

Sjögren's Disease: Bridging the 5-Year Diagnostic Gap to Emerging Therapies

Written by The Life Science Feed Editorial Team · Published 27 August 2026 · Edited by Mara Voss

Sjögren's disease (SjD) is a prevalent yet often delayed diagnosis among systemic rheumatic autoimmune conditions. Patients typically endure a five to six-year wait from symptom onset to diagnosis, during which time significant and irreversible damage can occur. This review synthesizes the current landscape, focusing on persistent challenges and the potential of novel therapeutic approaches.

KEY TAKEAWAYS

- **The Pivot:** Current SjD management is largely symptomatic, but emerging immunoselective therapies show promise in addressing systemic immunopathology.
- **The Data:** Patients experience an average diagnostic delay of 5-6 years, contributing to irreversible glandular and systemic damage.
- **The Action:** Earlier recognition, consistent use of validated outcome measures (ESSDAI, ESSPRI), and rational adoption of new therapies guided by biomarkers are crucial for improving patient outcomes.

Understanding Sjögren's Disease and Its Challenges

Sjögren's disease (SjD) is a chronic, systemic autoimmune condition characterized by the infiltration of lymphocytes into exocrine glands, leading to sicca symptoms, alongside significant extraglandular involvement. Despite being one of the most common systemic rheumatic autoimmune diseases, patients frequently experience a substantial diagnostic delay, averaging five to six years from the initial onset of symptoms. This prolonged period without a definitive diagnosis can result in the accumulation of irreversible glandular and systemic damage, underscoring a critical unmet need in clinical practice¹.

Current Management and Unmet Therapeutic Needs

Presently, there are no disease-modifying therapies specifically approved for SjD. Management primarily focuses on alleviating symptoms, utilizing interventions such as artificial tears for ocular dryness, sialogogues for oral dryness, and hydroxychloroquine. However, these treatments do not reliably halt the progression of systemic immunopathology. Key unmet needs include addressing the persistent burden of fatigue, cognitive dysfunction, chronic pain, and the elevated risk of lymphoproliferative disorders, which significantly impact patients' quality of life¹.

Diagnostic Tools and Outcome Measures

The review highlights the utility of the European Alliance of Associations for Rheumatology (EULAR) Sjögren's Syndrome Disease Activity Index (ESSDAI) and the EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI). These tools serve as complementary measures: ESSDAI quantifies systemic organ-based disease activity, while ESSPRI

captures the patient's self-reported symptom burden. Both indices are increasingly being adopted as primary endpoints in contemporary clinical trials for SjD, reflecting their growing importance in assessing treatment efficacy and disease progression¹.

Emerging Therapeutic Strategies

Several novel therapeutic strategies are under investigation, demonstrating promising efficacy signals in randomized controlled trials. These include immunoselective agents targeting specific pathways involved in SjD pathogenesis:

- Ianalumab: This therapy targets B-cells and the B-cell activating factor (BAFF) receptor, crucial components in autoimmune responses.
- Nipocalimab: An FcRn blocker, nipocalimab aims to reduce pathogenic autoantibody levels.
- Dazodalibep: This agent inhibits the CD40-CD40L pathway, a key co-stimulatory interaction involved in immune cell activation and inflammation¹.

These emerging therapies represent a potential shift from purely symptomatic management towards interventions that may modify the underlying disease process.

Clinical Implications and Future Directions

Improving outcomes for patients with SjD necessitates a multi-pronged approach. Earlier recognition of the disease is paramount to mitigate the accumulation of irreversible damage. Furthermore, the consistent application of validated outcome measures like ESSDAI and ESSPRI in routine clinical practice can provide a more objective assessment of disease activity and treatment response. The rational adoption of emerging immunoselective therapies, guided by biomarker-based patient stratification, holds significant promise for personalizing treatment and enhancing efficacy¹.

Why this matters for clinical practice today

The persistent diagnostic delay in Sjögren's disease means many patients present with established glandular and systemic damage. Clinicians should maintain a high index of suspicion for SjD in patients with persistent sicca symptoms, fatigue, or unexplained pain, especially given the availability of validated diagnostic criteria. The increasing use of ESSDAI and ESSPRI in trials suggests these tools will become more central to assessing disease activity and treatment response. As novel immunoselective therapies move closer to approval, understanding their mechanisms and potential for biomarker-guided use will be critical for rheumatologists to offer more targeted and effective treatment options beyond symptomatic relief.

Limitations and Next Steps

This review synthesizes current knowledge and highlights future directions. While emerging therapies show promise, further research is needed to fully characterize their long-term efficacy, safety profiles, and optimal patient populations. The development and validation of robust biomarkers for patient stratification will be crucial to ensure that these advanced therapies are deployed effectively and efficiently. Continued efforts to raise awareness among healthcare professionals about the early signs and symptoms of SjD are also essential to reduce diagnostic delays and improve patient prognosis¹.

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