What's new in 2025 for Sjögren's disease?

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Terminology

nature reviews rheumatology

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Consensus statement

Check for updates

2023 International Rome consensus for the nomenclature of Sjögren disease

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- Sjögren's syndrome = Sjögren's disease (SjD)
- "Associated SjD" (not secondary SjD)

Launch of Sjögren's Australia

Sjögren's Australia

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Sjögren's Australia

Advocating for Sjögren's disease patients and research

Sjogrenaustralia.com.au

25 August 2025

Sjögren's disease in Australia: why we need to pay attention

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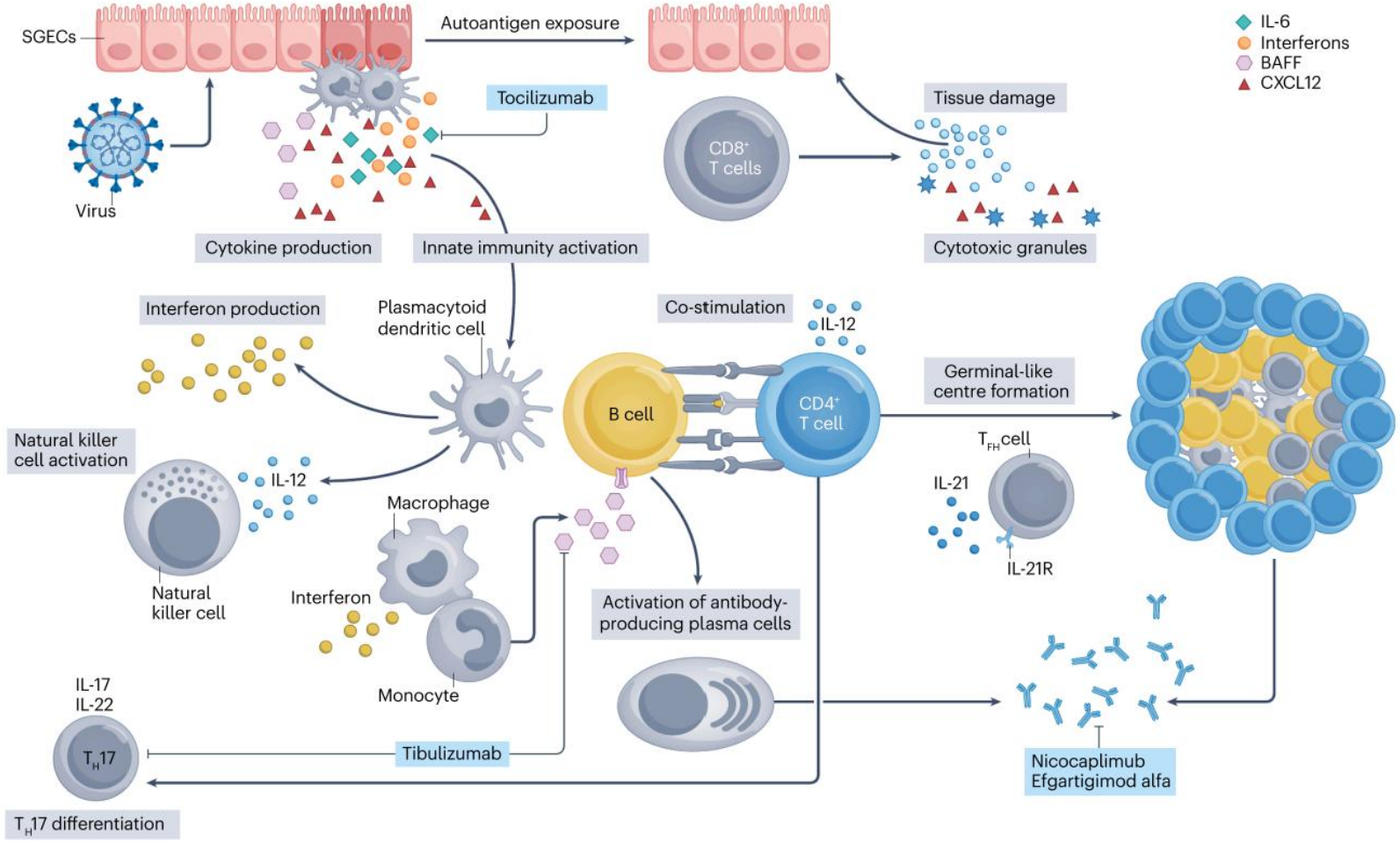
Most of us have heard of Sjögren's disease (or Sjögren's syndrome), an autoimmune condition that targets moisture-producing glands. We associate it with dry eyes and dry mouth (sicca symptoms), and while those symptoms are certainly hallmark features, they are only part of the story.

Sjögren's disease is a common systemic autoimmune disease, likely affecting about 1 in 300 Australians. This estimate is drawn from international studies, with Australian prevalence data expected in the future. Despite this, it continues to fly under the radar for many clinicians. Sjögren's disease extends well beyond the eyes and mouth, with the potential to involve multiple organ systems, from the lungs and kidneys to the skin, nervous system, and joints. Left undiagnosed or untreated, it can cause significant morbidity, and in some cases, irreversible organ damage.

Pathogenesis overview



Baldini et al. Nat Rev Rheumatol 2024

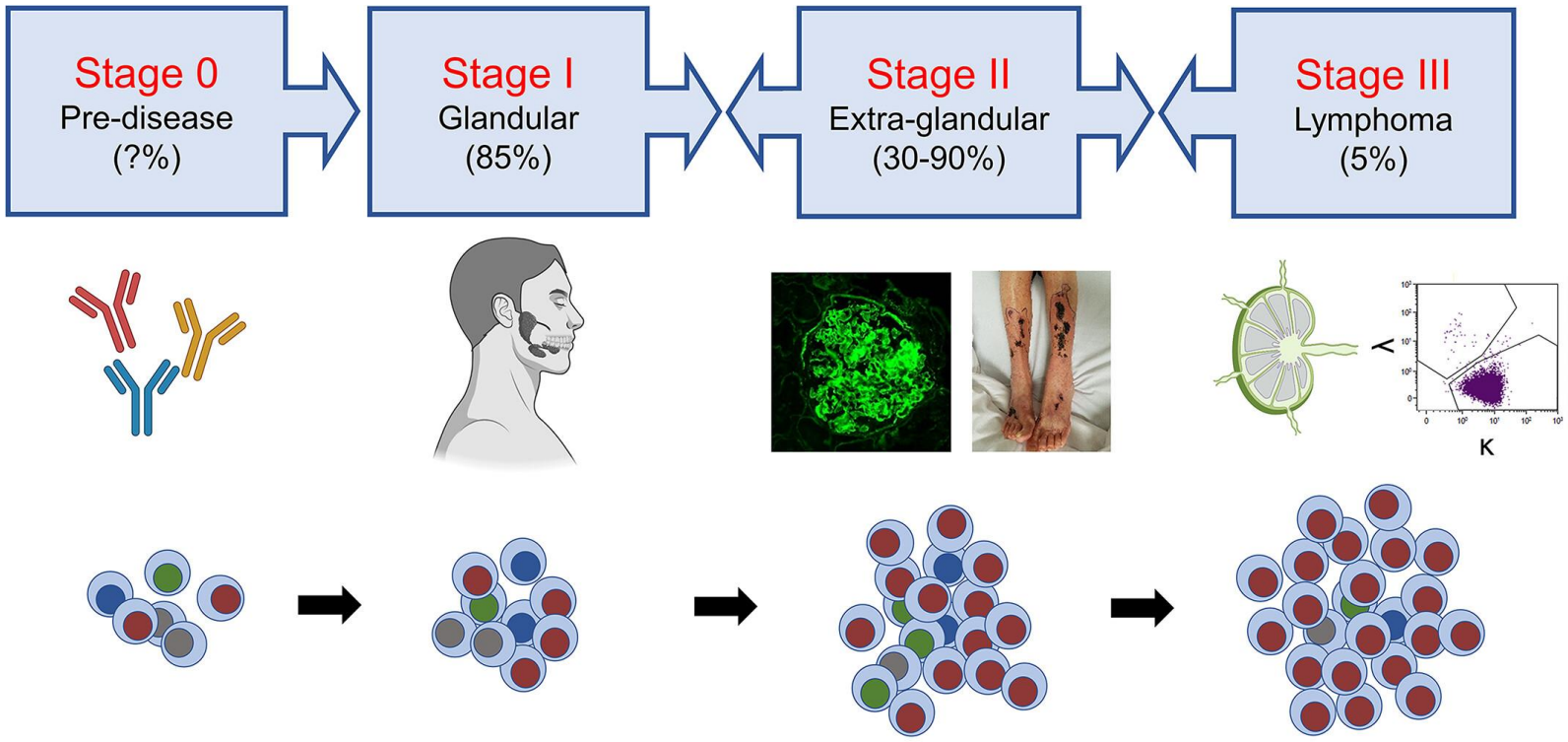
Epithelitis

- Epithelia of saliva gland
  - Environment sensing
  - Pro-inflammatory cytokines
  - Antigen presentation

- Increased apoptosis of SG cells
  - Release of autoantigens

Tang et al. J Leukoc Biol 2024
Chatzis et al. CER. 2025

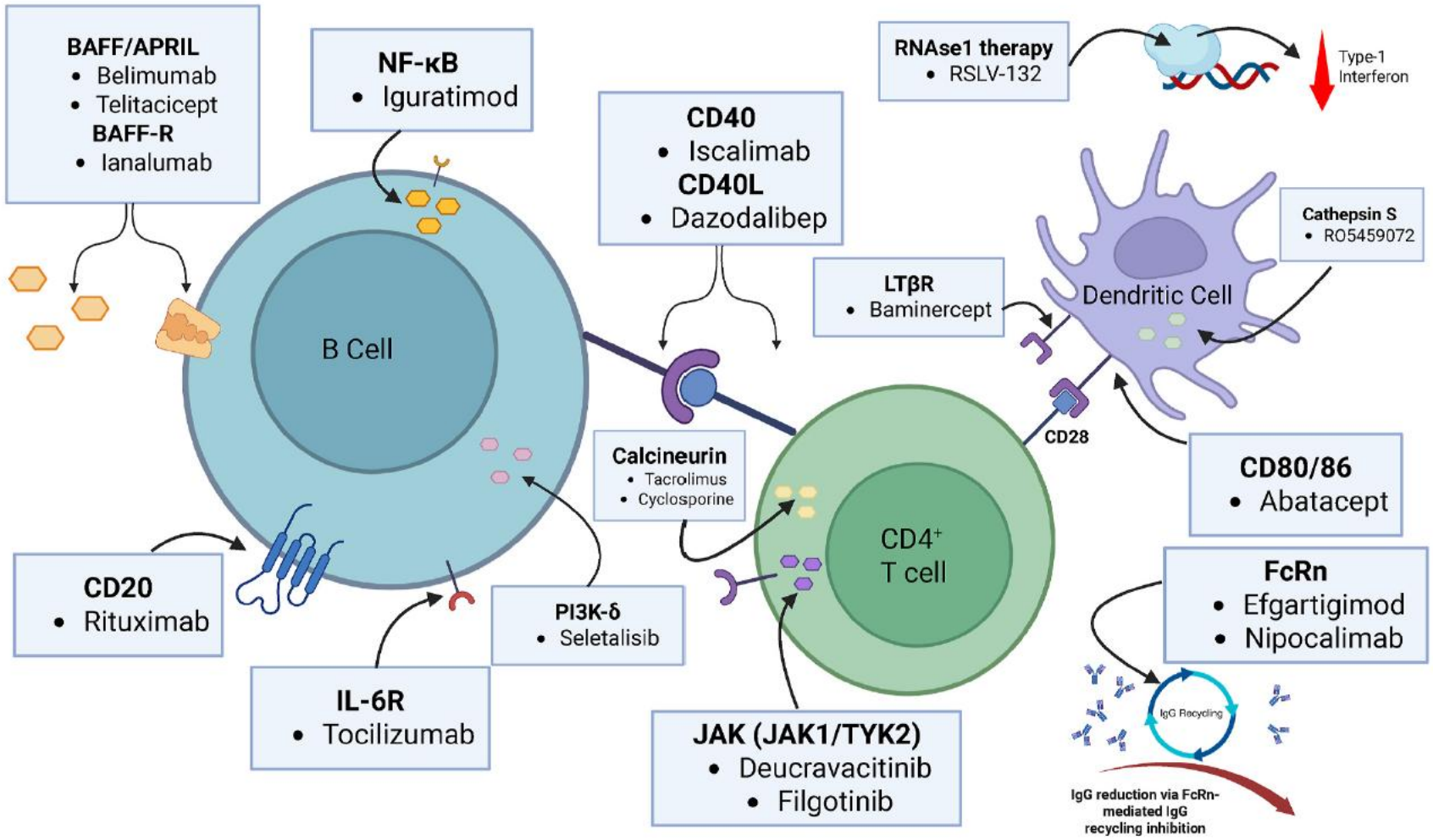
B cell hyperactivity disorder



Progressive B cell hyperreactivity, clonal selection and expansion

Lee et al. Arthritis Care Res. 2023

Emerging treatments



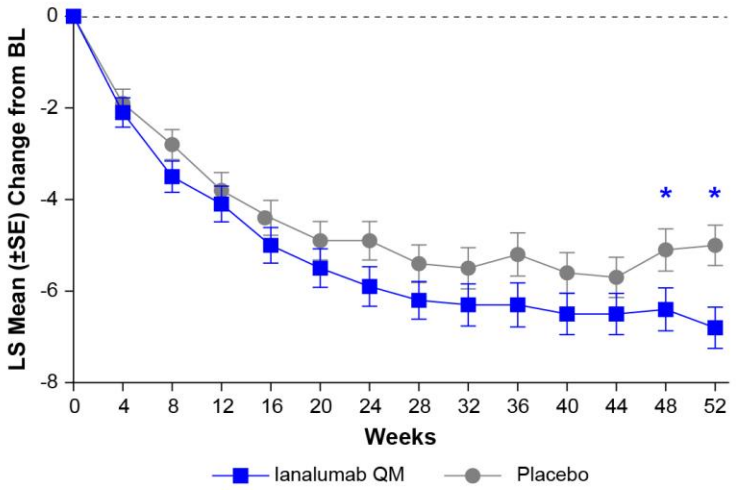
Pelkas et al. Best Pract Res Clin Rheumatol. 2025

Phase III trials for SjD

Investigational Product	Target(s)	ClinicalTrials.gov ID	Locations	Sponsor	Status
Ianalumab (VAY736)	BAFF-R, B cells	NCT05350072 (NEPTUNUS-1) NCT05349214 (NEPTUNUS-2)	International	Novartis Pharmaceuticals	Active, not recruiting
Telitacicept	BAFF and APRIL	NCT05673993	China	RemeGen Co., Ltd.	Completed
Nipocalimab	FcRn	NCT06741969 (DAFFODIL)	International	Janssen Research & Development	Recruiting
Dazodalibep	CD40L	NCT06245408	International	Amgen	Recruiting
Efgartigimod	FcRn	NCT06684847 (Unity)	International	Argenx	Recruiting

NEPTUNUS Trials

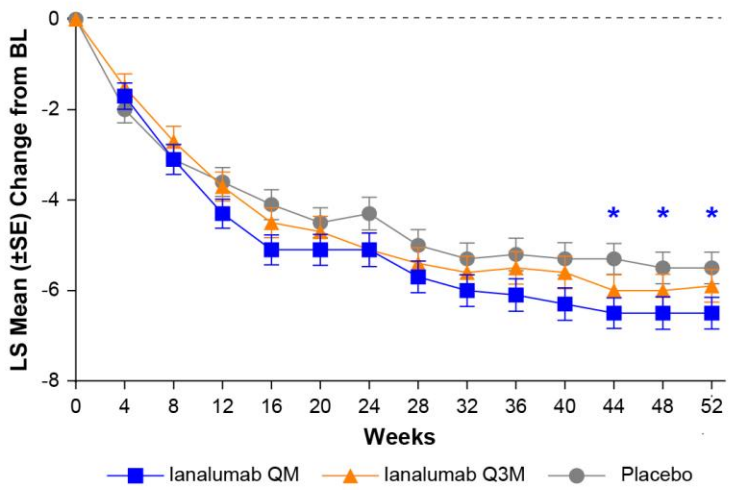
A



Change from BL in ESSDAI score at Week 48					
Treatment	LS mean (SE)	Comparison	Difference (Ianalumab - Placebo)		
			Diff. in LS mean (SE)	95% CI	p-value
Ianalumab QM (n/N=120/137)	**-6.4** (0.47)	vs Placebo	-1.3 (0.66)	(-2.6, 0.0)	0.0496
Placebo (n/N=123/138)	**-5.1** (0.46)				

BL ESSDAI Mean (SD): Ianalumab QM: 12.7 (6.81), Placebo: 12.6 (6.73)

B



Change from BL in ESSDAI score at Week 48					
Treatment	LS mean (SE)	Comparison	Difference (Ianalumab - Placebo)		
			Diff. in LS mean (SE)	95% CI	p-value
Ianalumab QM (n/N=145/168)	**-6.5** (0.36)	vs Placebo	-1.0 (0.51)	(-2.0, 0.0)	0.041
		vs Ianalumab Q3M	-0.6 (0.51)	(-1.6, 0.4)	0.2766
Ianalumab Q3M (n/N=145/167)	**-6.0** (0.36)	vs Placebo	-0.5 (0.51)	(-1.5, 0.5)	0.3413
Placebo (n/N=156/169)	**-5.5** (0.35)				

BL ESSDAI Mean (SD): Ianalumab QM: 11.7 (5.84), Ianalumab Q3M: 11.5 (6.18), Placebo: 12.1 (5.73)

*Indicates significant treatment effect observed with p-value <0.05.
#The primary endpoint was evaluated using an ANCOVA model with study treatment, ESSDAI strata, and region as factors and baseline score as covariate.
BL, baseline; ESSDAI, EULAR Sjögren's Syndrome Disease Activity Index; N, number of patients in each treatment group of the specified analysis set; n, number of patients with evaluable data; QM, monthly, Q3M, every 3 months.

Beck et al. ACR Abstract 2025

NEPTUNUS Trials

Category*#	NEPTUNUS-1		NEPTUNUS-2		
	Ianalumab QM (N=137) n (%)	PBO (N=138) n (%)	Ianalumab QM (N=168) n (%)	Ianalumab Q3M (N=167) n (%)	PBO (N=169) n (%)
AEs	116 (84.7)	111 (80.4)	146 (86.9)	145 (86.8)	145 (85.8)
AEs related to study treatment	62 (45.3)	48 (34.8)	90 (53.6)	82 (49.1)	69 (40.8)
AEs leading to treatment discontinuation	5 (3.6)	5 (3.6)	14 (8.3)	11 (6.6)	6 (3.6)
SAEs	5 (3.6)	12 (8.7)	16 (9.5)	13 (7.8)	18 (10.7)
Death	0	1 (0.7)	0	0	0
Infections and infestations (SOC)	78 (56.9)	81 (58.7)	92 (54.8)	98 (58.7)	113 (66.9)
Serious Infections and infestations (SOC)	3 (2.2)	1 (0.7)	5 (3.0)	5 (3.0)	8 (4.7)

AEs, adverse events; N, total number of patients per group; n, number of patients with an event; PBO, placebo, QM, monthly; Q3M. every 3 months; SAEs; serious AEs; SOC, system organ class.

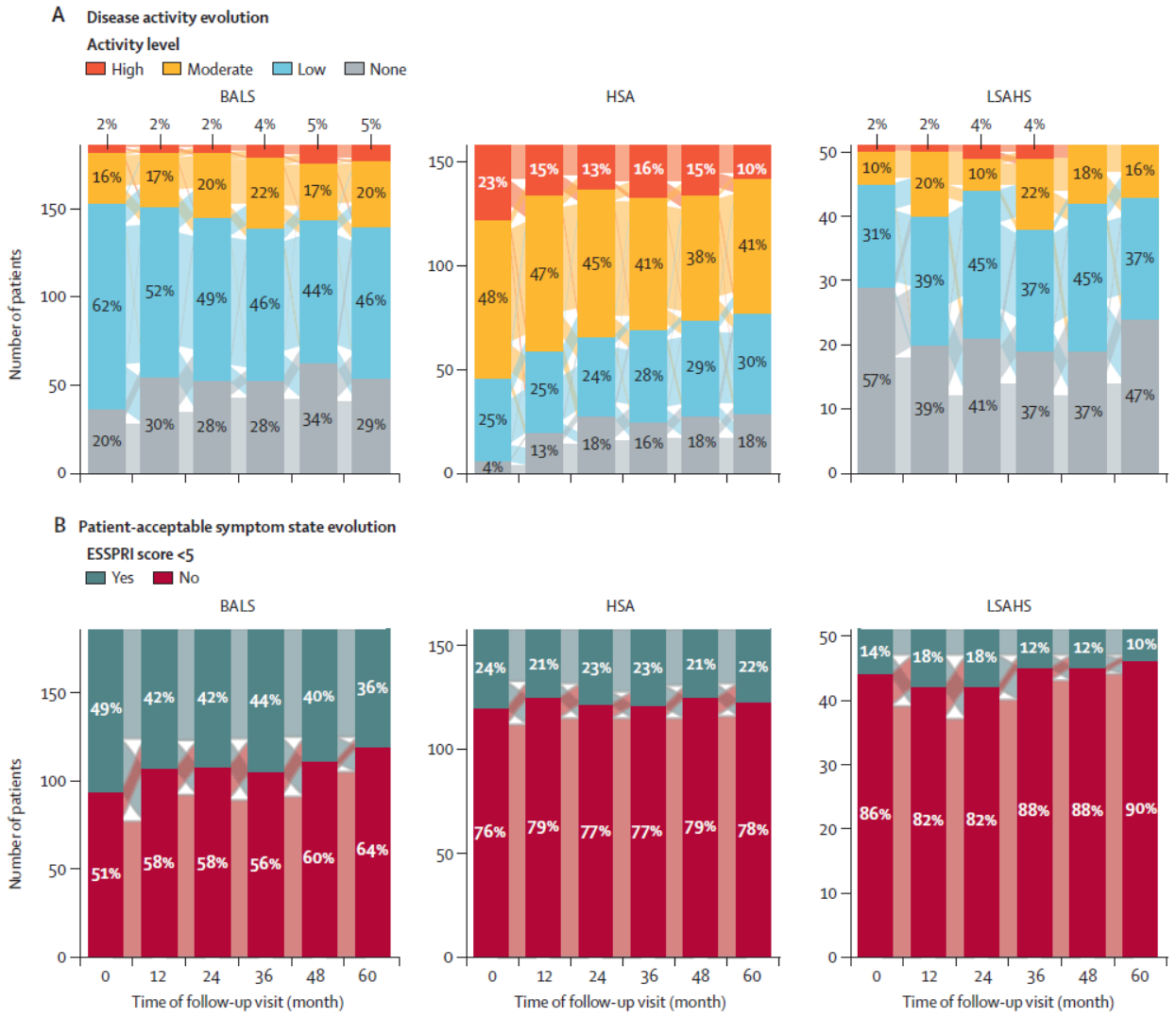
*A patient with multiple occurrences of an AE under one treatment is counted only once in the AE category for that treatment.

#A patient with multiple severity grades for an AE is only counted under the maximum grade.

Beck et al. ACR Abstract 2025

Sjögren's phenotypes

- BALS = B cell active disease and low symptom burden
- HAS = high systemic disease activity
- LSAHS = low systemic disease activity and high symptom burden



Nguyen et al. Lancet Rheum 2024

PNS manifestations of SjD

Arthritis Care & Research
Vol. 0, No. 0, Month 2026, pp 1–15
DOI 10.1002/acr.70004

AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

Clinical Practice Guideline for Evaluation and Management of Peripheral Nervous System Manifestations in Sjögren's Disease

Anahita Deboo, MD,[1] Robert Fox, MD, PhD,[2] Katherine M. Hammitt, MA,[3] Julie Frantsve-Hawley, PhD,[3,4] Matthew C. Baker, MD, MS,[5] Stamatina Danielides, MD,[6,7] Eduardo De Sousa, MD,[8] Brent P. Goodman, MD,[9] Jennifer K. King, MD, PhD,[10] Steven Mandel, MD,[11] Ghaith Noaiseh, MD,[12] Pantelis P. Pavlakis, MD, PhD,[13] George Sarka, MD, DrPH,[14,15,16] R. Hal Scofield, MD,[17,18,19] Arun Varadhachary, MD, PhD,[20] Daniel J. Wallace, MD,[10,14] Matt Makara, MPH,[3] Nancy Carteron, MD,[21,22] and Steven Carsons, MD,[23] in collaboration with the Consensus Expert Panel (CEP) members

- 8-60% of patients
- Assess for cranial neuropathies
  - GC
  - Carbamazepine
- Mononeuropathies e.g., ulnar nerve neuropathy

- Polyneuropathies (10-20%)
  - Pregabalin
  - Carbamazepine → TCAs
  - Glucocorticoids
  - IVIg in non-vasculitic neuropathies
  - GC/RTX for vasculitic neuropathies

- Autonomic neuropathies (up to 50%)
  - Specialised multidisciplinary team required

The following screening process is recommended for the initial assessment of potential autonomic nervous system (ANS) involvement in Sjögren's:

For primary screening, ask the following questions:

1. Do you experience postural lightheadedness, syncope (fainting), near-syncope, or a racing heart when upright?
2. Do you experience problems with sweating too little, or too much?
3. Do you have chronic GI symptoms or problems, such as:
   - Difficulty swallowing
   - Nausea
   - Abdominal pain
   - Feel like you fill up more quickly than you ought to when eating a meal (early satiety)
   - Diarrhea or constipation. If yes, does diarrhea occur at night?
   - Significant abdominal bloating
4. Do you have genitourinary problems, such as:
   - Sexual dysfunction
   - Difficulty emptying your bladder completely or incontinence
   - Frequent urination, particularly frequent nocturnal enuresis
   - Urogenital problems and/or pelvic pain

Summary

- Sjögren’s disease (not Sjögren’s syndrome)
- Systemic epithelitis
- Emerging phase III targeted therapies
- PNS manifestations are heterogenous

References / further reading

- Baldini et al. Nat Rev Rheumatol. 2024;20(8):473-491. doi: 10.1038/s41584-024-01135-3
- Deboo et al. Arthritis Care Res (Hoboken). 2025. doi: 10.1002/acr.70004
- Lee et al. Arthritis Care Res (Hoboken). 2023;75(7):1580-1587. doi: 10.1002/acr.25011
- Nguyen et al. Lancet Rheumatol. 2024;6(4):e216-e225. doi: 10.1016/S2665-9913(23)00340-5
- Pelkas et al. Best Pract Res Clin Rheumatol. 2025;39(4):102084. doi: 10.1016/j.berh.2025.102084
- Ramos-Casals et al. Nat Rev Rheumatol. 2025;21(7):426-437. doi: 10.1038/s41584-025-01268-z
- Tang et al. J Leukoc Biol. 2024;115(1):57-67. doi: 10.1093/jleuko/qiad049