

# Patient-Reported Symptom Burden, Quality of Life, and Productivity Impact of PBC Across France, Italy, Germany, Spain, the United Kingdom, and the United States of America: Analysis of a Real-World Dataset

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## Conclusions

- Many patients with itch due to primary biliary cholangitis (PBC) experience negative impacts on health-related quality of life, as shown by the disability and duration domains of the 5-D Itch scale, and some patients are unable to work or experience a decrease in their work productivity.
- The majority of patients who reported having moderate/severe itch also reported that their fatigue was moderate/severe.
- Despite most patients taking treatments to stop their PBC from progressing, many patients reported that improving itch and fatigue management was a key treatment goal.
- This suggests a need for an increased focus on treatments to help manage symptoms of PBC.

## Plain Language Summary

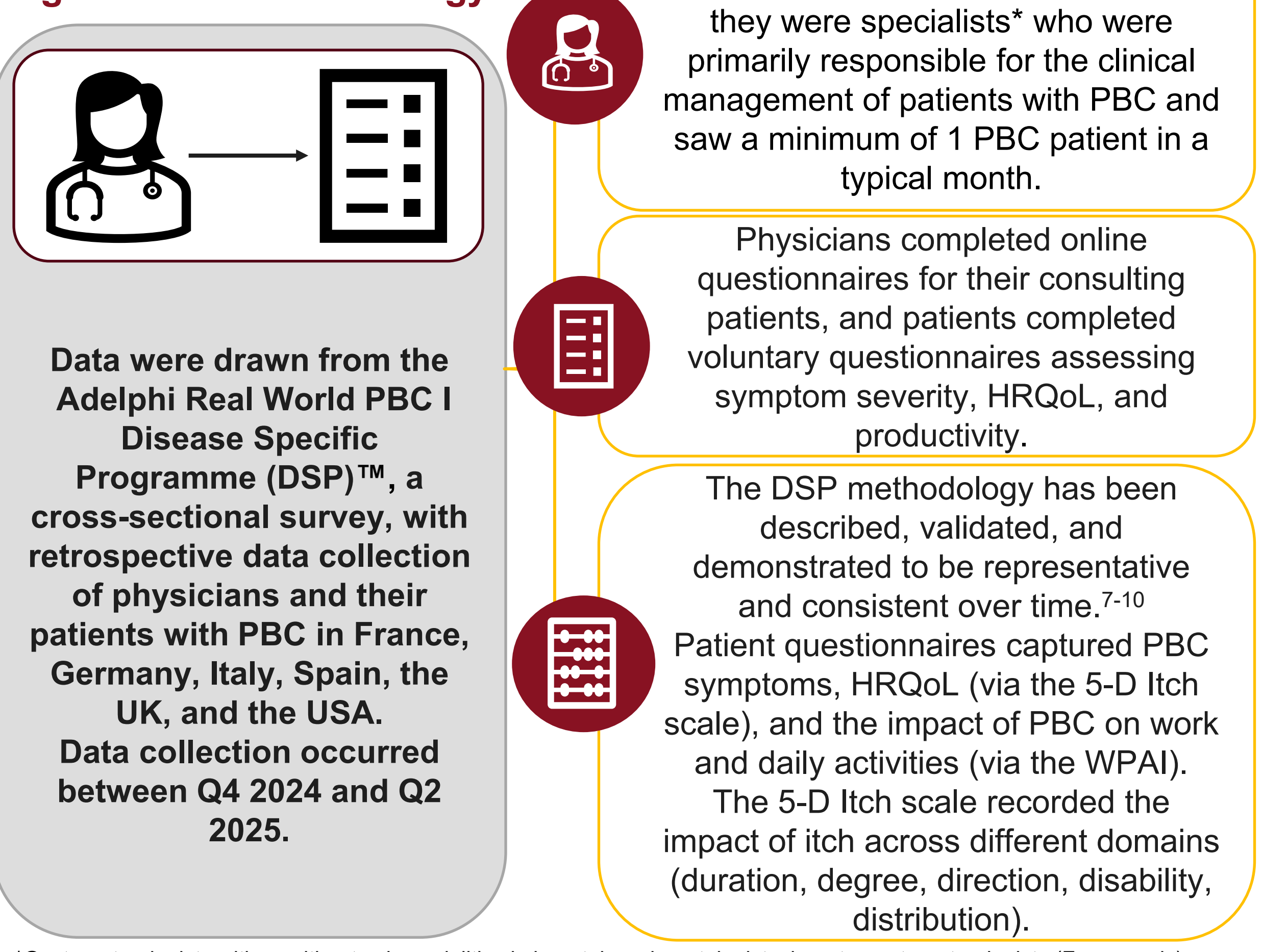
- Primary biliary cholangitis (PBC) is a long-term liver disease that can lead to scarring of the liver and, in some instances, the need for liver transplant.
- This study found that most patients with moderate/severe itch due to PBC also experienced moderate/severe fatigue, even though almost half were taking itch treatments, and almost all were taking treatments to prevent their PBC from getting worse.
- Many patients experience severe itching and fatigue, which have been known to negatively impact quality of life in various ways, such as a decline in work productivity and increased disability due to itch.
- Itching due to PBC is associated with negative impacts on quality of life. About half of patients in this study experienced increased disability due to itch. Some patients also experienced a decline in work productivity or reduced or stopped work due to PBC.
- Itch has been frequently undertreated in clinical practice, highlighted by patient treatment goals focusing on improving their symptoms.

## Introduction

- Primary biliary cholangitis (PBC) is a chronic autoimmune liver disease that damages the bile ducts and over time can lead to fibrosis, cirrhosis, and, in some instances, the need for liver transplant.<sup>1,2</sup> PBC incidence and prevalence estimates are around 1.76 and 14.60 per 100,000 people, respectively.<sup>3</sup>
- Many patients experience symptoms such as itching and fatigue that can significantly impact health-related quality of life (HRQoL).<sup>4,5</sup>
- Itch and fatigue are frequently undertreated in clinical practice despite their high prevalence among patients with PBC.<sup>4</sup> Based on medical records, around 33% of patients with clinically significant itch had never received any treatment for itch according to data from the TARGET-PBC study in the USA.<sup>6</sup>
- Novel therapies have been approved which significantly improve itch associated with PBC.
- This poster aims to describe symptoms, HRQoL, and work productivity, as reported by patients living with PBC experiencing itch in a real-world setting.

## Methods

Figure 1. DSP Methodology



## Results

### Survey Population

- Overall, 116 patients from France, Italy, Germany, Spain, the UK and the USA reported experiencing itch at the time of data collection.
- Analyses focused on patient-reported data on symptomatology and treatment goals as well as the 5-D Itch scale and Work Productivity and Activity Impairment (WPAl).
- Some physician-reported data like employment status and treatment status were included.
- Missing data were not included when calculating percentages, and missing values were not imputed.

### Symptom Burden and Treatments

- Patients were predominantly female (84%) and White (96%), and the average time since diagnosis was 3.7 ± 4.4 years (Table 1).
- Of those who reported itch (n = 116), 92 (79%) were also experiencing fatigue (Figure 2).
- Of those who reported itch severity (n = 113), 46 patients (41%) reported their itch as being moderate/severe, and 41 of those (89%) also experienced moderate/severe fatigue (Figure 3).
- Among patients with itch (n = 116), 92% were taking treatments to prevent PBC progression, and ursodeoxycholic acid (UDCA) was the most common (95%). Half of patients (51%) with itch were taking a treatment specifically for their itch, with cholestyramine being the most common (47%) (Figures 4a and 4b).

## Results

Table 1. Patient Demographics and Disease Characteristics

Patients Experiencing Itch (n = 116)	
Age, years, mean [SD]	52.9 [9.9]
Sex, Female, n (%)	97 (84%)
Race/ethnicity*, n (%)	(n = 96)
White, n (%)	92 (96%)
Years since PBC diagnosis (n = 113)	
Mean [SD]	3.7 [4.4]
PBC stage, n (%)	(n = 107)
Stage 1	35 (33%)
Stage 2	45 (42%)
Stage 3	22 (21%)
Stage 4	5 (5%)

\*Race/ethnicity not collected in France.

Figure 2. Patient-Reported Symptom Profile Among Patients with PBC Experiencing Itch (n = 116)

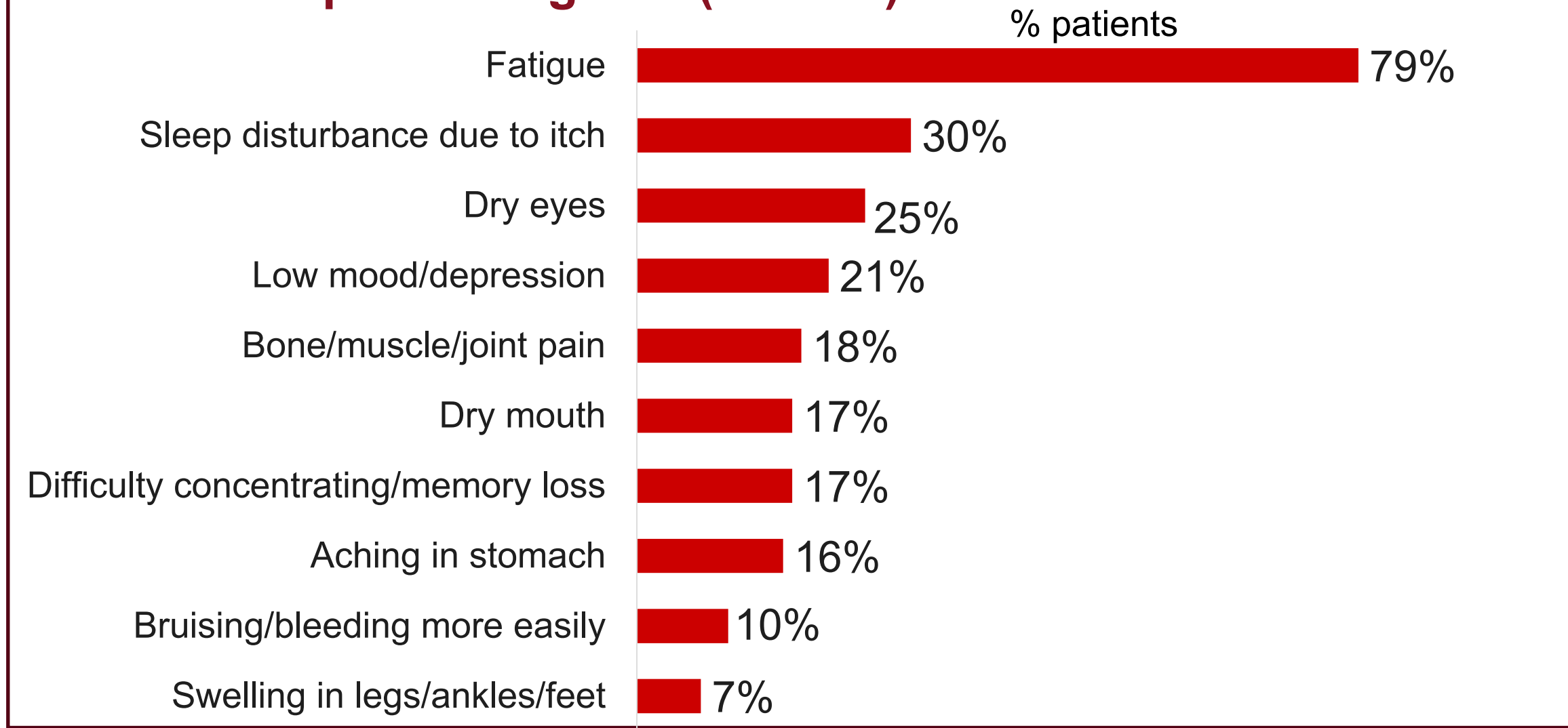


Figure 3. Patient-Reported Itch and Fatigue Severity

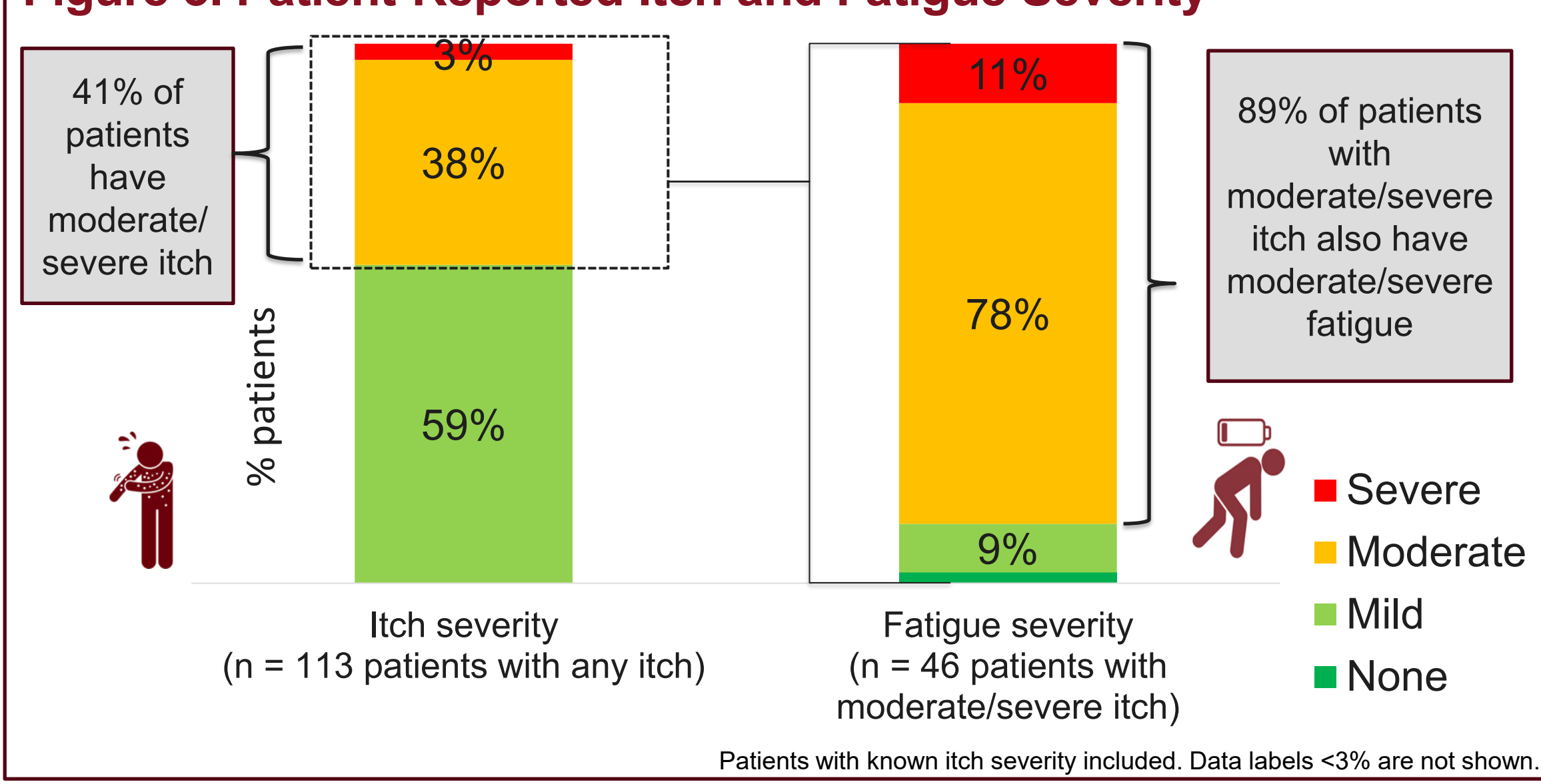


Figure 4a. Most Common Treatments Prescribed to Prevent PBC Progression Among Patients Experiencing Itch (n = 107)

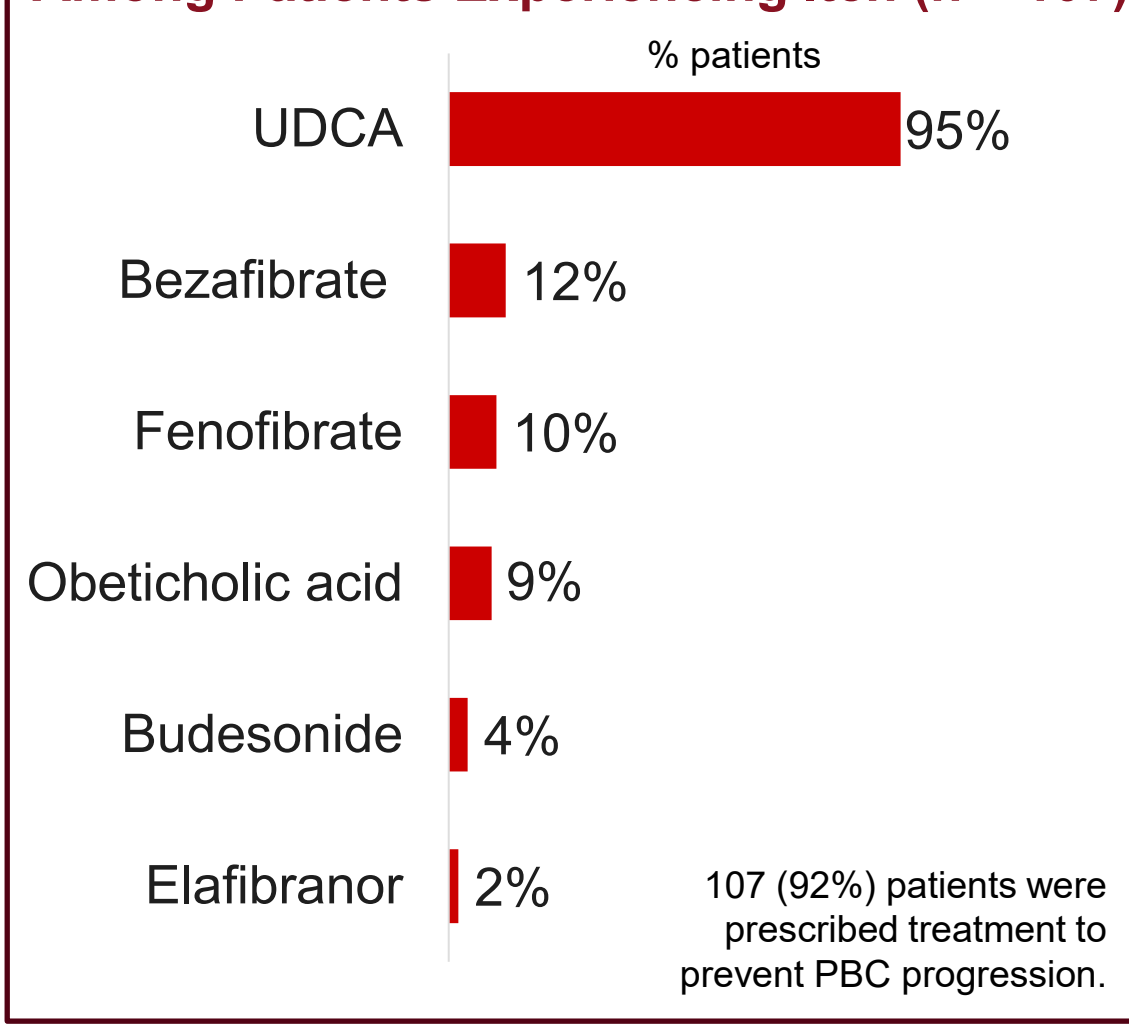
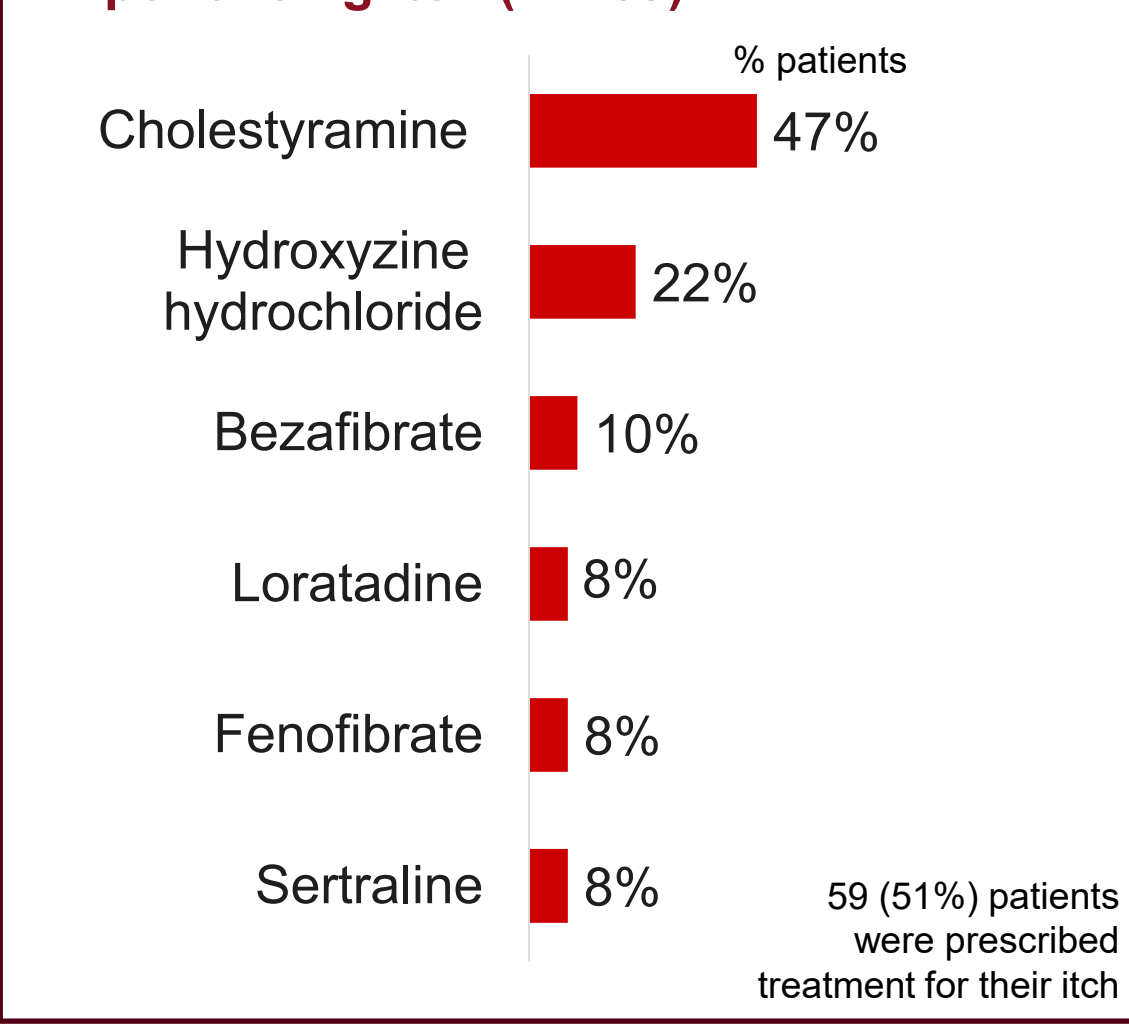


Figure 4b. Most Common Treatments Prescribed to Treat Itch Among Patients Experiencing Itch (n = 59)



### HRQoL and WPAl

- For patients with itch who completed the 5-D Itch scale, 48% experienced itch for 6+ hours a day (n = 116), 28% reported 6+ body areas affected (n = 114), 20% reported activities of daily living being frequently/always affected (n = 82), and 36% of patients stated itching was unchanged/getting worse compared to the previous month (n = 116) (Figure 5).
- Just over half (54%) of patients with itch were working full time. Of those who were working part time, retired, or on long-term sick leave, a quarter (24%) had reduced work or stopped working due to their PBC. Around 4 out of 10 patients (38%) received caregiver support (Figure 6).
- For patients with itch who completed the WPAl, the mean ± SD percent activity impairment was 38.7% ± 24.8 (n = 114). For those currently in full- or part-time employment, mean ± SD percent overall work impairment was 39.4% ± 27.8 (n = 46) (Figure 7).
- The most common treatment goals reported by patients experiencing itch were to help itching (87%), help tiredness (80%), and improve liver tests (60%) (Figure 8).

Figure 5. 5-D Itch Domains

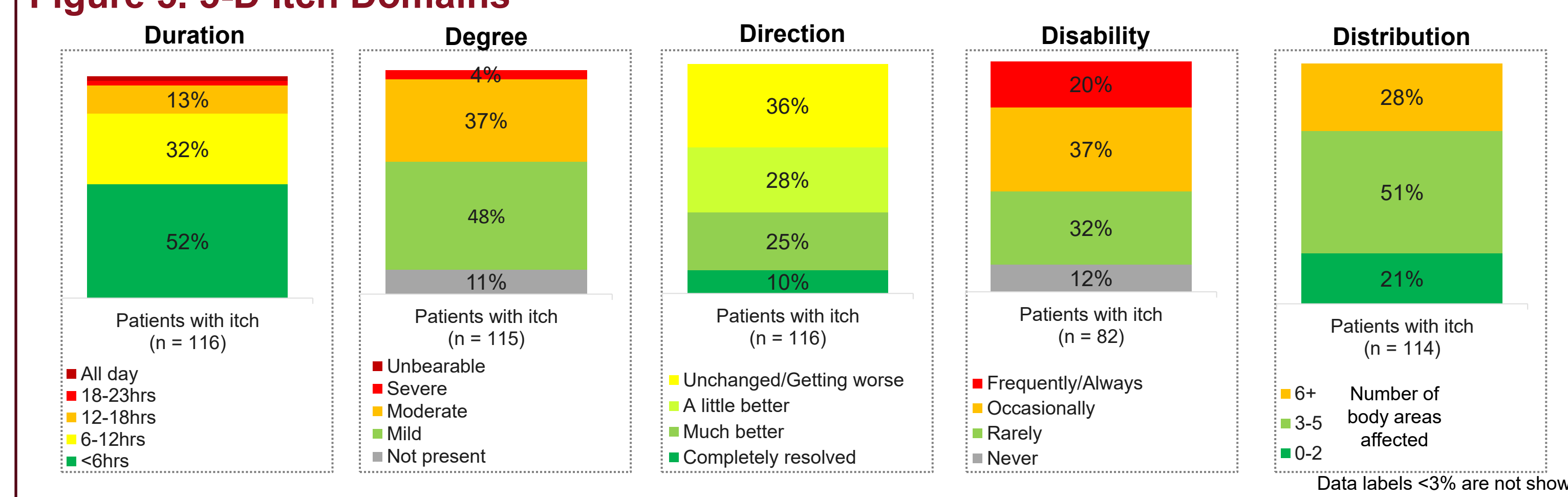


Figure 6. Employment and Caregiver status Among Patients Experiencing Itch

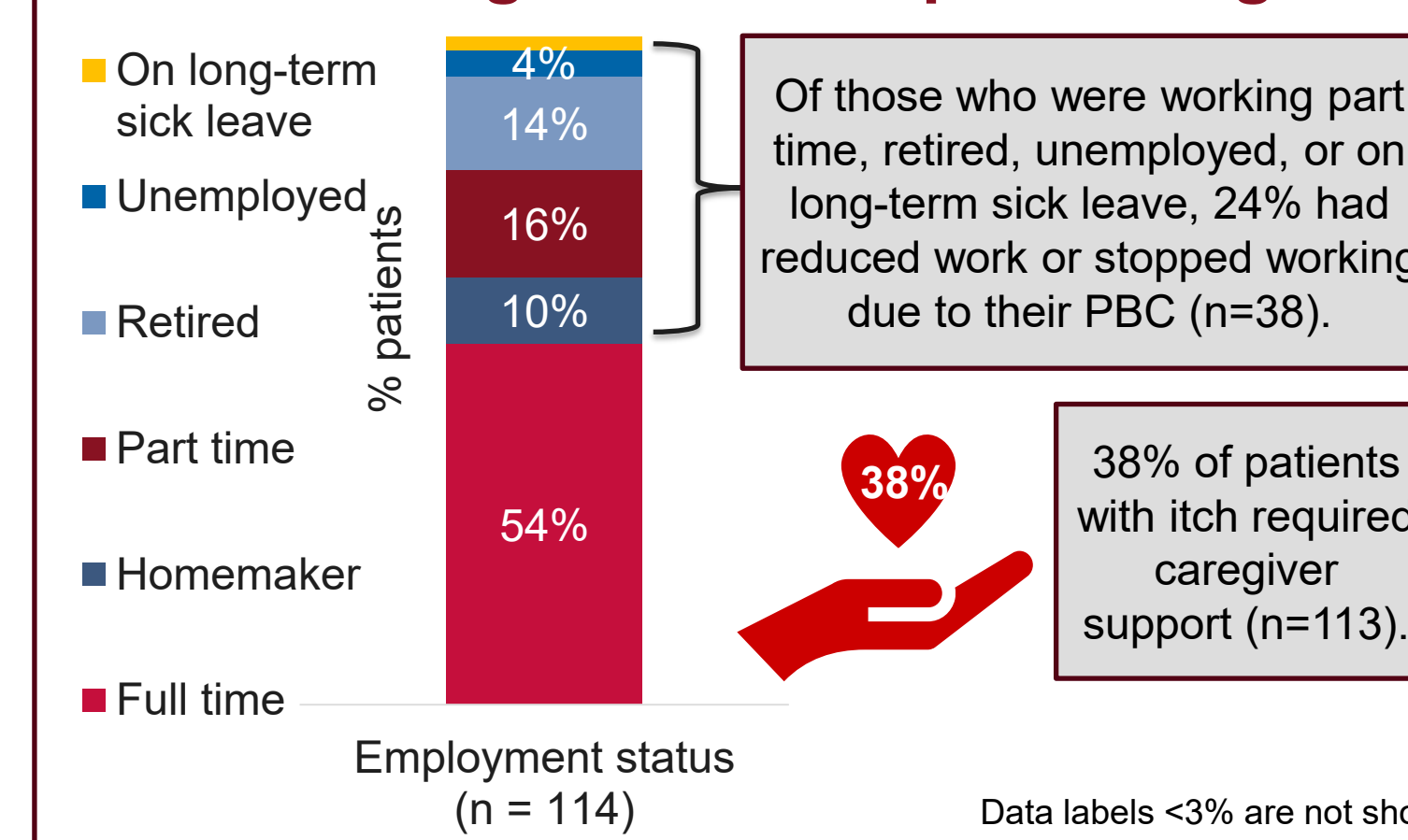


Figure 7. Mean WPAl Scores Among Patients Experiencing Itch

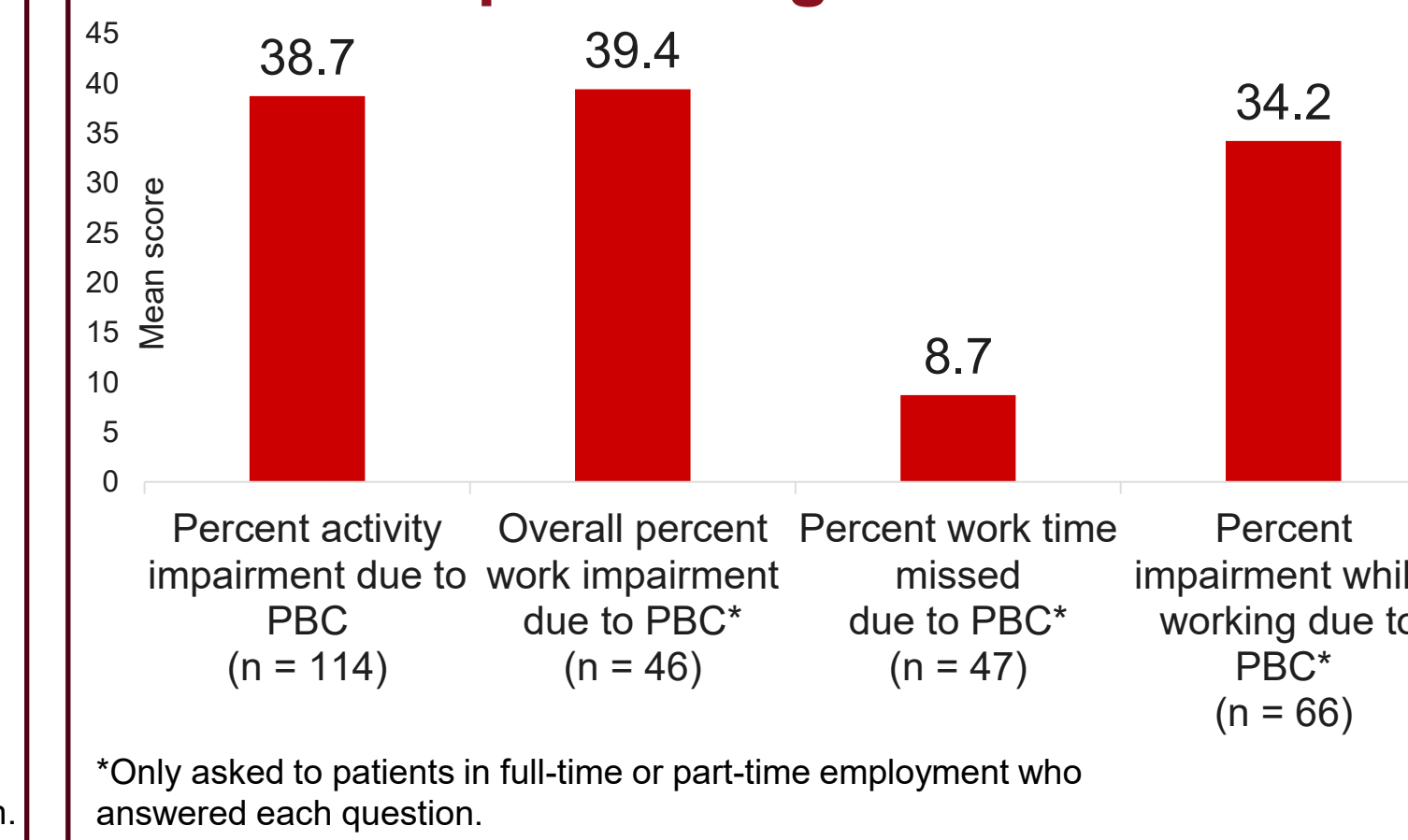
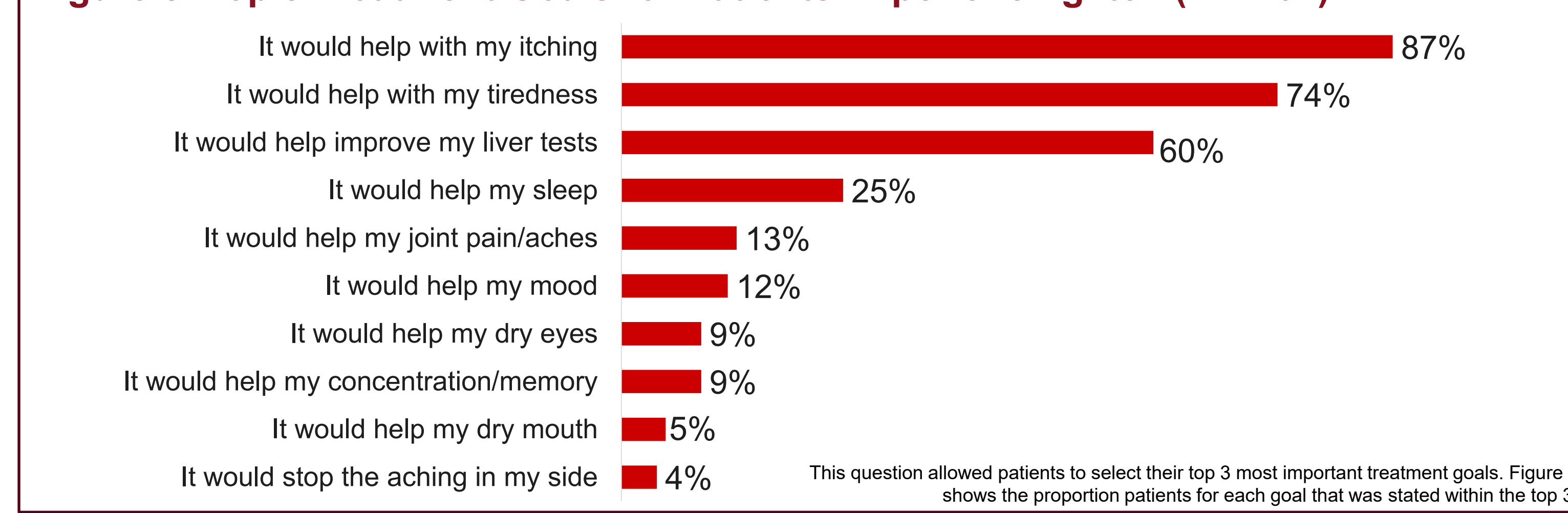


Figure 8. Top 3 Treatment Goals for Patients Experiencing Itch (n = 101)



## Limitations

- Participants from the PBC I DSP do not constitute a true random sample and represent a more pragmatic sample, and although minimal selection criteria were imposed to identify physicians for inclusion, participation is influenced by the willingness of physicians and patients to complete the survey.
- The study design required physicians to recruit consecutive patients and complete the physician survey on the day of the visit to mitigate against selection and recall bias. However, some selection bias remains, as more frequently consulting patients and those with more severe disease activity were more likely to be captured.
- The cross-sectional design of the DSP prevented any conclusions about causal relationships.

Abbreviations: DSP: Disease Specific Programme; EUR: France, Germany, Italy, Spain, and the UK; HRQoL: health-related quality of life; hrs: hour; PBC: primary biliary cholangitis; Q: quarter; SD: standard deviation; UDCA: ursodeoxycholic acid; UK: United Kingdom; USA: United States of America; WPAl: Work Productivity and Activity Impairment

References: 1. Kaplan MM, et al. *N Engl J Med*. 2005;353:1261-73. 2. Primary biliary cholangitis. *The Mayo Clinic*. Accessed August 7, 2025;995-1005. 3. Trivella J, et al. *Hepatology Commun*. 2023;7(6):e179. 4. Mayo MJ, et al. *Dig Dis Sci*. 2023;68(3):995-1005. 5. Rice S, et al. *Clin Gastroenterol Hepatol*. 2021;19(4):768-76. 6. Levy C, et al. *Hepatology Commun*. 2018;2(5):484-91. 7. Anderson P, et al. *Curr Med Res Opin*. 2008;24(11):3063-72. 8. Anderson P, et al. *Curr Med Res Opin*. 2023;39(12):1707-15. 9. Babineaux SM, et al. *BMJ Open*. 2016;6(8):e010352. 10. Hoggins V, et al. *Diabetes Metab Syndr*. 2016;9:371-80.

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