Abstract N°: **761**
Track: **B) Clinical research**
Topic: **Sjögren's syndrome**
Sub-Topic: **Adult Rheumatology**
Keywords: **Quality of life , Observational studies / registry , Patient-led research , Real-world evidence**

Real-World Insights into the Burden of Sjögren's Disease: A Patient-Centered Analysis

Jessica Marvel[1], Gayle Kenney[2], Janet Church[3], Wan-Fai Ng[4], Robert Fox[6], Yuko Kaneko[8], Kaori Komori[7], Gavin Harper[5], Lucy Howard[5], Thom Dewar[5], Morgan Fox[5]

[1]Novartis Services Inc., East Hanover, New Jersey, United States of America, [2]Novartis Pharma AG, Basel, Switzerland, [3]Sjögren's Foundation,, Reston, VA, United States of America, [4]HRB Clinical Research Facility, University College Cork,, Cork, Ireland, [5]Adelphi Real World,, Bollington, United Kingdom, [6]Rheumatology, Scripps Memorial Hospital and Research Foundation, San Diego, CA, United States of America, [7]Department of Environmental Medicine, Kochi Medical School, Kochi University,, Kochi, Japan, [8]Department of Rheumatology, Keio University School of Medicine, Tokyo, Japan

Background:

Sjögren's is a chronic autoimmune disease affecting up to 1% of the global population, predominantly women (1-2). It is characterized by dryness symptoms (e.g., dry eyes, mouth and skin) alongside extra-glandular manifestations involving multiple organs and systems (3-4). Systemic features, such as fatigue, muscle or joint pain, neuropathies, and organ involvement, significantly affect patients' health-related quality of life (HRQoL) (5). Diagnosis is often delayed due to the heterogeneous nature of clinical presentations, further compounding disease burden (6). Despite its prevalence, real-world data on disease burden and patient reported outcomes (PROs) are limited (7). This study aims to provide global, real-world insights into the burden of Sjögren's.

Objectives:

The aim of this study is to better understand the burden, unmet needs, and treatment satisfaction among adults with Sjögren's. This abstract addresses the primary objective of quantifying the disease burden related to Sjögren's.

Methods:

A quantitative, cross-sectional online survey of adults (≥18 years) diagnosed with Sjögren's, excluding those with concomitant systemic lupus erythematosus, rheumatoid arthritis, and/or systemic sclerosis. Data were collected between December 2023 and September 2024 across eight countries: USA, China, Japan, France, Germany, Italy, Spain and the UK. Participants were recruited via treating physicians or patient associations, ensuring diversity in disease severity and clinical presentation. Survey variables included demographics, symptom burden, emotional well-being, work and financial impacts, and treatment expectations. The Work Productivity and Activity Impairment (WPAI) instrument was used to assess the impact of Sjögren's on work-related productivity and daily activities. All analyses were descriptive.

Results:

A total of 1,155 adults completed the survey (88% female, median age 54 years [IQR: 45.0, 65.0]), with a median diagnosis age of 47 years (IQR: 40.0, 56.0), an average of 6.9 years ago. The mean time from first noticing the signs and symptoms of Sjögren's to formal diagnosis was 5.3 years. Concomitant conditions affecting joints (41%), muscles (22%), bowels (19%), and lungs (16%) were commonly reported. Self-reported general health was rated as 'poor' or 'fair' by 65%.

The most commonly reported symptoms included dry mouth, dry eyes, dry skin and physical fatigue. Nearly all participants (94%) experienced at least one other systemic manifestation in addition to sicca symptoms.

Participants identified their top five priority symptoms to improve, or resolve were dry or itchy eyes (61%) and dry mouth or lips (59%), followed by physical fatigue (45%), tiredness (37%), and joint stiffness/soreness (31%). Physical fatigue was rated a median 6.0 out of 10.0 at its worst in the past 24 hours, where 0 was "absent" and 10 was "worst imaginable", with 42% rating it as 7 or higher. Sixty-four percent (n=735) reported experiencing their top-priority symptoms daily over the past month.

When asked about the extent Sjögren's interferes with usual daily activities, the most highly impacted areas of life were sports / physical activities, sexual desire / activity, and daily activities such as housework or gardening.

Sleep disturbances were also prevalent, with 64% reporting poor sleep quality, defined as waking unrefreshed ≥3 mornings a week. Poor sleep quality greatly impacted overall HRQoL for 59%, who rated the impact as 5-7 on a 7-point scale, where 7 was a 'significant impact'. Emotional wellbeing was also significantly impacted, with 58% rating a high impact of Sjögren's on their emotional wellbeing and 31% reporting symptoms of depression in the previous month.

WPAI results revealed substantial work productivity and daily activity impairment. Among paid employed participants (52%), presenteeism was reported at 43% and absenteeism at 11%. Overall activity impairment due to Sjögren's was reported at 48%, reflecting its broad impact on functionality and productivity.

Conclusion:

This real-world study highlights the multifaceted burden faced by adults with Sjögren's, and the impact on activities of daily living and HRQoL. High presenteeism reflects substantial impairment even while working. Sleep disturbances and mental health stressors, including depression, further compromise emotional well-being. These findings underscore the need for more effective or new therapies as well as comprehensive patient support to address the physical and emotional burden of Sjögren's.

References:

1. Carsons SE, Patel BC. Sjögren's Syndrome. StatPearls. Treasure Island (FL): StatPearls Publishing; 2022.
2. Parisis D, Chivasso C, Perret J, Soyfoo MS, Delporte C. Current state of knowledge on primary Sjögren's syndrome, an autoimmune exocrinopathy. J Clin Med. 2020;9(7):1-12.
3. Mariette X, Criswell LA. Primary Sjögren's Syndrome. N Engl J Med. 2018;378(10):931-939.
4. Negrini S, Emmi G, Greco M, Borro M, Sardanelli F, Murdaca G, et al. Sjögren's syndrome: a systemic autoimmune disease. Clin Exp Med. 2022;22(1):9-25.
5. Miyamoto ST, Valim V, Fisher BA. Health-related quality of life and costs in Sjögren's syndrome. Rheumatology. 2019;60:2588-2601.
6. Hammitt KM. Sjögren's: the patients' perspective. Clin Exp Rheumatol. 2020;38(Suppl 126(4)):25-26.
7. Lackner A, Ficjan A, Stradner MH, Hermann J, Unger J, Stamm T, et al. It's more than dryness and fatigue: The patient perspective on health-related quality of life in primary Sjögren's syndrome - a qualitative study. PLoS One. 2017;12(2):e0172056.

Acknowledgements:

Disclosure of interest: Jessica Marvel Jessica Marvel is a holder of Novartis stock and stock options., Jessica Marvel is employed by Novartis Services Inc, Gayle Kenney Gayle Kenney is an employee of Novartis Pharma AG, Janet Church Sjogren's Foundation received funding from Novartis for the email and access campaign to Member Sjogren's patients for the survey. This funding supports the mission of the Foundation., Wan-Fai Ng Wan-Fai Ng has provided consultations for Novartis, Johnsons & Johnsons Innovations, Bristol Myers Squibb, Sanofi, Argenx, IQVIA, Quotients & Resolves Therapeutics, Robert Fox: None declared, Yuko Kaneko Yuko Kaneko received honoraria from Novartis, Yuko received advisor fee for participation in Advisory Board on this study, Kaori Komori Kaori received advisor fee for participation in Advisory Board on this study, Gavin Harper Gavin Harper is employed by Adelphi Real World who received sponsorship / funding from Novartis to complete this study. Institutional non-financial interest declared., Lucy Howard Lucy Howard is employed by Adelphi Real World who received sponsorship / funding from Novartis to complete this study. Institutional non-financial interest declared., Thom Dewar Thom Dewar is employed by Adelphi Real World who received sponsorship / funding from Novartis to complete this study. Institutional non-financial interest declared., Morgan Fox Morgan Fox is employed by Adelphi Real World who received sponsorship / funding from Novartis to complete this study. Institutional non-financial interest declared.