2. DACH ANCA VASKULITIS FORUM 2024

22. & 23. NOVEMBER 2024 | MÜNCHEN

CSL Vifor

Begleitung der AAV-Patienten und Erhalt der Lebensqualität

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München

LMU KLINIKUM
Gemeinsam. Fürsorglich. Wegweisend.

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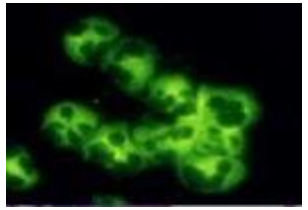
Disclosures: **Advisory Board/Studienteilnahme:**
CSL Vifor, Alexion/AstraZeneca, Sanofi-Aventis, Hansa Biopharma

Vortrag: CSL Vifor, Novartis, Sanofi-Aventis

ANCA-assoziierte Vaskulitiden (AAV) – Outcome



1971 → 2024

… von einer fatalen Prognose …

(90%ige Mortalität der unbehandelten GPA in den ersten 2 Jahren)

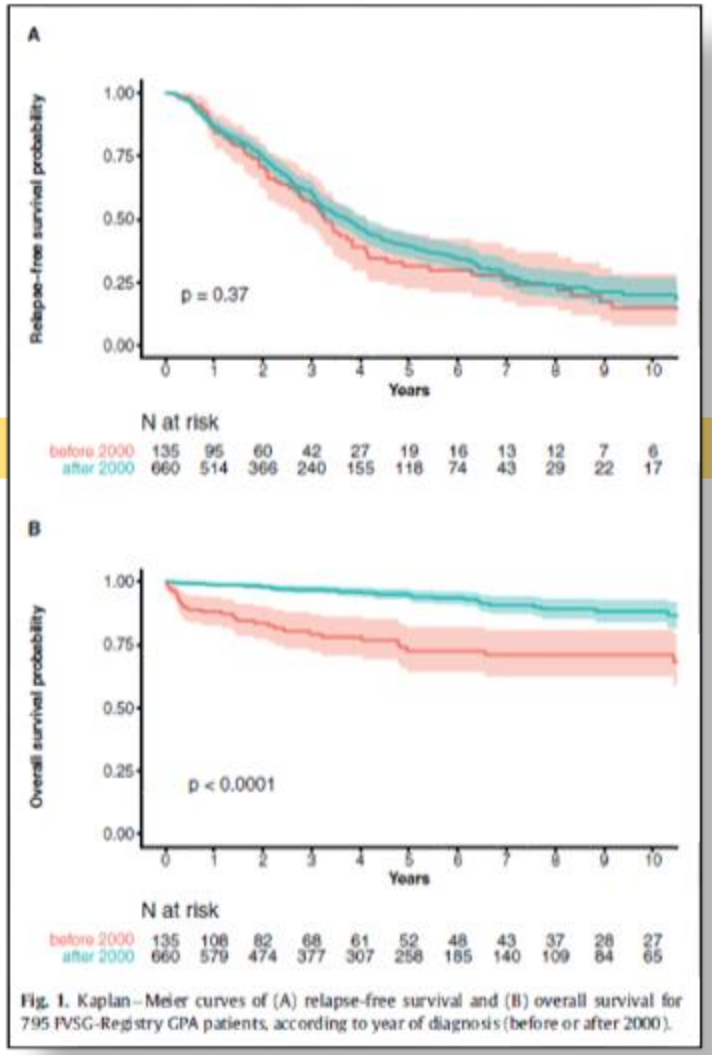


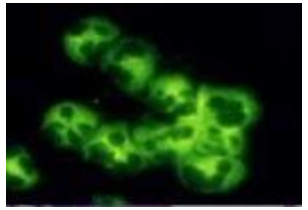
Fig. 1. Kaplan–Meier curves of (A) relapse-free survival and (B) overall survival for 795 PVSG-Registry GPA patients, according to year of diagnosis (before or after 2000).

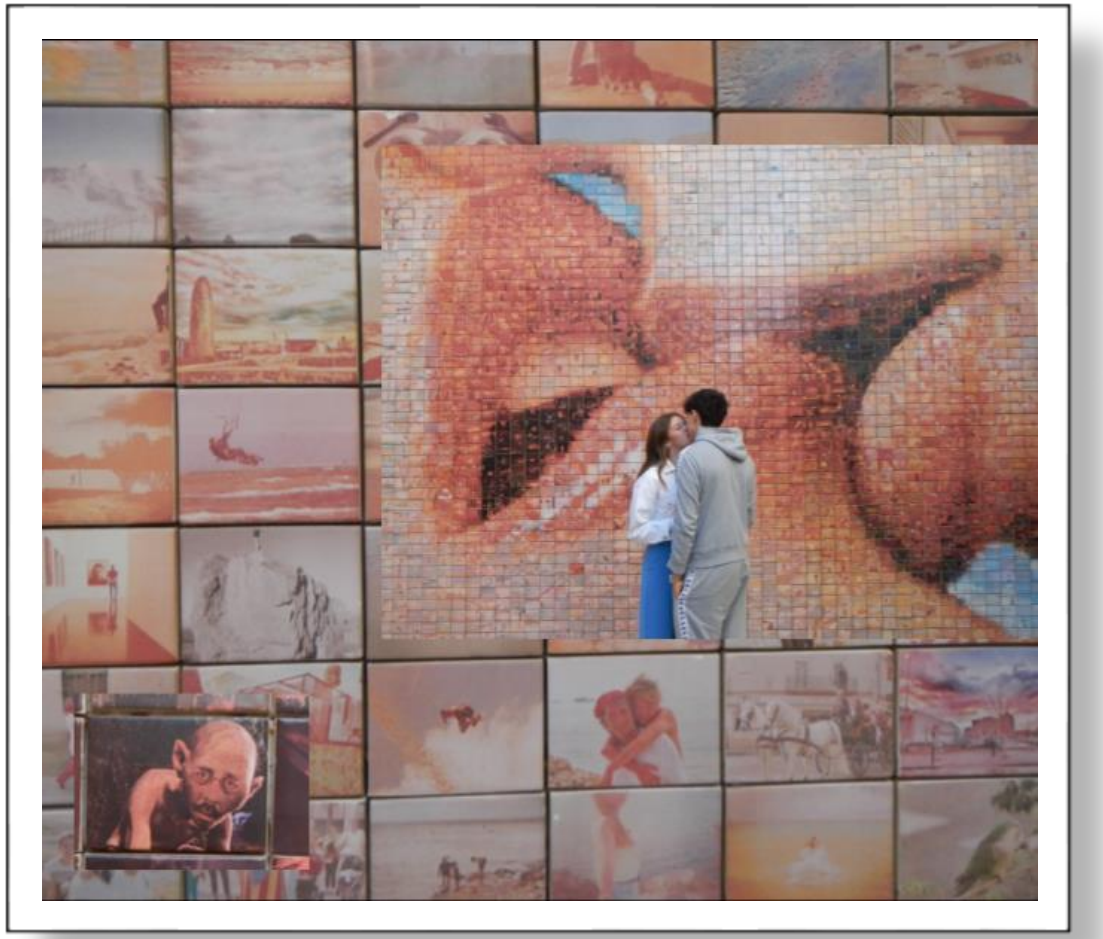
… zu einer chronischen und rezidivierenden Erkrankung …

(5-Jahres-Überlebensrate von 70–80%, in einigen Kohorten auf das Niveau der Normalbevölkerung; Therapie-assoz. Nebenwirkungen und Akkumulation von Organ-Damage)

Iudici M et al. Seminars in Arthritis and Rheumatism 2021;51:339-346

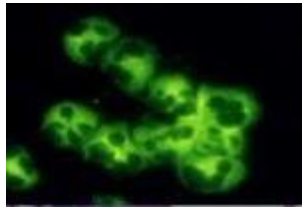
ANCA-assoziierte Vaskulitiden (AAV) – Langzeitbetreuung





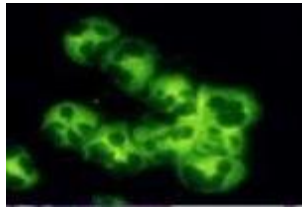
Die unterschiedlichen Facetten einer chronischen Erkrankung.

ANCA-assoziierte Vaskulitiden (AAV) – Langzeitbetreuung



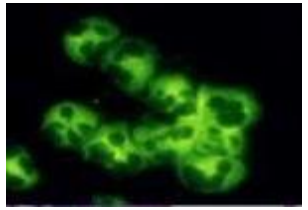
Die unterschiedlichen Facetten einer chronischen Erkrankung.

ANCA-assoziierte Vaskulitiden (AAV) – „harte Endpunkte“



- Mortalität
- Rezidiv
- CKD / ESKD / Dialyse
- Lungenfibrose
- Osteoporose
- Kardiovaskuläre Komplikationen/ Thromboembolien
- Malignome
- Infektionen
- Hypogammaglobulinämie

ANCA-assoziierte Vaskulitiden (AAV) – „harte Endpunkte“



- Mortalität
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- Osteoporose
- Kardiovaskuläre Komplikationen/ Thromboembolien
- Malignome
- Infektionen
- Hypogammaglobulinämie

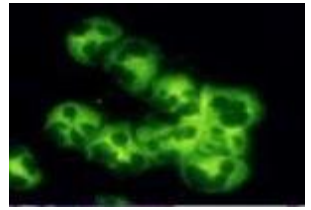
Als Folge von:

Vaskulitis

chronischen Organschäden

Medikamenten-Toxizität

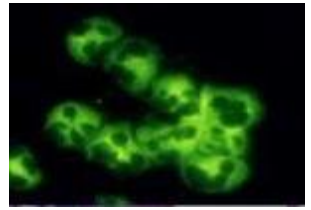
ANCA-assoziierte Vaskulitiden (AAV) – „harte Endpunkte“



Den Vaskulitis-Patienten muss man <u>auch</u> sehen als Patienten

- mit CKD
- mit Lungenerkrankung
- mit Osteoporose-Risiko
- mit erhöhtem kardiovaskulären Risiko
- mit erhöhtem Malignom-Risiko
- mit erhöhtem Infekt-Risiko

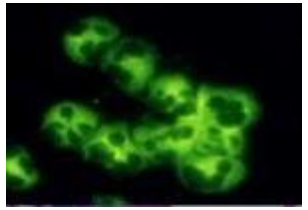
ANCA-assoziierte Vaskulitiden (AAV) – „harte Endpunkte“

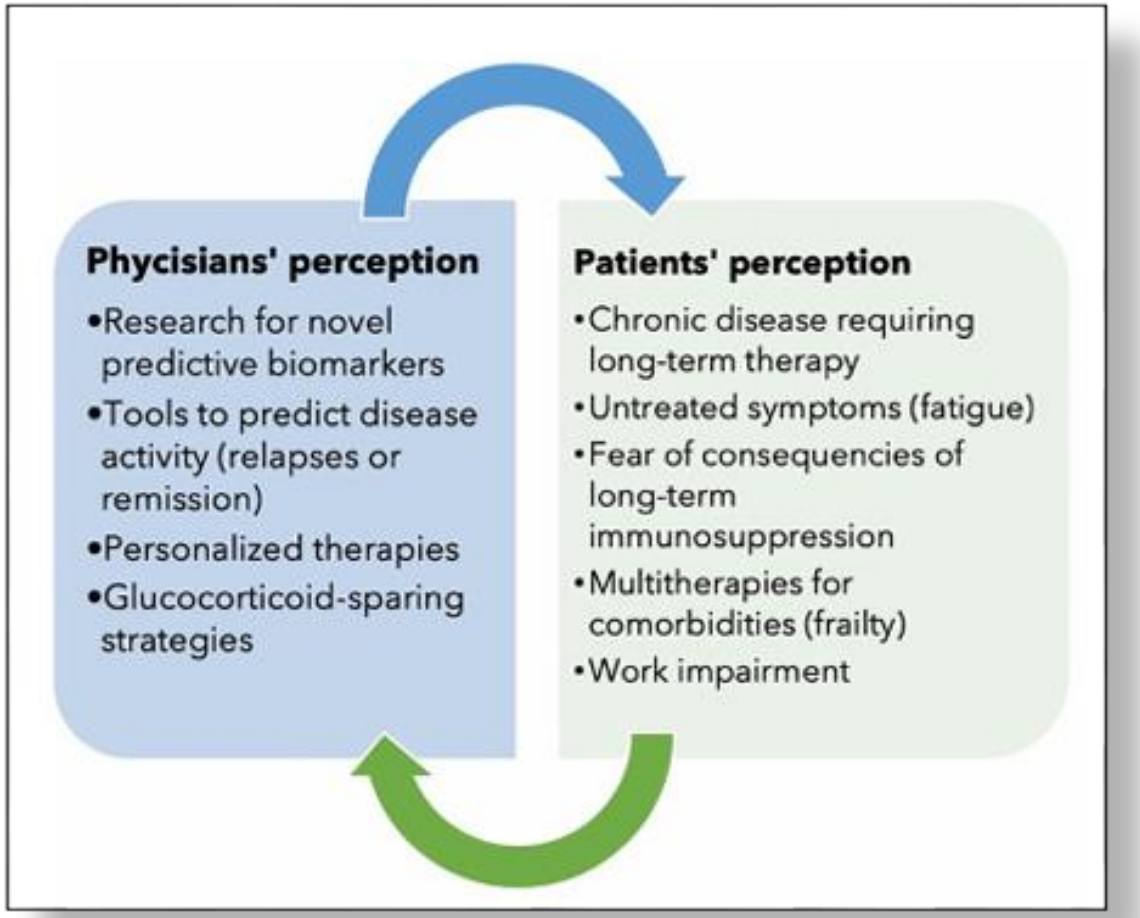


Allgemeine Empfehlungen für AAV-Patienten:

- Therapie der Begleiterkrankungen
- Osteoporose-Prophylaxe
- Pneumocystis-Prophylaxe
- Kardiovaskuläres Risiko behandeln
- Impfungen
- regelmäßige Verlaufskontrollen

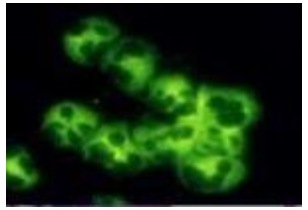
AAV – Die Arztsicht ist nicht alles –> die Patientensicht





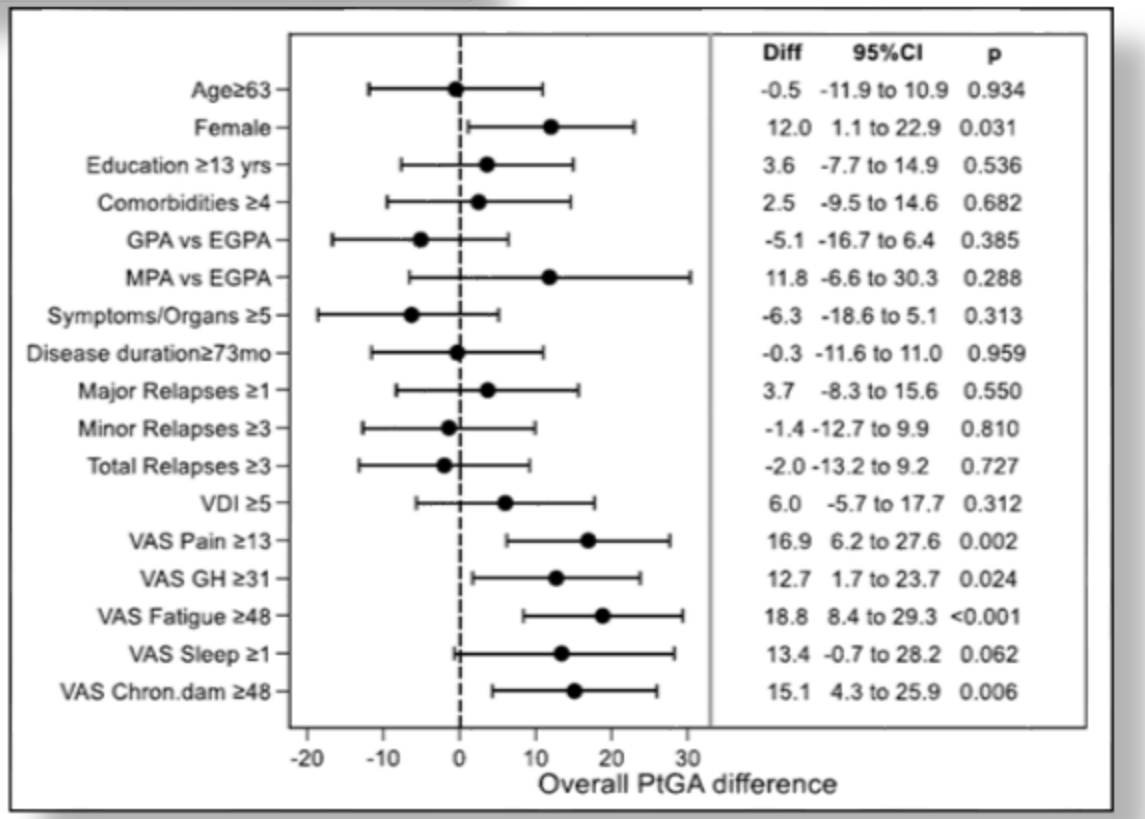
Quartuccio L et al. Front. Immunol. 2023;14:1112899

AAV – Die Arztsicht ist nicht alles –> die Patientensicht



Factors influencing patient-reported outcomes in ANCA-associated vasculitis: correlates of the Patient Global Assessment

- 65 AAV-Patienten in Remission
- 37% erhöhter PtGA = unkontrollierte Aktivität
- Keine Assoziation mit Alter, Komorbiditäten, …, Krankheitsdauer, VDI.
- Pos. Assoziation mit ♀ Geschlecht (51% vs. 18%)
- Schmerzen und Fatigue als Hauptfaktoren



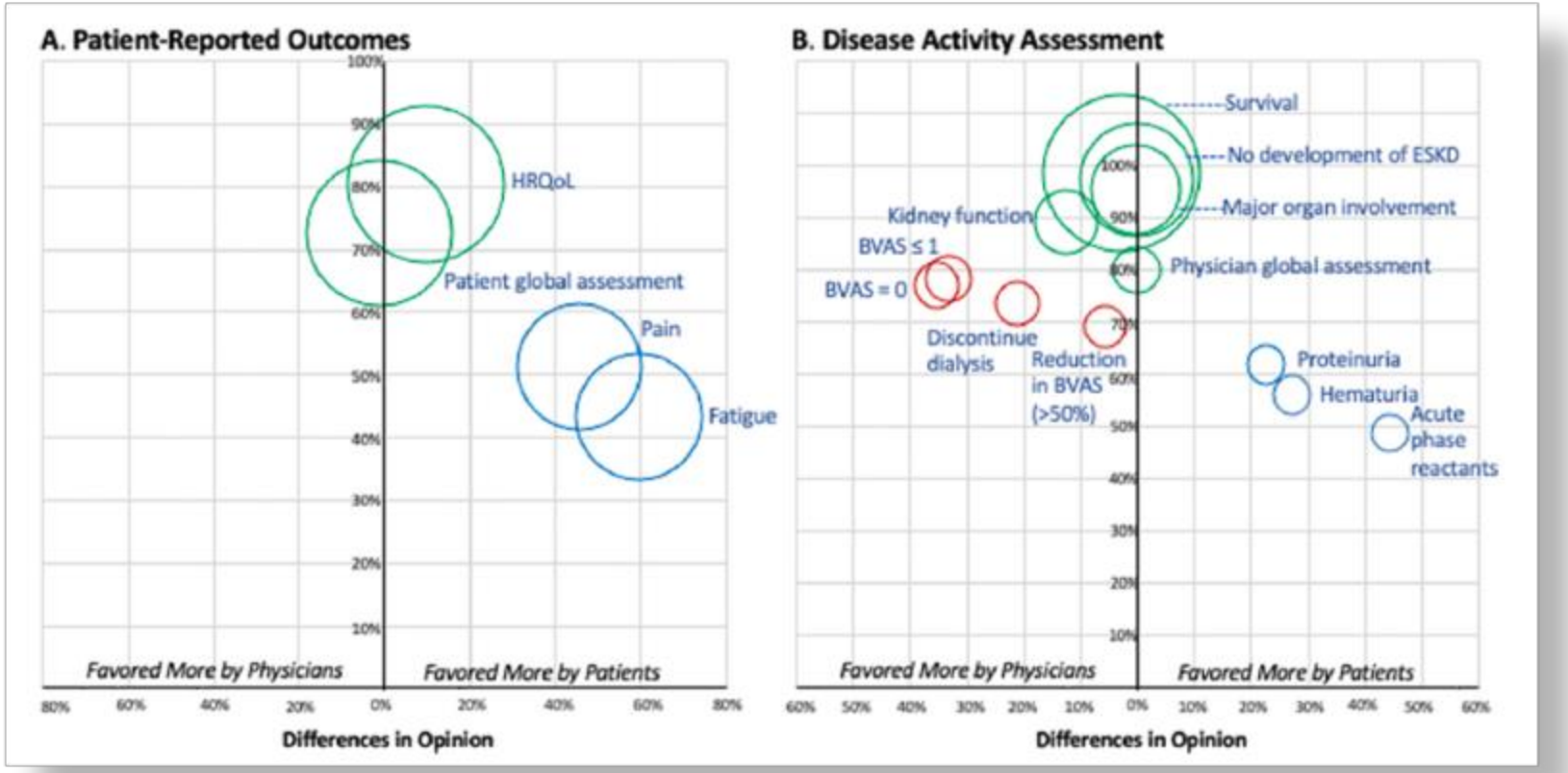
Monti S et al. Seminars in Arthritis and Rheumatism 2022;56:152048

PROMs = Patient-related outcomes – die Sicht der Patienten

Quinn K et al. Seminars in Arthritis and Rheumatism. 2022;55:152021

PROMs = Patient-related outcomes – die Sicht der Patienten

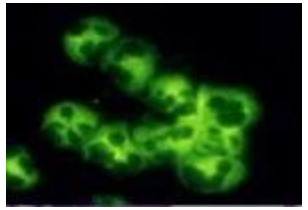
An international Delphi exercise to identify items of importance for measuring response to treatment in ANCA-associated vasculitis☆



- Konsens zw. Pat. und Ärzten für viele Items.
- Items nur von Pat. hoch bewertet: Laborwerte [Urinanalyse, akute Phase-Werte], Schmerzen, Fatigue.

Quinn K et al. Seminars in Arthritis and Rheumatism. 2022;55:152021

Verwendete Tools zur Outcome-Beurteilung bei AAV



Tool	Purpose	Completed by	Further details
BVAS (97)	Measure the level of disease activity, by identifying all the possible organ clinical manifestations	Physician	Score is divided into 9 organ-based systems. Includes both persistent and new or worsening signs and symptoms deemed to be due to vasculitis.
VDI (92)	Distinguish vasculitis-induced chronic damage from active inflammation or persistent disease	Physician	Comprises 64-item checklist in 11 categories. Does not differentiate between disease- and treatment-induced damage.

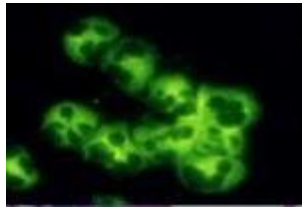
Tool	Purpose	Completed by	Further details
AAV-PRO (17; 98)	Provide AAV-specific evaluation of patient-reported quality of life and patient perception of disease and treatment effects	Patient	Comprises 35-item questionnaire relating to patient-perceived impact of AAV and its treatment on various aspects of life Validated tool to collect patient opinions on the impact on symptoms, side effects, physical function and social activity and emotional wellbeing.

Tool	Purpose	Completed by	Further details
SF-36 (99)	Generic tool for evaluating health-related quality of life	Patient and physician	Comprises 36 questions that cover eight domains of health
GTI (100) (101)	Measure change in glucocorticoid morbidity over time	Physician	Include 31 symptoms of toxicity
HAQ (102)	Patient-reported evaluation of functional status	Patient	Comprises 20 items in eight domains related to measuring difficulty in performing daily activities
EQ-5D (103)	Generic tool for evaluating health-related quality of life	Patient and physician	Includes one question for each of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and a visual analogue scale (0–100) for patient to rate their perceived health status.

AAV-pro, AAV patient-reported outcomes; BVAS, Birmingham Vasculitis Activity Score; EQ-5D, EuroQol- 5 Dimension Questionnaire; GTI, Glucocorticoid Toxicity Index; HAQ, Health Assessment Questionnaire; SF-36, 36-Item Short-Form Health Survey; VDI, Vasculitis Damage Index.

Alberici F et al. Front. Immunol. 2024;15:1409129

Verwendete Tools zur Outcome-Beurteilung bei AAV



Association of the AAV-PRO questionnaire with established outcome measures in AAV

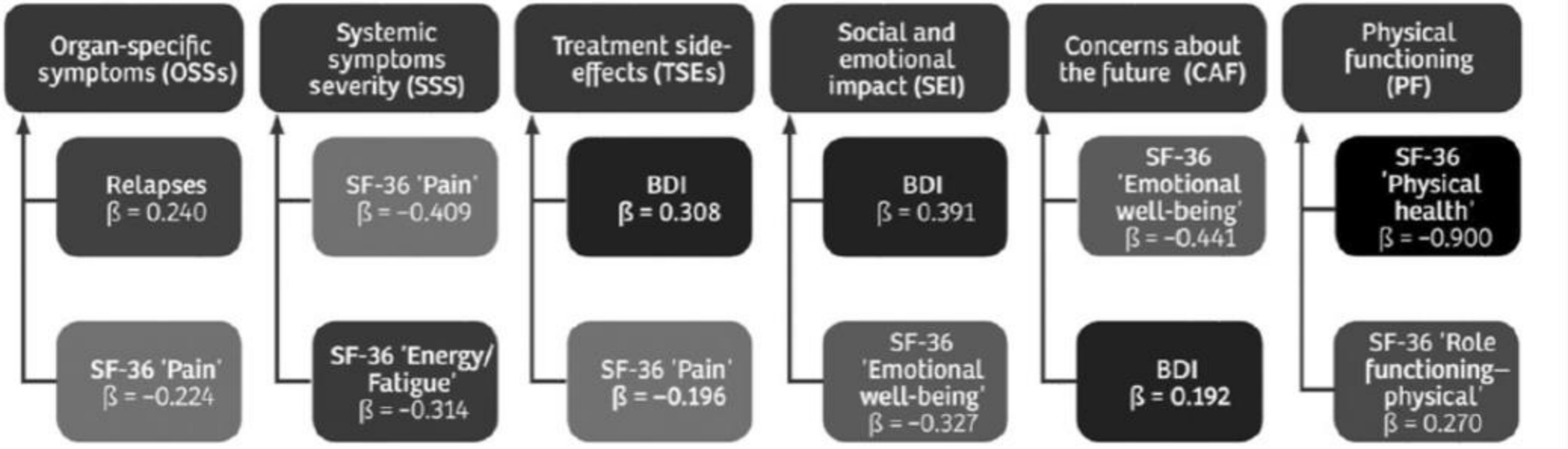


Figure 1. Regression analyses of the AAV-PRO domains with BDI, SF-36, BVAS, VDI and the number of relapses (t1). AAV-PRO: ANCA-associated vasculitis patient-reported outcome; BDI: Beck's depression inventory; SF-36: Short-Form-36; t1: baseline; VDI: Vasculitis Damage Index

Conclusion: Our data show convergent validity for all AAV-PRO subdomains, using the established questionnaires BDI and SF-36. The AAV-PRO domains scores were not correlated with clinician-derived instruments (including the BVAS and the VDI). Thus, we regard the AAV-PRO questionnaire as a valuable measure of outcomes that might complement traditional end-points in clinical trials.

Maunz A et al. Rheumatology. 2024;63:174–180

Was spielt eine Rolle …

Psyche

sozial

Physisch

Depression

Kognitive Verschlechterung

Angst

Fatigue

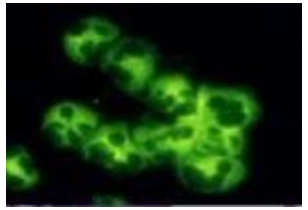
Berufstätigkeit

Schlafstörung

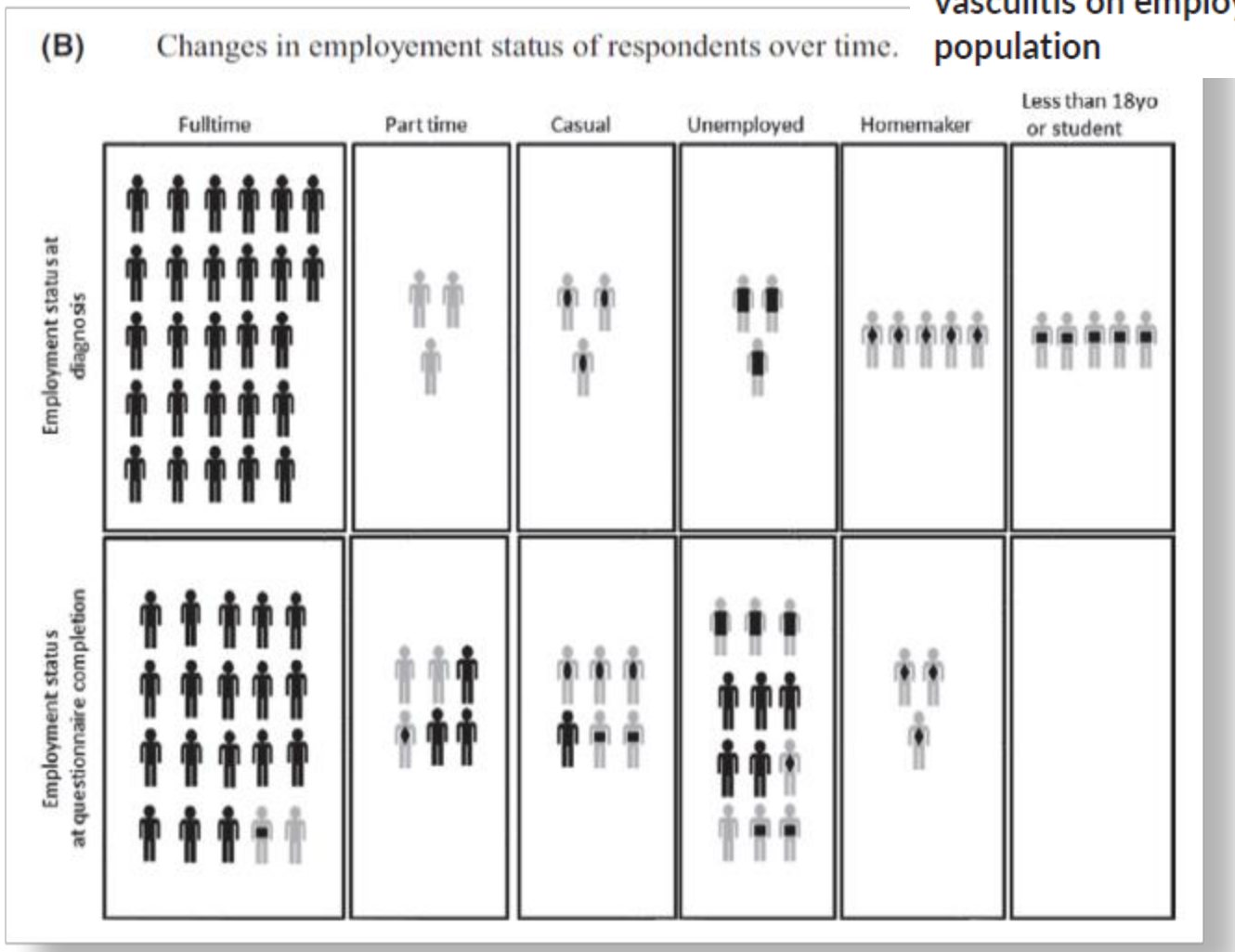
Einkommen

Soziale Teilnahme

AAV-Patienten – Berufstätigkeit



The impact of antineutrophil cytoplasmic antibody-associated vasculitis on employment and work disability in an Australian population



47 Pat. (60 Monate nach ED)

21% mit Verlust der Berufstätigkeit

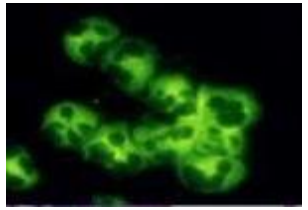
11% mit Reduktion der Arbeitszeit

42% Selbsteinschätzung: „work impaired“

45% mit negativem Einfluss auf die finanzielle Stabilität

Heron V et al. Int J Rheum Dis. 2021;24:904–911

AAV-Patienten – Berufstätigkeit



Markers for work disability in anti-neutrophil cytoplasmic antibody-associated vasculitis

TABLE 1 Independent associations of work disability among working-age AAV patients ($n = 208$)

	Odds ratio	95% CI		PAR, %
Fatigue (CFS)	7.1	1.5	33.1	72.9
Overweight (BMI > 25)	3.4	1.3	8.9	39.3
Depression (HADS)	4.4	1.8	10.8	29.5
Severe disease damage (VDI > 4)	3.9	1.01	14.7	9.0

AAV: ANCA-associated vasculitis; PAR: population attributable risk; CFS: Chalder Fatigue Scale, dichotomized at the general population mean; HADS: Hospital Anxiety and Depression Scale; VDI: Vasculitis Damage Index.

Basu N et al. Rheumatology 2014;53:953956

AAV-Patienten – Depression

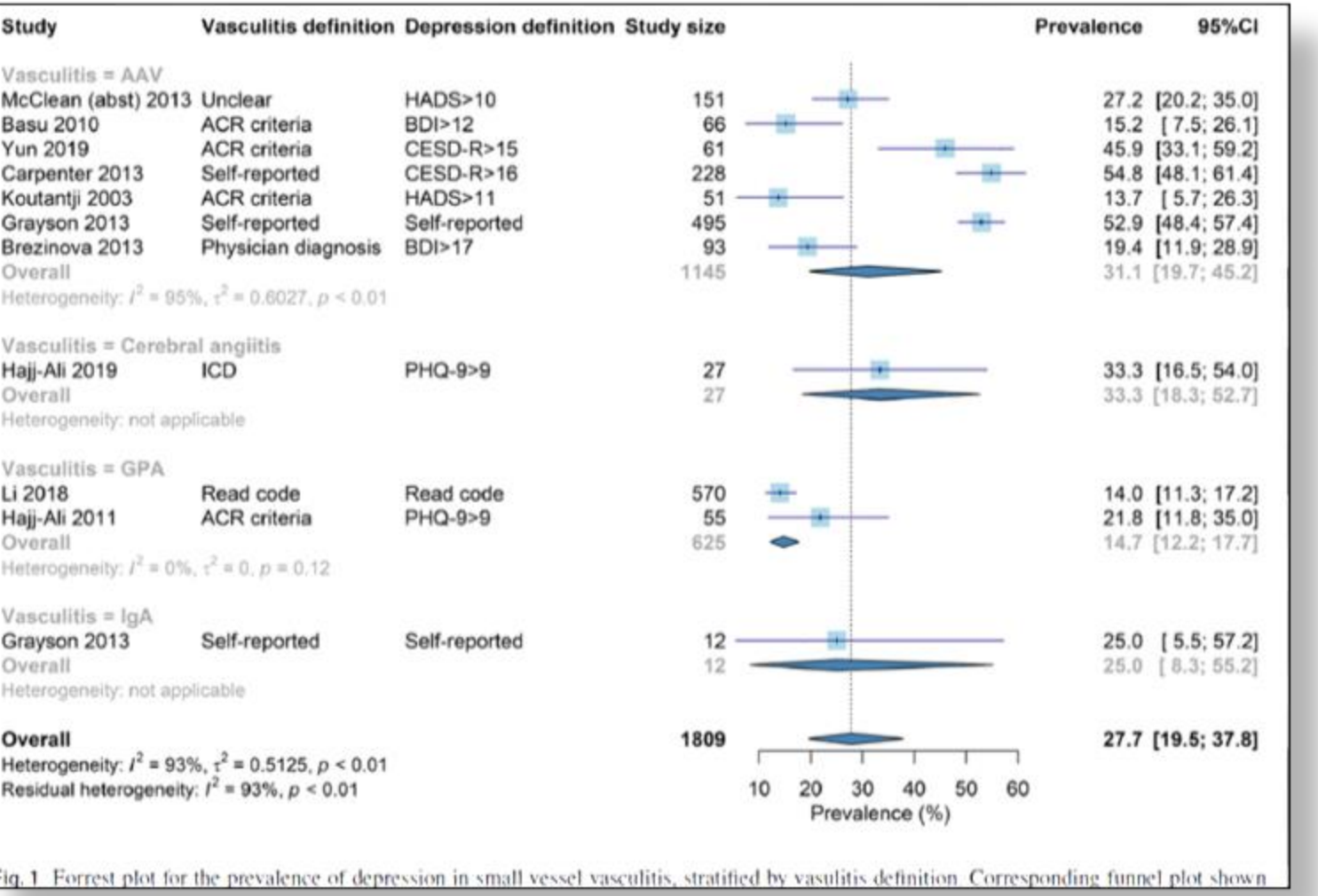
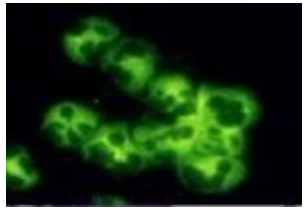


Fig. 1 Forrest plot for the prevalence of depression in small vessel vasculitis, stratified by vasulitis definition. Corresponding funnel plot shown



Depression

Prävalenz 28%

Assoziiert mit schlechterer Lebensqualität, Adhärenz und Erwerbsunfähigkeit.

Nicht assoziiert mit Disease Damage oder Disease activity.

Pittam B et al. Rheumatology International. 2020;40:1215–1221

AAV-Patienten – Fatigue

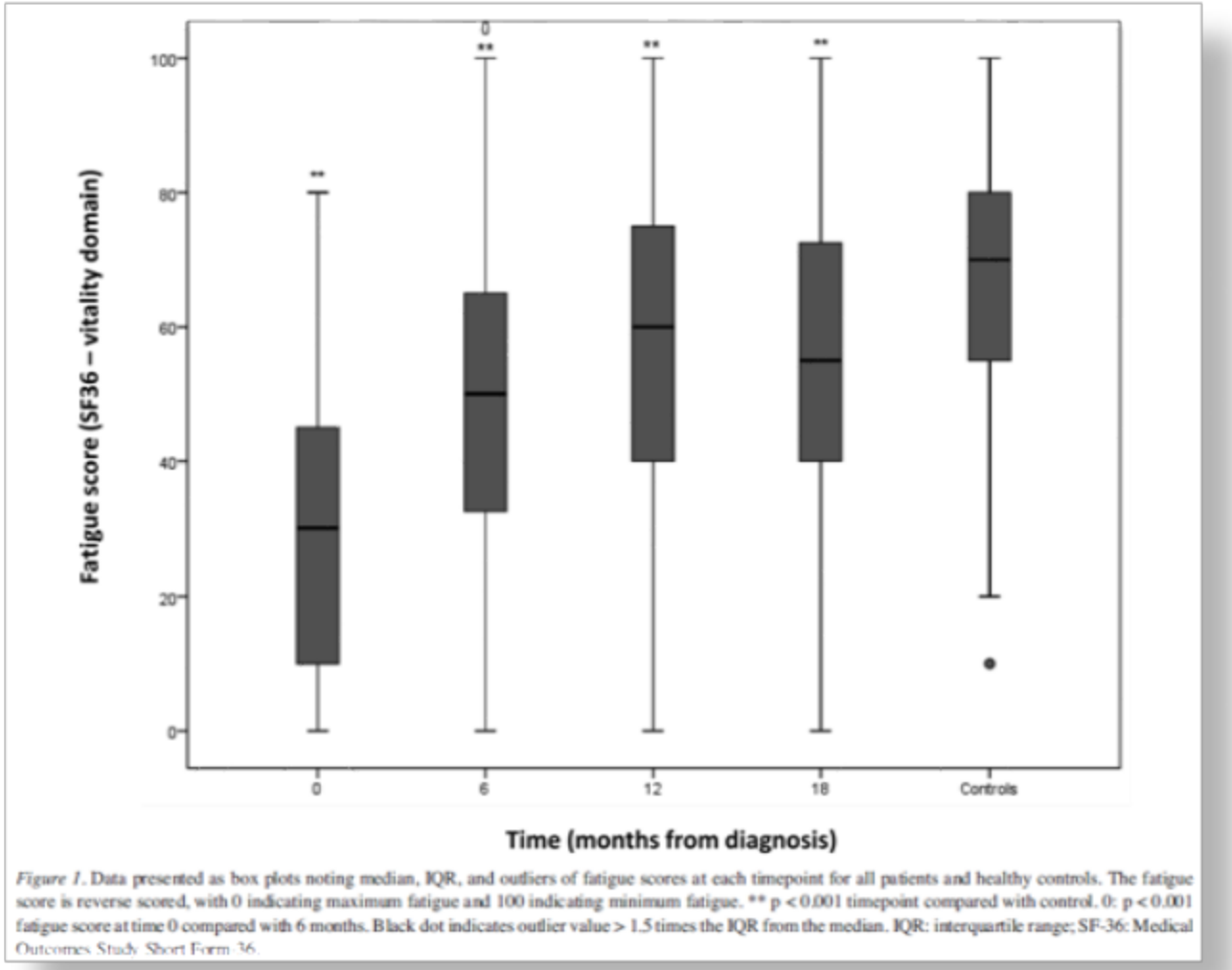
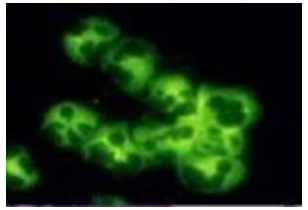


Figure 1. Data presented as box plots noting median, IQR, and outliers of fatigue scores at each timepoint for all patients and healthy controls. The fatigue score is reverse scored, with 0 indicating maximum fatigue and 100 indicating minimum fatigue. ** $p < 0.001$ timepoint compared with control. 0: $p < 0.001$ fatigue score at time 0 compared with 6 months. Black dot indicates outlier value > 1.5 times the IQR from the median. IQR: interquartile range; SF-36: Medical Outcomes Study Short Form 36.



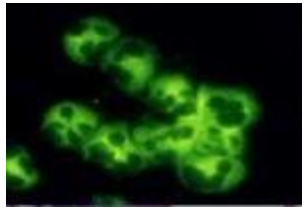
Fatigue

46% schwere Fatigue

Verbesserung über die Zeit, aber schlechter als bei HC

O'Malley L et al. J Rheumatol 2020;47:572–9

AAV-Patienten – Fatigue



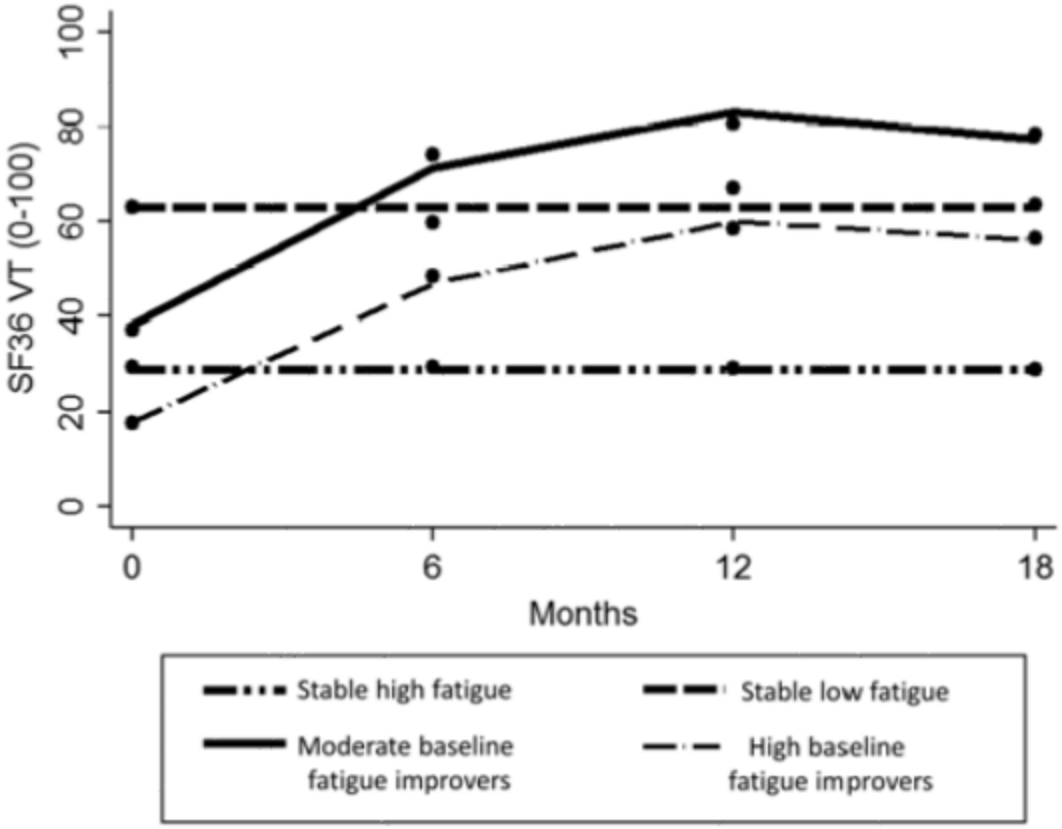


Figure 2. Trajectory analysis identified 4 distinct groups of patients based on changes (or stability) of their fatigue. SF36 VT: Medical Outcomes Study Short Form-36 vitality subscale.

25% mit bleibender ausgeprägter Fatigue

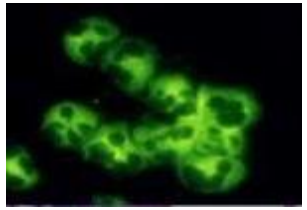
Table 2. Fatigue score of each GBTM group associated with time.

Time, mos	Stable High Fatigue, n = 37	High Baseline Fatigue Improvers, n = 61	Moderate Baseline Fatigue Improvers, n = 29	Stable Low Fatigue, n = 23	Controls
0	30 (15–45)	15 (5–25)	40 (30–49)	70 (60–75)	70 (55–80)
6	25 (15–40)	45 (40–55)	80 (70–80)	60 (50–65)	
12	28 (20–40)	58 (50–66)	80 (75–90)	70 (50–80)	
18	30 (15–40)	55 (45–70)	80 (70–85)	65 (50–70)	
P values	0.81	< 0.001	< 0.001	0.11	

P values are derived from Friedman's test for repeated measures for change in fatigue score over time within the GBTM group. Values are median (IQR) unless otherwise specified. GBTM: group-based trajectory modeling; IQR: interquartile range.

O'Malley L et al. J Rheumatol 2020;47:572–9

AAV-Patienten – Fatigue – gibt es Unterschiede?



Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and fibromyalgia: PR3-versus MPO-ANCA-associated vasculitis, an exploratory cross-sectional study

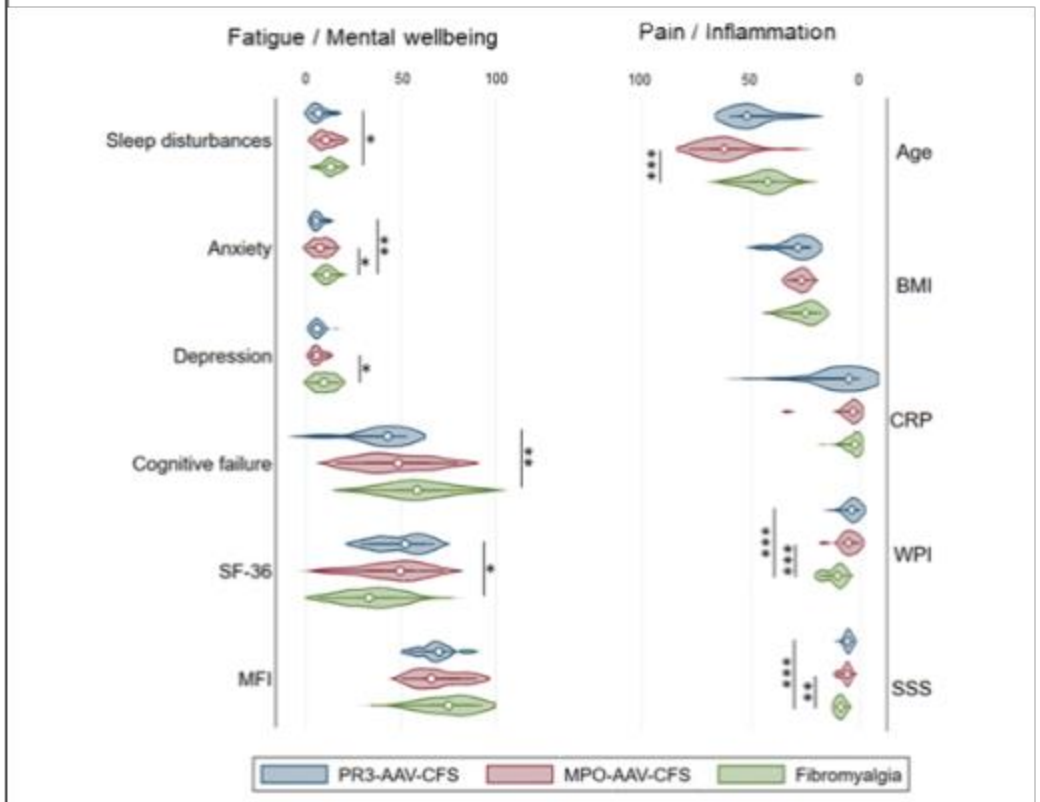


Fig. 1: **Comparison of fatigue/mental wellbeing and pain/inflammation between fatigued PR3- and MPO-ANCA patients and fibromyalgia controls.** Violin plots showing median and interquartile range. *p < 0.05, **p < 0.01, ***p < 0.001

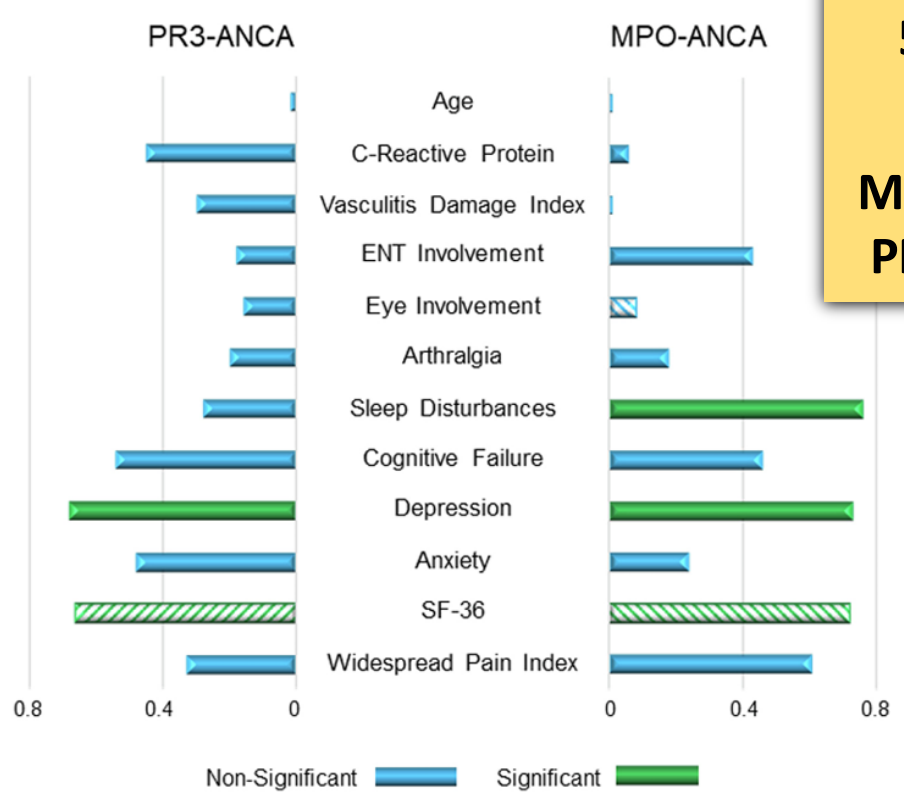


Fig. 2: **Pairwise correlations with multidimensional fatigue inventory.** Comparison of fatigue correlates between PR3- and MPO-ANCA patients. Diagonal stripes indicate negative correlations.

51,9% ME/CFS

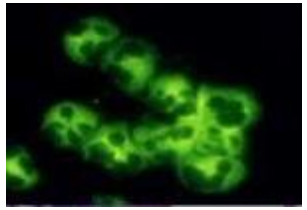
37% FMS

MPO-AAV (43,7%)

PR3-AAV (27,3%)

Van Eeden et al. The Lancet Regional Health- Americas 2023;20: 100460

AAV-Patienten – Fatigue

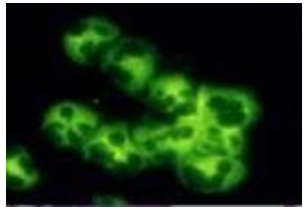


Fatigue in ANCA-associated vasculitis (AAV) and systemic sclerosis (SSc): similarities with Myalgic encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). A critical review of the literature

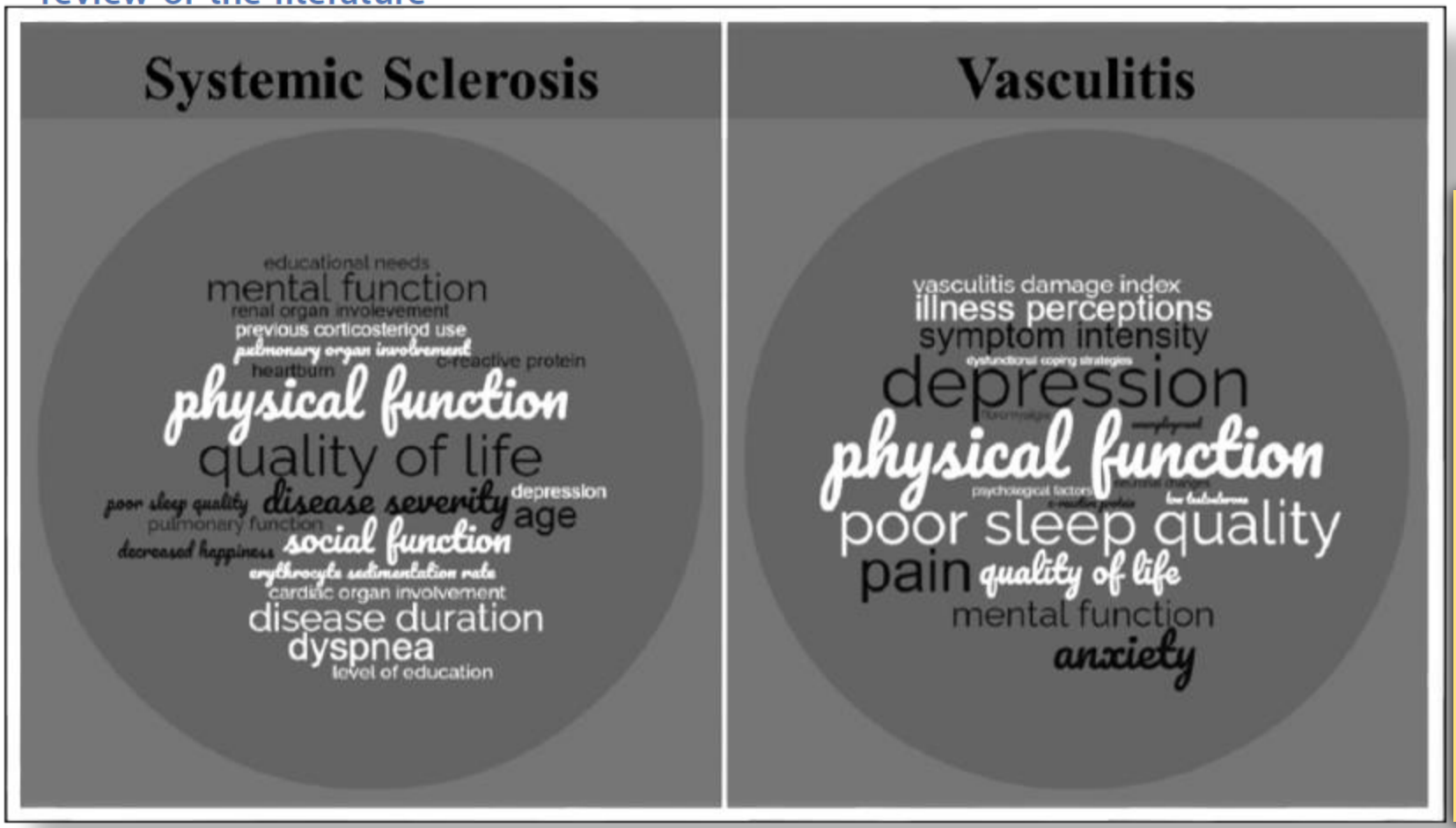
	ME/CFS	SSc	AAV
Immune and Metabolic Involvement	Autoantibodies Metabolic dys. Mitochondrial dys. Immune dys.	Autoantibodies Metabolic dys. Mitochondrial dys. Immune dys.	Autoantibodies Metabolic dys. Mitochondrial dys. Immune dys.
Organ Involvement		Skin Kidney Lung Heart	Skin Kidney Lung ENT
Tissue pathology		Vasculopathy Fibrosis	Vasculitis Granulomatous inflammation Glomerulonephritis

Van Eeden C et al. EXPERT REVIEW OF CLINICAL IMMUNOLOGY 2022;18(10):1049–1070

AAV-Patienten – Fatigue



Fatigue in ANCA-associated vasculitis (AAV) and systemic sclerosis (SSc): similarities with Myalgic encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). A critical review of the literature



Persistent fatigue is a prominent feature and not associated with disease activity / progression

Similarities between AAV and ME/CFS suggest common pathways and the requirement of alternative tx approaches

Van Eeden C et al. EXPERT REVIEW OF CLINICAL IMMUNOLOGY 2022;18(10):1049–1070

Welche Interventionen sind sinnvoll / getestet?

Psyche

sozial

Depression

Kognitive Verschlechterung

Angst

Therapie der Vaskulitis

Reduktion der Steroide

Fatigue

Berufstätigkeit

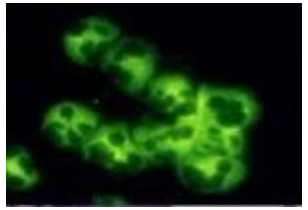
Schlafstörung

Einkommen

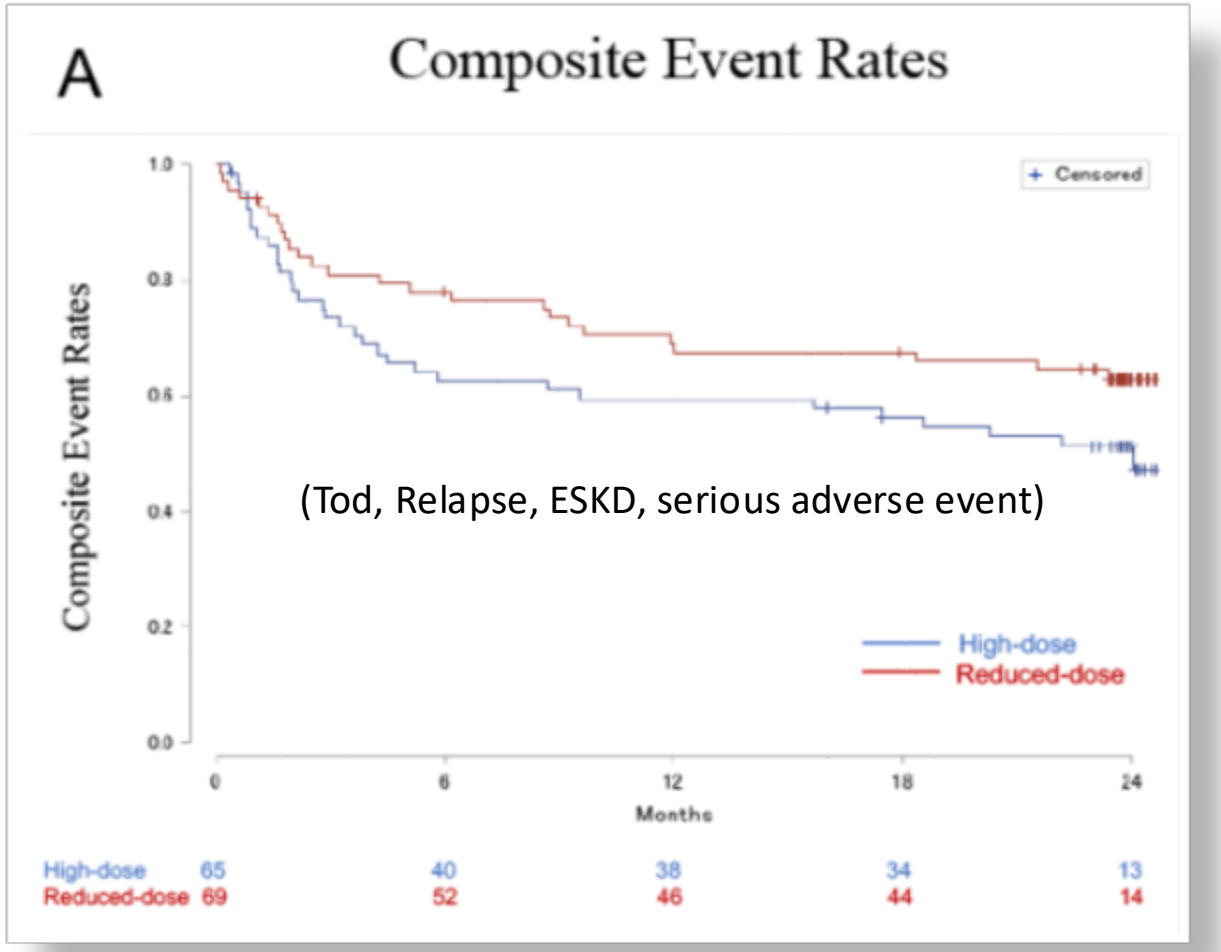
Soziale Teilnahme

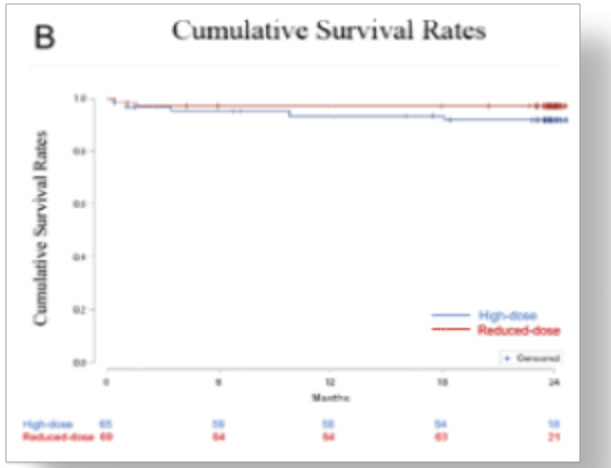
Physisch

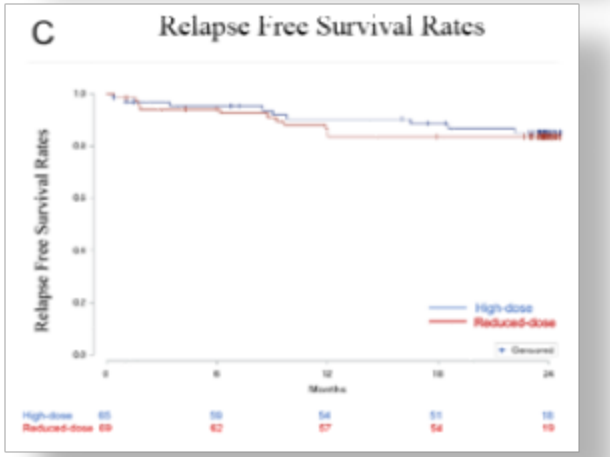
Reduktion der Steroiddosis: LoVas und PEXIVAS



140 Pat. mit AAV (GFR > 15 ml/min, keine pulm. Hämorrhagie), MPO-ANCA+
Low vs. high dose prednisolone (0.5 vs. 1 mg/kg/d) plus RTX (375 mg/m²/w×4), Monat 5 STOP vs. 10 mg

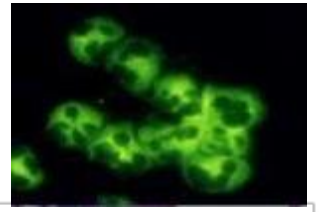






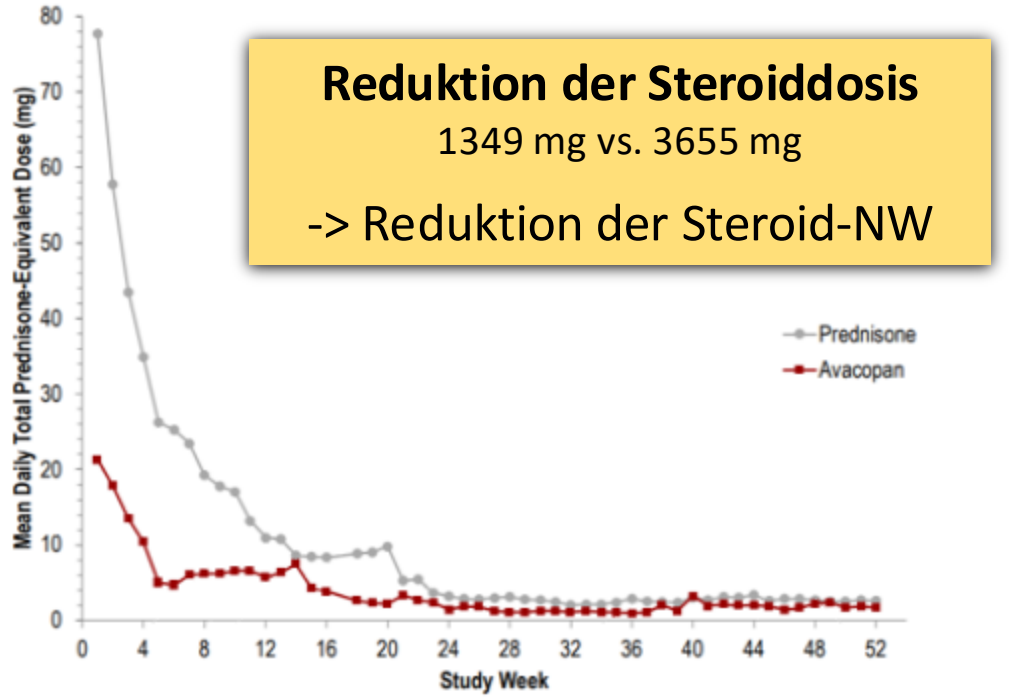
Furuta S et al. Ann Rheum Dis. 2024;83(1):96-102

Reduktion der Steroide: ADVOCATE- Avacopan – oraler C5a-Rezeptor-Blocker



331 Pat. mit AAV

Figure S7. Mean Daily Total Prednisone-Equivalent Glucocorticoid Dose (in mg) by Study Week by Treatment Group



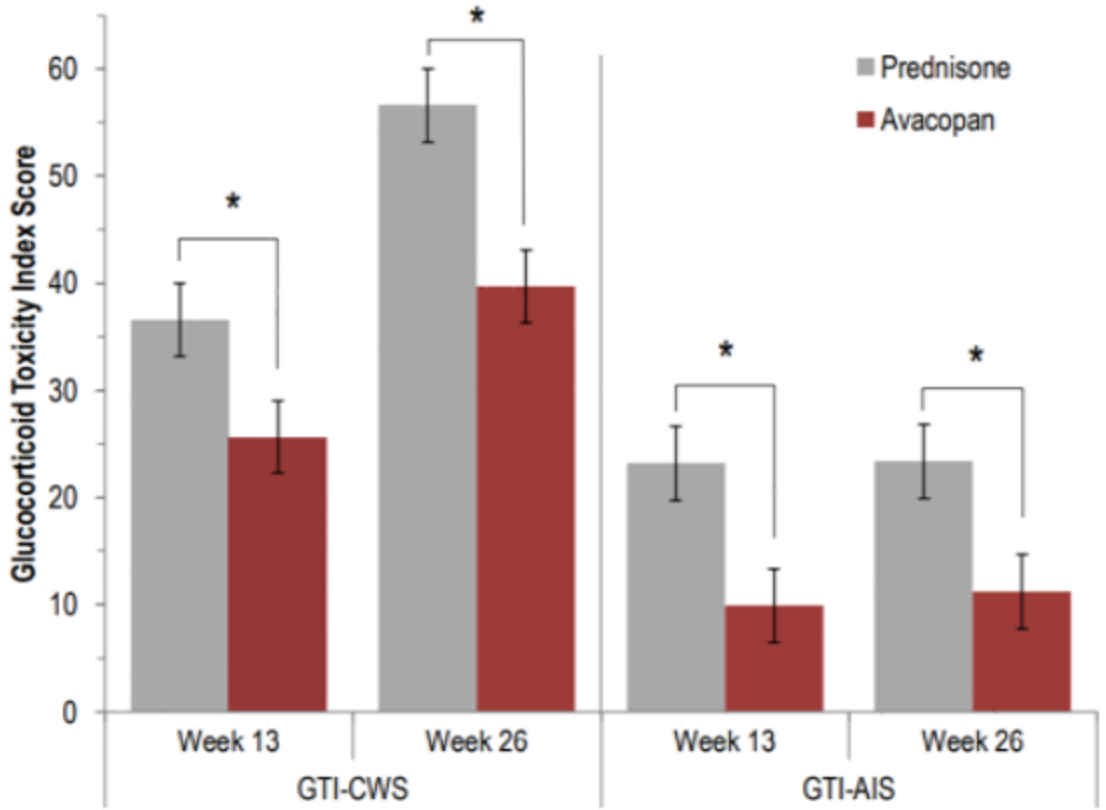
Reduktion der Steroiddosis

1349 mg vs. 3655 mg

-> Reduktion der Steroid-NW

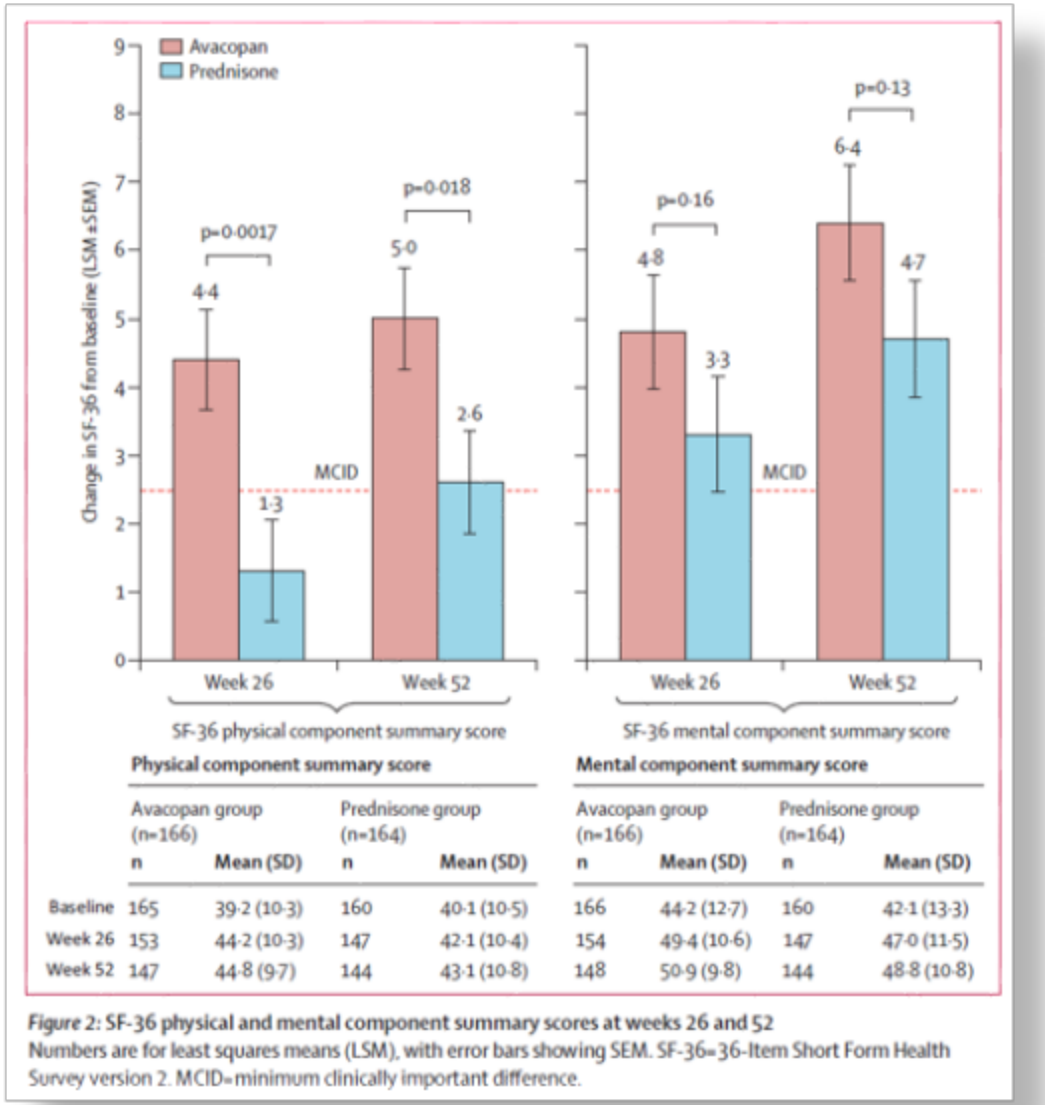
The weekly mean values were calculated based on all recorded systemic (oral or intravenous) glucocorticoid use by all patients in the respective treatment group at the start of each study week.

Figure S2. Glucocorticoid Toxicity Index



Jayne D et al. N Engl J Med. 2021;384(7):599-609

Reduktion der Steroide: ADVOCATE- Avacopan – oraler C5a-Rezeptor-Blocker



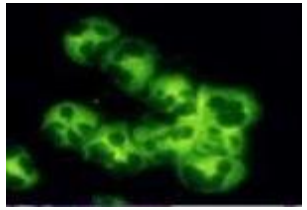
Physical component summary score

	Avacopan group (n=166)		Prednisone group (n=164)	
	n	Mean (SD)	n	Mean (SD)
Baseline	165	39·2 (10·3)	160	40·1 (10·5)
Week 26	153	44·2 (10·3)	147	42·1 (10·4)
Week 52	147	44·8 (9·7)	144	43·1 (10·8)

Mental component summary score

	Avacopan group (n=166)		Prednisone group (n=164)	
	n	Mean (SD)	n	Mean (SD)
Baseline	166	44·2 (12·7)	160	42·1 (13·3)
Week 26	154	49·4 (10·6)	147	47·0 (11·5)
Week 52	148	50·9 (9·8)	144	48·8 (10·8)

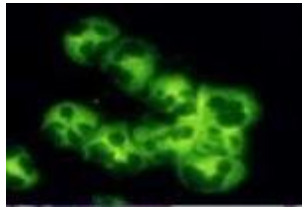
Figure 2: **SF-36 physical and mental component summary scores at weeks 26 and 52**
Numbers are for least squares means (LSM), with error bars showing SEM. SF-36=36-Item Short Form Health Survey version 2. MCID=minimum clinically important difference.



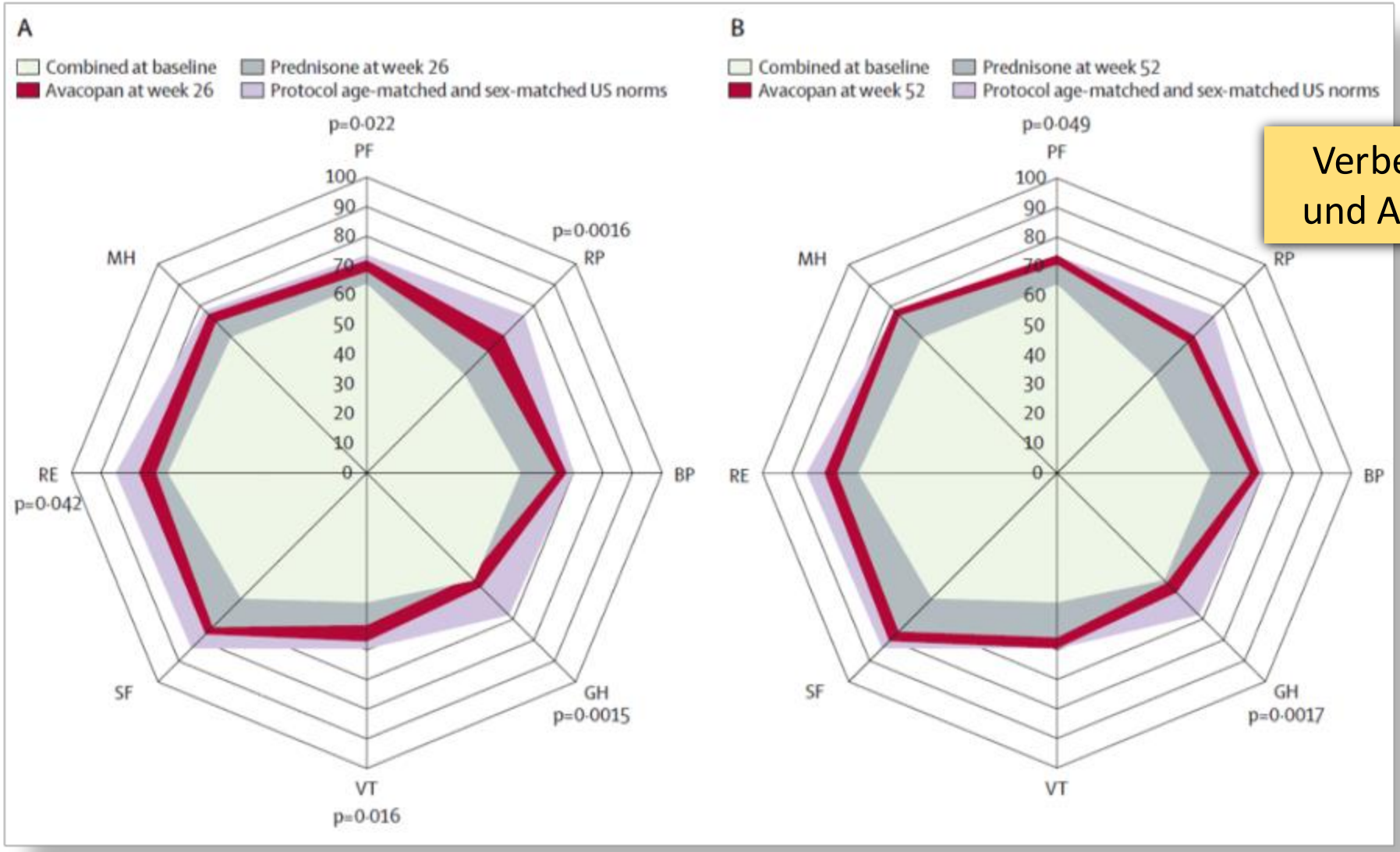
Verbesserung der Fatigue- und Allgemeinsymptomatik

Strand V et al. Lancet Rheumatol 2023;5:e451–60

Reduktion der Steroide: ADVOCATE- Avacopan – oraler C5a-Rezeptor-Blocker



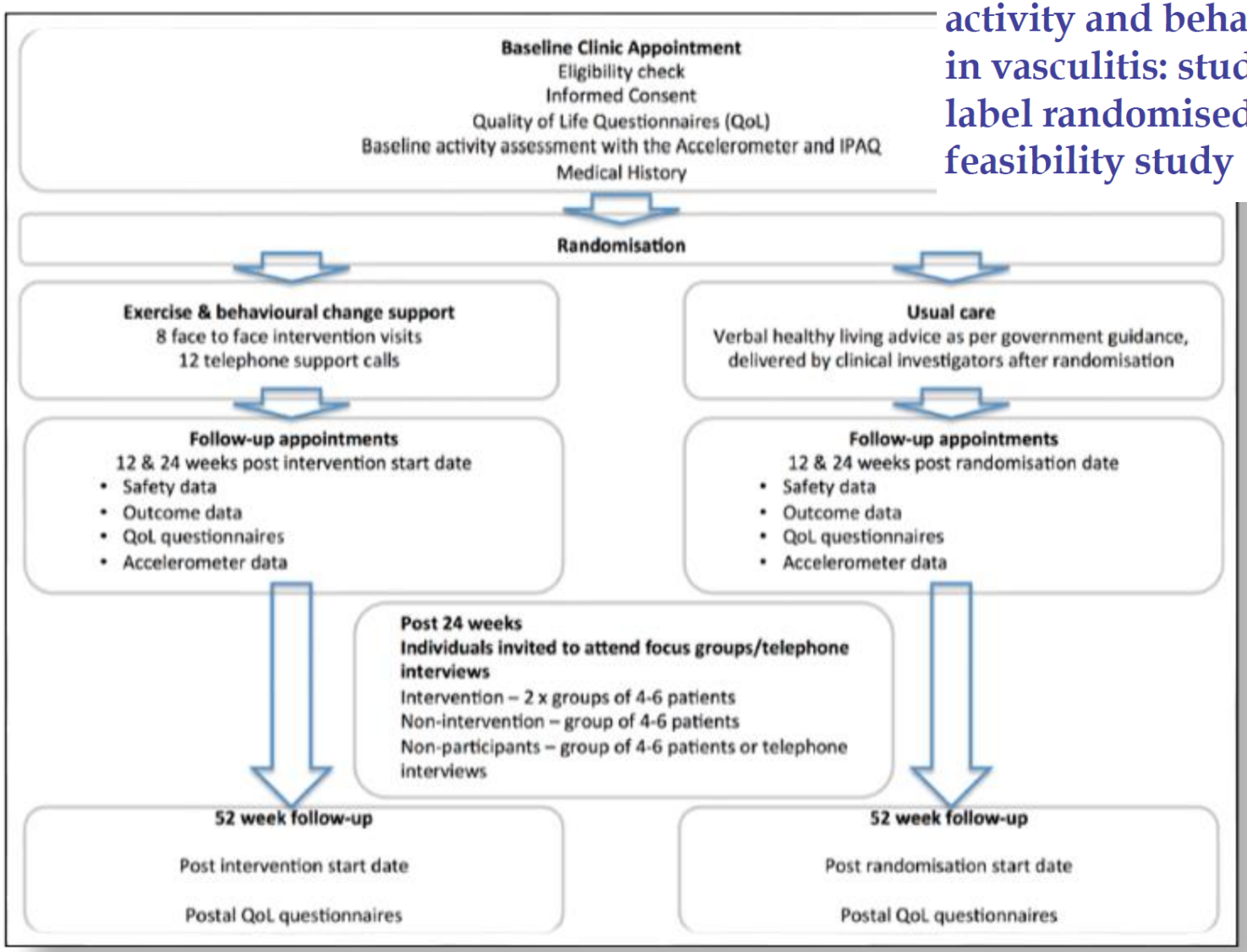
Verbesserung der Fatigue- und Allgemeinsymptomatik



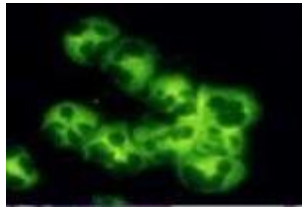
PF=physical functioning. RP=role physical. BP=bodily pain. GH=general health. VT=vitality. SF=social functioning. RE=role emotional. MH=mental health.

Strand V et al. Lancet Rheumatol 2023;5:e451–60

AAV-Patienten: Therapie der Fatigue

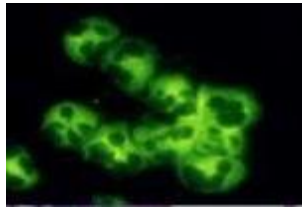


Treatment of fatigue with physical activity and behavioural change support in vasculitis: study protocol for an open-label randomised controlled feasibility study



Harper L et al. BMJ Open 2018;8:e023769.

AAV-Patienten: Therapie der Fatigue



Management of fatigue with physical activity and behavioural change support in vasculitis: a feasibility study

TABLE 3 Patient reported outcome measures

	Baseline		12 weeks			24 weeks			52 weeks		
	Intervention	Standard care	Intervention	Standard care	Adjusted mean difference[a] (95% CI)	Intervention	Standard care	Adjusted mean difference[a] (95% CI)	Intervention	Standard Care	Adjusted mean difference[a] (95% CI)
MFI-20: General fatigue	16.3 (2.6, 22)	16.9 (2.1, 19)	14.2 (3.0, 19)	15.5 (3.6, 20)	−0.8 (−3.1, 1.6)	13.4 (2.7, 17)	14.3 (3.1, 18)	−0.7 (−2.7, 1.4)	13.8 (4.0, 14)	14.7 (2.8, 18)	−0.6 (−3.3, 2.1)
BRAF-MDQ: Total	34.1 (12.1, 17)	35.6 (11.7, 18)	26.3 (13.9, 16)	27.5 (12.9, 15)	−2.9 (−11.9, 6.2)	31.0 (17.2, 12)	29.2 (14.4, 13)	5.3 (−6.4, 16.9)	31.0 (13.6, 12)	30.4 (13.7, 19)	3.2 (−6.0, 12.4)
SF-36: General health	42.4 (19.0, 19)	34.0 (16.1, 21)	46.6 (19.7, 19)	39.3 (18.6, 21)	−0.1 (−10.2, 10.1)[b]	47.8 (22.0, 18)	38.7 (18.9, 19)	1.0 (−10.9, 12.9)[b]	39.2 (22.0, 13)	38.9 (24.0, 19)	−14.5 (−27.9, −1.0)[b]
HADS: Depression	5.0 (3.3, 20)	6.5 (3.5, 21)	4.2 (3.0, 17)	5.9 (3.2, 20)	−1.0 (−2.9, 0.8)	5.1 (4.0, 19)	5.7 (4.1, 18)	0.3 (−1.8, 2.4)	5.5 (3.5, 14)	5.7 (4.3, 19)	0.7 (−1.4, 2.8)
HADS: Anxiety	6.5 (3.0, 21)	7.3 (4.3, 20)	6.4 (3.0, 18)	6.6 (4.4, 20)	0.1 (-1.8, 2.0)	6.9 (4.4, 19)	5.7 (4.5, 18)	1.8 (−0.7, 4.2)	7.2 (4.6, 14)	6.1 (4.7, 19)	1.8 (−0.7, 4.3)
PSQI: Global	9.50 (3.84, 18)	9.45 (4.21, 20)	8.45 (4.94, 20)	8.47 (4.91, 17)	1.07 (−0.82, 2.96)	8.64 (4.31, 14)	8.06 (4.78, 17)	0.59 (−1.71, 2.89)	8.77 (3.83, 13)	7.5 (4.49, 18)	1.95 (0.01, 3.88)

[a]Adjusted for age and baseline score. Adjusted mean differences <0 favour intervention group for MFI-20, BRAF-MDQ, HADS and PSQI. [b]Adjusted mean differences >0 favour intervention group for SF-36. Data presented as Mean (SD, *N*), adjusted mean difference presented as mean difference (95% CI) MFI domain scores range from 4 to 20, where higher scores suggest a higher degree of fatigue. SF-36 domain scores range from 0 to 100, where lower scores suggest greater presence of limitations in that domain. BRAF-MDQ total score ranges from 0 to 70, where higher scores suggest a higher degree of fatigue. HADS domain scores range from 0 to 21, a score of <7 in either anxiety or depression subscale is regarded as normal, a score of 8–10 is suggestive of the presence of the respective mood disorder and a score of ≥11 indicating the probable presence of mood disorder. PSQI global score ranges from 0 to 21, and a score >5 indicates overall poor sleep quality. MFI-20, Multi-dimensional Fatigue Inventory 20; BRAF-MDQ, Bristol Rheumatoid Arthritis Fatigue-Multidimensional Questionnaire; SF-36, Short Form-36; HADS, Hospital Anxiety and Depression Score; PSI, Pittsburgh Sleep Index; *N*, number.

Rheumatology key messages

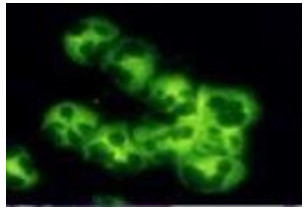
- There are no recommended therapies to treat fatigue but physical activity may improve symptoms.
- ANCA vasculitis patients with fatigue can be recruited to a physical activity intervention.
- A large RCT is required to assess the clinical benefits and cost-effectiveness of a physical activity intervention.

The trial recruitment rate of 32% is similar to studies of PA interventions in patients with cancer.

Harper L et al. Rheumatology 2021;60:4130–4140

AAV-Patienten: Ein Blick zur Seite – Therapie des FMS

Das Fibromyalgiesyndrom als Schmerzsyndrom in der Rheumatologie



▶ **Tab. 2** Pharmakotherapie des FMS, Empfehlungen aus [12].

Medikament	Amitriptylin	Pregabalin	Duloxetin	Fluoxetin	Tramadol
Zulassung	chronische Schmerzen	neuropathischer Schmerz, generalisierte Angststörung	depressive Störung, generalisierte Angststörung	depressive Störung, generalisierte Angststörung	mäßig starke bis starke Schmerzen
Dosierung	10–50 mg/die	150–450 mg/die	60 mg/die	20–40 mg/die	50–400 mg/die
Evidenzlevel	EL1a	EL1a	EL1a	EL2a	EL2a
Empfehlung	Empfehlung, starker Konsens	Empfehlung, starker Konsens	Empfehlung, starker Konsens	Offene Empfehlung	Keine Empfehlung; offene Empfehlung in LONTS [20]

LONTS – Leitlinie zur „Langzeitanwendung von Opioiden bei nicht tumorbedingten Schmerzen" [20]

Klinische Relevanz

Bei der Behandlung des FMS sind Aufklärung und Bewegung wichtige Therapiesäulen, bei schweren Verläufen sollte eine multimodale Behandlung erwogen werden. Auch eine kognitive Verhaltenstherapie kann sinnvoll sein. Eine pharmakologische Therapie wird nur nachrangig im Rahmen von Komorbiditäten (z. B. einer Depression) empfohlen. Insbesondere Opioide sollten nicht eingesetzt werden.

Klinische Relevanz

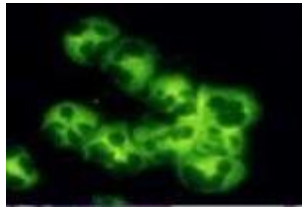
Spannend sind die vorliegenden Daten zu Naltrexon, das in niedriger Dosierung möglicherweise beim FMS eingesetzt werden könnte. Die positiven Ergebnisse zur TENS-Nutzung sind vielversprechend, auch wenn der Stellenwert dieses einfachen Verfahrens erst durch weitere Untersuchungen endgültig bestimmt werden kann.

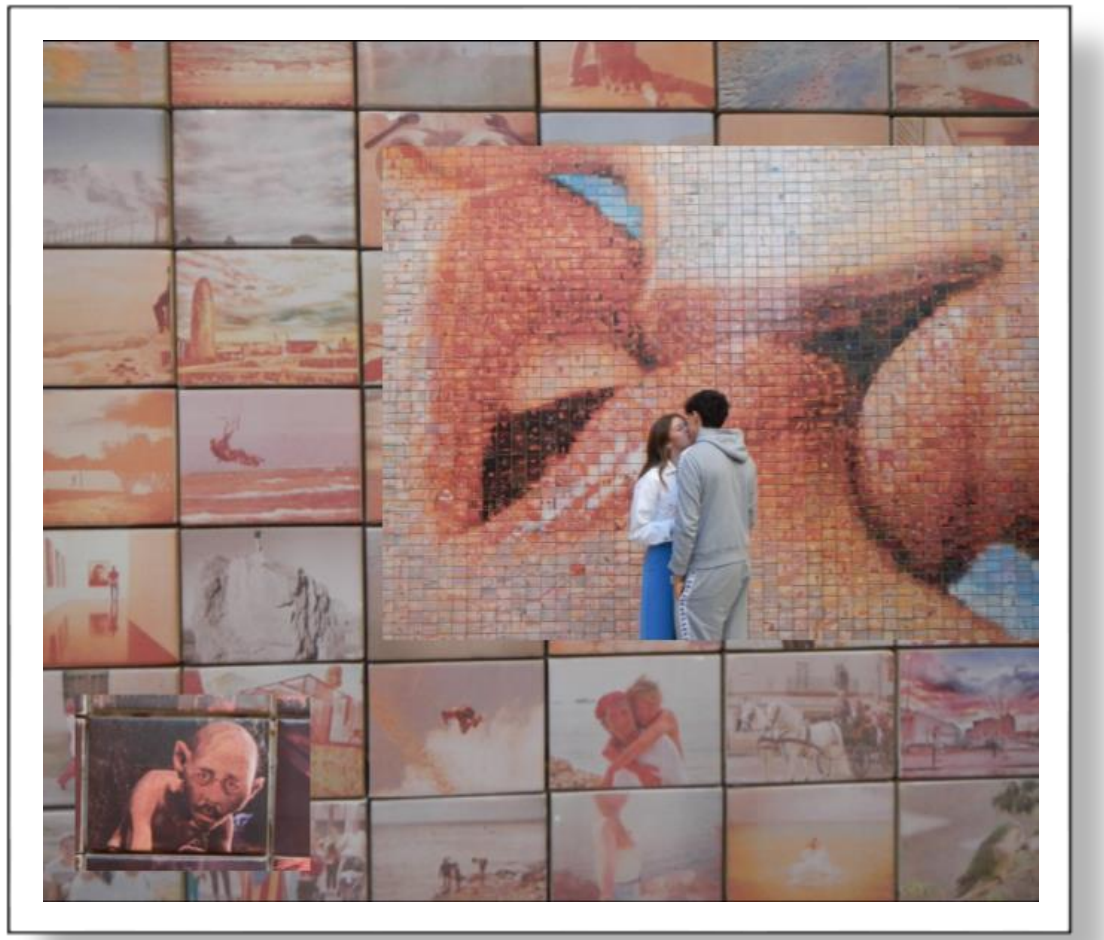
Hinsichtlich der Einschätzung des möglichen Nutzens einer Behandlung mit Cannabinoiden sind größere placebokontrollierte Studien, insbesondere auch zu den einzelnen Präparaten, erforderlich. Die Evidenz ist hier noch sehr gering.

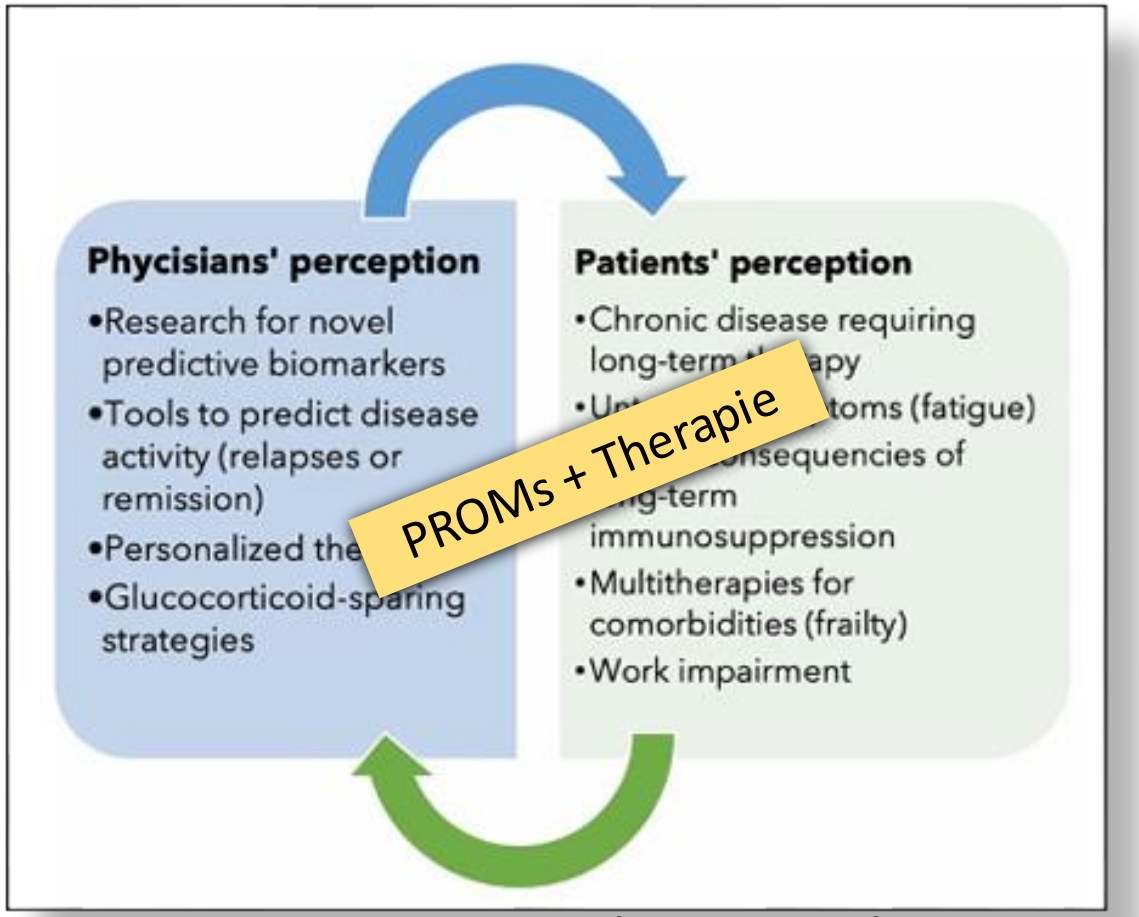
Krasselt M et al. Dtsch Med Wochenschr 2023;148:1467–1472

Begleitung der AAV-Patienten und Erhalt der Lebensqualität.

Vielen Dank !







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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.