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Psychometric testing of the ICECAP-A in patients with coeliac disease: a comparative analysis with EQ-5D-5L

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Abstract

Objectives This study aimed to assess the psychometric properties of the ICEpop CAPability measure for Adults (ICECAP-A) in patients with coeliac disease (CD) and compare its performance with EQ-5D-5L.

Methods An online cross-sectional survey was conducted among 312 adult patients with CD in Hungary, who completed both the ICECAP-A and EQ-5D-5L. Psychometric properties assessed included distributional characteristics, convergent validity with the Gastrointestinal Symptom Rating Scale (GSRS), Satisfaction with Life Scale (SWLS), and known-group validity.

Results Mean age was 35.8 years (range: 18–80), and 70.2% were female. On the ICECAP-A, 51% (attachment) to 81% (stability) of patients reported limitations, while on the EQ-5D-5L, 2% (self-care) to 41% (pain/discomfort) reported problems. Ceiling effect was not observed for the ICECAP-A (6.7%), but reached 38.8% for EQ-5D-5L. The mean index value was 0.85 for the ICECAP-A and 0.92 for the EQ-5D-5L. ICECAP-A correlated strongly with SWLS (r=0.698), moderately with EQ-5D-5L (r=0.551) and weakly with GSRS (r=-0.284). Both the ICECAP-A and EQ-5D-5L were able to differentiate between known groups based on general health status and relevant clinical variables (e.g. symptoms, comorbidities, duration on gluten-free diet and adherence to it); however, the EQ-5D-5L typically showed somewhat larger effect sizes.

Conclusion This study is the first to validate ICECAP-A in patients with CD, demonstrating good psychometric performance, including strong convergent and known-group validity. Its ability to capture broader aspects of well-being supports its use as a valuable tool in outcome assessments for this patient population.

Keywords Coeliac disease, EQ-5D-5L, ICECAP, Health-related quality of life, Well-being

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Introduction

Coeliac disease (CD) is a food-related autoimmune condition that primarily affects the small intestine and has an estimated global prevalence of 1% [1]. It is triggered by the ingestion of gluten in genetically predisposed individuals, with the only effective treatment being strict adherence to a gluten-free diet (GFD). The clinical presentation of CD is heterogeneous and may include gastrointestinal problems, malabsorption, and extraintestinal symptoms, such as dermatitis herpetiformis, arthritis, neurological symptoms, and anaemia [2]. Adhering to a GFD poses significant challenges, including limited dietary variety, increased financial burden and the risk of nutritional deficiencies [3]. Given the various symptoms and the demands of maintaining a strict GFD, a decline in health-related quality of life (HRQoL) among patients is well-documented. Although previous studies have consistently shown that adherence to a GFD improves HRQoL, it does not fully normalise it [4]. In addition to its impact on HRQoL, CD is associated with an increased risk of depression, attention deficits, and eating-related anxiety, such as embarrassment when requesting gluten-free food in social settings or frustration related to the GFD [5]. Social functioning may also be impaired, with patients reporting feelings of being different, excluded, misunderstood by others, all of which may have serious implications for their overall well-being [6].

HRQoL measures have been widely used in patients with CD; they include both generic instruments such as the EQ-5D and SF-36, and condition-specific tools, such as the Coeliac Disease Questionnaire, Quality of Life Questionnaire for Coeliac Disease, and Coeliac Disease Quality of Life Survey [7–10]. However, these instruments may not able to capture the broader burden of living with CD as many patients report feelings of social isolation, anxiety around food, and limitations in dining out, travel, or work-related events, even when their clinical condition is stable [11–13]. To date, relatively few studies have examined the well-being of patients with CD, most of which rely on the Psychological General Well-being index [6, 14–16]. Moreover, the psychometric properties of these well-being measures remain underexplored in the CD literature.

The capability approach is a normative framework that defines well-being in terms of functioning (i.e. the states of being and doing that individuals actually achieve) and capability (i.e. the full range of real opportunities that people have to achieve those outcomes) [17, 18]. This perspective shifts the focus away from resources or subjective satisfaction, emphasising what people are genuinely able to be and do in their lives [19]. It captures a broader and more inclusive view of well-being and may be particularly useful in economic evaluations seeking to reflect the full impact of health and social interventions [20].

Considering the multifaceted impact of CD on patients' lives, this study aims to validate the adult version of a widely used capability well-being measure, the ICEpop CAPability measure for Adults (ICECAP-A), within this population. Specifically, we assess its distributional characteristics, convergent validity with both HRQoL and subjective well-being measures, and known-group validity. The comparative analysis with the EQ-5D-5L further explores the added value of measuring capability well-being alongside HRQoL to capture the broader quality of life impacts experienced by patients with CD.

Methods

Study population

An online cross-sectional survey was conducted between December 2020 and January 2021 among 312 Hungarian adults diagnosed with CD [7, 21]. Ethical approval was granted by the Research Ethics Committee of Corvinus University of Budapest (Reference No. KRH/390/2020). Participation was voluntary, anonymous, and uncompensated. The survey was administered using Qualtrics (Qualtrics 2020, Provo, UT, USA). A convenience sampling strategy was employed to recruit respondents through patient organisations and social media platforms. Eligibility criteria included being at least 18 years of age, providing informed consent, and self-reporting physician-diagnosed CD.

Study survey

A self-administered questionnaire was developed and consisted of four main parts, presented in a fixed order. The first section included questions about CD-related clinical characteristics, adherence to a GFD, general health status, the presence of comorbidities from a predefined list common in CD populations (e.g. diabetes, thyroid disease, allergies, other food intolerance, gastro-oesophageal reflux disease) and CD-related symptoms, specifically whether participants had experienced gastrointestinal or extraintestinal symptoms during the previous week, from a list including diarrhoea, constipation, abdominal pain, bloating, hair loss, and mood changes [22, 23]. The second part assessed HRQoL and well-being, while the third included preference elicitation tasks, such as time trade-off and willingness-to-pay questions, which have been published elsewhere [21]. The final part collected sociodemographic data, such as age, gender, place of residence, and education. All questions in sections one, two, and four were mandatory, resulting in complete data for HRQoL and well-being measures.

Outcome measures

All measures were administered in Hungarian using official self-complete digital versions.

ICECAP-A

The ICECAP-A measures capability well-being across five attributes: stability (feeling settled and secure), attachment (having love, friendship and support), autonomy (being independent), achievement (being able to achieve and progress), and enjoyment (experiencing enjoyment and pleasure) [24]. These attributes reflect key aspects of a person's life: stability relates to continuity in areas such as friendships, employment, and living situation; attachment highlights the value of emotional support and social bonds; autonomy reflects the importance of independence and self-sufficiency; achievement captures personal growth and goal attainment; and enjoyment represents the ability to find joy in daily life. The measure asks respondents to assess themselves with a recall period of 'at the moment.' Each attribute has four response levels, ranging from 'no capability' (level 1) to 'full capability' (level 4) resulting in 4^5 = 1,024 possible response combinations. Index values were derived using the Hungarian value set, which assigned a value to each response profile between 0 (no capability) and 1 (full capability) [25]. The Hungarian version of the ICECAP-A has previously undergone validation in general population and patient samples, supporting its reliability and validity [26–28].

SWLS

The Satisfaction with Life Scale (SWLS) was employed to evaluate patients' subjective well-being [29]. It has been extensively validated across diverse populations, making it a robust tool for comparing life satisfaction across different groups [30–34]. The instrument consists of five statements, each rated by respondents on a 7-point Likert scale ranging from 'strongly disagree' (1) to 'strongly agree' (7). The five items capture cognitive judgements of one's life in relation to personal ideals, perceived life conditions, overall satisfaction, accomplishments, and the extent of desired change. The recall period of the measure is unspecified. The total SWLS score was calculated by summing the individual item scores. The total score ranges from 5 to 35, with lower scores indicating reduced subjective well-being and higher scores reflecting greater levels of well-being.

EQ-5D-5L

The EQ-5D-5L is a generic preference-accompanied measure of HRQoL [35]. It consists of two components: a descriptive system that assesses HRQoL across five dimensions, and a visual analogue scale (EQ VAS) that captures self-rated health. The five dimensions include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on a five-level severity scale, ranging from 'no problems' (level 1) to 'extreme problems/unable to' (level 5). A total of 5^5=3125 unique health profiles can be described using this system. To calculate the EQ-5D-5L index values, we applied the Hungarian value set [36]. For the EQ VAS, respondents rated their health on a vertical scale ranging from 0 ('the worst health you can imagine') to 100 ('the best health you can imagine'). The recall period for both the descriptive system and EQ VAS is 'today.'

GSRS

As none of the common CD-specific HRQoL measures were available in Hungarian at the time of the data collection and cross-cultural validation was beyond the scope of our study, we selected the Gastrointestinal Symptom-Rating Scale (GSRS), which was available in Hungarian, to assess gastrointestinal symptom severity [37]. The GSRS is a widely used symptom-specific instrument in patients with CD [38–40], and familiar to regulatory authorities, such as the US Food and Drug Administration [41]. The GSRS consists of 15 items categorised into five domains: reflux (two items), abdominal pain (three items), indigestion (four items), diarrhoea (three items), and constipation (three items). The recall period is the past 7 days. Each item is rated on a seven-point Likert scale, ranging from 'no discomfort at all' (1) to 'very severe discomfort' (7). The total GSRS score, obtained by summing the item responses, ranges from 15 to 105, with lower scores indicating fewer gastrointestinal symptoms.

Analyses

Data were analysed using Stata 14.0 (StataCorp, 2015, College Station, TX, USA), and IBM SPSS Statistics 29.0 (IBM Corp., 2022, Armonk, NY, USA). For all analyses, a p-value<0.05 was considered statistically significant. The applied analyses framework used in the present study has been used in previous ICECAP-A and ICECAP-O validation studies in general population and various patient samples [27, 42, 43]. Measurement properties of the ICECAP-A were assessed and compared with those of the EQ-5D-5L to evaluate overall instrument performance.

Distributional characteristics

The distributions of responses across the ICECAP-A attributes and EQ-5D-5L dimensions were presented as relative frequencies and visualised using stacked bar charts. Ceiling values were calculated at both the level of individual attributes (or dimensions) and the overall instrument. Floor and ceiling effects were considered present if more than 15% of respondents reported the lowest or highest ICECAP-A or EQ-5D-5L index value, respectively [44]. Index values for the ICECAP-A and

Table 1 ICECAP-A, EQ-5D-5L, and EQ VAS scores by sociodemographic and clinical characteristics

Characteristics of the patient population			ICECAP-A index value[a]		*P* value	Effect size	EQ-5D-5L index value[a]		*P* value	Effect size	EQ VAS		*P* value	Effect size
	N	%	Mean	SD			Mean	SD			Mean	SD		
Total	312	100%	0.85	0.16			0.92	0.13			79.69	18.52		
Gender														
Female	219	70.19%	0.85	0.17	0.540	d = 0.076	0.92	0.14	0.071	d = 0.225	77.87	19.91	0.002	d = 0.334
Male	93	29.81%	0.86	0.15			0.94	0.10			83.99	13.94		
Age (years)														
18–24	59	18.91%	0.87	0.15	0.167	$\eta^2 = 0.021$	0.94	0.11	0.070	$\eta^2 = 0.028$	83.80	14.24	< 0.001	$\eta^2 = 0.068$
25–34	98	31.41%	0.87	0.15			0.93	0.12			81.47	16.33		
35–44	73	23.40%	0.85	0.17			0.93	0.11			81.41	14.96		
45–54	68	21.79%	0.82	0.18			0.90	0.15			75.41	23.50		
55+	14	4.49%	0.77	0.17			0.85	0.20			61.79	25.86		
Place of residence														
Capital	93	29.81%	0.88	0.13	0.013	$\eta^2 = 0.035$	0.93	0.10	0.235	$\eta^2 = 0.014$	82.14	12.32	0.128	$\eta^2 = 0.018$
County town	69	22.12%	0.88	0.14			0.94	0.08			81.70	17.90		
Other town	76	24.36%	0.82	0.20			0.90	0.17			76.05	24.94		
Village	74	23.72%	0.82	0.17			0.91	0.14			78.49	17.50		
Highest level of education														
Primary and vocational school	39	12.50%	0.79	0.20	0.017	$\eta^2 = 0.032$	0.90	0.16	0.561	$\eta^2 = 0.007$	73.85	22.94	0.160	$\eta^2 = 0.017$
Secondary school	116	37.18%	0.83	0.19			0.92	0.14			79.44	21.77		
College/university	157	50.32%	0.88	0.13			0.93	0.11			81.33	13.97		
Employment														
Employed	230	73.72%	0.86	0.15	0.011	d = 0.328	0.93	0.11	0.092	d = 0.217	80.11	18.07	0.507	d = 0.085
Not employed	82	26.28%	0.81	0.20			0.90	0.17			78.52	19.80		
Number of comorbidities														
0	33	10.58%	0.88	0.13	< 0.001	$\eta^2 = 0.073$	0.98	0.03	< 0.001	$\eta^2 = 0.120$	89.48	10.77	< 0.001	$\eta^2 = 0.159$
1	74	23.72%	0.91	0.09			0.97	0.05			85.58	9.64		
2–3	101	32.37%	0.85	0.16			0.93	0.13			82.51	13.66		
4+	104	33.33%	0.79	0.19			0.87	0.16			69.65	24.24		
General health status														
Excellent health	20	6.41%	0.92	0.12	< 0.001	$\eta^2 = 0.189$	1.00	0.01	< 0.001	$\eta^2 = 0.215$	96.90	4.80	< 0.001	$\eta^2 = 0.353$
Good health	76	24.36%	0.91	0.09			0.97	0.04			89.87	6.95		
Fair health	141	45.19%	0.87	0.13			0.94	0.08			81.19	12.84		
Poor & very poor health	75	24.04%	0.73	0.22			0.82	0.20			61.97	23.80		
Symptoms during last week														
No symptoms	90	28.85%	0.89	0.13	0.001	d = 0.379	0.97	0.11	< 0.001	d = 0.496	87.67	12.04	< 0.001	d = 0.628
Symptoms	222	71.15%	0.83	0.17			0.91	0.13			76.46	19.70		
GSRS tertiles														

Table 1 (continued)

Characteristics of the patient population			ICECAP-A index value[a]		*P* value	Effect size	EQ-5D-5L index value[a]		*P* value	Effect size	EQ VAS		*P* value	Effect size
	N	%	Mean	SD			Mean	SD			Mean	SD		
≤ 21	111	35.58%	0.90	0.12	< 0.001	$\eta^2 = 0.065$	0.97	0.08	< 0.001	$\eta^2 = 0.134$	86.86	14.01	< 0.001	$\eta^2 = 0.138$
22–30	99	31.73%	0.85	0.15			0.94	0.06			81.21	13.01		
31+	102	32.69%	0.80	0.20			0.86	0.18			70.41	23.08		
GFD duration														
less than a year	29	9.29%	0.75	0.22	0.002	$\eta^2 = 0.046$	0.88	0.16	0.044	$\eta^2 = 0.026$	69.34	26.65	0.005	$\eta^2 = 0.040$
1–5 years	109	34.94%	0.85	0.16			0.91	0.16			78.55	17.42		
6–10 years	71	22.76%	0.88	0.14			0.95	0.06			82.42	14.16		
more than 10 years	103	33.01%	0.86	0.15			0.93	0.11			81.93	18.72		
Self-reported frequency of dietary errors[b]														
Weekly - monthly	67	21.47%	0.84	0.16	0.214	$\eta^2 = 0.010$	0.94	0.08	0.579	$\eta^2 = 0.004$	80.66	13.56	0.314	$\eta^2 = 0.008$
Quarterly - half yearly	43	13.78%	0.82	0.16			0.94	0.07			83.37	10.53		
Less than half year	192	61.54%	0.86	0.16			0.92	0.15			78.79	21.15		

Abbreviations. d: Cohen's D, η^2: eta-squared, ICECAP-A: ICEpop CAPability measure for Adults, EQ VAS: EQ Visual Analogue Scale, GSRS: Gastrointestinal Symptom Rating Scale, GFD: gluten-free diet

[a]Index values were calculated using the respective Hungarian value sets for the ICECAP-A and EQ-5D-5L

[b]The self-reported frequency of dietary errors among 10 respondents is unknown

EQ-5D-5L, and EQ VAS were visualised using histograms, and stratified by age group using line charts.

Convergent and divergent validity

We assessed convergent validity to examine whether ICECAP-A attributes and index values aligned with similar constructs of other measures, and divergent validity to test whether they differed from unrelated ones. Correlations between ICECAP-A and EQ-5D-5L, EQ VAS, GSRS, and SWLS were assessed [45]. For attribute- or dimension-level correlations, Spearman's rank-order correlation (r_s) was used, while Pearson's correlation (r_p) was applied to index values or instrument-level scores. The absolute values of correlation coefficients were interpreted as follows: very weak (<0.20), weak (0.20–0.39), moderate (0.40–0.59), and strong (≥0.60) [46]. We hypothesised that the ICECAP-A stability attribute would show at least moderate correlation with the anxiety/depression dimension of the EQ-5D-5L, given their shared focus on emotional and psychological aspects [47]. Weak correlations were expected with the EQ-5D-5L mobility, self-care, and pain/discomfort dimensions, as these reflect physical health aspects less relevant to capability well-being. We anticipated moderate correlations between ICECAP-A autonomy and achievement and EQ-5D-5L usual activities dimension, given their mutual emphasis on daily functioning. Moreover, we expected moderate-to-strong correlations between ICECAP-A attributes and the SWLS [48, 49]. At the instrument level, we hypothesised that ICECAP-A index values would be moderately correlated with EQ-5D-5L index values based on previous studies [50–53].

Known-group validity

Known-group validity was evaluated by testing whether the ICECAP-A could differentiate between groups based on characteristics expected to potentially affect capability well-being, including, comorbidities, symptoms, gastrointestinal problems (measured by GSRS), GFD duration, adherence to GFD, age, general health status, gender, education, place of residence, and employment. Differences in ICECAP-A scores between groups were assessed using t-tests (for two-group comparisons) and one-way ANOVA (for comparisons involving more than two groups). Effect sizes and their 95% confidence intervals were calculated: Cohen's d for two groups and eta-squared (η^2) for more than two groups. Effect sizes were interpreted as trivial (d=0–0.19, η^2<0.01), small (d=0.20–0.49, η^2=0.01–0.05), moderate (d=0.50–0.79, η^2=0.06–0.13), or large (d≥0.80, η^2≥0.14) [54–56]. For GSRS groups and general health status, we expected larger effect sizes for the EQ-5D-5L than for ICECAP-A given their health-specific focus. We expected both better health and capabilities in those following the GFD for

a longer duration, and in patients adhering more strictly to the GFD [57]. We hypothesised that with more comorbidities, as well as older patients and women would have significantly lower capability values [4, 40, 58], but we expected higher capability values among individuals with better self-perceived health, higher education levels, and employment status [24, 26]. Meanwhile, for sociodemographic factors such as education and employment status, we anticipated larger effect sizes for the ICECAP-A, reflecting its broader conceptualisation of well-being [50–53, 59].

Results

Sample characteristics

A total of 312 adults with CD participated in the study (response rate: 42.5%). The mean age of the sample was 35.8 years (SD=11.5), and 70.2% were female (Table 1). Our sample demographics and high GFD adherence correspond to prior international CD cohorts, characterised by female predominance, early- to mid-adulthood diagnosis, and strong health awareness [1, 60, 61]. The majority of respondents were employed (73.7%) and had completed tertiary education (50.3%). Over two-thirds (71.2%) reported experiencing CD-related symptoms in the previous week, 65.7% had two or more comorbidities. Among the 103 patients, 33.0% followed a GFD for over 10 years, and all reported strict adherence; moreover, 61.5% indicated that potential GFD lapses occurred less frequently than once every six months.

Distributional characteristics

The greatest reported limitations on the ICECAP-A were found in the attributes of stability and achievement, with 81% and 78% of respondents, respectively (Fig. 1). The attributes with the highest ceiling (i.e. proportion of 'full capability') were attachment (49%), enjoyment (42%), and autonomy (37%). For the EQ-5D-5L, most respondents reported no problems in self-care (98%) and mobility (83%). However, substantial proportions reported issues in the pain/discomfort and anxiety/depression dimensions (both 41%).

At the instrument level, the mean ICECAP-A index value was 0.85 (SD=0.17), with only 6.7% of respondents reaching the maximum score of 1.0, indicating the absence of ceiling effect (Fig. 2). The EQ-5D-5L index value averaged 0.92 (SD=0.13) and demonstrated a pronounced ceiling effect, with 38.8% of respondents achieving the maximum score. The mean EQ VAS score was 79.69 (SD=18.52).

ICECAP-A index values decreased from 0.87 among respondents aged 25–34 to 0.77 among those aged 55 and older (Fig. 3). EQ-5D-5L index values showed a similar trend, declining from 0.94 among the youngest group (aged 18–24) to 0.85 in the oldest. Likewise, EQ VAS scores fell from 83.80 in the youngest group to 61.79 in the oldest.

Convergent and divergent validity

ICECAP-A attributes demonstrated trivial-to-moderate correlations with EQ-5D-5L dimensions (r_s=-0.005 to -0.435), with the strongest correlation observed between ICECAP-A stability and EQ-5D-5L anxiety/depression (r_s=-0.435) (Table 2). Correlations between ICECAP-A attributes and SWLS score were stronger (r_s=0.261 to 0.617) than those between EQ-5D-5L dimensions and SWLS score (r_s=-0.089 to -0.364). ICECAP-A attributes also showed weak-to-moderate correlations with GSRS score (r_s=-0.160 to -0.368). The strongest correlations between ICECAP-A attributes and GSRS score were seen for stability (r_s=–0.368) and enjoyment (r_s=–0.264), while EQ-5D-5L dimensions such as pain/discomfort (r_s=0.534) and usual activities (r_s=0.376) showed stronger correlations with GSRS score.

At the instrument level, ICECAP-A index values correlated moderately with the EQ-5D-5L index values (r_p=0.551) and with EQ VAS scores (r_p=0.459). ICECAP-A index values also showed a stronger correlation with SWLS scores (r_s=0.698) than did EQ-5D-5L index values

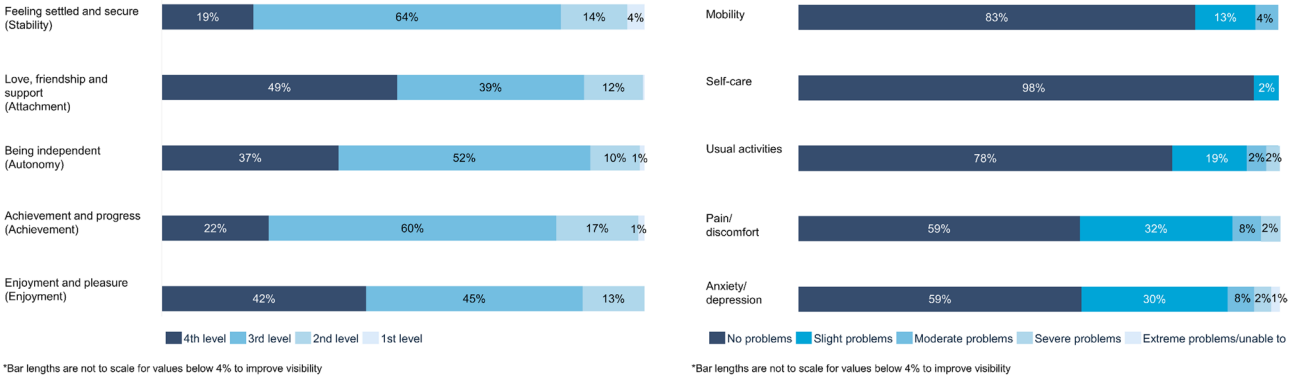

Fig. 1 Comparison of ICECAP-A attribute and EQ-5D-5L dimension responses in coeliac disease. Abbreviation. ICECAP-A: ICEpop CAPability measure for Adults

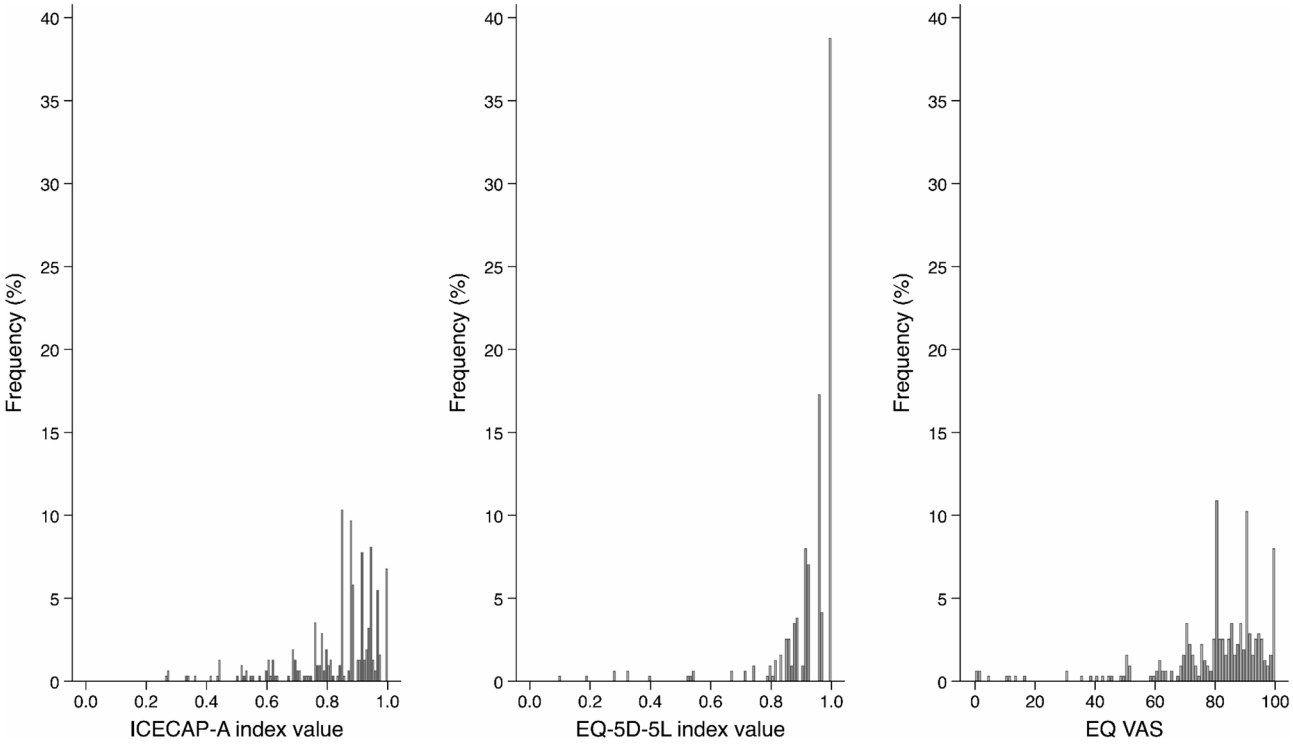

Fig. 2 Distribution of ICECAP-A and EQ-5D-5L index values and EQ VAS scores. *Abbreviations.* ICECAP-A: ICEpop CAPability measure for Adults, EQ VAS: EQ Visual Analogue Scale

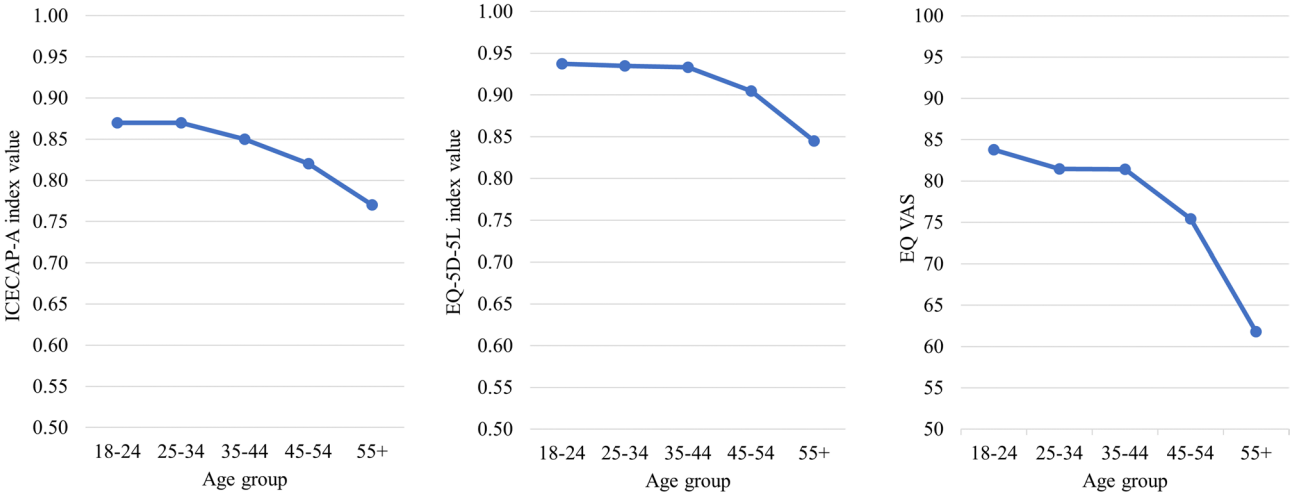

Fig. 3 Mean ICECAP-A and EQ-5D-5L index values, and EQ VAS scores by age group. *Abbreviations.* EQ VAS: EQ Visual Analogue Scale, ICECAP-A: ICEpop CAPability measure for Adults

(r_p=0.369). GSRS scores were moderately correlated with EQ-5D-5L index values (r_p=-0.458) and EQ VAS scores (r_p=-0.416), but only weakly with ICECAP-A index values (r_p=-0.284) and SWLS scores (r_p=-0.292).

Known-group validity

The ICECAP-A index values differentiated between several predefined groups (Table 1). Significant differences were observed across CD-related variables (symptoms during the last week, GSRS tertiles, and GFD duration), clinical variables (general health status and comorbidities), and sociodemographic characteristics (employment, education, and place of residence). EQ-5D-5L and EQ VAS consistently showed larger effect sizes than ICECAP-A for CD-related and clinical variables. For CD-related variables, GSRS tertiles produced moderate effect sizes across all outcome measures: ICECAP-A (η^2=0.065), EQ-5D-5L (η^2=0.134) and EQ VAS

Table 2 Convergent and divergent validity of the EQ-5D-5L and ICECAP-A

		ICECAP-A index value	ICECAP-A attributes					EQ VAS	EQ-5D-5L index value	EQ-5D-5L dimensions					SWLS
			Stability	Attachment	Autonomy	Achievement	Enjoyment			Mobility	Self-care	Usual activities	Pain / discomfort	Anxiety / depression	
ICECAP-A attribute	Stability	0.709													
	Attachment	0.745	0.382												
	Autonomy	0.538	0.388	0.245											
	Achievement	0.729	0.515	0.413	0.454										
	Enjoyment	0.771	0.520	0.577	0.274	0.515									
EQ VAS		0.459	0.440	0.236	0.195	0.260	0.326								
EQ-5D-5L index value		0.551	0.487	0.329	0.251	0.323	0.463	0.606							
EQ-5D-5L dimensions	Mobility	-0.185	-0.259	-0.104*	-0.082*	-0.113	-0.223	-0.329	-0.477						
	Self-care	-0.135	-0.204	-0.126	-0.156	-0.005*	-0.116	-0.193	-0.240	0.285					
	Usual activities	-0.386	-0.414	-0.236	0.254	-0.323	-0.311	-0.424	-0.591	0.429	0.300				
	Pain / discomfort	-0.374	-0.365	-0.253	-0.171	-0.250	-0.374	-0.542	-0.831	0.365	0.240	0.499			
	Anxiety / depression	-0.419	-0.435	-0.298	-0.273	-0.244	-0.367	-0.317	-0.733	0.159	0.174	0.273	0.407		
SWLS		0.698	0.530	0.521	0.261	0.483	0.617	0.394	0.369	-0.158	-0.089*	-0.294	-0.344	-0.364	
GSRS		-0.284	-0.368	-0.202	-0.160	-0.231	-0.264	-0.416	-0.458	0.222	0.139	0.376	0.534	0.344	-0.292

*$p \geq 0.05$

Abbreviations. ICECAP-A: ICEpop CAPability measure for Adults, EQ VAS: EQ Visual Analogue Scale, GSRS: Gastrointestinal Symptom Rating Scale; SWLS: Satisfaction with Life Scale

(η^2=0.138). Symptoms during the last week were associated with small effect sizes for both ICECAP-A (d=0.379) and EQ-5D-5L (d=0.496), but a moderate effect size for EQ VAS (d=0.628). GFD duration showed small but statistically significant effect sizes: ICECAP-A (η^2=0.046), EQ-5D-5L (η^2=0.026) and EQ VAS (η^2=0.040). General health status showed large effect sizes for all measures: ICECAP-A (η^2=0.189), EQ-5D-5L (η^2=0.215) and EQ VAS (η^2=0.353). A similar pattern was seen for comorbidities, with ICECAP-A (η^2=0.073) and EQ-5D-5L (η^2=0.120) showing moderate effect sizes, while EQ VAS (η^2=0.159) reached a large effect size.

For socioeconomic characteristics, ICECAP-A showed small effect sizes for education (η^2=0.032) and place of residence (η^2=0.035), whereas EQ-5D-5L and EQ VAS showed only trivial effect sizes (η^2<0.02). Neither ICECAP-A nor EQ-5D-5L differentiated by age or gender, while EQ VAS detected a moderate effect size for age (η^2=0.068) and small effect size for gender (d=0.334).

Discussion

This is the first study to assess the psychometric properties of the ICECAP-A in patients with CD and to compare it with the EQ-5D-5L. ICECAP-A demonstrated generally good psychometric performance, including the absence of a ceiling effect, comparable known-group validity to the EQ-5D-5L, and convergent validity with the SWLS. Previous studies have highlighted the limited sensitivity of generic HRQoL measures like the EQ-5D-5L in capturing the broader impacts of CD, supported by findings from the UK, Poland, and Slovenia, where patients with CD reported higher EQ-5D scores than the general population [62–64]. We also observed a notable ceiling effect in EQ-5D-5L index values, but none on ICECAP-A. In contrast, substantial capability limitations were reported across all ICECAP-A attributes. Only 19% of respondents reported full capability in the stability attribute, indicating perceived emotional and environmental insecurity, which is an aspect not directly addressed by HRQoL instruments. These findings highlight the value of ICECAP-A in capturing broader capability-related aspects of patient experience that may remain limited even when general HRQoL appears overall good. This is particularly important in chronic but manageable conditions such as CD, where individuals may report relatively high HRQoL while still experiencing constraints in some aspects of life.

With respect to known-group validity, the EQ-5D-5L demonstrated a stronger ability to distinguish between groups defined by CD-specific and clinical variables, reflecting its emphasis on HRQoL. At the same time, it was characterised by a more pronounced ceiling effect, which may reduce its ability to capture differences among individuals with relatively good health. In these higher

ranges, the ICECAP-A may retain greater sensitivity, as it is less constrained by such measurement limits. Furthermore, the differing correlation patterns observed for ICECAP-A and EQ-5D-5L reflect their different underlying conceptual foundations. The EQ-5D-5L is a generic HRQoL measure and primarily captures physical symptoms and functional limitations, which likely explains its stronger correlation with the GSRS compared to the ICECAP-A. In contrast, the ICECAP-A capability well-being measure showed stronger convergence with the SWLS and only moderate associations with GSRS, suggesting that ICECAP-A captures aspects of well-being that extend beyond physical symptoms. In addition to their conceptual differences, the instruments also vary in response structure and framing, which may partly explain the variation in their psychometric performance. For instance, ICECAP-A is more positively framed than the EQ-5D-5L, encouraging respondents to reflect on capabilities rather than problems. They also differ in the number of response levels per item.

The findings of this study highlight the potential for ICECAP-A and EQ-5D-5L to serve complementary roles in economic evaluation and healthcare decision-making. The EQ-5D, a preference-accompanied HRQoL measure, is widely used in cost-utility analyses and is recommended in health technology assessment (HTA) guidelines across more than 20 countries, including Hungary [65, 66]. Its widespread adoption is supported by the availability of value sets for over 30 countries, enabling standardised QALY calculations [67]. In contrast, ICECAP-A is currently included in only a few HTA guidelines, such as those in the UK and the Netherlands, primarily for assessing non-health effects or non-curative interventions, and value sets for ICECAP-A are also available for only a limited number of countries [68, 69]. Furthermore, unlike the EQ-5D-5L, ICECAP-A does not support the calculation of QALYs, as it is grounded in a capability-based rather than health utility framework. Despite these limitations, ICECAP-A offers distinct advantages for evaluating interventions that affect broader life domains, including those relevant to long-term condition management such as CD. Given these strengths, using ICECAP-A alongside EQ-5D-5L can provide a more comprehensive assessment of value by capturing both health-related and non-health-related benefits of care.

Several limitations of this study should be acknowledged. First, due to limited sample size within certain subgroups, some known-group validity analyses may have been underpowered. Second, the cross-sectional design did not allow for the assessment of test-retest reliability and responsiveness to change. In addition, CD diagnosis and symptom data were self-reported and respondents were recruited via convenience sampling and patient networks, which may lead to selection bias and limited generalisability. Furthermore, outcome measures were administered in a fixed order, which may have introduced order effects or response bias. Data collection also took place during the COVID-19 pandemic, which may have influenced the responses. Finally, although widely used instruments were included in this study, future research could benefit from incorporating additional CD-specific measures and conducting head-to-head comparisons with other well-being measures to further contextualise the performance of ICECAP-A. Longitudinal studies are also recommended to assess the responsiveness of ICECAP-A to dietary adherence, symptom changes, and long-term disease management.

Conclusion

This study provides the first evaluation of the psychometric performance of the ICECAP-A instrument in patients with CD. ICECAP-A demonstrated overall good measurement properties in this population. Compared to the EQ-5D-5L, ICECAP-A exhibited no ceiling effects and showed stronger associations with the SWLS. However, the ICECAP-A was less sensitive than the EQ-5D-5L in differentiating between clinically relevant known groups. These findings suggest that ICECAP-A is a valuable tool to assess well-being of patients with CD and offers a useful complement to the EQ-5D-5L in outcome measurement.

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Author contributions

Conceptualization and design: M.M.A., S.P., P.L.L., V.B., F.R.; Acquisition of data: M.M.A., F.R.; Statistical analysis: M.M.A.; Interpretation of data : M.M.A., S.P., P.L.L., V.B., F.R.; Drafting of the manuscript: M.M.A.; Critical revision of the paper for important intellectual content: M.M.A., S.P., P.L.L., V.B., F.R. All authors reviewed and approved the final version of the manuscript.

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Data availability

All data of this study are available from the corresponding author upon reasonable request.

Declarations

Ethical approval and consent to participate

Ethical approval was obtained from the Research Ethics Committee of the Corvinus University of Budapest (no. KRH/390/2020). Informed consent was obtained from all patients included in the study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with

the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Role of funder
The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Patient consent for publication
Not applicable.

Competing interests
F.R. serves as Co-Editor-in-Chief of *Health and Quality of Life Outcomes* and had no involvement in the editorial or peer review process for this manuscript. F.R. is also a member of the EuroQol Group. Views expressed in the article are those of the authors and are not necessarily those of the EuroQol Research Foundation.

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