

The Pervasive Impact of Pruritus on Quality of Life in Patients with Primary Biliary Cholangitis (PBC): Real World Experience in TARGET-PBC

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Introduction

- The purpose of this analysis is to assess the impact of pruritus on quality of life (QOL) in patients in the TARGET-PBC cohort.

Methods

- TARGET-PBC is a longitudinal observational study of patients (n=667) enrolled at 38 US sites.
- PBC-40, 5D Itch and PROMIS Fatigue surveys are collected in addition to clinical and treatment data.
- Responses to PBC-40 were used to grade pruritus: clinically significant (CS) itch was defined as ≥ 7 points on the itch domain¹.
- Kruskal-Wallis tests were used to compare median differences in symptoms between the itch groups.

Results

- PBC-40 domain scores correlated with pruritus severity, with higher scores indicating more impairment across all domains in the CS itch group vs. mild or no itch.
- The largest difference was seen in cognitive and social domains; median scores in the CS itch group were $\sim 80\%$ higher than those in the mild itch group.
- In other domains (fatigue, symptoms, emotional) the difference was smaller with median scores 42%, 46% and 50% greater respectively for the CS itch group.
- Differences between groups remained significant in multivariable analysis when adjusting for covariates.

Table 1: Patient Characteristics by PBC-40 Itch Severity

	= 0 No itch	≥ 1 to < 7 Mild itch	≥ 7 Clinically significant itch	P value
All Participants, n (%)	41 (19%)	107 (51%)	63 (30%)	
Gender Female, n (%)	38 (93%)	97 (91%)	59 (94%)	0.844
Current Age (years)				
Median (Q1 - Q3)	64 (56 - 71)	64 (55 - 71)	58 (52 - 64)	0.0124
Age at Diagnosis (years)				
Median (Q1 - Q3)	52 (42 - 59)	54 (46 - 60)	49 (39 - 56)	0.0398
Most Recent ALP				
Median (Q1 - Q3)	153 (126 - 228)	143 (116 - 187)	177 (133 - 284)	0.0019
Cirrhosis n (%)	15 (37%)	29 (27%)	30 (48%)	0.0277
Decompensated Cirrhosis n (%)	5 (33%)	7 (24%)	18 (60%)	0.0174

Figure 1: Median PBC-40 Domain Scores by Itch Severity

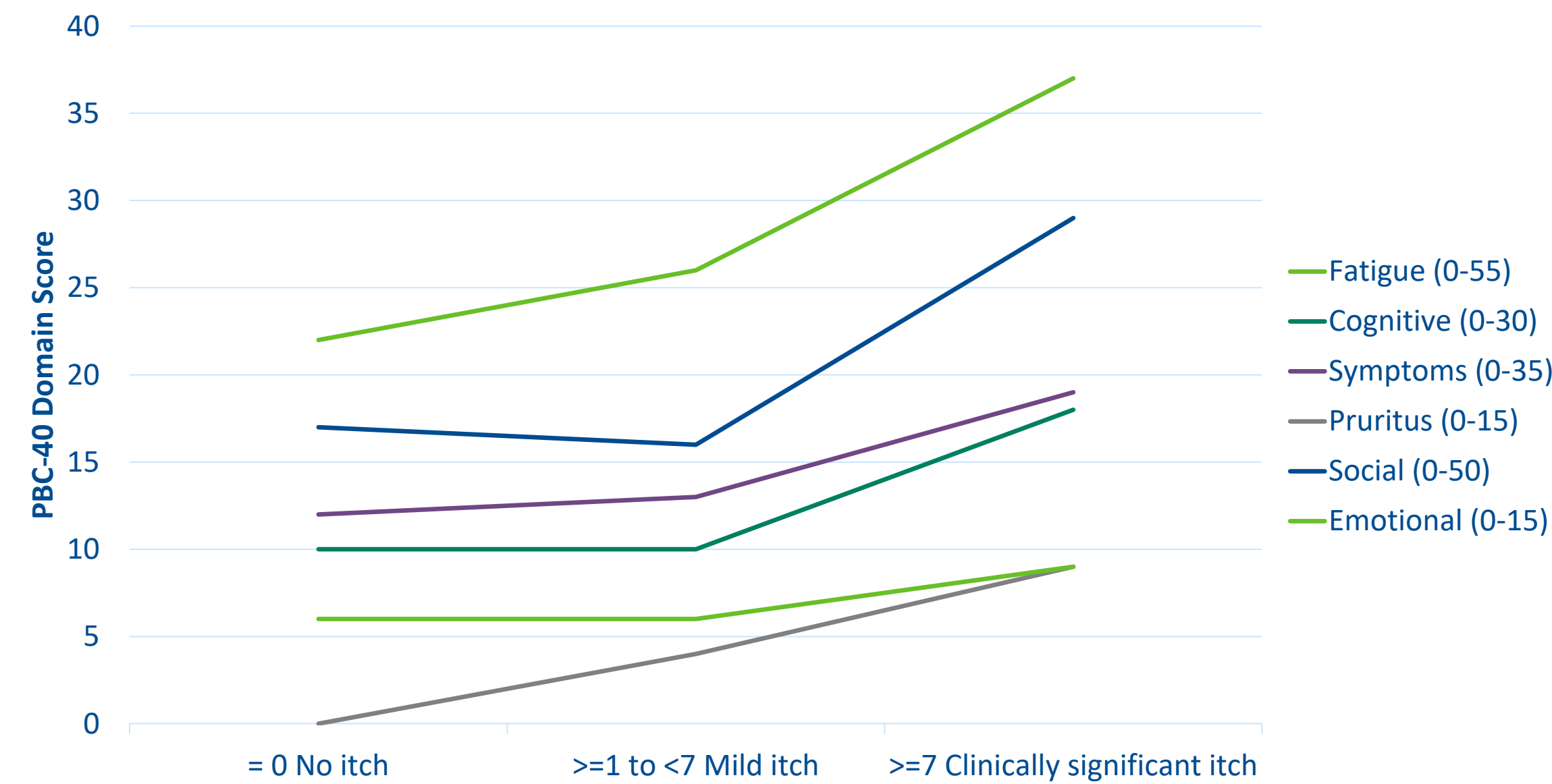
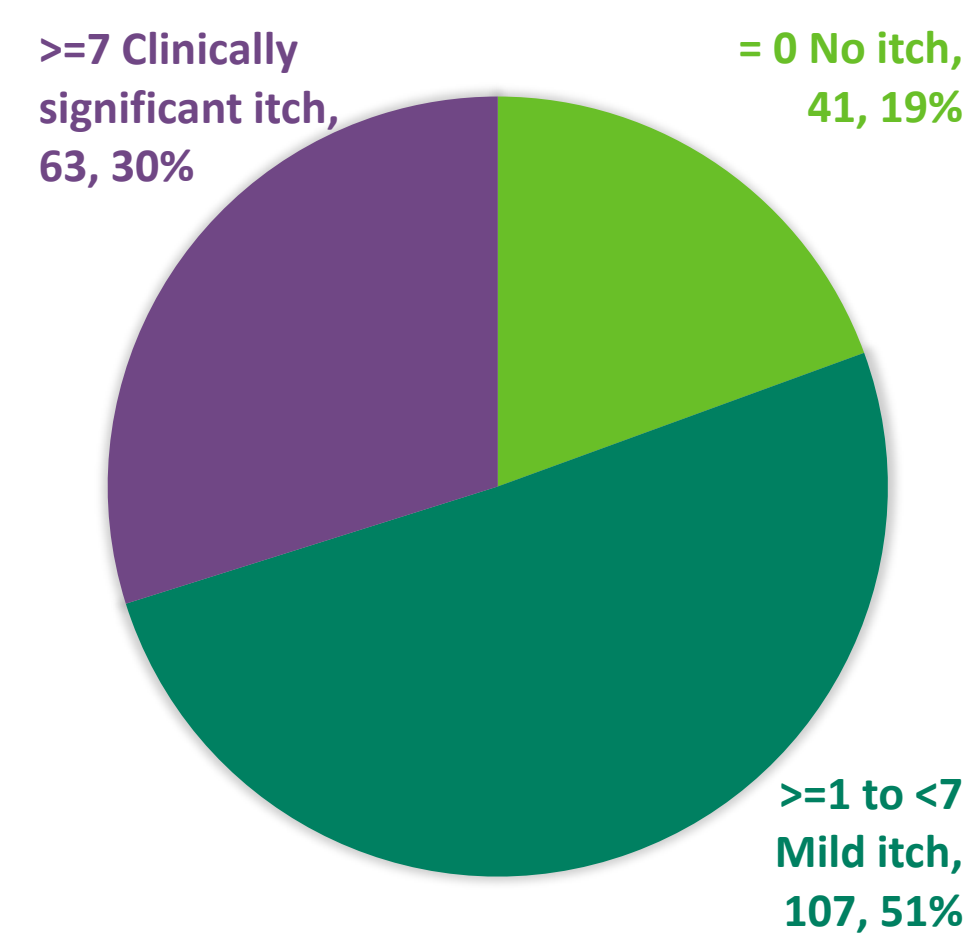


Figure 2: Cohort Itch Severity (PBC-40 Itch Domain)



- 211 patients completed the PBC-40
- Of those who reported any itch (170), 63% had mild itch and 37% clinically significant itch.
- The population in this analysis was 92% female, 35% cirrhotic.
- Patients with CS itch were younger at diagnosis (Table 1) and currently and more frequently had cirrhosis (48 vs 27 and 36%, $p = 0.03$) and had higher alkaline phosphatase compared to those with mild or no itch, respectively.

Conclusion

Pruritus in PBC has a significant impact on many aspects of QoL; fatigue, social, emotional, cognitive and other symptoms.

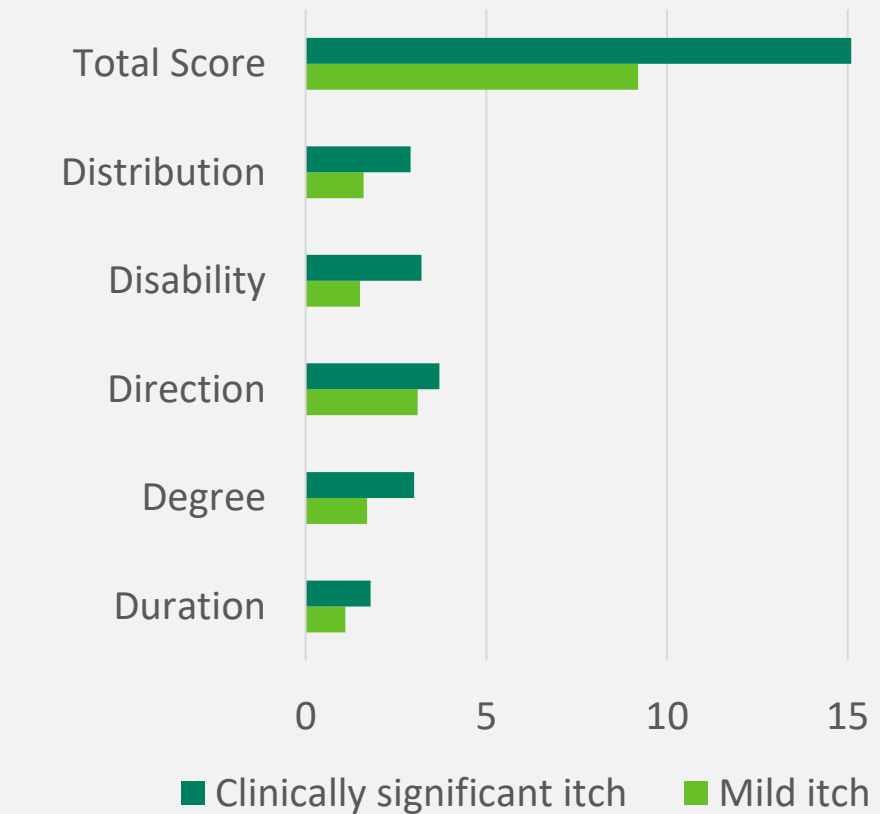
References:

1. Mellis GF et al. Impact of primary biliary cirrhosis on perceived quality of life: the UK-PBC national study. *Hepatology*. 2013;58(1):273-83

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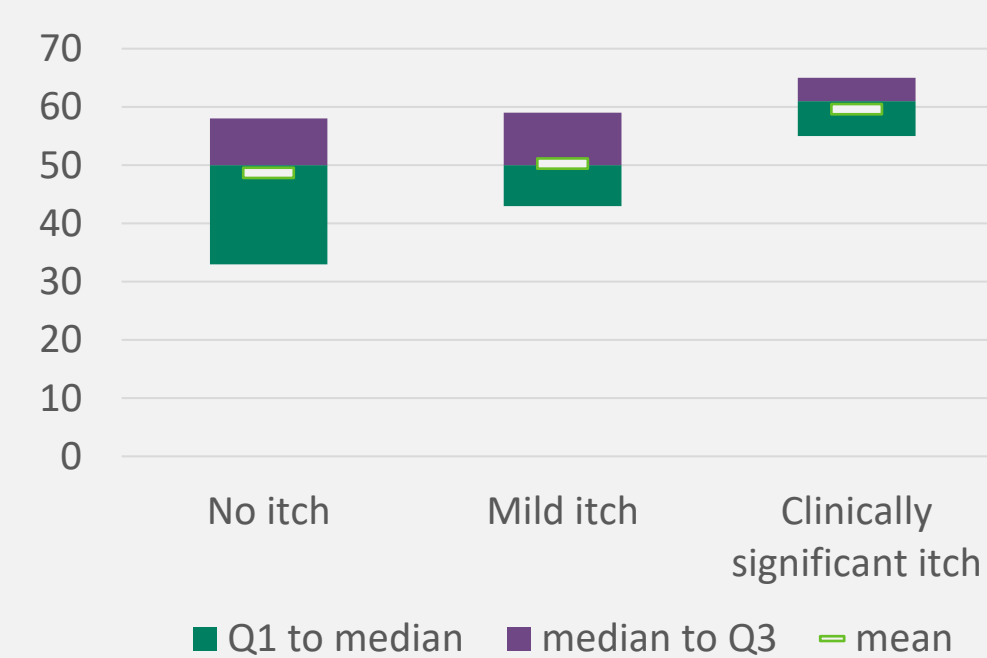
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Figure 3: Mean Scores on 5D Itch by PBC-40 Itch Severity



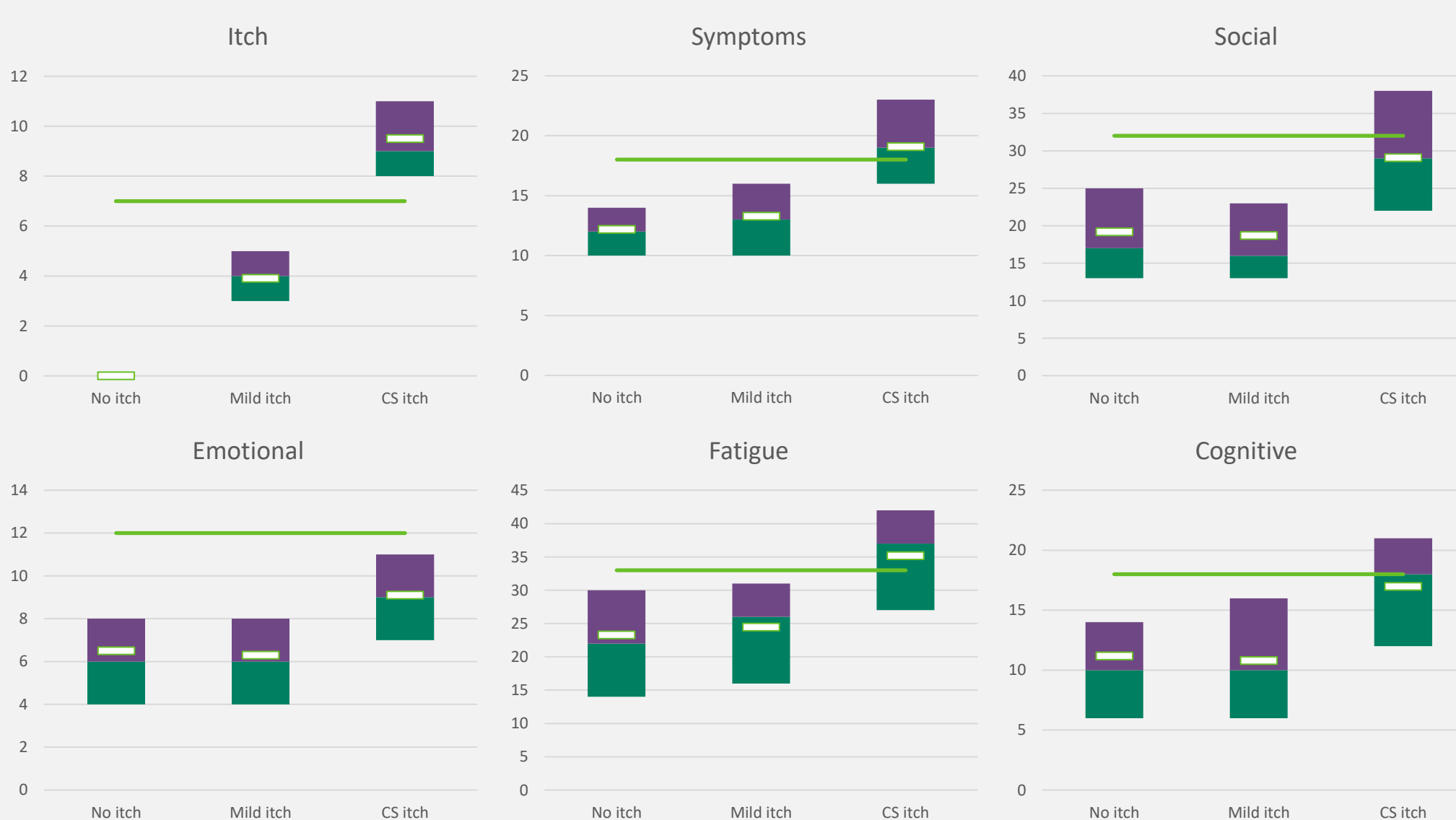
The 5D itch scores were consistent with the PBC-40 itch domain; those with clinically significant itch scored significantly higher (worse) than those with mild itch across all domains with the exception of Direction (has itching gotten better/worse) where both groups scored similarly although the variation in the clinically significant group was lower (SD 0.9 vs. 1.3).

Figure 4: Mean, Median and IQR PROMIS Fatigue



Patients with CS itch reported significantly greater fatigue on the PROMIS fatigue instrument than those with mild and no itch. Median scores in the CS, mild and no itch groups were 61, 50 and 50, respectively ($p < 0.0001$ CS vs. mild).

Figure 5: Mean, Median and Interquartile Range, PBC-40 Domain Scores and Clinical Significance Threshold (—)



Across all domains of the PBC-40, patients with mild itch and no itch scored similarly whereas those with CS itch scored notable worse (all $P < 0.0001$). Using the definition of clinical significance suggested by the developers of the PBC-40 instrument¹, those with CS itch also report CS fatigue and other symptoms and more than 50% have CS cognitive impairment and more than 25% have social difficulties.