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

CSL Vifor

Histopathologische Scores und eGFR-Prädiktion

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Göttingen

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UNIVERSITÄTSMEDIZIN GÖTTINGEN UMG ST. JOSEF-STIFT SENDENHORST

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München 23.11.2024

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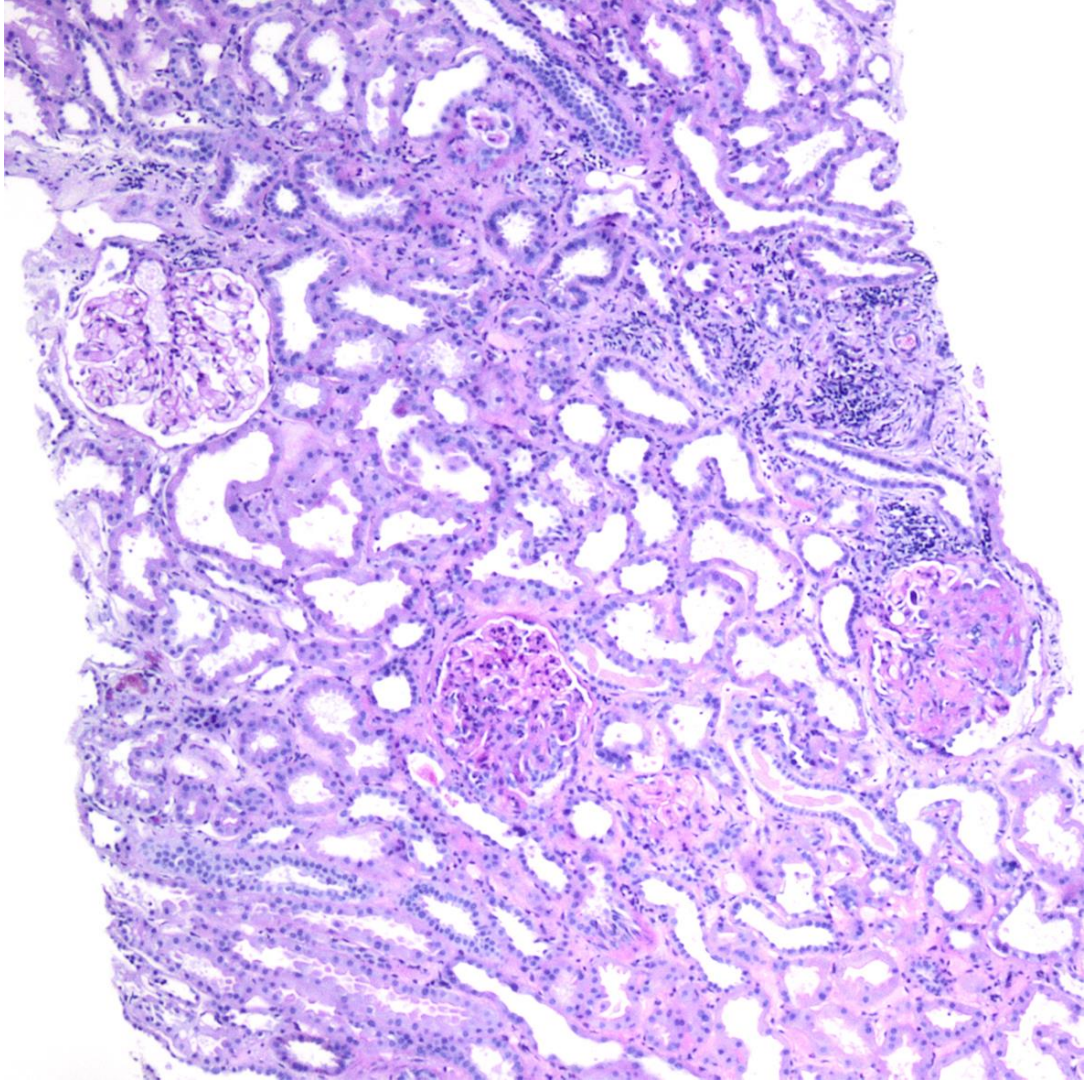
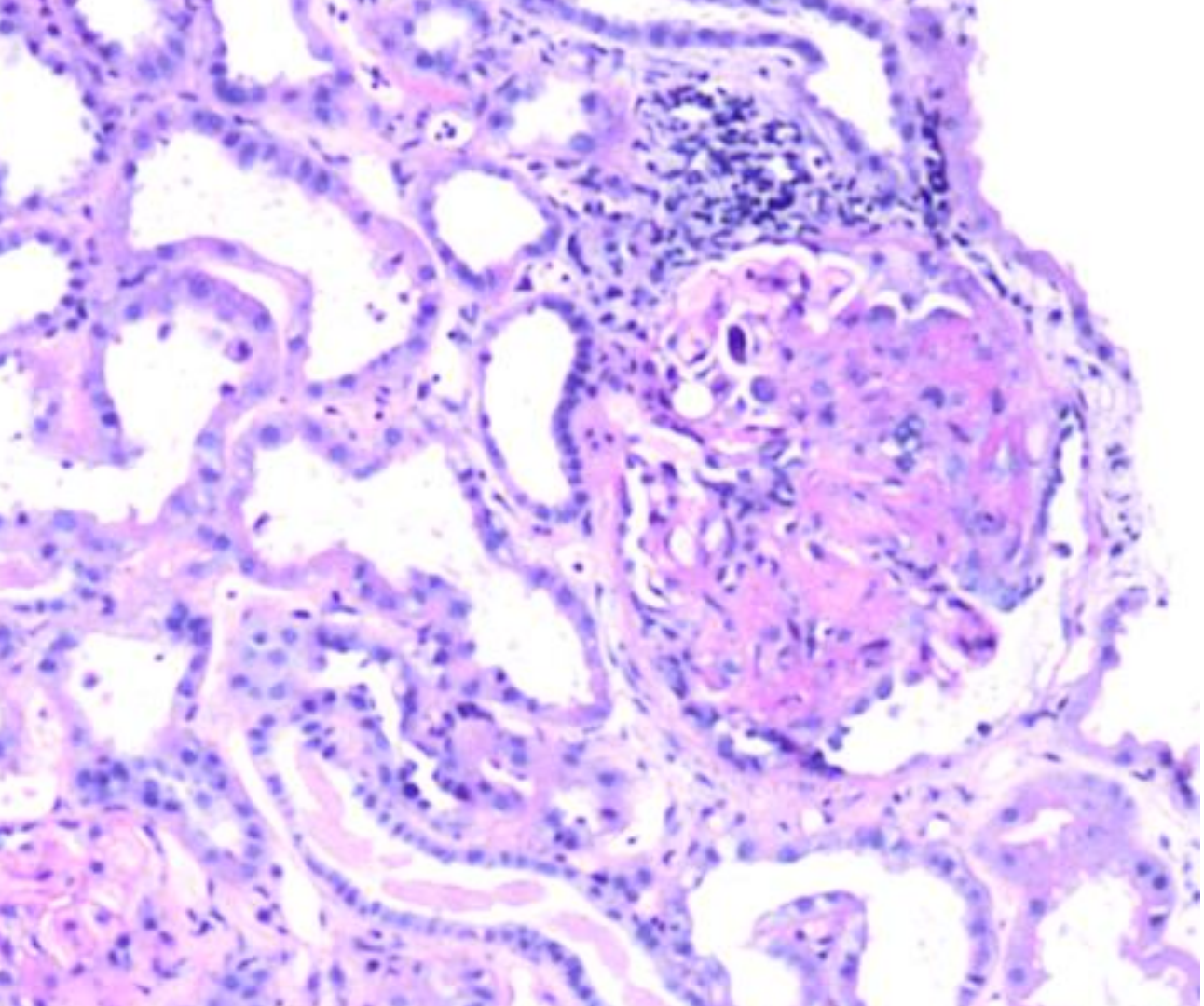
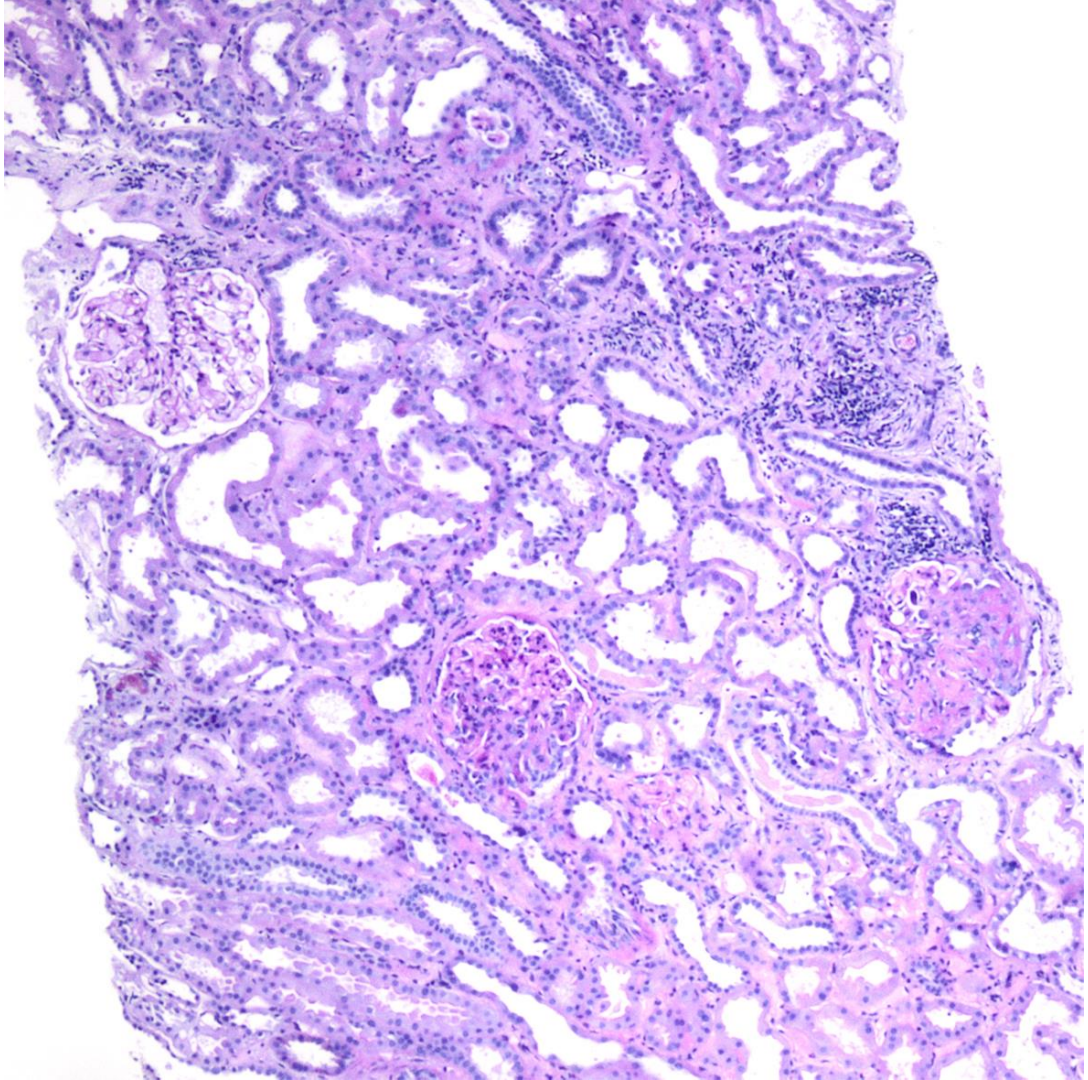
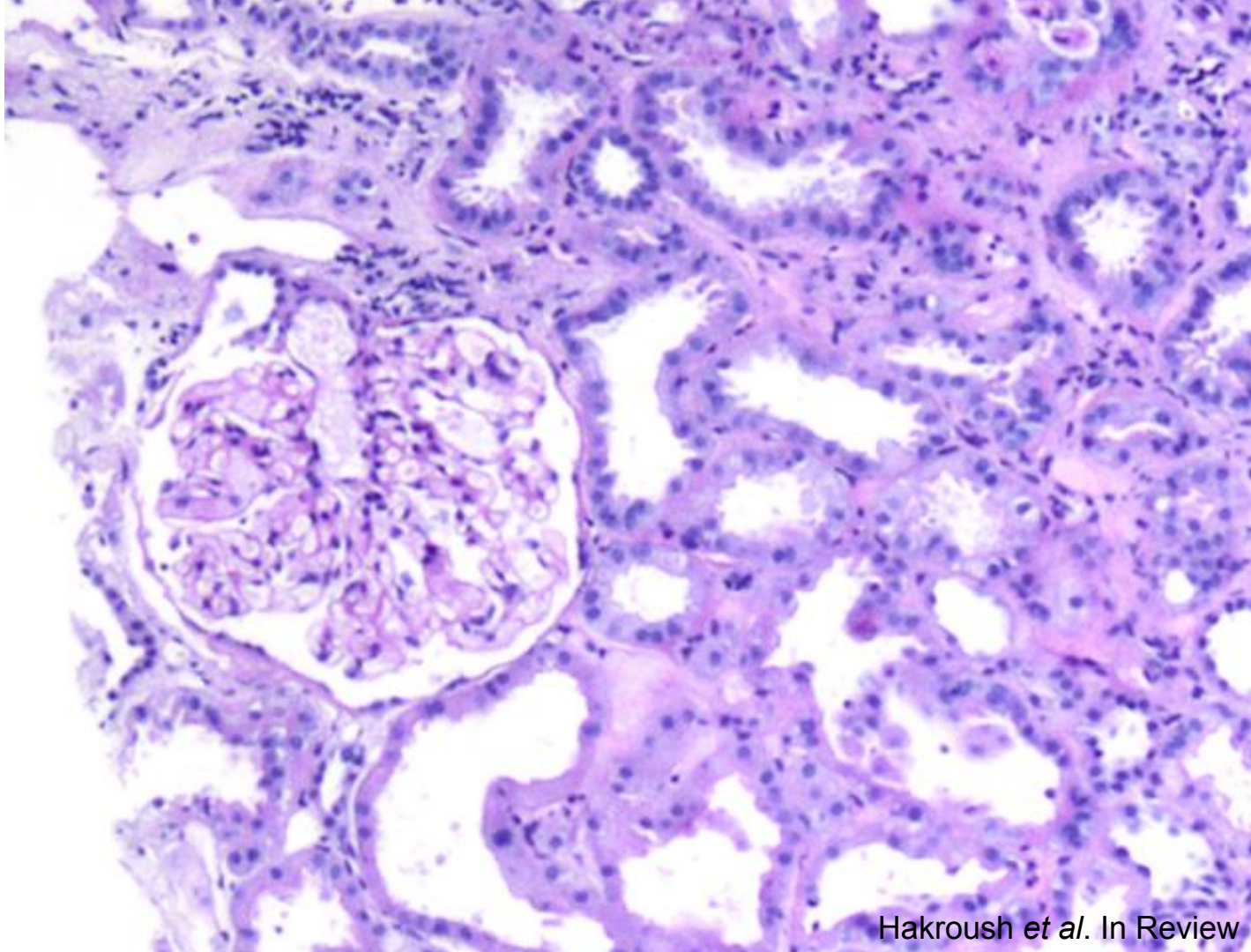
Disclosures

Wissenschaftliche Unterstützung durch
Vifor Pharma, Evotec SE

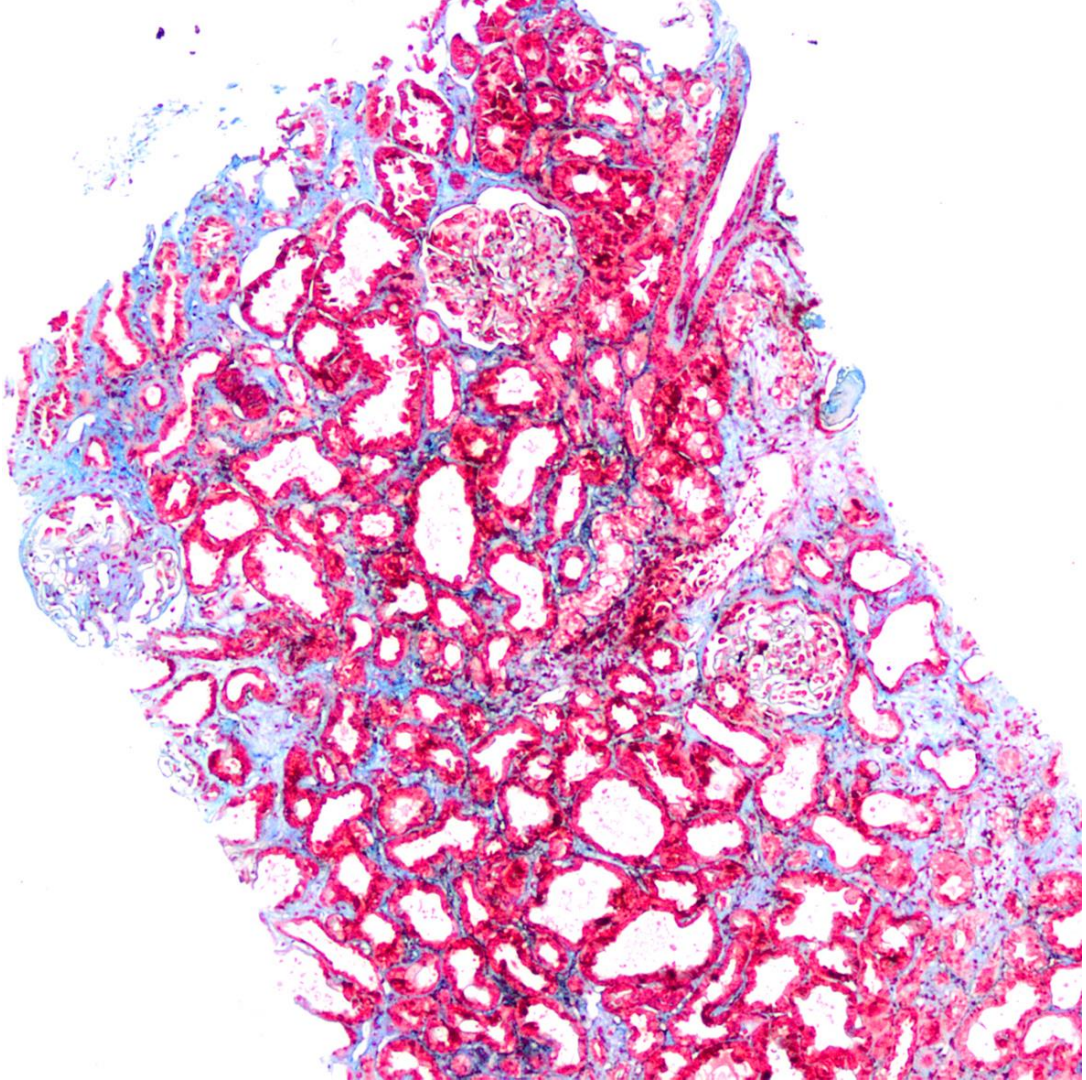




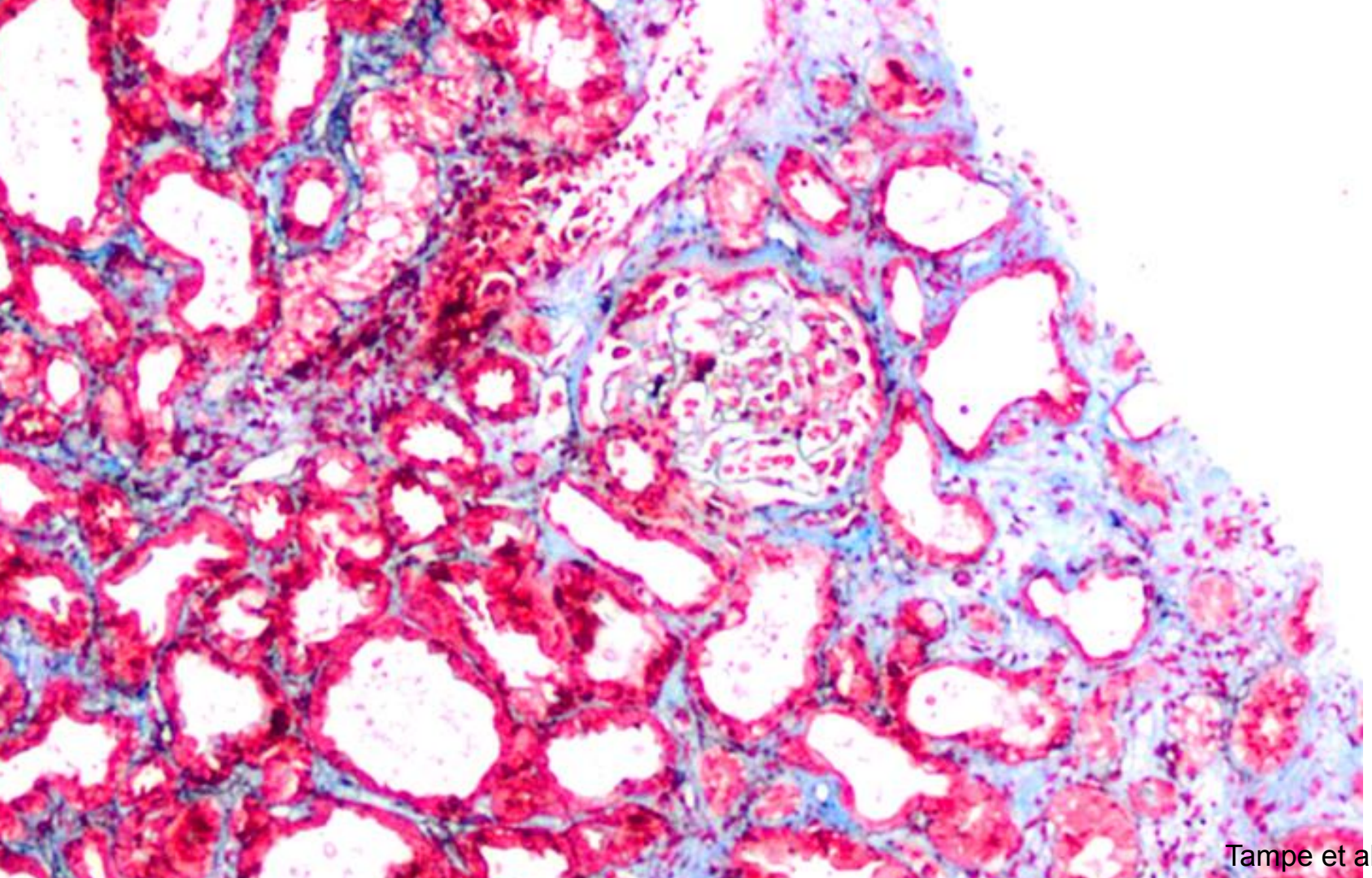




Hakroush *et al*. In Review



Tampe et al. *Cells* 2021



Tampe et al. *Cells* 2021

60TH ERA CONGRESS
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JUNE 15-18, 2023

ANCA Renal Risk Score 2023: the updated and revised ARRS

Sebastian Bate[1,2], Dominic McGovern[3,4], Francesca Costigliolo[5,6], Pek Ghe Tan[7,8], Vojtech Kratky[9,10], Jennifer Scott[11], Gavin Chapman[12], Nina Brown[13,14], Lauren Floyd[13,15], Benoit Brilland[16], Eduardo Martín[17], Mehmet F Aydin[18], Duha Ilyas[13,19], Arslan Butt[14], Marek Kollar[20], Jennifer Lees[3,4], Abdülmecit Yıldız[18], Andrea Hinojosa[17], Ajay Dhaygude[13,15], Stephen A Roberts[1,2], Thorsten Wiech[21], Charles D Pusey[22], Rachel B Jones[23,24], David R W Jayne[23,24], Ingeborg Bajema[25], Charles Jennette[26], Avi Rosenberg[27], Kate Stevens[3,4], Jean Francois Augusto[16], Juan Mejía-Vilet[17], Neeraj Dhaun[12], Stephen P McAdoo[7,22], Vladimir Tesar[9,10], Mark A Little[11], Geetha Duruvu[28], Silke R Brix[1,19,29]

NHS Manchester University NHS Foundation Trust

MANCHESTER 1824 The University of Manchester

BACKGROUND

Reliable prediction tools are needed to improve prognostication and personalisation of treatment in anti-neutrophil cytoplasmic antibody (ANCA) glomerulonephritides (GN). We aimed to validate and update the ANCA Renal Risk Score (ARRS) prediction model[1].

METHODS

The ARRS working group collated a retrospective multicenter international longitudinal cohort from referral centers and registries across the globe to revise the ARRS in a validation and recalibration study. The primary endpoint was end stage kidney disease (ESKD). Patients were censored at last follow-up. Cox proportional hazards models were used to reweight risk factors and develop a modified scoring system. Kaplan-Meier estimates, Harrell's C statistics and calibration plots were used to assess model performance.

Baseline characteristics

Patients (n)	1439
Age (median; IQR)	64.0 (53.0-73.0)
Male sex (n; %)	750 (52.1)
Creatinine (median µmol/L; IQR)	234.0 (150.3-402.0)
eGFR (median mL/min; IQR)	21.0 (10.9-36.4)

eGFR, estimated glomerular filtration rate.

RESULTS

Clinical Outcome

Follow up (years)	3.6 (1.1-5.9)
Kidney Recovery (n; %)	136/291 (46.7)
ESKD (n; %)	325 (22.6)
Death (n; %)	315 (21.9)
Death without ESKD (n; %)	199 (13.8)

ESKD, end stage kidney disease.

ARRS Validation

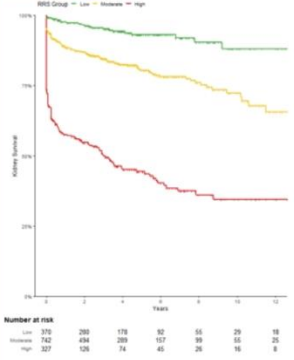

Figure 1 | Kidney survival according to the stratification of the Original ANCA Renal Risk Score (ARRS). Kaplan-Meier curve depicting development of end stage kidney disease (ESKD) of patients with ANCA glomerulonephritis. Patients of the development cohort are assigned points according to eGFR (G0: ≥15 ml/min/1.73 m², G1: ≤15 ml/min/1.73 m²), percentage of normal glomeruli in the kidney biopsy (N0: >25%, N1: 10-25%, N2: <10%) and degree of IFTA (T0: none/mild or ≤25%, T1: ≥ mild to moderate or ≥25%). Points are calculated (G0=0, G1=3, N0=0, N1=4, N2=6, T0=0, T1=2) and risk groups created – low (0), moderate (2 - 7), and high-risk group (8 – 11). Number of patients at risk in each group at each time point is stated below the graph. Patient outcomes differ per risk group, C=0.800, P<0.001.

Recovery of Kidney Function

Derivation cohort n= 185

Variables	HR	CI	P
Age	1.266	(0.890-1.802)	0.189
Sex: Male	0.892	(0.620-1.282)	0.536
Antibody: PR3	0.995	(0.982-1.008)	0.443
eGFR	1.007	(0.987-1.028)	0.499
Log(Creatinine)	1.011	(1.004-1.017)	<0.001
Normal Glomeruli (%)	0.440	(0.305-0.633)	<0.001
Crescentic Glomeruli (%)	1.266	(0.890-1.802)	0.189
IFTA: ≥ Mild - Moderate	0.892	(0.620-1.282)	0.536

eGFR, estimated glomerular filtration rate; IFTA, interstitial fibrosis and tubular atrophy; PR3, proteinase 3; HR, Hazard ratio; CI, confidence interval; P, p value.

End Stage Kidney Disease

Derivation cohort n= 1130

Variables	HR	CI	P
Age	1.006	(0.994-1.018)	0.362
Sex: Male	1.309	(0.924-1.853)	0.130
Antibody: PR3	0.863	(0.613-1.215)	0.399
eGFR	1.027	(1.011-1.043)	0.001
Log(Creatinine)	5.764	(3.802-8.738)	<0.001
Normal Glomeruli (%)	0.977	(0.968-0.987)	<0.001
Crescentic Glomeruli (%)	0.997	(0.992-1.003)	0.294
IFTA: ≥ Mild - Moderate	1.812	(1.251-2.624)	0.002

Regression Tree

Figure 2 | Regression tree dividing patients according to kidney outcome.

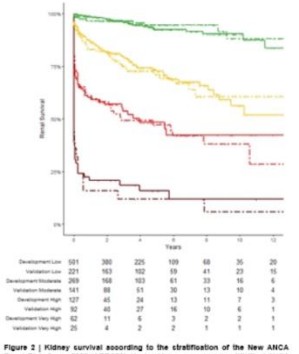

Figure 2 | Kidney survival according to the stratification of the New ANCA Renal Risk Score 2023 (ARRS23). Kaplan-Meier curve depicting ESKD of ANCA GN patients of the development (solid line) and validation cohort (dashed line). Patients are assigned points as per the ARRS23 according to creatinine (K0: <250 µmol/l, K1: 250-450 µmol, K2: >450 µmol), percentage of normal glomeruli (N0: >25%, N1: 10-25%, N2: <10%) and IFTA (T0: none/mild or <25%, T1: ≥ mild-moderate or ≥25%). Patient outcomes differ per risk group, C=0.831, P<0.001.

CONCLUSIONS

We demonstrated the out-of-sample validity of the ARRS and present here the modified and improved score to optimise prognostication and risk stratification for clinical practice and trials.

REFERENCE

1 Brix SR, Noriega M, Tennstedt P, et al. Development and validation of a renal risk score in ANCA-associated glomerulonephritis. Kidney Int. 2018 Dec;94(6):1177-1188. doi: 10.1016/j.kint.2018.07.020.

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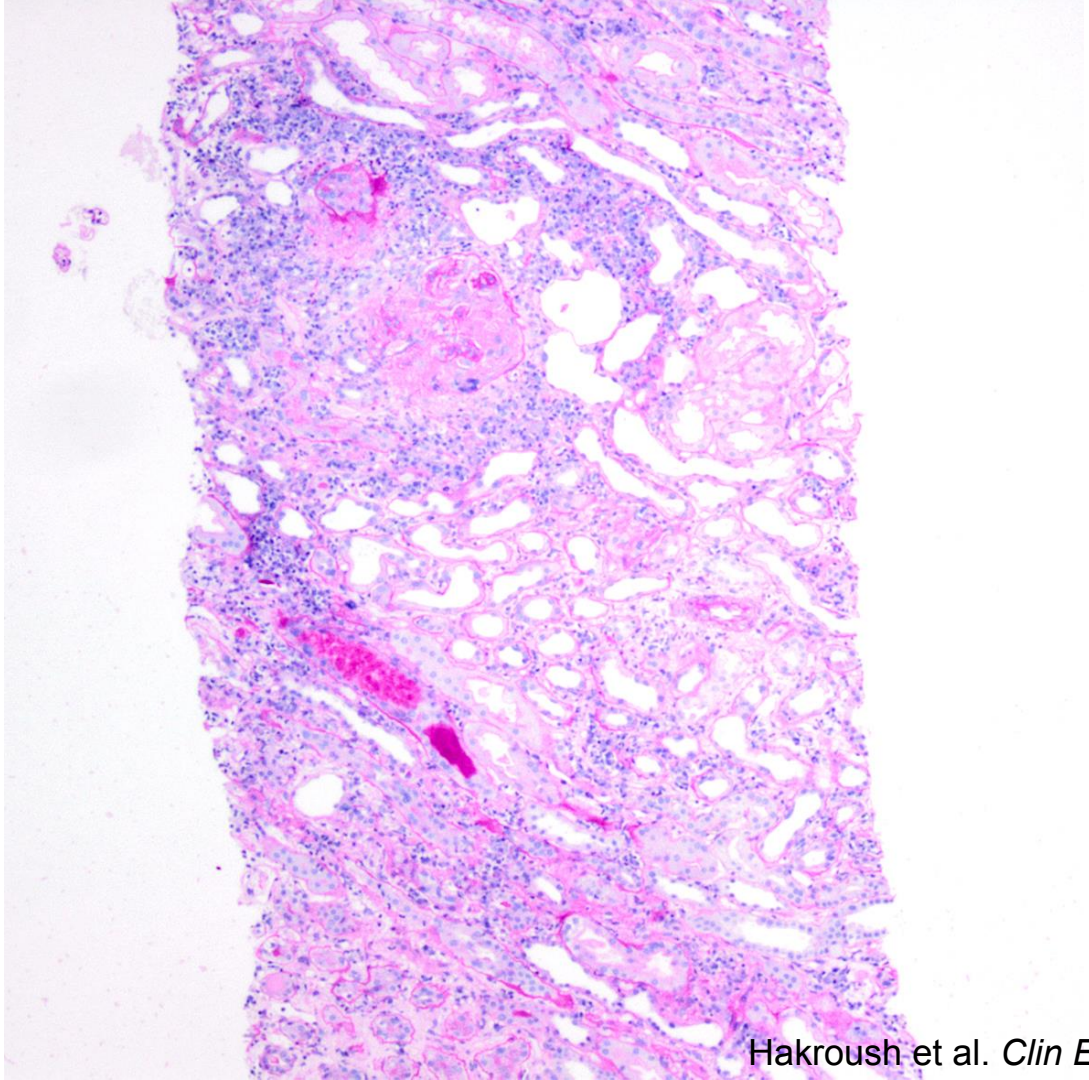
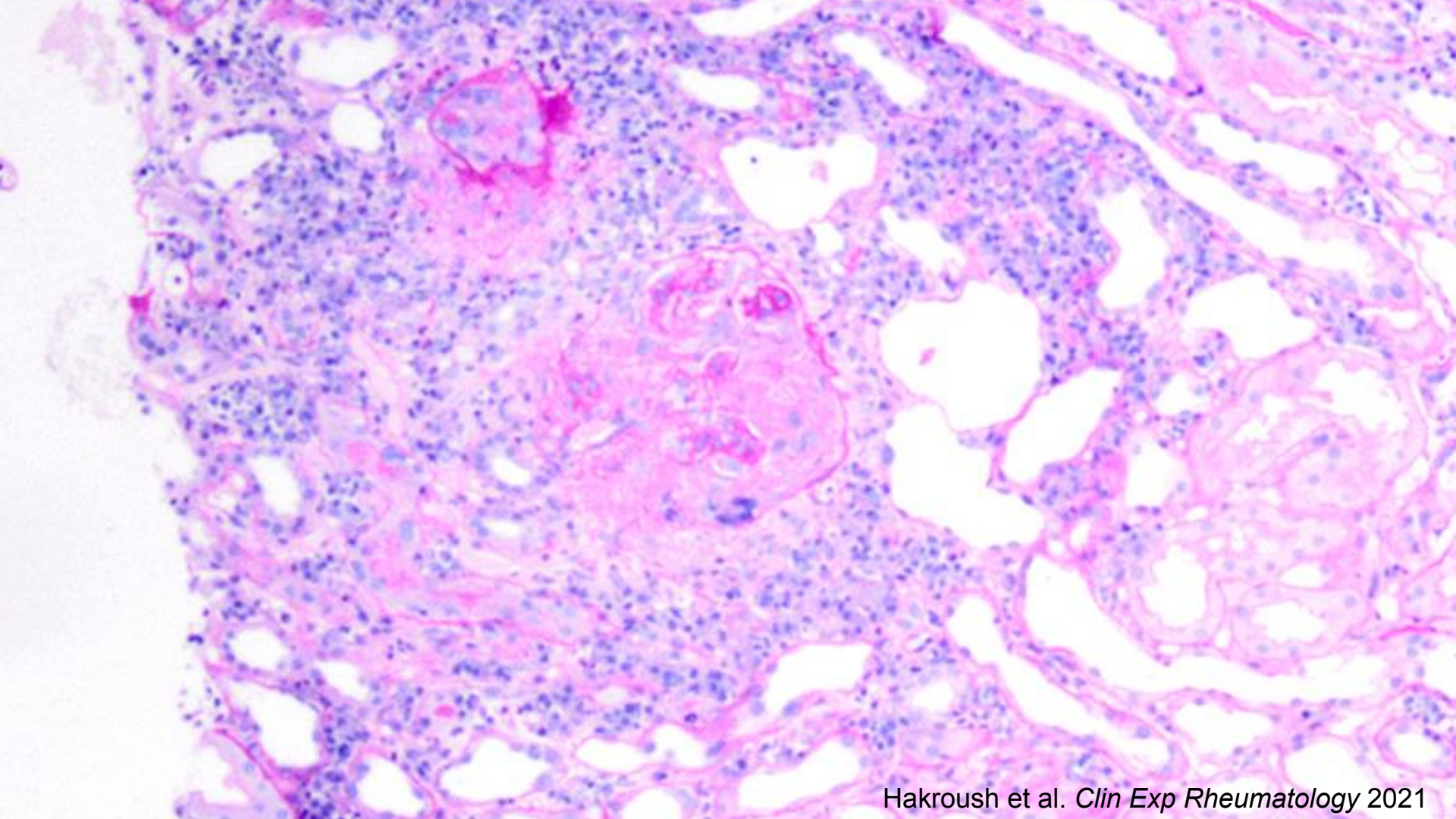
Interstitielle Läsionen bei ANCA-RPGN?

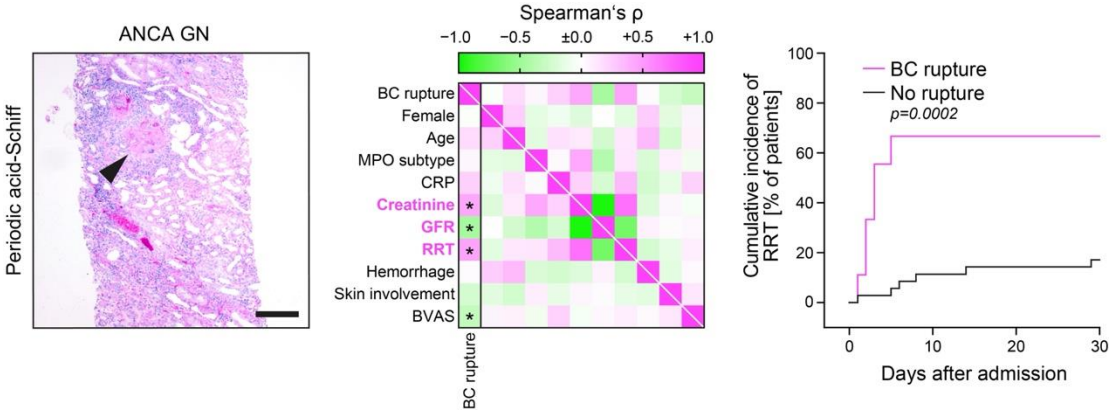


Hakroush et al. *Clin Exp Rheumatology* 2021



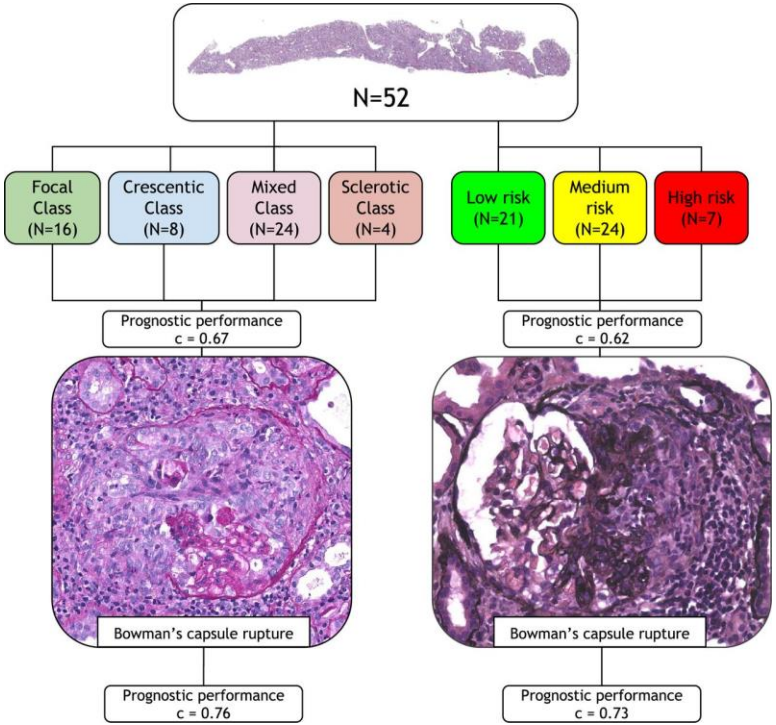
Hakroush et al. *Clin Exp Rheumatology* 2021

Bowman‘s Kapselruptur ist mit schlechtem renalen Kurzzeit-Outcome bei ANCA-RPGN assoziiert



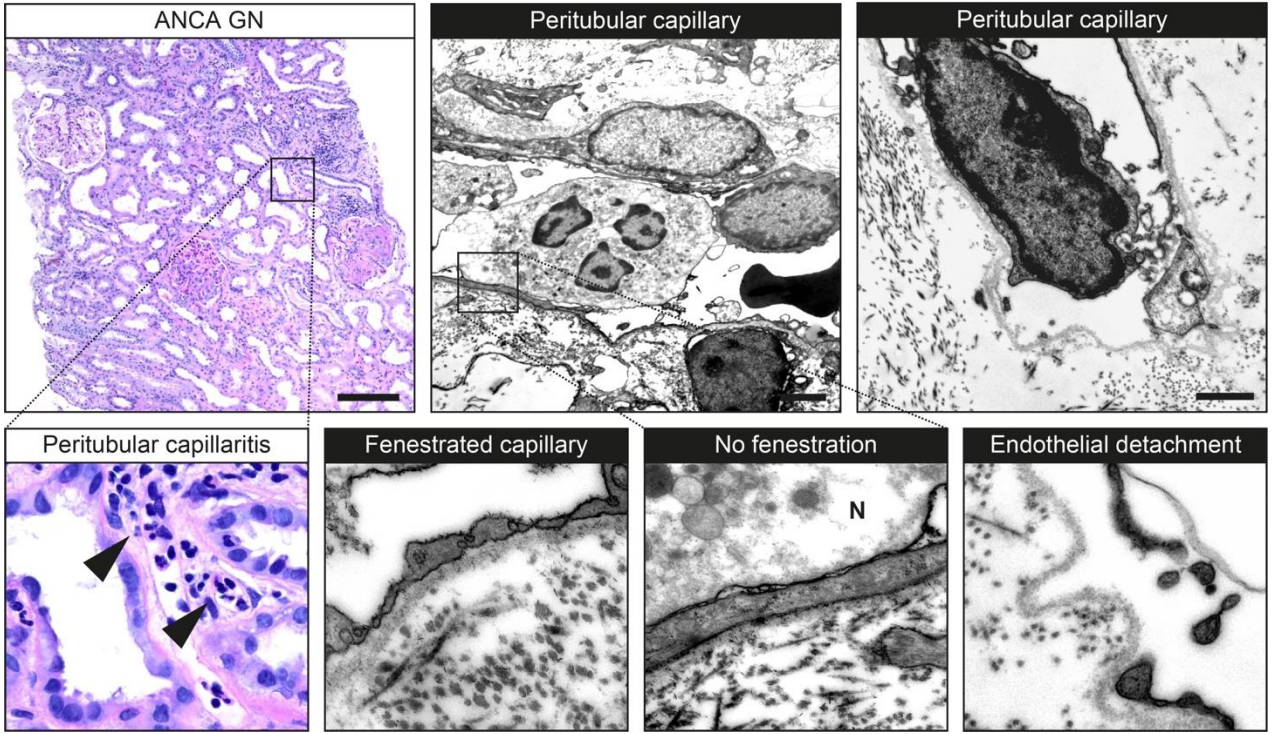
Hakroush et al. *Clin Exp Rheumatology* 2021

Bowman‘s Kapselruptur ist mit schlechtem renalen Langzeit-Outcome bei ANCA-RPGN assoziiert



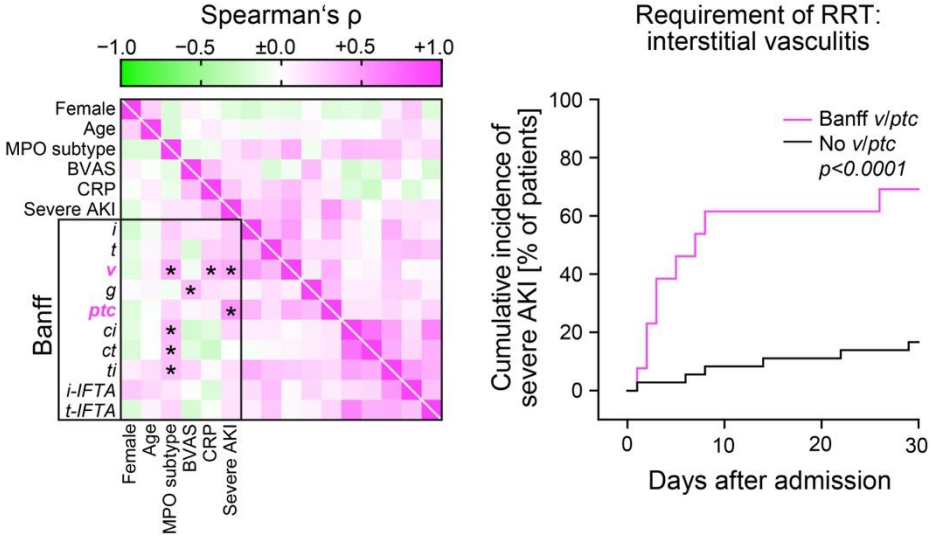
L’Imperio *et al*. ARD 2020

Peritubuläre Kapillaritis bei ANCA-RPGN: Zeichen der interstitiellen Kleingefäßvaskulitis



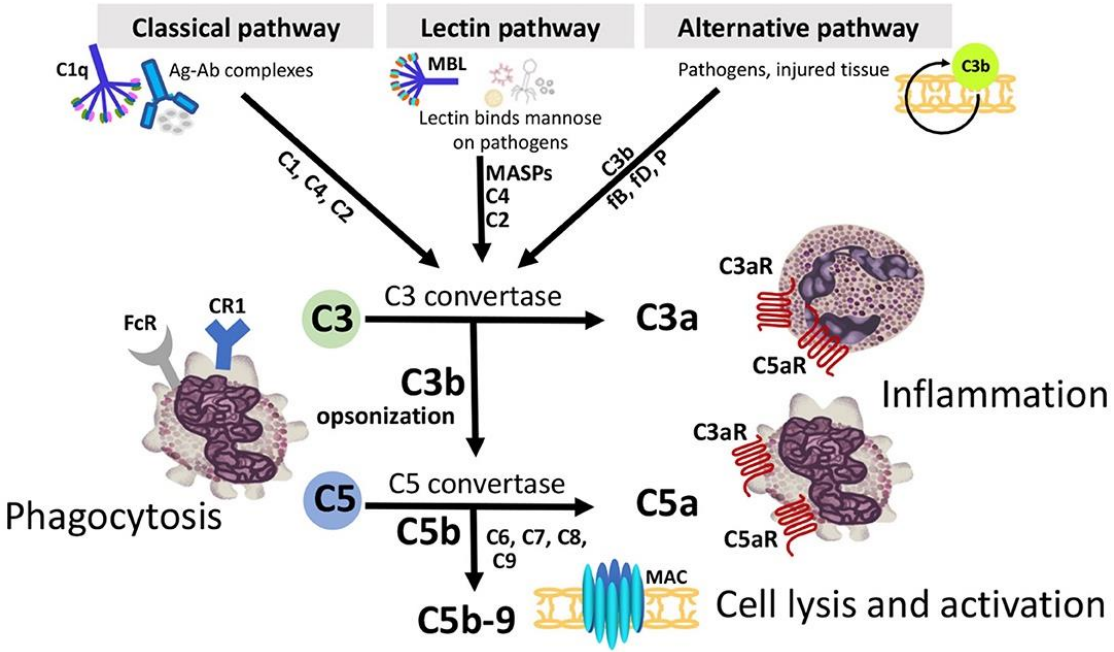
Hakroush *et al*. In Revision

Peritubuläre Kapillaritis bei ANCA-RPGN ist assoziiert mit Dialysepflicht im kurzzeitigen Verlauf



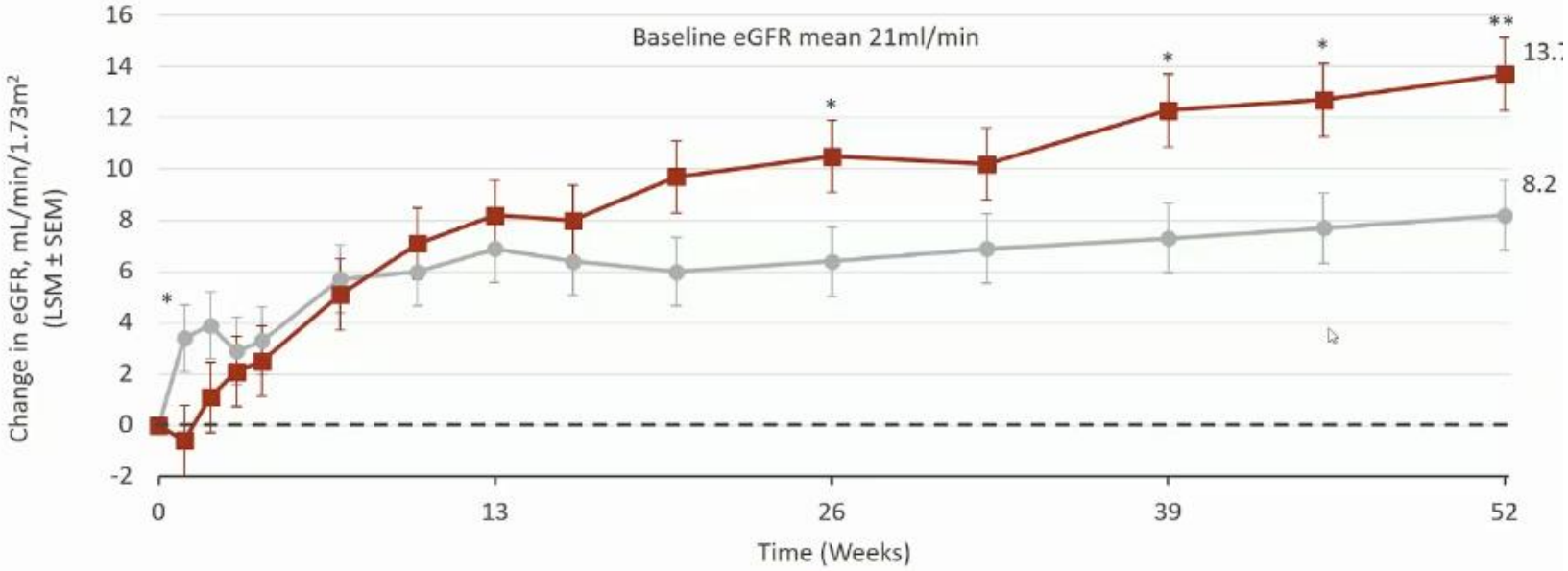
Hakroush *et al*. In Review

Das Komplementsystem



Girardi et al. *Frontiers Immunology* 2022

Change in eGFR for subgroup with GFR < 30ml/min/1.73 m^2 at baseline (subgroup analysis)



*P<0.05
**P<0.01 for avacopan compared to prednisone
This study was not powered to detect differences in the secondary/exploratory endpoints
LSM, least squares mean; SEM, standard error of the mean; GC, glucocorticoid
Jayne DR et al. *N Engl J Med* 2021; 384: 599-609; Jayne DR et al. J Am Soc Nephrol 2021 (Oral presentation FR-OR63 ASN Kidney Week 2021).

Jayne. ERA-EDTA 2022

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Change in Albuminuria in Patients with ANCA-Associated Vasculitis Treated with Avacopan

Duvuru Geetha,[1] Frank B. Cortazar,[2] Alexandre Karras,[3] Annette Bruchfeld,[4,5] Huibin Yue,[6] Peter A. Merkel,[7] and David R.W. Jayne[8] for the ADVOCATE Study Group

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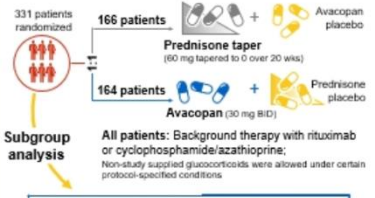
BACKGROUND

- Urinary albumin:creatinine ratio (**UACR**) is an important biomarker of active glomerulonephritis, a common complication of ANCA-associated vasculitis (AAV)
- High UACR levels and low estimated glomerular filtration rates (eGFR) are associated with the long-term risk of end-stage kidney disease, cardiovascular disease, and death[1]
- In the Phase 3 **ADVOCATE** trial,[2] reduction in UACR at earlier timepoints was observed in the **avacopan** group compared to the prednisone-tapering regimen

AIM

To compare the time to achieve the maximum mean difference in percent change in UACR from baseline between the avacopan and prednisone taper groups in the ADVOCATE trial (NCT02994927)

METHODS



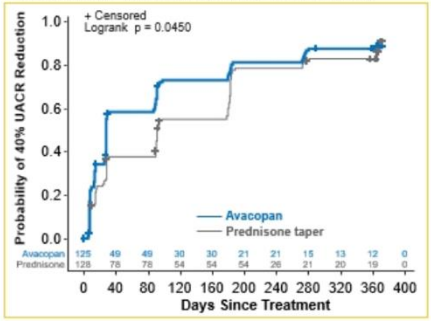
Time to achieve maximum mean difference in percent change in UACR used Kaplan-Meier survival analysis

SUBGROUP RESULTS

Baseline UACR (mg/g)

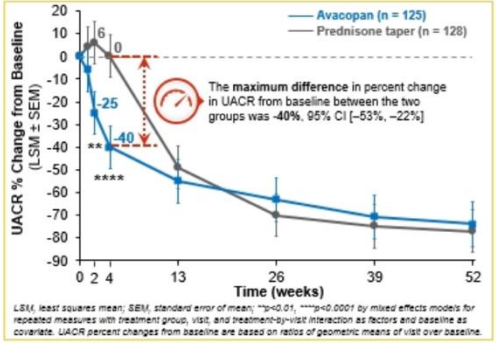
	Avacopan	Prednisone taper
Geometric mean	433	312
Range	20 to 6,461	11 to 5,367

Figure 2. Time to 40% Reduction UACR in the Avacopan vs Prednisone Taper Groups (Post Hoc Analysis)



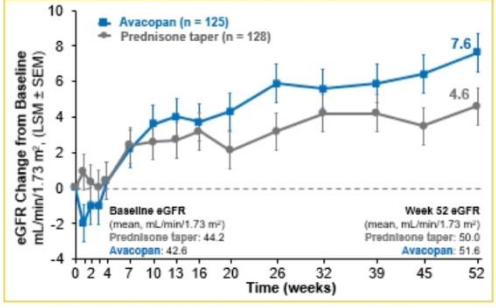
	Achieved 40% UACR Reduction		Median time to 40% UACR Reduction	
	%	n/N	No. of days	95% CI
Avacopan	84%	105/125	29 days	[29, 88]
vs				
Prednisone taper	83%	106/128	92 days	[91, 180]

Figure 1. Percent Change in UACR from Baseline in the Avacopan vs Prednisone Taper Groups (Pre-Specified Analysis)



*LSM, least squares mean; SEM, standard error of mean; **p<0.01, ****p<0.0001 by mixed effects models for repeated measures with treatment group, visit, and treatment-by-visit interaction as factors and baseline as covariate. UACR percent changes from baseline are based on ratios of geometric means of visit over baseline.*

Figure 3. Change in eGFR from Baseline in the Avacopan vs Prednisone Taper Groups (Post Hoc Analysis)



KEY TAKEAWAYS

- In the ADVOCATE trial, **UACR improved three times faster** in the avacopan group vs the prednisone taper group
- The **faster improvement in UACR** seen in patients with AAV (granu… with polyangiitis or microsco… polyangiitis) receiving avacopan suggests more rapid control of glomerular inflammation, which **may have contributed to the observed subsequent greater eGFR improvement** over time

ADDITIONAL INFORMATION

Disclosures: DG, FBC, AB, DRWJ, PAM: Consulting fees from Amgen. **AK, AB, DRWJ:** Consulting and/or lecture fees from CSL Vifor. **HY:** Employee of Amgen.

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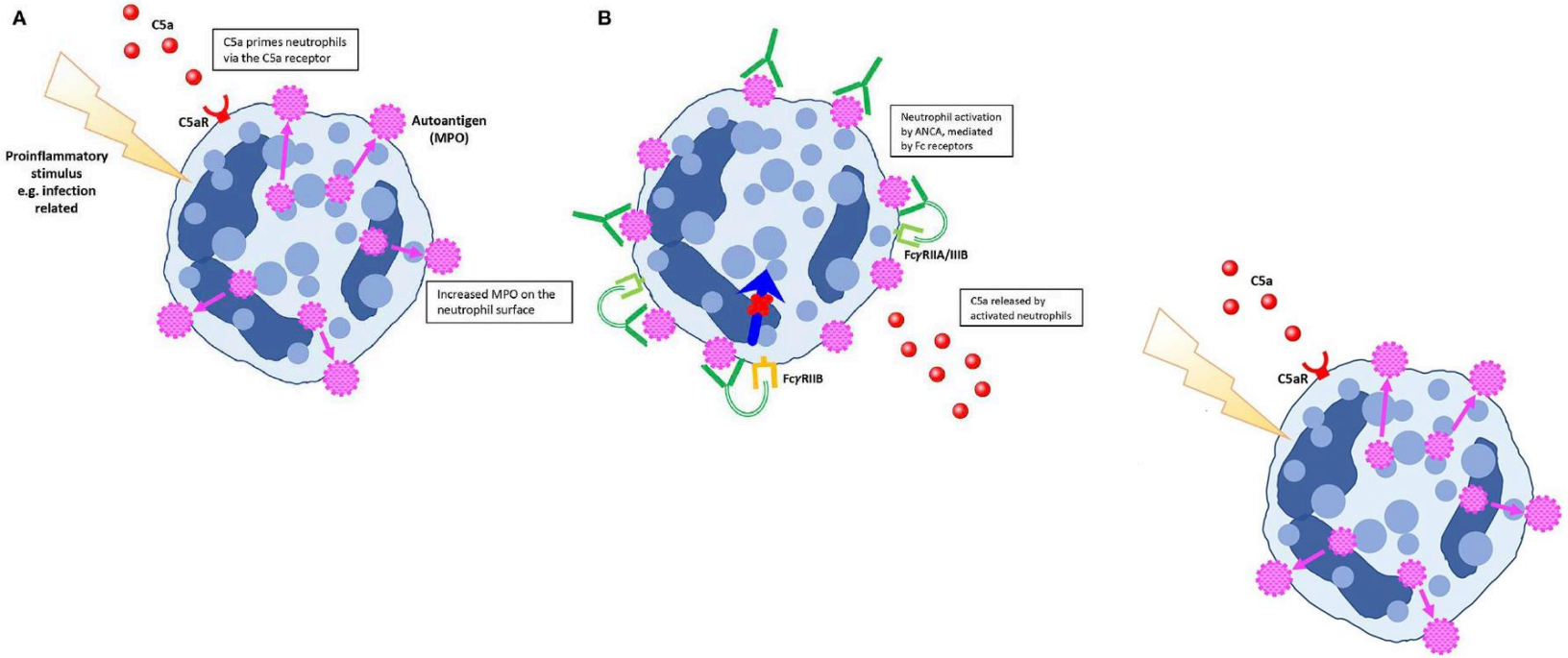
1. Levey AS, Grams ME, Inker LA. Uses of GFR and Albuminuria Level in Acute and Chronic Kidney Disease. *N Engl J Med*. 2022;386(22):2120-2128.
2. Jayne DRW, Merkel PA, Schall TJ, Bekker P. Avacopan for the Treatment of ANCA-Associated Vasculitis. *N Engl J Med*. 2021;384(7):599-609.

CONTACT | medinfo@amgen.com

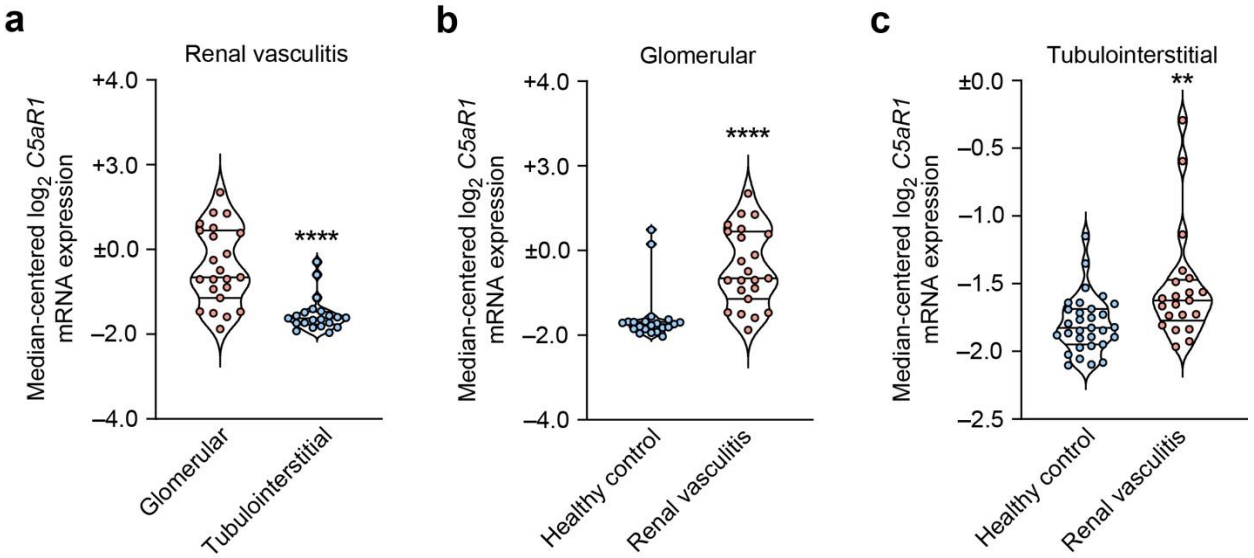
C5a/C5aR-vermittelter Mechanismus der Neutrophilen-Aktivierung



Shochet et al. *Frontiers Immunology* 2020 (modified)

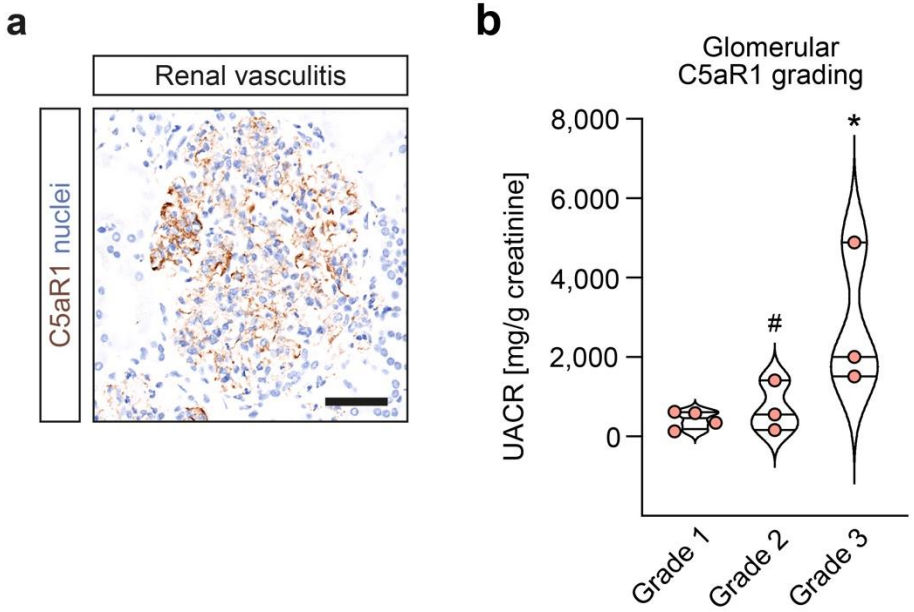
Senkung der uACR-Senkung durch C5aR1-Blockade: Direkte Effekte in Podozyten?

Prädominante C5aR1-Expression im glomerulären Kompartment in ANCA-RPGN



Korsten *et al.* In Review

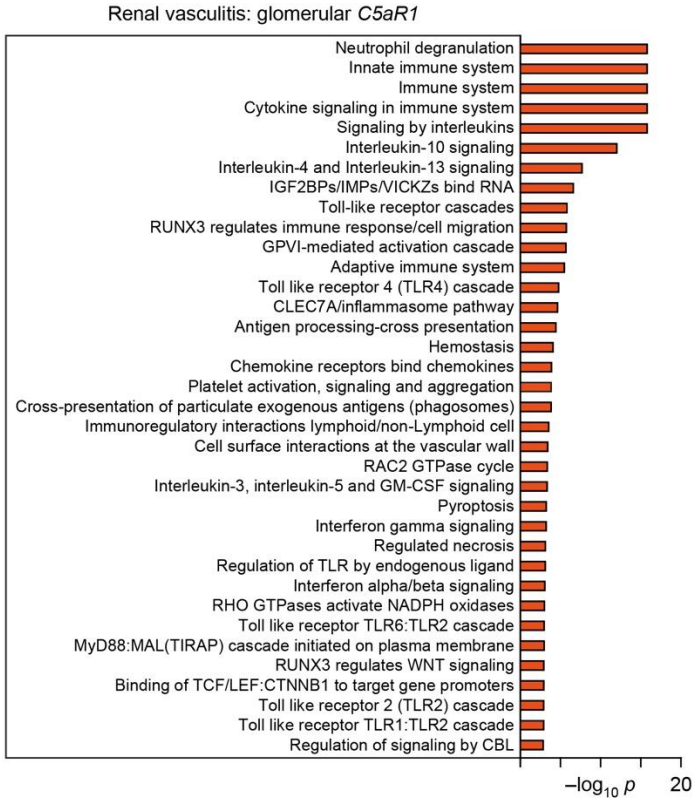
Glomeruläre C5aR1-Expression korreliert mit uACR



Korsten *et al.* In Review

Frühe uACR-Senkung, eGFR-Erholung, und glomeruläre C5aR1-Expression: Mechanistischer link?

Glomerulär C5aR1-Expression in ANCA-RPGN: „innate immunity“



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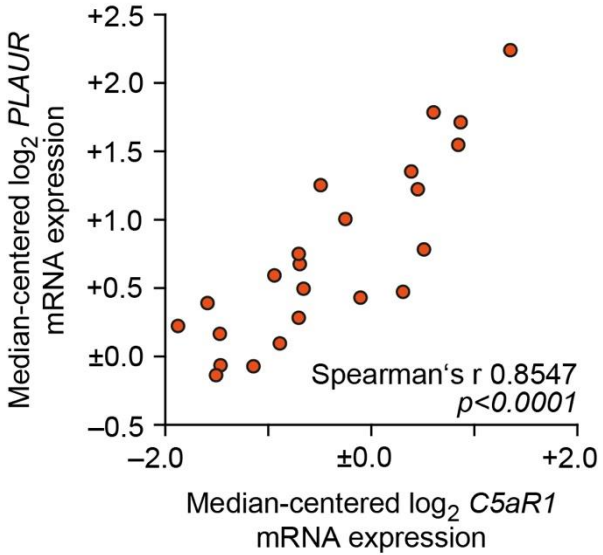
Top Hit in Korrelation mit glomerulärem C5aR1: *PLAUR* (kodiert uPAR)



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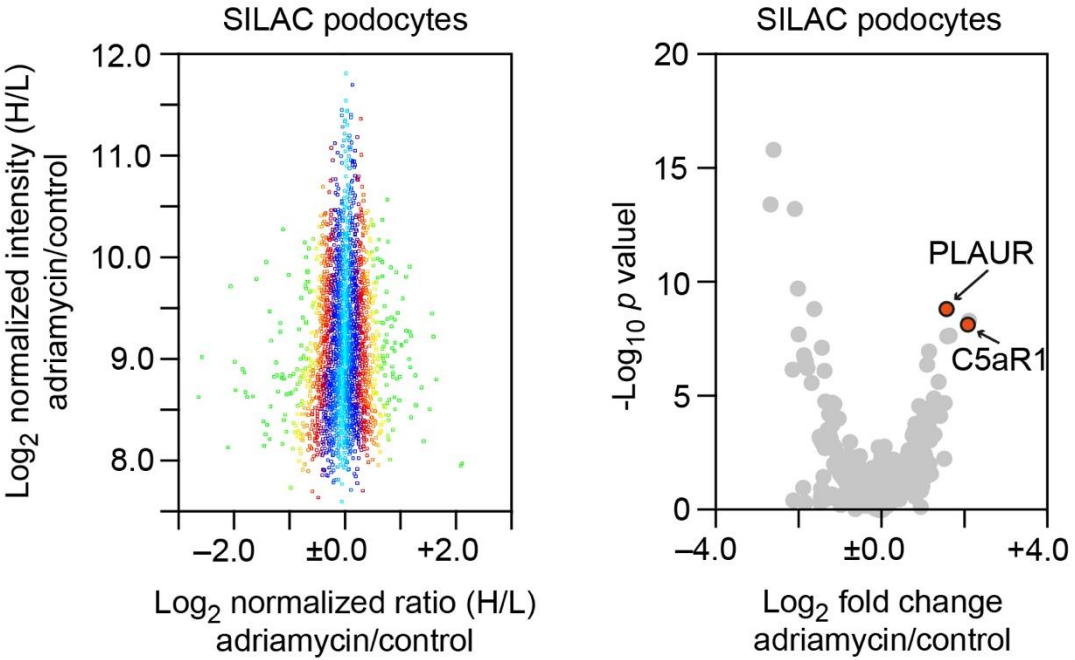
Induktion von C5aR1 und uPAR in gestressten Podozyten



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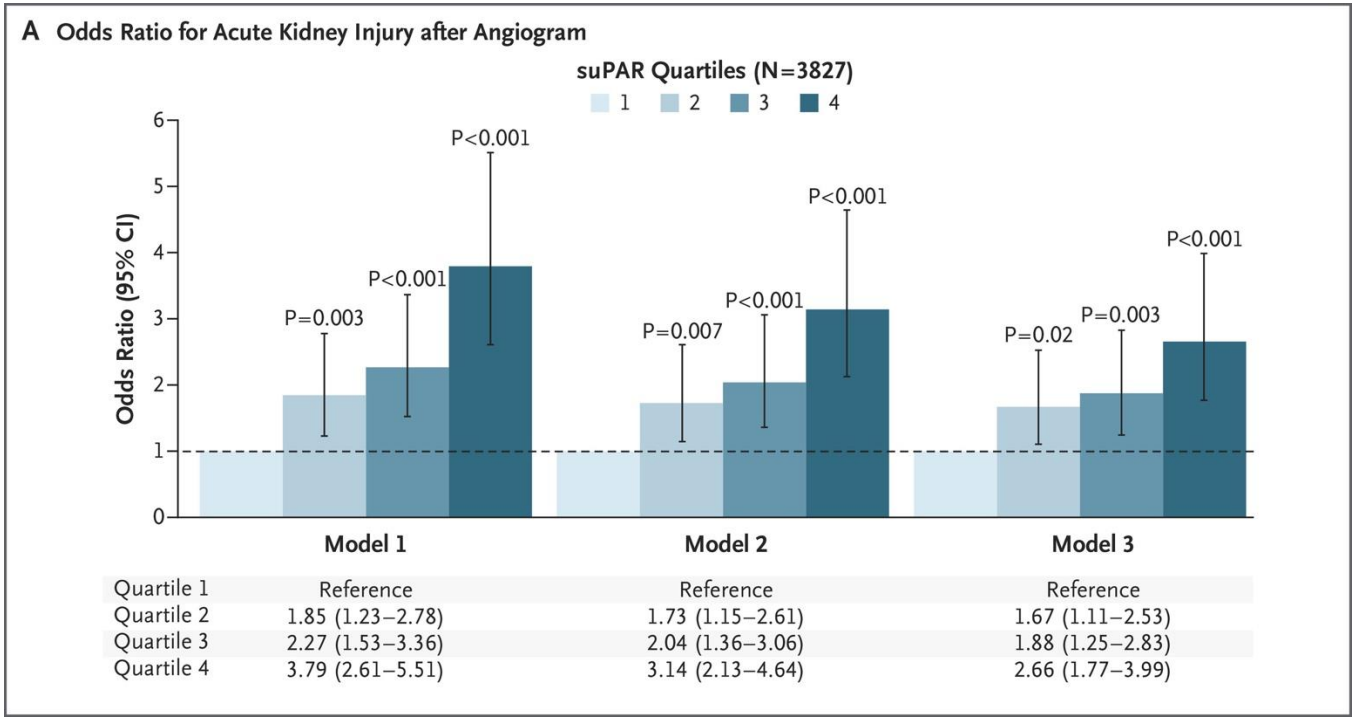
suPAR und eGFR-Verlust in AKI



	Model 1	Model 2	Model 3
Quartile 1	Reference	Reference	Reference
Quartile 2	1.85 (1.23–2.78)	1.73 (1.15–2.61)	1.67 (1.11–2.53)
Quartile 3	2.27 (1.53–3.36)	2.04 (1.36–3.06)	1.88 (1.25–2.83)
Quartile 4	3.79 (2.61–5.51)	3.14 (2.13–4.64)	2.66 (1.77–3.99)

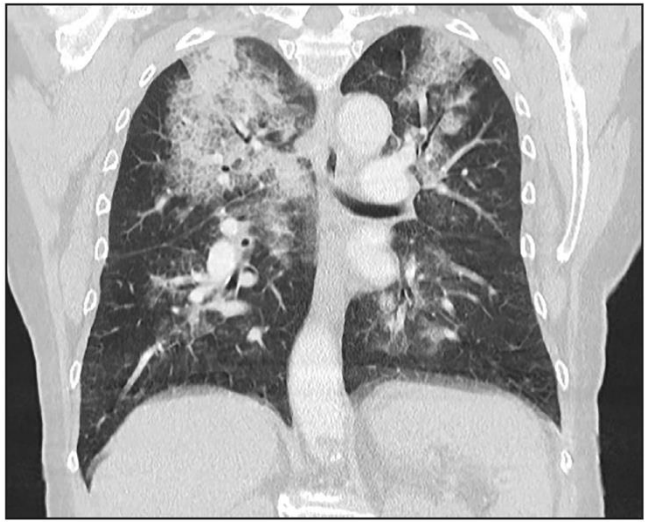
Hayek SS et al. *NEJM* 2020

Relevanz von suPAR bei ANCA-RPGN: Proof-of-principle

Fall: 75a, weiblich
DAH und crescentic RPGN

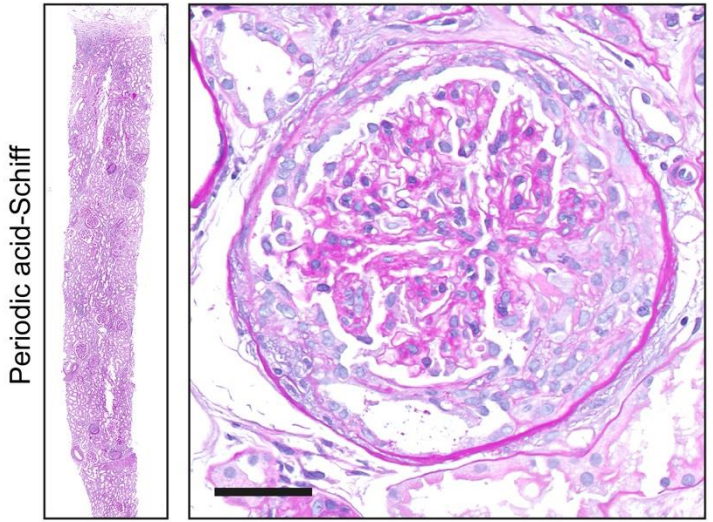
B

Chest CT



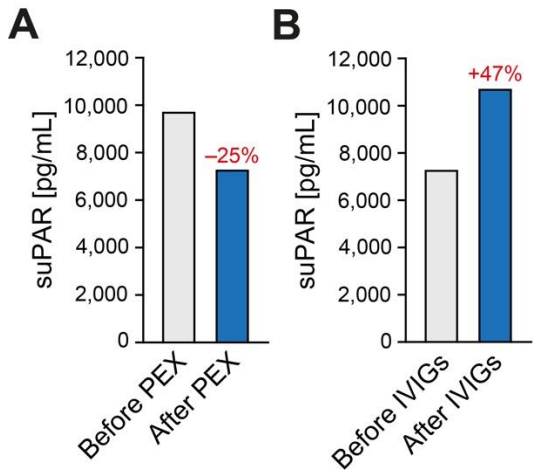
C

Kidney biopsy



Schäfer AK et al. *Front Immunology* 2023

Spiegel von „freiem“ suPAR bei PEX und IVIGs



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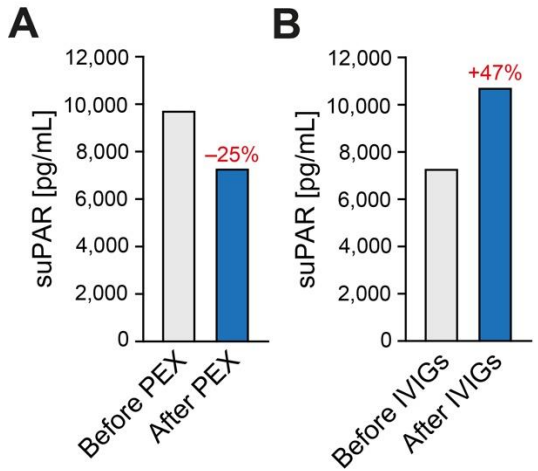

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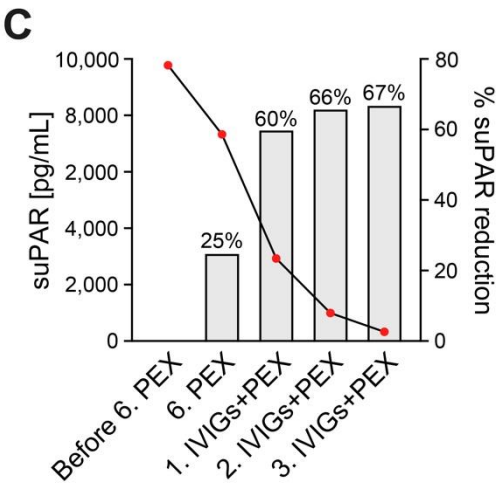

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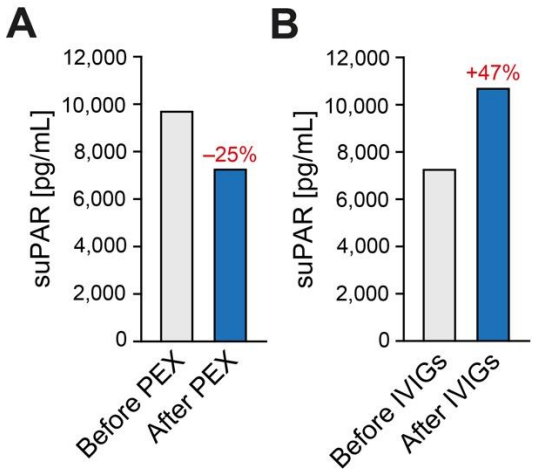

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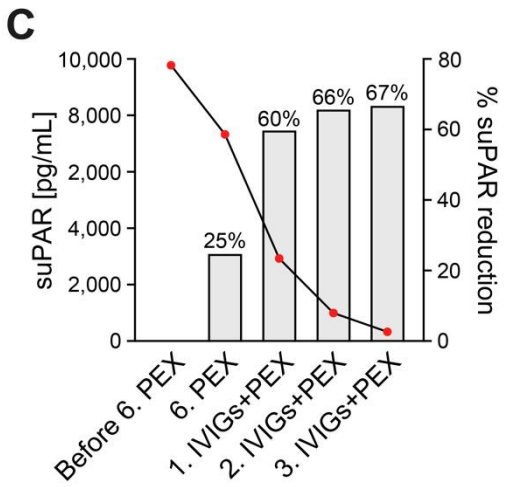
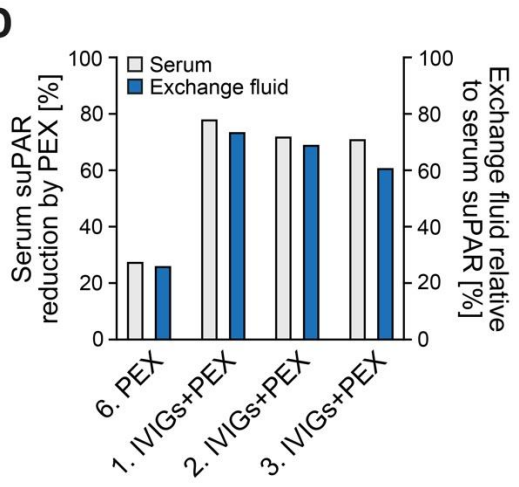


Elimination korreliert mit Konzentration im Extravasat



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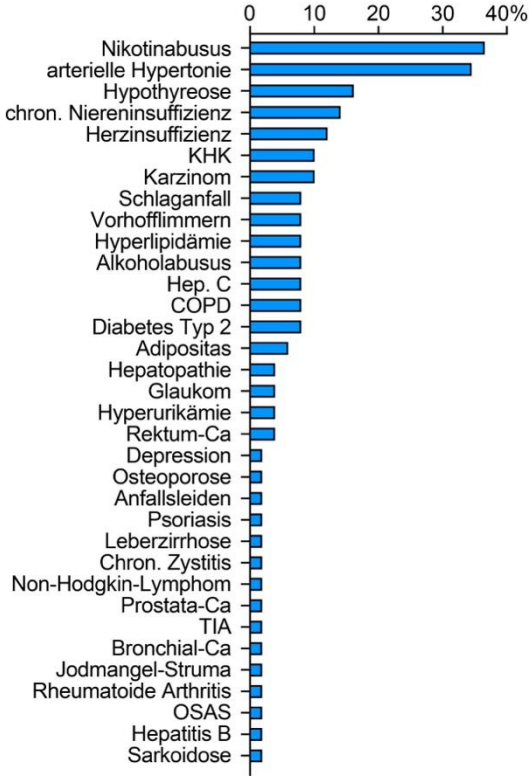
Beeinflussen Komorbiditäten die Manifestation und das Outcome bei ANCA-RPGN?

Systematische Analyse von Komorbiditäten: Präliminäre Daten



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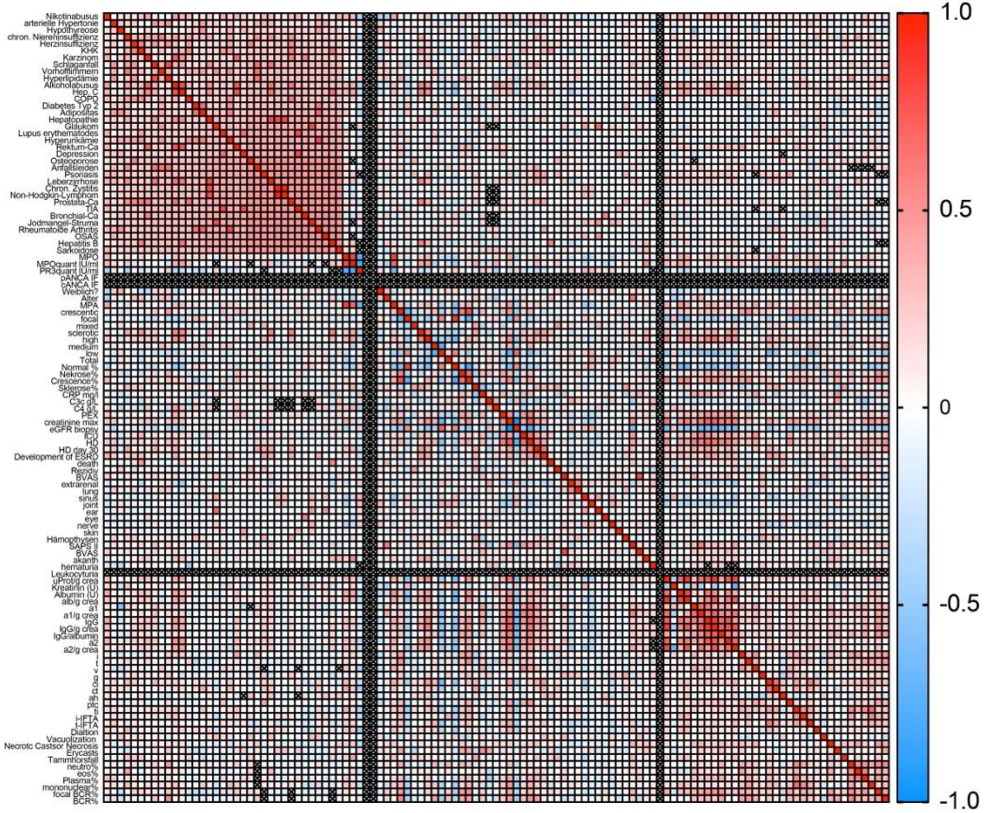

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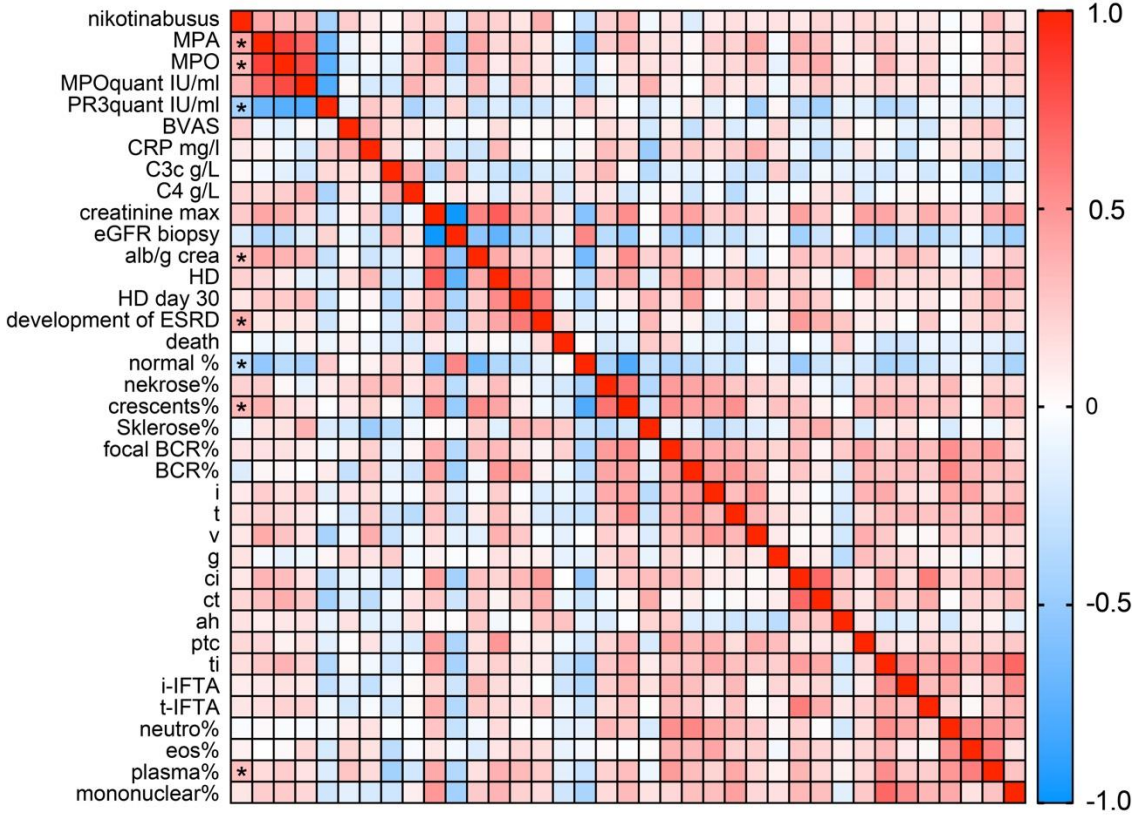
Vorheriger Nikotinabusus vs. klinisch-pathologische Manifestation



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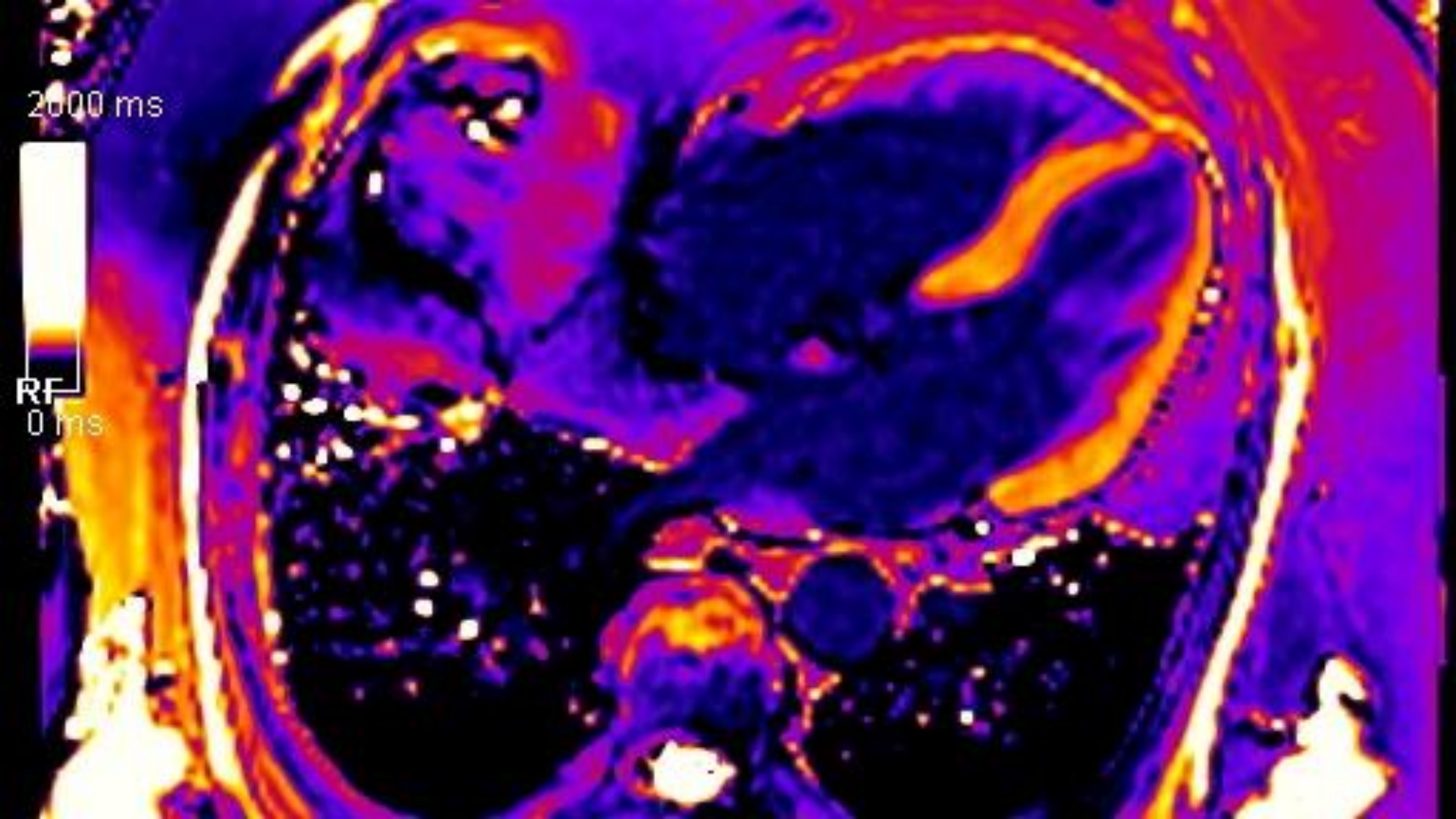
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Take Home

In der Akutphase sind infektiöse Komplikationen bei der ANCA-Vaskulitis relevant.

Reduktion der kumulativen Steroiddosis ist bei der Remissionsinduktion nicht unterlegen und reduziert die infektiösen Komplikationen.

Mit Avacopan steht eine steroidfreie Therapiemöglichkeit zur Verfügung, welche das Risiko für infektiöse Komplikationen weiter reduzieren kann.

Molekular scheint insbesondere die glomeruläre C5aR1-Expression relevant zu sein, welche mit uPAR-Interferonaktivierung assoziiert ist und einen direkten Mechanismus von Albuminurie erklären könnte.

Komorbiditäten könnten bei ANCA-RPGN mechanistisch Einfluss haben.

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Lisa Metz, UMG

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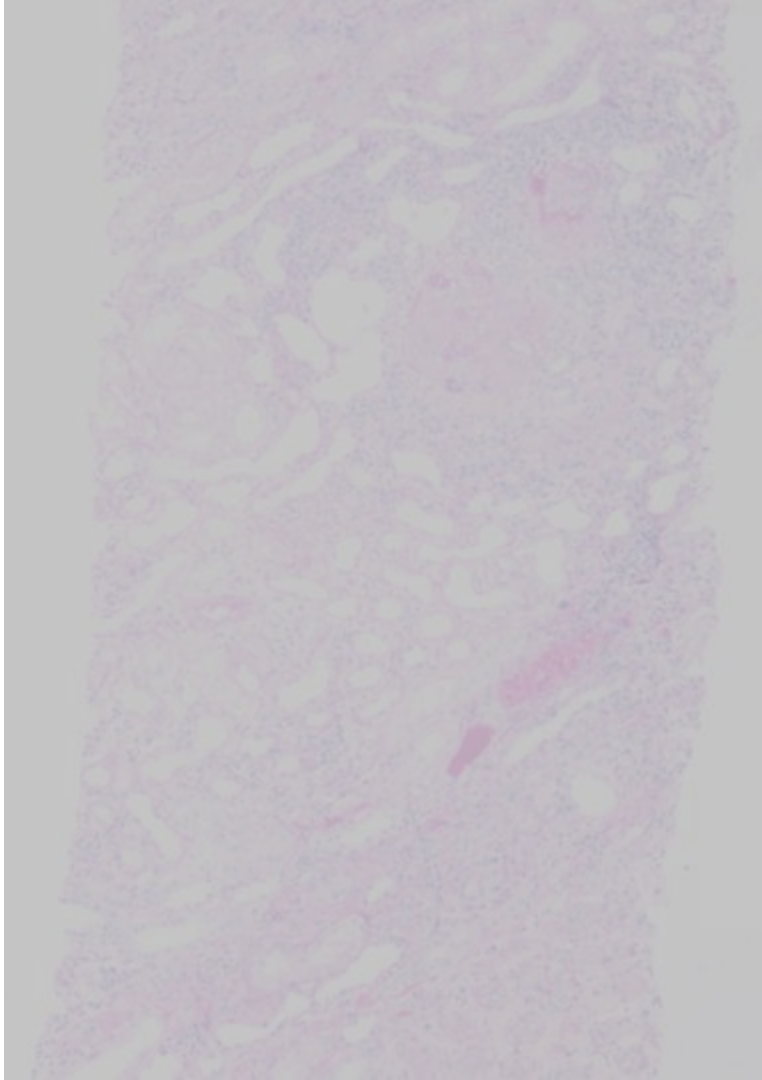
Amelie Gründel
Maike Heffels
Alexander Lukasiewicz
Nina Woysch
…



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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.

Gekürzte Verschreibungsinformationen

Österreich:

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.