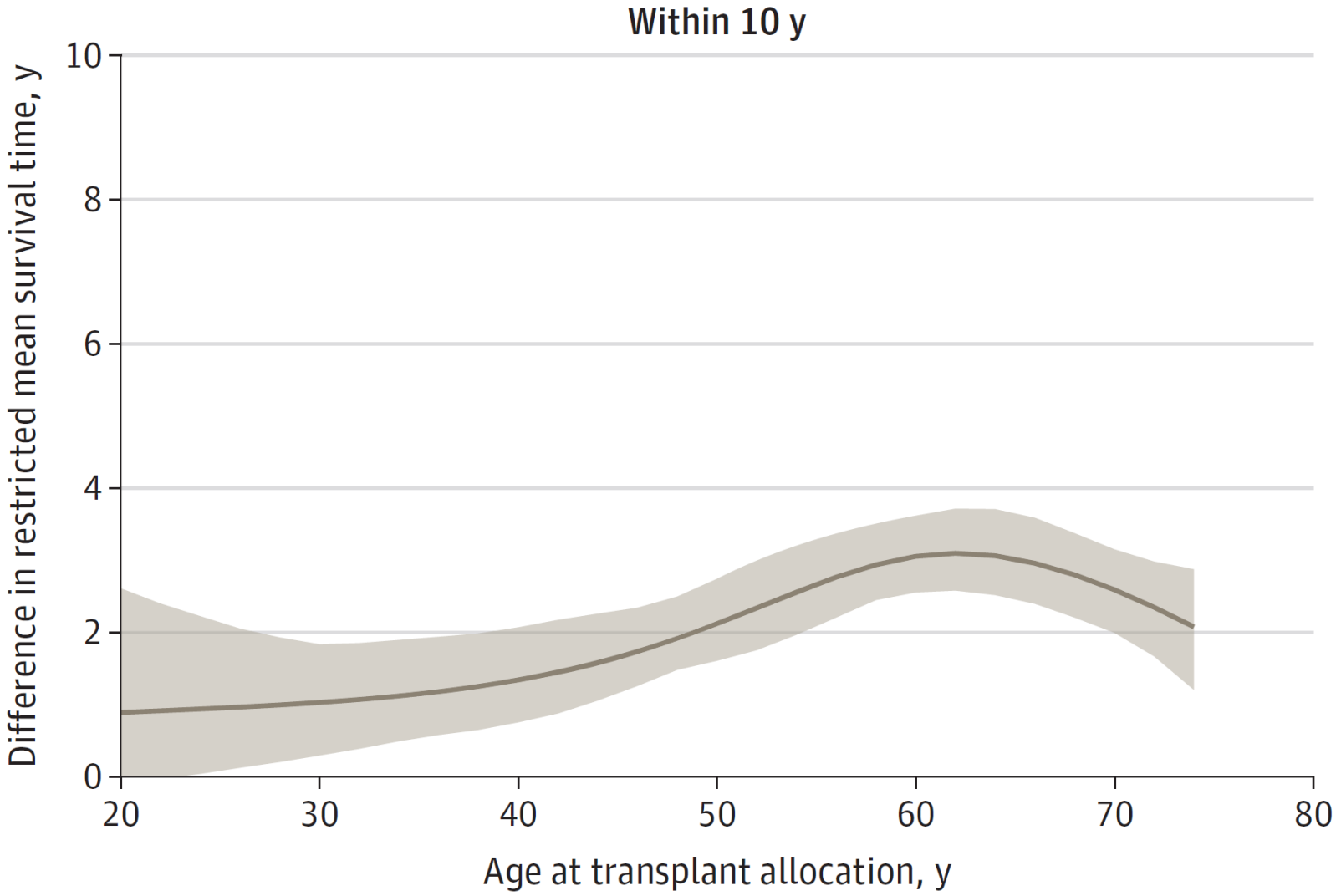
Wolfe T et al. NEJM 1999; 341:1725-30

Does KTX prolong life vs HD?



Wald A Annals of Mathematical Statistics,1939, S. 299-326

Kidney Transplant vs WL on Dialysis: Survival Benefit?



Strohmayer S et al. JAMA NO. 2022 Oct 3;5(10):e2234971

Relapse risk and outcome of AAV patients after kidney transplantation

Study	Publication year	Tx period	Number of patients	Relapse rate/patient/year	Relapse rate % (*N*)	Follow up after tx (months, mean/median)	Type of relapse	Graft survival	Patient survival
Schmitt et al. [15]	1993	1982–1993	20	0.10	25 (5)	48	5 nonrenal	NA	NA
Allen et al. [16]	1998	1974–1997	22 (24 grafts)	0.02	9.1 (2)	NA	2 nonrenal	5y: 69%	5y: 85%
Nachman et al. [17][a]	1999	1970–1997	127	0.07	17.3 (22)	44	12 renal, 10 nonrenal	NA	NA
Deegens et al. [18]	2003	1968–2000	33	0.01	3 (1)	62	1 nonrenal	5y: 60%	5y: 77%
Elmedhem et al. [19]	2003	1987–2000	9	0.04	22.2 (2)	62	2 nonrenal	NA	NA
Moroni et al. [20]	2007	1987–2006	19	0.08	36.8 (7)	58	7 renal	10y: 84%	10y: 87%
Little et al. [21]	2009	1987–2007	107	0.01	4.7 (5)	66	3 renal, 2 nonrenal	5y: 90% 10y: 70%	5y: 90% 10y: 65%
Gera et al. [22]	2010	1996–2005	35	0.02	8.6 (3)	53	3 nonrenal	5y: 100%	5y: 94%
Geetha et al. [23]	2011	1996–2010	85	0.02	8.2 (8)	64	4 renal, 4 nonrenal	5y: 98% 10y: 79%	5y: 93% 10y: 67%
Shen et al. [24]	2011	1996–2007	919	NA	1.3 (12)	NA	12 renal (7 graft losses)	5y: 82% 10y: 64%	5y: 91% 10y: 79%
Marco et al. [25]	2013	1984–2007	49	0.01	6.1 (3)	62	2 renal, 1 nonrenal	10y: 64%	10y: 67%
Tang et al. [26]	2013	1996–2010	93	NA	2.15 (2)	NA	2 renal (NA for nonrenal)	5y: 82% (MPA) 96% (GPA) 10y: 50% (MPA) 62% (GPA)	5y: 82% (MPA) 96% (GPA) 10y: 68% (MPA) 85% (GPA)
Göceroglu et al. [27]	2016	1984–2011	113	0.033	11.5 (13)	NA	14 renal, 2 nonrenal	1y: 95% 5y: 83%	5y: 95%
Buttigieg et al. [28]	2017	1987–2013	24 (34 grafts)	0.022	16.7 (4)	60	1 renal, 4 nonrenal	1y: 93% 5y: 71%	1y: 92% 5y: 88%

Sagmeister M et al. J Nephrol 2019 Dec;32(6):919-926

Registry data of patient and graft survival of AAV patients after kidney TX

Study	Publication year	Registry	Tx period	Number of patients	Graft survival	Patient survival
Briggs et al. [29]	1999	ERA-EDTA registry	1982–1990	GPA: 115 MPA: 112 PRD: 26,533	MPA/GPA/PRD 3y: 60%/70%/69%	MPA/GPA/PRD 3y: 77%/86%/91%
Schmitt et al. [30]	2002	CTS	1982–1993	WG: 378	10y: 65%	10y: 80%
Shen et al. [24]	2011	OPTN/UNOS	1996–2007	WG: 919 Other: 165,639	WG/other 5y: 82%/73% 9y: 64%/52%	WG/other 5y: 91%/86% 9y: 79%/73%
Tang et al. [26]	2013	ANZDATA	1996–2010	MPA: 46 GPA: 47 Other: 8193	MPA/GPA/other 5y: 82%/96%/85% 10y: 50%/62%/70%	MPA/GPA/other 5y: 82%/96%/92% 10y: 68%/85%/83%
Hruskova et al. [31]	2015	ERA-EDTA registry	1993–2012	AAV: 618 Matched controls: 2472	AAV/GN/DM/non-DM 10y: 64%/57%/46%/59%	AAV/GN/DM/non-DM 10y: 75%/71%/56%/71%
O'Shaughnessy et al. [32]	2017	USRDS	1996–2011	AAV: 1367 IgAN: 7379 ADPKD: 18,457 DM: 57,190	AAV/IgAN/ADPKD/DM 5y: 82%/86%/85%/70% 10y: 60%/70%/68%/43% 15y: 42%/58%/50%/24%	AAV/IgAN/ADPKD/DM 5y: 91%/97%/94%/83% 10y: 82%/93%/84%/67% 15y: 70%/90%/74%/56%
Wallace et al. [10]	2018	USRDS	1995–2014	GPA: 946	NA	1y: 96% 4y: 69%

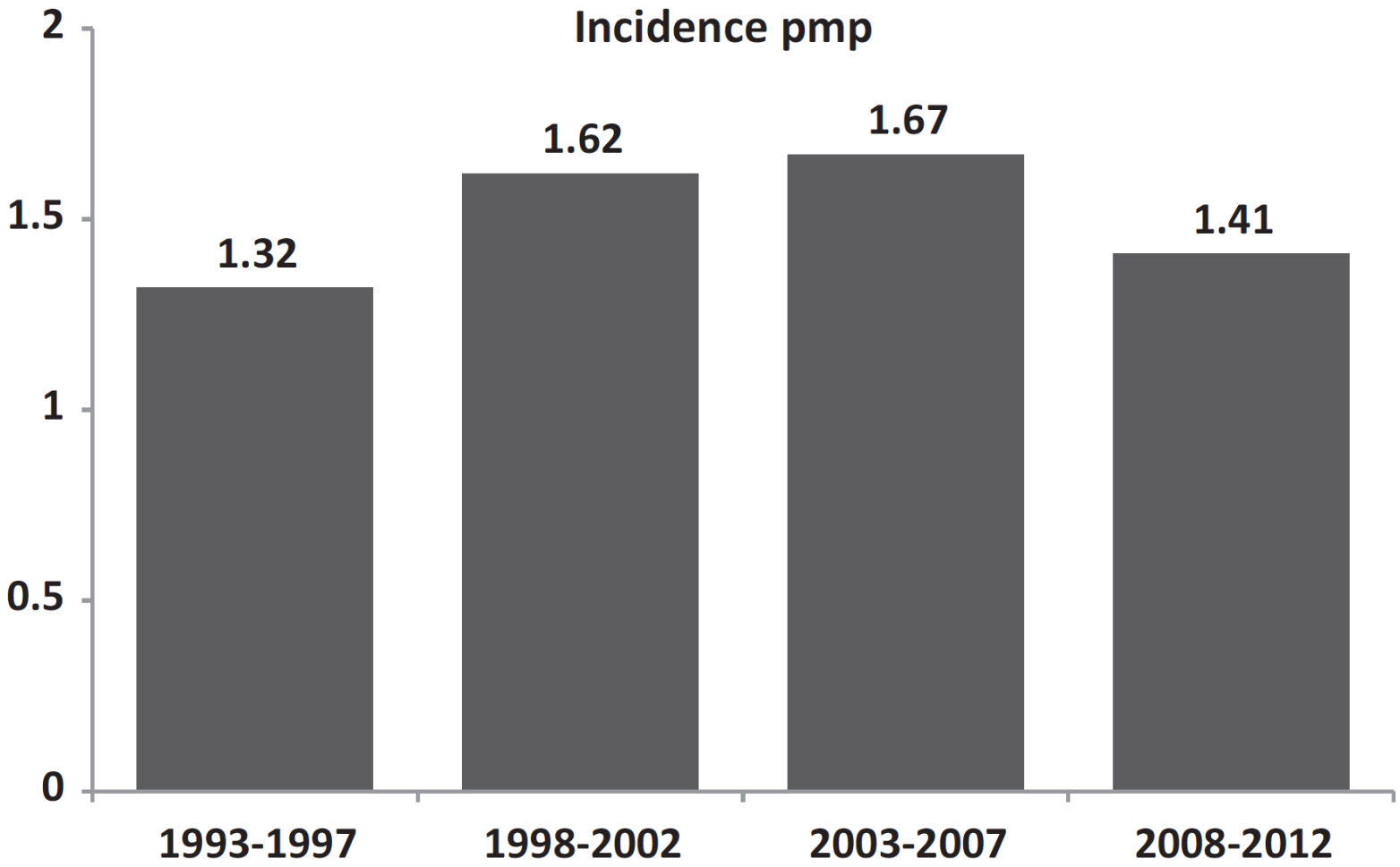
Sagmeister M et al. J Nephrol 2019 Dec;32(6):919-926

Reported four cases of de novo AAV after kidney transplantation

Reference	Asif et al., Schultz et al. [47, 48]	Tabata et al. [49]	Haruayama et al. [50]	Sagmeister et al. [51]
Gender, age (years)	Female, 38	Female, 34	Female, 61	Female, 65
Cause of ESRD	Unknown (ANCA negative)	IgA nephropathy	Chronic glomerulonephritis	ADPKD (ANCA negative)
Immunosuppression at time of AAV diagnosis	Cyclosporine (225 mg), methylprednisolone 4/6 mg alternatively	Mizoribine (100 mg), tacrolimus 4 mg, methylprednisolone 2 mg	Mizoribine (50 mg), prednisolone 5 mg	Cyclosporine (100 mg), prednisolone 5 mg
Time after transplantation	14 years	14 years 10 months	31 years	20 months
ANCA type	MPO-ANCA	MPO-ANCA	MPO-ANCA	PR3-ANCA
Kidney function (creatinine at baseline → at AAV diagnosis)	1.2 → 2.6 mg/dl	1.0 → 2.4 mg/dl	0.6 → 1.27 mg/dl	1.8 → 2.6 mg/dl
Kidney biopsy	Crescentic glomerulonephritis	Crescentic glomerulonephritis	Crescentic glomerulonephritis	Crescentic glomerulonephritis
Extra-renal manifestation	Subarachnoid hemorrhage	None	None	ENT
Treatment	MPS, oral cyclophosphamide	MPS	MPS	MPS, RTX, PLEX
Outcome	Creatinine 4 mg/dl at 6 months follow-up	Graft loss 5 years after diagnosis	Creatinine 1.1 mg/dl 2 years after diagnosis	Graft failure 4 months after diagnosis

Sagmeister M et al. J Nephrol 2019 Dec;32(6):919-926

Incidence of RRT for ESKD due to AAV – an ERA Analysis



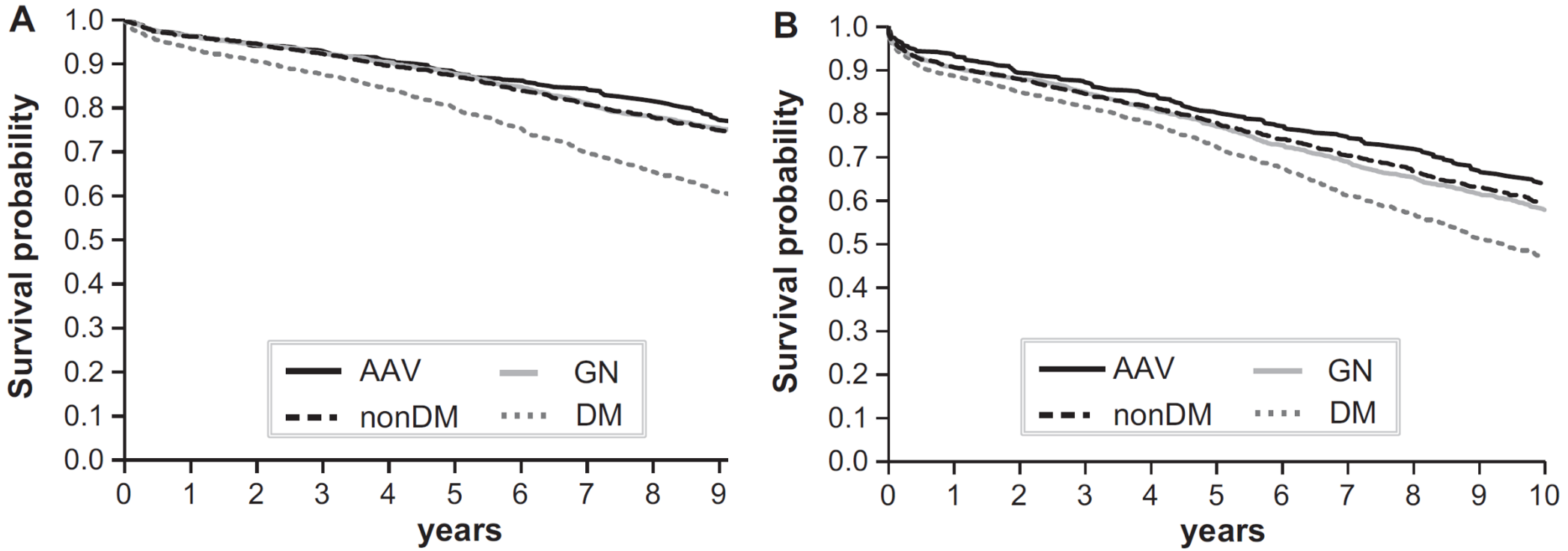
Hruskova Z et al. ERA. Am J Kidney Dis. 2015;66(4):613-620

Causes of Death in Patients Who Initiated RRT for Kidney Failure Due to AAV

	AAV (n = 2,511; 1,439 deaths), %	Control: GN (n = 10,044; 5,712 deaths)		Control: DM (n = 10,044; 6,971 deaths)		Control: Non-DM (n = 10,044; 6,071 deaths)	
		%	*P*[a]	%	*P*[a]	%	*P*[a]
Cardiovascular causes	27.3	38.2	<0.001	42.4	<0.001	34.7	<0.001
Myocardial ischemia/infarction	8.1	9.7	0.07	12.8	<0.001	9.2	0.1
Heart failure	6.2	8.0	0.02	8.0	0.07	7.8	0.06
Cardiac arrest; other cause/unknown	8.6	13.3	<0.001	14.5	<0.001	11.4	0.01
Cerebrovascular accident	4.4	7.2	<0.001	7.1	<0.001	6.4	0.006
Infection	23.0	17.1	<0.001	17.6	0.002	15.6	<0.001
Suicide/refusal of treatment	4.0	2.6	0.008	2.9	0.08	2.9	0.08
Withdrawal	6.7	4.8	<0.001	5.4	0.02	5.1	0.003
Cachexia	3.7	3.4	0.7	2.3	0.01	3.0	0.3
Malignancy	8.3	8.3	0.4	4.2	<0.001	10.3	0.5
Miscellaneous	12.5	11.5	0.6	9.9	0.07	12.4	0.7
Unknown/unavailable/missing	14.5	14.2	0.6	15.5	0.8	15.9	0.4

Hruskova Z et al. ERA. Am J Kidney Dis. 2015;66(4):613-620

Patient (A) and Graft (B) Survival after kidney transplantation



Hruskova Z et al. ERA. Am J Kidney Dis. 2015;66(4):613-620

Patient and Graft Survival after kidney transplantation

	Death After Kidney Transplantation			Transplant Failure After Kidney Transplantation		
	AAV vs GN	AAV vs DM	AAV vs Non-DM	AAV vs GN	AAV vs DM	AAV vs Non-DM
Unadjusted	0.87 (0.72-1.06)	0.53 (0.44-0.64)	0.84 (0.69-1.01)	0.81 (0.69-0.95)	0.59 (0.51-0.69)	0.82 (0.70-0.96)
Adjusted for time period and country	0.86 (0.71-1.04)	0.52 (0.43-0.63)	0.81 (0.67-0.99)	0.80 (0.68-0.94)	0.58 (0.49-0.68)	0.82 (0.69-0.96)

Hruskova Z et al. ERA. Am J Kidney Dis. 2015;66(4):613-620

Summary

- 20% of AAV progress to ESKD
- ~1% of all ESKD are caused by AAV
- Between 3% and 20% of AAV cases receive a KTX
- Relapse rate <<10%
- Patient and graft survival is similar to (or even better than) other causes of ESKD
- Higher rate of infections and malignancies
- De novo AAV after KTX is ultra rare

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Gekürzte Verschreibungsinformationen

Schweiz:

Tavneos®. Z: Avacopan. **I:** Tavneos, als ergänzende Therapie zu einer immunsuppressiven Standardbehandlung auf Basis von Rituximab oder Cyclophosphamid mit Glukokortikoiden, ist für die Behandlung erwachsener Patienten mit schwerer aktiver ANCA Vaskulitis (GPA/MPA) indiziert. **D:** Orale Einnahme morgens und abends 2x täglich 30 mg (3 Kapseln zu je 10 mg) mit Nahrung. **KI:** Überempfindlichkeit gegen den Wirkstoff oder einen der Hilfsstoffe. **VM:** Hepatotoxizität; Angioödem; Überwachung des Blutbildes (weisse Blutkörperchen); Schwere Infektionen; Reaktivierung des Hepatitis-B-Virus; Herzbeschwerden; Bösartige Tumore; Macroglycerinhydroxystearat. **S/S:** Eine Anwendung während der Schwangerschaft und bei Frauen im gebärfähigen Alter, die keine Verhütungsmethode anwenden, ist nicht empfohlen. Es ist nicht bekannt, ob Avacopan in die Muttermilch ausgeschieden wird. Der Nutzen des Stillens für das Kind sollte gegen den Nutzen der Behandlung für die Patientin abgewogen werden. **UW:** Sehr häufig: Infektion der oberen Atemwege, Nasopharyngitis; Kopfschmerzen; Erbrechen, Durchfall, Übelkeit; erhöhter Lebertest; verminderte Anzahl weisser Blutkörperchen. Häufig: Lungenentzündung, Infektion der unteren Atemwege, Influenza, Bronchitis, Zellulitis, Infektion der Harnwege, Herpes zoster, Sinusitis, orale Candidose, Herpes im Mundbereich, Otitis media, Rhinitis, Gastroenteritis; Neutropenie; Oberbauchschmerzen; Anstieg der Kreatinphosphokinase im Blut. Gelegentlich: Angioödeme. **IA:** Avacopan ist ein Substrat von CYP3A4. Die gleichzeitige Verabreichung von Induktoren oder Inhibitoren dieses Enzyms kann die Pharmakokinetik von Avacopan beeinflussen. Siehe Fachinformation. **P:** Tavneos 10 mg: 30 und 180 Hartkapseln. **Liste B**. Detaillierte Informationen**:** www.swissmedicinfo.ch. Stand der Information**:** Januar 2024. **Zulassungsinhaberin:** Vifor Fresenius Medical Care Renal Pharma Ltd., St. Gallen. **Vertrieb:** Vifor Pharma Switzerland AG, CH-1752 Villars-sur-Glâne |

▼Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Für weitere Informationen, siehe Fachinformation TAVNEOS® auf www.swissmedicinfo.ch.

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Tavneos® Fachkurzinformation
Tavneos®10mg Hartkapsel

Zusammensetzung: Jede Hartkapsel enthält 10 mg Avacopan. Sonstige Bestandteile mit bekannter Wirkung:245 mg Macrogolglycerolhydroxystearat(Ph.Eur). **Anwendungsgebiete:** Tavneos® ist in Kombination mit einem Rituximab- oder Cyclophopamid-Dosierungsschema indiziert zur Behandlung erwachsener Patienten mit schwerer aktiver Granulomatose mit Polyangiitis (GPA) oder mikroskopischer Polyangiitis (MPA). **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen der sonstigen Bestandteile. **Pharmakotherapeutische Gruppe:** Komplement-Inhibitoren **ATC- Code:** L04AJ05 **Inhaber der Zulassung:** Vifor France, 100-101 Terrasse Boieldieu Tour Franklin La Defense 8 92042 Paris La Defense Cedex, Frankreich. Rezept- und apothekenpflichtig. Weitere Angaben zu Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln oder sonstigen Wechselwirkungen, Schwangerschaft und Stillzeit und Nebenwirkungen sowie Gewöhnungseffekten sind der veröffentlichten Fachinformation zu entnehmen. Stand der Information: Mai 2023

▼Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Dies ermöglicht eine schnelle Identifizierung neuer Sicherheitsdaten. Angehörige der Gesundheitsberufe werden gebeten, alle Verdachtsfälle von unerwünschten Wirkungen zu melden.