

POS0657

# Understanding disease progression in patients with Sjögren’s Disease: Insights from the United Kingdom Primary Sjögren's Syndrome Registry

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## Introduction

- Sjögren’s disease (SjD) is a chronic, progressive autoimmune condition, with a global prevalence of 0.01% to 3%, primarily affecting women
- Symptoms vary from mild discomfort to debilitating symptoms, including ocular and oral dryness, fatigue, joint pain, and organ dysfunction
- Despite the significant clinical burden of SjD, the disease progression is not well understood

## Objectives

- To describe the patient characteristics and understand the change in disease activity among patients with SjD
- To describe the fatigue severity among patients with SjD

## Methods

### Study design and data source

- A registry-based retrospective study was conducted using the United Kingdom Primary Sjögren's Syndrome Registry (UKPSSR)

### Study period

- This study utilized data collected between 2009 and 2019

### Patient population

- Patients with data collected at two visits were included in the analysis

### Measurements

- Patient characteristics
- Socio-demographic and clinical characteristics, including age, gender, Body Mass Index (BMI), disease duration, comorbidities, and past/current medications, were described at visit 1 and visit 2
- Disease activity
  - Disease activity was evaluated using the EULAR Sjögren’s Syndrome Disease Activity Index (ESSDAI) score at visit 1 and visit 2
  - ESSDAI is a clinician-reported index comprising of 12 domains to assess systemic disease activity
  - Overall ESSDAI score was categorized into three disease activity levels: low (0-4), moderate (5-13), and high (14+)
- Change in the disease activity level (i.e., improved, deteriorated, or remained the same) from visit 1 to visit 2 was reported for the overall ESSDAI score and individual domains
- Fatigue severity
  - Fatigue severity was assessed at visit 1 and visit 2 using the Profile of Fatigue (ProF) Questionnaire
  - ProF evaluates 2 domains of fatigue: physical and mental fatigue, each ranging from 0 to 7, with higher scores indicating worse functioning
  - Physical and mental fatigue scores were classified into 4 fatigue groups: minimal (0–1), mild (2–3), moderate (4–5), and severe (6–7)
  - Change in the fatigue severity (i.e., improved, deteriorated, or remained the same) from visit 1 to visit 2 was reported for both domains

### Statistical analysis

- Descriptive statistics were used to summarize patient characteristics, ESSDAI scores, physical and mental fatigue at visit 1 and visit 2
- Change in the disease activity level from visit 1 to visit 2 was reported as the percentage of patients for the overall ESSDAI score and each domain
- Change in the fatigue severity from visit 1 to visit 2 was reported as the percentage of patients for ProF physical and mental domain

## Results

- A total of 1,030 patients with at least one visit and 313 patients with 2 visits were identified
- The average time between the two visits was 3.7 years [Standard Deviation (SD): 1.5]
- The mean age was 59.6 years [SD: 12.1] at visit 1 and 63.3 years [SD: 12.2] at visit 2
- Most of the patients were female (89.1%)
- More than 95% of patients reported to receive symptomatic treatment, while at least 70% reported to receive immunosuppressive treatment at both visits (Table 1)

Table 1. Patient characteristics

Description	At Visit 1 (N=313)	At Visit 2 (N=313)
Time interval between visit 1 and visit 2 in years, Mean [SD]	3.7 [1.5]	
Age at visit (years), Mean [SD]	59.6 [12.1]	63.3 [12.2]
Female, N (%)	279 (89.1)	
Disease duration (years), Mean [SD]	6.7 [6.4]	10.4 [6.9]
Body Mass Index (kg/m <sup>2</sup> ), Mean [SD]	27.4 [5.6]	27.5 [5.7]
Comorbidities, N (%)		
Endocrine/Metabolic system	207 (66.1)	205 (65.5)
Musculoskeletal	187 (59.7)	185 (59.1)
Gastro-intestinal; hepatic system	174 (55.6)	159 (50.8)
Past/Current Medications, N (%)		
Immunosuppressive treatment <sup>a</sup>	218 (69.7)	245 (78.3)
Symptomatic treatment <sup>b</sup>	299 (95.5)	295 (98.0)

<sup>a</sup> Immunosuppressive treatment includes the following medications: Corticosteroids, Hydroxychloroquine, Azathioprine, Mycophenolate mofetil, Methotrexate, Leflunomide, Cyclophosphamide, IVIg, Etanercept, Infliximab, Rituximab  
<sup>b</sup> Symptomatic Treatment includes the following medication: Pilocarpine, Cevimeline, Lachrymal substitute, Saliva substitute, non-steroidal anti-inflammatory drugs, Analgesics  
N, Number of patients; SD, Standard Deviation

- The mean overall ESSDAI score was 5.1 [SD: 5.1] at visit 1 and 4.4 [SD: 5.4] at visit 2
- Average change in overall ESSDAI score between visit 1 and visit 2 was -0.5 [SD: 5.7]
- At visit 2, 26.5% of patients showed an improvement of at least 3 points in the ESSDAI scores, with a mean change of -6.8 [SD: 3.7], while 19.5% of patients reported worsening of ESSDAI scores by at least 3 points, with a mean change of 7.2 [SD: 4.7]
- For the overall ESSDAI score, most patients had low disease activity level at both visits (53.4% at visit 1 and 61.0% at visit 2). At visit 1, 44.4% of patients reported moderate or high disease activity levels, while 33.9% had moderate or high disease activity levels at visit 2 (Table 2)

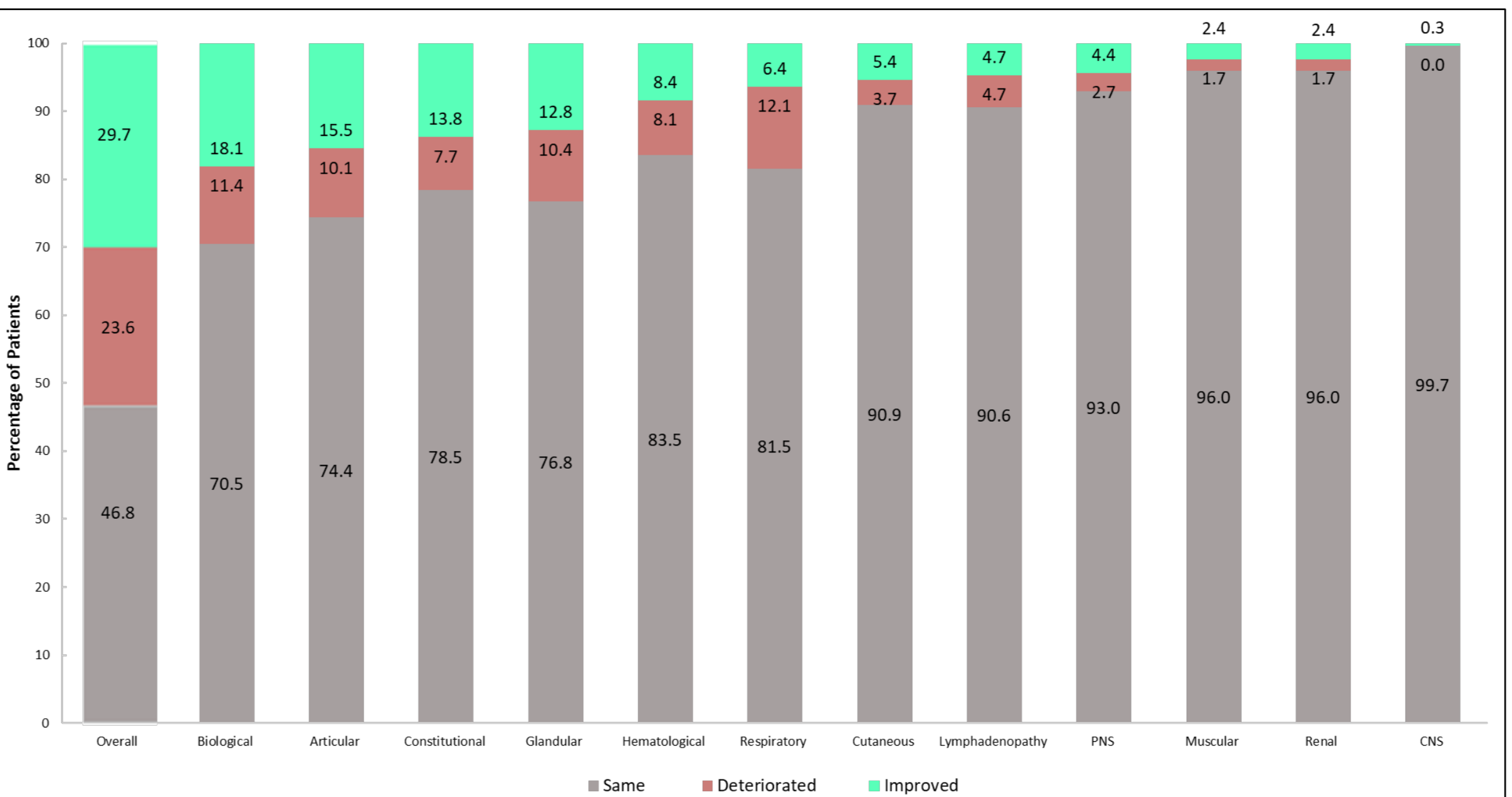
Table 2. Summary statistics for ESSDAI scores

Description	At Visit 1 (N=313)	At Visit 2 (N=313)
Overall ESSDAI score		
N (%)	306 (97.8)	297 (94.9)
Mean [SD]	5.1 [5.1]	4.4 [5.4]
Disease activity level (Overall ESSDAI Score), N (%)		
Low activity	167 (53.4)	191 (61.0)
Moderate or high activity	139 (44.4)	106 (33.9)
Missing	7 (2.2)	16 (5.1)
Change in ESSDAI score between visit 1 and visit 2		
Overall	293 (93.6)	
N (%)	-0.5 [5.7]	
Mean [SD]		
Increase in ESSDAI score by at least 3 points	61 (19.5)	
N (%)	7.2 [4.7]	
Mean [SD]		
Decrease in ESSDAI score by at least 3 points	83 (26.5)	
N (%)	-6.8 [3.7]	
Mean [SD]		

ESSDAI, EULAR Sjögren’s Syndrome Disease Activity Index; SD, Standard Deviation

- Disease activity level (as measured by overall ESSDAI scores) improved for 29.7% of patients, worsened for 23.6%, and remained the same for 46.8% between visit 1 and visit 2
- Within each ESSDAI domain, at least 70% of patients did not have any change in their disease activity level between visit 1 and visit 2
- Among all the domains, the highest improvement was observed in the biological domain, with 18.1% of patients showing an improvement and 11.4% of patients worsened
- Respiratory is the only domain in which more patients worsened (12.1%) than improved(6.4%) between visit 1 and visit 2 (Figure 1)

Figure 1. Percentage of patients by change in disease activity level between visit 1 and visit 2 for overall and domain-specific ESSDAI scores



Same: Represents the percentage of patients who remained in the same disease activity level at both visits (none, low, moderate, high)  
Deteriorated: Represents the percentage of patients with worsened scores at visit 2 (moved to a higher activity level)  
Improved: Represents the percentage of patients with improved scores at visit 2 (moved to a lower activity level)  
Missing category was not considered in the denominator while calculating percentages

CNS, Central Nervous System; ESSDAI, EULAR Sjögren’s Syndrome Disease Activity Index; PNS, Peripheral Nervous System

- The average ProF physical fatigue score was 3.8 [SD: 1.7] and 4.1 [SD: 1.7], while the average ProF mental fatigue score was 3.1 [SD: 1.8] and 3.4 [SD: 1.8] at visit 1 and visit 2, respectively (Table 3)

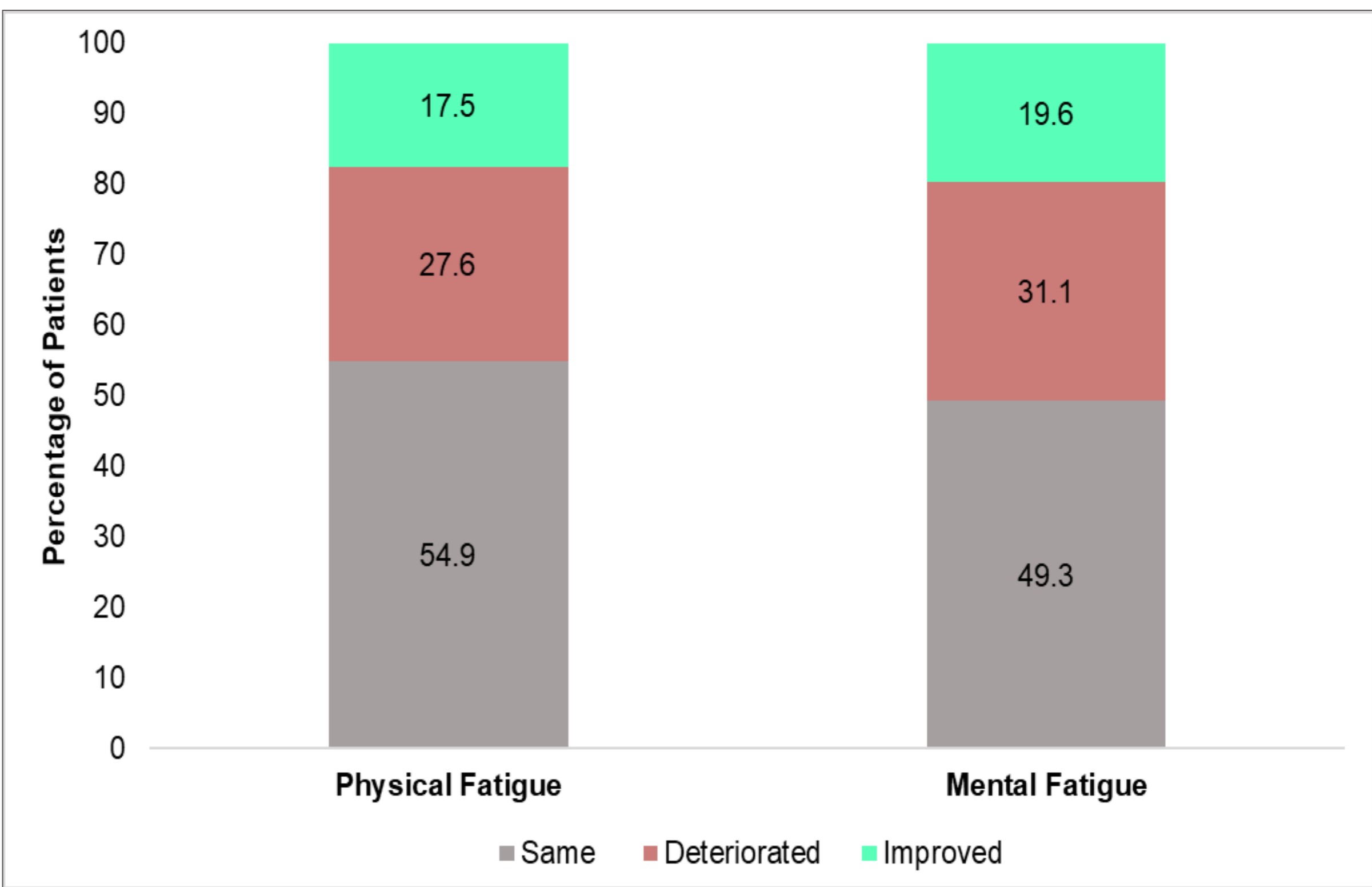
Table 3. Summary statistics for ProF physical and mental fatigue scores

Description	At Visit 1 (N=313)	At Visit 2 (N=313)
ProF physical fatigue score		
N (%)	306 (97.8)	293 (93.6)
Mean [SD]	3.8 [1.7]	4.1 [1.7]
Change in score between visit 1 and visit 2, Mean [SD]	0.3 [1.4]	
ProF mental fatigue score		
N (%)	307 (98.1)	292 (93.3)
Mean [SD]	3.1 [1.8]	3.4 [1.8]
Change in score between visit 1 and visit 2, Mean [SD]	0.3 [1.6]	

ProF, Profile of Fatigue; SD, Standard Deviation

- Around 50% of patients remained in the same physical and mental fatigue group between visit 1 and visit 2
- ProF physical fatigue scores improved for only 17.5% of patients, whereas 27.6% of patients reported worsening between visit 1 and visit 2
- ProF mental fatigue scores improved for only 19.6% and worsened for 31.1% of patients between visit 1 and visit 2 (Figure 2)

Figure 2. Percentage of patients by change in physical and mental fatigue groups between visit 1 and visit 2



Same: Represents the percentage of patients who remained in the same fatigue severity groups at both visits (mid, minimal, moderate, severe)  
Deteriorated: Represents the percentage of patients with worsened physical or mental fatigue scores at visit 2 (moved to a higher fatigue group)  
Improved: Represents the percentage of patients with improved physical or mental fatigue scores at visit 2 (moved to a lower fatigue group)  
Missing category was not considered in the denominator while calculating percentages

## Conclusions

- Majority of the patients either remained at the same activity level or deteriorated for the overall and domains-specific ESSDAI scores, highlighting the unmet need in patients with SjD
- Change in domain-specific disease activity level was highly variable between domains, indicating the heterogeneous impact of SjD on body systems reported by patients
- Persistent or worsening fatigue over time underscores the limited improvement and persistent burden experienced by patients with SjD
- Findings from this study may have limited generalizability to the broader SjD population due to the small sample size of UKPSSR patients with 2 visits

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### Declaration of Interests

- WFN has consulted for Amgen, BMS, J&J Innovations, Novartis, Sanofi, Argenx, Quotient, Resolve Therapeutics, EQT & Veloxis, and has received royalties from Oxford University Press and inventor share for the development of the Newcastle Sjogren’s Stratification Tool
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- KM, MS, and JC are employees of Complete HEOR Solutions (CHEORS), Chalfont, PA, USA, which received financial compensation to conduct the study

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