

# The added value of the cognition, dining, gastrointestinal problems, sleep and tiredness bolt-ons for the EQ-5D-5L in patients with coeliac disease

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## INTRODUCTION

The EQ-5D is one of the most commonly used generic preference-based health-related quality of life measures in the world, which is recommended by the health technology assessment guidelines in more than 20 countries, including Hungary. However, EQ-5D has been found to potentially overestimate health-related quality of life (HRQoL) among patients with coeliac disease (CD).

## OBJECTIVE

This study aims to examine the benefits of adding bolt-ons to the EQ-5D-5L by assessing their psychometric properties in CD patients.

## METHODS

In 2020-2021, a cross-sectional online survey was conducted amongst 312 CD patients (age range: 18 to 80 years) in Hungary. Patients completed the EQ-5D-5L and five bolt-ons [cognition (CO), dining (DI), gastrointestinal problems (GI), sleep (SL), and tiredness (TI)], Gastrointestinal Symptom Rating Scale (GSRS) and the Satisfaction with Life Scale (SWLS). Reduction in ceiling, improvement in known-group validity based on self-perceived health, GSRS and SWLS groups, and multivariate linear regressions on EQ VAS and SWLS scores were used to determine the added value of bolt-ons. Spearman's correlations were used to examine convergent validity of the GI bolt-on with GSRS total score and divergent validity between the five core dimensions and bolt-ons.

## RESULTS

Figure 1. Responses on five EQ-5D-5L dimensions and five bolt-ons

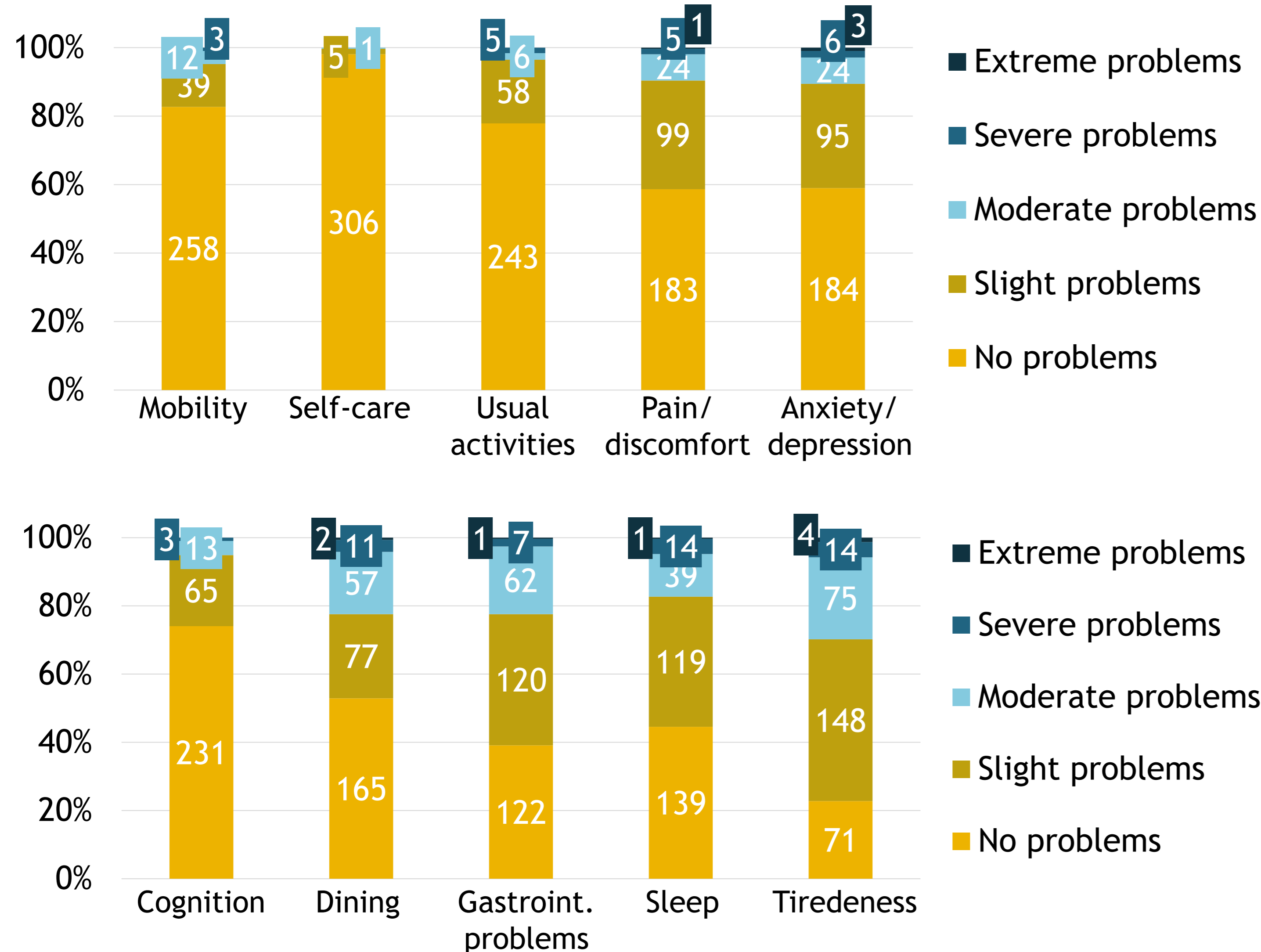


Table 2. The explanatory power of EQ-5D-5L and bolt-ons on EQ VAS and SWLS

Selection of domains	EQ VAS		Selection of domains	SWLS	
	Adjusted R <sup>2</sup>	ΣΔ Adjusted R <sup>2</sup>		Adjusted R <sup>2</sup>	ΣΔ Adjusted R <sup>2</sup>
<b>EQ-5D-5L domains</b>					
Mobility (MO)	0.1587	-	Mobility (MO)	0.0345	-
Self-care (SC)	0.0886	-	Self-care (SC)	0.0044	-
Usual activities (UA)	0.3039	-	Usual activities (UA)	0.1101	-
Pain/discomfort (PD)	0.3012	-	Pain/discomfort (PD)	0.1156	-
Anxiety/depression (AD)	0.1826	-	Anxiety/depression (AD)	0.1399	-
<b>Bolt-on domains</b>					
Gastrointestinal problems (GI)	0.1787	-	Gastrointestinal problems (GI)	0.0954	-
Cognition (CO)	0.1958	-	Cognition (CO)	0.0950	-
Sleep (SL)	0.1085	-	Sleep (SL)	0.0718	-
Tiredness (TI)	0.1617	-	Tiredness (TI)	0.1029	-
Dining (DI)	0.0652	-	Dining (DI)	0.0802	-
<b>EQ-5D-5L(+bolt-on) domains</b>					
MO+SC+UA+PD+AD	0.4109	-	MO+SC+UA+PD+AD	0.1934	-
MO+SC+UA+PD+AD+CO	0.4293	0.0184	MO+SC+UA+PD+AD+DI	0.2039	0.0105
MO+SC+UA+PD+AD+CO+GI	0.4402	0.0109	MO+SC+UA+PD+AD+DI+SL	0.2052	0.0013
			MO+SC+UA+PD+AD+DI+SL+GI	0.2057	0.0005

## CONCLUSION

Relevant bolt-ons enhance the validity of EQ-5D-5L in patients with CD. The GI bolt-on demonstrated strong psychometric performance in multiple tests, suggesting its value in capturing important aspects of HRQoL potentially missed by the core five dimensions.

The ceiling of the EQ-5D-5L was 39%. Adding the TI, SL, GI, DI and CO individual bolt-ons reduced the ceiling to 17%, 23%, 24%, 26% and 37%, respectively. The GI bolt-on significantly improved the discriminatory power for all known-groups with relative efficiencies ranging between 1.30 (95%CI 1.14-1.49) and 1.84 (95%CI 1.56-2.23). The GI bolt-on was strongly correlated with GSRS total score ( $r_s=0.71$ ). Very weak to moderate correlations were found between the bolt-ons and the five core dimensions (range of  $r_s=0.02$  to 0.51). GI and CO improved the explained variance in EQ VAS from 0.41 to 0.44, and DI, SL and GI in SWLS from 0.19 to 0.21.

Table 1. Ceiling and informativity of EQ-5D-5L and bolt-ons

	Ceiling		Ceiling in EQ-5D-5L + bolt-ons		Informativity of EQ-5D-5L + bolt-ons	
	n	%	n	%	Sh. index H'	Sh. index J'
<b>EQ-5D-5L</b>						
Mobility (MO)	258	82.7%				
Self-care (SC)	306	98.1%				
Usual activities (UA)	243	77.9%	121	38.8%	3.71	0.32
Pain/discomfort (PD)	183	58.7%				
Anxiety/depression (AD)	184	59.0%				
<b>(EQ-5D-5L +) Bolt-ons</b>						
Dining (DI)	165	52.9%	82	26.3%	4.95	0.36
Gastrointestinal problems (GI)	122	39.1%	75	24.0%	4.84	0.35
Cognition (CO)	231	74.0%	114	36.5%	4.33	0.31
Sleep (SL)	139	44.6%	72	23.1%	4.94	0.35
Tiredness (TI)	71	22.8%	53	17.0%	4.88	0.35
<b>EQ-5D-5L + all bolt-ons</b>			23	7.4%	7.28	0.31

Table 3. Discriminatory power for GSRS tertiles, self-perceived health, and symptomatic and asymptomatic patient groups

Health and quality of life	Mean (SD) EQ-5D-5L+bolt-on LSS (0-100)			ANOVA F	RE (95%CI), ref: previous row
Health status	Poor-fair	Good	Very good-excellent		
n	75	141	96	-	-
EQ-5D-5L	17.6 (14.25)	6.81 (7.45)	2.45 (4.04)	63.94	-
EQ-5D-5L+GI	20.83 (13.44)	9.31 (7.69)	3.56 (4.87)	82.85	1.30 (1.14-1.49)
<b>Gastrointestinal symptoms (GSRS tertiles)</b>					
n	<21	22-30	30+		
n	111	99	102	-	-
EQ-5D-5L	3.24 (5.59)	6.97 (6.84)	14.36 (13.94)	37.68	-
EQ-5D-5L+GI	3.75 (5.36)	9.43 (7.16)	18.30 (13.05)	69.18	1.84 (1.56-2.23)
<b>Symptomatic</b>					
n	No symptoms	At least one symptom			
n	90	222		-	-
EQ-5D-5L	3.00 (7.10)	10.11 (10.99)		32.23	-
EQ-5D-5L+GI	3.56 (6.45)	13.04 (11.11)		57.59	1.79 (1.49-2.44)

Table 4. Spearman's correlation coefficients between EQ-5D-5L, bolt-ons, EQ VAS and GSRS

Variables	EQ-5D-5L					Bolt-ons					EQ VAS	GSRS total score	
	MO	SC	UA	PD	AD	DI	GI	CO	SL	TI			
SC	0.285	-											
UA	0.429	0.300	-										
PD	0.365	0.240	0.499	-									
AD	0.159	0.174	0.273	0.407	-								
DI	0.163	0.098	0.333	0.283	0.271	-							
GP	0.200	0.103	0.357	0.508	0.372	0.383	-						
CO	0.165	-0.016	0.391	0.374	0.365	0.326	0.369	-					
SL	0.202	0.087	0.269	0.335	0.294	0.245	0.309	0.314	-				
TI	0.313	0.136	0.390	0.465	0.425	0.355	0.403	0.399	0.376	-			
EQ VAS	-0.329	-0.193	-0.424	-0.542	-0.317	-0.229	-0.504	-0.347	-0.262	-0.388	-		
GSRS total score	0.222	0.139	0.376	0.534	0.344	0.359	0.712	0.331	0.364	0.492	-0.462	-	