

Translation, validation, and first application of the Greek version of an irritable bowel syndrome severity scoring system

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Abstract

Background The Irritable Bowel Syndrome Severity Scoring System (IBS-SSS) is a self-administered questionnaire that categorizes patients according to symptom severity. We aimed to translate and adapt the English IBS-SSS, validate the Greek version, and detect factors predictive of IBS severity.

Methods The original English version was obtained from the Rome Foundation, and the final Greek version arose through a process of translation, comprehensibility evaluation and back-translation. The 141 participants enlisted in the study were enrolled from 2 tertiary hospitals and were divided into 2 groups (98 patients and 43 healthy volunteers). We evaluated the questionnaire properties based on COSMIN criteria.

Results The recruited patients reported either diarrhea-predominant (34.7%), constipation-predominant (28.6%), or mixed subtype (36.7%) IBS. No significant variations were found regarding the frequency and intensity of abdominal pain and flatulence among the 3 IBS subtypes. Severity scores among healthy volunteers were significantly lower compared to IBS patients, irrespective of their disease subtype ($P < 0.001$). The Cronbach coefficient (α) was calculated at 0.953, suggesting high inter-item internal consistency. The intraclass correlation coefficient was calculated and found to be high, suggesting good responsiveness of the questionnaire. Two-way MANOVA evaluation showed that demographic variables (age, family status, body mass index [BMI], smoking, and alcohol consumption) in the Greek population affect the IBS-SSS score and syndrome severity.

Conclusions The Greek version of IBS-SSS is a reliable, valid and responsive tool for assessing Greek IBS patients' symptom severity. Older age, smoking, alcohol use and higher BMI are indicative of greater symptom severity.

Keywords Irritable bowel syndrome, irritable bowel syndrome severity scoring system, severity, questionnaire, patient-reported outcomes

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Introduction

Irritable bowel syndrome (IBS) is a chronic functional disorder of the lower gastrointestinal system affecting the bowels, with a global prevalence of approximately 5-10% in the general population [1]. IBS disrupts the balance in the gut-brain axis, leading to systemic effects influenced by both central and peripheral stimuli [2,3]. The condition is characterized by abdominal pain and changes in bowel habits. Symptoms can range from mild to severe, occurring intermittently or persistently [4]. Self-perceived severity estimates suggest that around 40% of cases are mild, 35% are moderate, and 25% are severe [5]. Currently, the severity of IBS is determined through

symptom reports and behaviors, rather than through blood tests or histopathological markers in the bowel [6]. However, relying solely on patient reports can lead to unnecessary investigations or treatments [7].

It is crucial to categorize patients with IBS into meaningful subgroups according to symptom severity, as this understanding will contribute to establishing appropriate treatment strategies [8,9]. Several studies have attempted to measure severity in IBS using different approaches, such as grading scales for individual symptoms, or composite measures of multiple symptoms or behaviors [6]. Various physician-based tools have also been developed to assess the severity of IBS using multiple components [10,11].

Among these scales, the most commonly used measure for evaluating IBS severity is the IBS Severity Scoring System (IBS-SSS), developed by Francis *et al* in 1997 [11]. The IBS-SSS evaluates the intensity of IBS symptoms, including abdominal pain, distension, stool frequency and consistency, and their impact on daily life over a 10-day reference period. Patient-rated IBS symptom severity is adjusted based on the physician's overall assessment, helping to address subjectivity [11].

To date, the IBS-SSS has been extensively used in clinical trials and real-world studies to monitor disease progression and assess the severity of IBS, contributing to a better understanding of the disorder [12-16]. However, there has been no similar questionnaire available in the Greek language, preventing clinicians from effectively addressing the challenges posed by IBS. To bridge this knowledge gap, our study aimed initially to translate the IBS-SSS into Greek and evaluate its psychometric qualities and factorial structure. Secondly, we aimed to identify potential predictors of severe IBS among the sociodemographic and clinical characteristics of our population, laying the groundwork for future research.

Patients and methods

Participants and design

This multi-center study took place at the University Hospital of Larissa, the sole tertiary referral center for functional gastrointestinal disorders in central Greece, and the "Attiko" University Hospital in southern Greece. Prior to commencement, the study protocol was approved by the Ethics committee and the Advisory board of the University Hospital of Larissa (D.N.49001/11-12-2020).

The study population consisted of healthy volunteers and IBS patients. Healthy volunteers were recruited from their

primary health provider, who was informed about the study protocol but did not participate in the study, whereas IBS patients were recruited from the gastroenterology and dietetic outpatient clinics of the participating centers from 08/2021 to 02/2022. All participants had been diagnosed by a specialist gastroenterologist following regular laboratory and endoscopic examination within the previous 12 months, and thus no organic disease other than IBS was considered responsible for the reported symptoms. In total, 141 subjects took part in the present study: 43 were healthy volunteers and 98 were allocated to the IBS group. To have an adequate sample size for the present validation study, we relied on the recommended sample size for factor analyses, which may vary from 50 to more than 1000 samples, while the recommended item-to-response ratio is from 1:3 to 1:20 for a 5-item questionnaire [17-19]. In addition, in order to enter the study participants had to be adults, able to speak and write Greek, and their IBS diagnosis had to be in line with the Rome IV criteria. Participants diagnosed with an organic gastrointestinal disease were excluded from this study. Participation was voluntary, with each individual being allowed to withdraw his/her consent at any time during the study.

Several studies have reported associations with proposed psychosocial factors such as stress [20], sexual abuse [21], depression [22], anxiety disorder [23], or social status [24]. To avoid confounding factors such as psychological comorbidities, we excluded participants who reported either depressive or anxiety symptoms, or those under medical treatment.

The data collected included a diary card with the characteristics of the population and the Greek version of IBS-SSS, completed during the initial visit by the participants themselves. However, for the evaluation of the measuring properties of IBS-SSS, 2 additional visits were scheduled. More specifically, to assess the responsiveness of the questionnaire, the first 41 IBS patients recruited were asked to complete the IBS-SSS again after 24 h (2nd visit), and 1 month following their planned therapeutic intervention. Throughout the literature, these time intervals between assessments were not precisely predefined but were expected to be long enough to prevent recall bias. In our study, the time intervals were set in accordance with those used in similar studies [11]. IBS patients' change in disease severity compared to the initial visit (baseline to 1st visit) was assessed by the participants themselves, using a 5-point Likert-type scale, and confirmed by the treating physician. On this scale, the value 1 corresponded to the worst status and the value 5 to the best. Given that we administered and examined the validation properties of a questionnaire specially designed to detect symptoms and level of disease severity among IBS patients, our initial intention was not to test its properties in relation to healthy volunteers, given that a score under 75 is indicative of absent or quiescent disease. Accordingly, we included an adequate number of healthy volunteers (based on a 1:10 ratio) for a 5-item questionnaire [17,18] and based on the original research which administered the IBS-SSS in 40 healthy volunteers [11]. All data were collected by the site coordinators and were handled anonymously.

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Population characteristics

The diary card included information regarding participants' sex, age, place of residence, education level, family and employment status, smoking and alcohol consumption, as well as biometric values, including height, weight, and body mass index (BMI). IBS has been found to be associated with the gut-brain axis and several studies have reported its side-effects on disease severity [25,26]. According to Data of Alcohol Consumption EE-27 2019 [27], Greece is among the EU-27 countries with generally low alcohol consumption and a low prevalence of heavy episodic drinking; nevertheless, we measured alcohol consumption in our study population and categorized the participants based on a yes/no response if they consumed alcohol. According to the National Institute of Alcohol Abuse and Alcoholism (NIAAA) [28] and "Dietary Guidelines for Americans 2020-2025, U.S. Department of Health and Human Services and U.S. Department of Agriculture" [29], adults can choose not to drink or to drink in moderation by limiting intake to 2 drinks or less in a day for men and 1 drink or less in a day for women, when alcohol is consumed. On the other hand, NIAAA defines binge drinking as a pattern of drinking alcohol that changes blood alcohol concentration. For a typical adult, this pattern corresponds to consuming 5 or more drinks (male), or 4 or more drinks (female). Therefore, we allocated the participants to the "yes" group if they reported that they consumed less than 2 drinks or 1 for men and women, respectively. Participants were allocated to the "no" group if they reported no alcohol consumption at all. Participants who reported excess alcohol consumption based on the NIAAA guidelines were excluded from the study.

IBS-SSS questionnaire

The IBS-SSS questionnaire was developed and validated in 1997 by Francis *et al* [11]. It is a 5-item self-administered questionnaire. The first 3 questions ask patients with IBS to self-assess the frequency and intensity of abdominal pain and abdominal distension experienced in the last 10 days preceding the completion of the questionnaire. The other 2 questions require patients to self-assess their overall satisfaction with their bowel habits and the degree to which IBS interferes in their daily routine. The score for each question ranges from 0-100, except for the question that refers to the number of days that patients experience abdominal pain which is scored from 0-10. However, for the calculation of the final score, the score of the abovementioned question is also converted to a 0-100 point score, by multiplying the answer given by 10. In all questions, extreme values indicate the absence (0) or the highest value (100) of the variable investigated. The final score of IBS-SSS ranges from 0-500. According to the creators of the questionnaire, IBS-SSS can discriminate IBS patients from healthy volunteers, and concurrently stratify IBS patients into 4 severity classes, based on their final score. The first class indicates quiescent IBS and includes total IBS-SSS scores <75; the second class indicates mild IBS and includes scores that

range from 75-175; the third class indicates moderate IBS and includes scores that range from 175-300; and the fourth class indicates severe IBS including scores that exceed 300.

IBS-SSS translation process

Written permission for the translation of the original English version of IBS-SSS and its subsequent use in our population was acquired from the Rome Foundation in March 2021. Final approval of the Greek translation was received in April 2021. The translation process was conducted according to the Rome Foundation guidelines, under the supervision and coordination of a gastroenterologist with proven experience in the management of IBS patients, appointed by the Rome Foundation as a counselor.

In the first stage, 2 professional Greek translators with experience in medical translations conducted the forward translation of the English version to the Greek language. Translators worked independently, creating 2 versions of the questionnaire in the target language. A reconciliation process followed, involving the 2 translators and the Rome Foundation-appointed counselor. During this process, the 2 forward versions were compared for potential differences and one commonly accepted version emerged, constituting the final Greek version of the questionnaire. At the end of this stage, the final version was presented to 2 healthy adolescent volunteers who were native Greek speakers for cognitive debriefing.

Both volunteers confirmed that they fully understood the meaning and purpose of all of the questions of the questionnaire, providing appropriate answers to all questions. In addition, both volunteers interpreted all 5 questions reasonably well, and showed an adequate understanding of the meaning of each question without the need for additional explanations.

In the second stage of the process, a third professional translator, who was a native English speaker and a fluent speaker of the Greek language, was appointed and conducted the backward translation of the final Greek version to the English language. Both English versions were subsequently compared for language similarity (literal translation) and for comparability of interpretation (cultural adaptation).

In the last stage, the final Greek version and the English backward translation of the original IBS-SSS were first approved by the Rome Foundation-appointed counselor, and were then submitted for approval to the Rome Foundation. The final approval of the Greek version was received by the administrative board of the Foundation on 19th May, 2021 (see Supplementary material).

Statistical analysis

Mean value, standard deviation, median and interquartile range (IQR) were used to describe quantitative variables, depending on whether the data followed the normal distribution or not. Data collected for the IBS-SSS questionnaire were used with new quantitative variables, created by calculating

the differences in values between different time points when needed. The Kolmogorov-Smirnov (for $N > 50$) and the Shapiro-Wilk (for $N < 50$) tests were run to check the normality of the distributions. In the case of asymmetrical distribution, logarithmic transformations of the variables were used, but did not achieve normal distribution in data. Accordingly, the non-parametric Mann-Whitney U test was used to compare quantitative variables between the 2 groups. Multivariate analysis of variance (MANOVA) was used to assess any interaction effect between health status and the total score on the IBS-SSS questionnaire. The evaluation of the measurement properties of the questionnaire was conducted in accordance with international recommendations [30,31]. Confirmatory factor analysis (CFA) was performed on the variance-covariance matrix of the IBS-SSS items to test the good fit of our data in premeditated structural models [11,32,33]. The fit of our data was assessed using the chi-square test, the comparative fit index, the Tucker-Lewis index, the normed fit index, the relative fit index, the root mean squared error of approximation and the incremental fit index. Internal consistency was tested by calculating Cronbach's alpha coefficient, where values > 0.7 indicate strong correlation. To test the responsiveness of IBS-SSS, intraclass correlation coefficients (ICC) were used. An ICC > 0.7 was considered the minimum standard for reliability. The Wilcoxon signed-rank test and Cohen's d were used to follow-up IBS-SSS scores between the 2 visits. Values of 0.2, 0.5 and 0.8 were regarded as small, medium and large effect sizes, respectively. Measurement error was represented by the standard error of measurement: $SEM = SD1 \times \sqrt{1 - ICC}$, where $SD1$ is the standard deviation at 1st visit. The smallest detectable change (SDC) for the individual (SDCIND) and the group score (SDCGROUP) were calculated according to Terwee *et al* [30,31]. Two-way MANOVA was used to examine the effect and association between demographic variables and participants' performance in the IBS-SSS questionnaire. The significance level was set at $P = 0.05$. For our analysis, we used statistical software for Windows, SPSS 26, and IBM AMOS 26.0.

Results

A total of 141 individuals were screened for eligibility and recruited over the study period. The overall population was subsequently divided into 2 groups consisting of 43 healthy volunteers and 98 patients with IBS. Among the IBS patients, 34.7% (34/98) were suffering from diarrhea-predominant IBS (IBS-D), 28.6% (28/98) from constipation-predominant IBS (IBS-C), and 36.7% (36/98) from mixed-type IBS (IBS-M). Both groups were demographically comparable and homogeneous in terms of sex, employment status, family status, smoking, age, weight, and BMI. Differences between the 2 groups were statistically significant for residence, education level, alcohol and height. The study population's characteristics collected are shown in Table 1.

Table 1 Population characteristics

Demographics	Irritable bowel syndrome participants (N1=98)	Healthy volunteers (N2=43)	P-value
Sex			
Female/Male	62/36	23/20	0.147
Residence			
Rural/Urban	67/31	43/0	<0.001
Education			
High school	33	7	0.050
University	57	34	
Other	8	2	
Employment status			
Unemployed	22	5	
Blue collar work	9	4	
White collar work	67	34	0.223
Family status			
Single/Married	40/58	14/29	0.520
Smoking			
Yes/No	28/70	6/37	0.224
Alcohol			
Yes/No	41/57	9/34	0.01
Age (mean±SD)	43.58±11.94	47.07±13.93	0.416
Weight (mean±SD)	72.5 (23)	74 (19)	0.695
Height (mean±SD)	167 (16)	172 (9)	0.04
BMI (mean±SD)	25.3 (7.22)	25.4 (3.65)	0.569

BMI, body mass index; SD, standard deviation

Face validity and cross-cultural adaptation

The face validity and cross-cultural adaptation of IBS-SSS were confirmed during the translation process.

Structural validity

Based on the literature and our clinical observations, we tested our data for the goodness of fit in 2 CFA models. The first model was the one proposed by the developers of the questionnaire and was the one used in all similar studies. This model was based on the assumption that all 5 items can be loaded into 1 single factor, providing a unidimensional assessment of the IBS severity. The second model was created from the first model, with the addition of correlated error terms between questions 1 and 2, based on clinical observations indicating the importance of the frequency and intensity of abdominal pain in determining the burden of IBS.

The results of the CFA analysis are shown in Table 2. The first model showed marginal fit in all basic comparisons, except for the probability of rejecting the hypothesis that the root mean squared error of approximation was not significant. The

Table 2 Confirmatory factor analysis: fit indices for the premeditated structural models of the irritable bowel syndrome-severity scoring system

Model	Chi-square	df	NFI	RFI	IFI	TLI	CFI	RMSEA	PCLOSE
1-factor	23	5	0.92	0.85	0.94	0.88	0.94	0.19	0.00
Adapted 1-factor	8.3	4	0.97	0.93	0.99	0.96	0.99	0.10	0.15

Df, degrees of freedom; NFI, normed fit index; RFI, relative fit index; IFI, incremental fit index; TLI, tucker-lewis index; CFI, comparative fit index; RMSEA, root mean square error of approximation; PCLOSE, P value of close fit

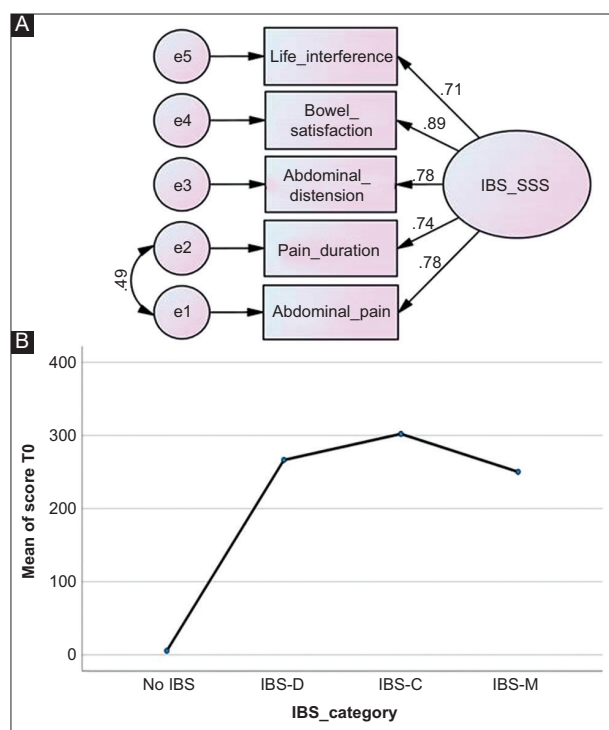


Figure 1 (A) Illustrative representation of the adapted 4-structural model of the Irritable Bowel Syndrome-Severity Scoring System (IBS-SSS), with standardized factor loadings. The decimal numbers indicate the standardized regression weights. (B) Illustrative representation of the mean score differences between IBS patients and healthy volunteers IBS-D, diarrhea-predominant IBS; IBS-C, constipation-predominant IBS; IBS-M, mixed-type IBS

second model was the one for which our data showed the most adequate fit; it is depicted in Fig. 1A.

Severity variability among the 3 IBS subtypes

Symptom severity variability among the 3 IBS subtypes is shown in Table 3. Among the different IBS subtypes, abdominal pain and distension were found to be present in >86% of the IBS patients. However, no significant variations were found regarding the frequency and intensity of abdominal pain and flatulence among the 3 IBS subtypes. Nevertheless, there was a tendency for patients with IBS-D to experience less intense pain and distension compared to the other 2 IBS subtypes.

Based on the second structural model, the mean score and standard deviation achieved by healthy volunteers were 5.6 ± 9.3 . The respective scores achieved by IBS patients are shown in Table 3.

Similar differences were recorded when the mean scores of healthy volunteers were compared to the scores that the IBS patients achieved in IBS-SSS after being stratified according to IBS severity, (mean \pm SD: healthy volunteers 5.6 ± 9.3 , mild IBS 119.7 ± 29.7 , moderate IBS 246.8 ± 43.3 , severe IBS 388.9 ± 52.7).

Internal consistency

The Cronbach coefficient (α) was 0.953, suggesting a high inter-item internal consistency and excellent reliability. No additional improvement in the reliability of the questionnaire was noticed when successive removal of each question was attempted.

Floor-ceiling effect (content validity)

There was no missing data in our analysis. No ceiling and floor effects were recorded.

Criterion validity

Criterion validity was not tested, since there is no other questionnaire or gold standard that measures the severity of symptoms of IBS patients.

Measurement error

SEM, SDCIND, and SDCGROUP were calculated for IBS-SSS. For the sum score, SEM, SDCIND and SDCGROUP were found to be 7.05, 19.54 and 3.05 respectively.

Discriminant ability

Severity scores differed significantly ($P < 0.001$) between healthy volunteers and IBS patients, irrespective of their IBS subtype. Fig. 1B illustrates the mean score differences between IBS patients and controls.

Responsiveness

The first 41 IBS patients of our population completed the IBS-SSS for the second time 24 h after their first visit. The ICC was calculated for these 41 patients 24 h after the baseline

Table 3 Symptom severity in irritable bowel syndrome (IBS) patients according to disease subtype

Symptom severity	IBS (N1 = 98)	IBS-D ¹ (n = 34)	IBS-C ² (n = 28)	IBS-M ³ (n = 36)
Abdominal pain (yes/no)	94/4	32/2	27/1	35/1
Level of abdominal pain ⁴	60 (30-80)	40 (31-86)	60 (32.5-80)	65 (30-80)
Duration of abdominal pain, days ⁴	4 (2-7)	4 (3-7.255)	4 (2-8.75)	4.5 (1-6)
Abdominal flatulence/discomfort, (yes/no)	90/8	32/2	27/1	31/5
Level of abdominal flatulence/discomfort ⁴	60 (20-80)	70 (20-80)	60 (40-87.5)	55 (20-80)
Dissatisfaction with bowel function ⁴	60 (30-80)	50 (20-82)	65 (42.5-70)	65 (30-80)
Effects of abdominal symptoms in everyday life ⁴	70 (20-80)	70 (22-84.5)	70 (42.5-90)	70 (20-80)
Severity score variation (Mean ± SD)	270.7 ± 128.2	266.5 ± 133.2	302.1 ± 126.6	250.3 ± 123.2

IBS-D: Diarrhea-predominant IBS

²IBS-C: Constipation-predominant IBS³IBS-M: Mixed type IBS⁴Results presented as median (IQR)

IQR, interquartile range; SD, standard deviation

Table 4 Responsiveness of irritable bowel syndrome (IBS)-severity scoring system: comparison of scores between the 2 visits for the first 41 IBS patients. The intraclass correlation coefficient (ICC) was calculated in 41 patients 24 h after the first visit. Effect size was calculated using Cohen's d in 28 patients who reported a change in their condition 1 month after their initial visit

Response	n	1 st visit	2 nd visit	Mean difference	ICC	Cohen's d
Stable patients	41	231.7	233.9	-2.2	0.997	
Improved patients	28	222.1	165	-57.1		0.45

visit, indicating excellent reliability. Effect size was calculated with Cohen's d in 28 patients who reported changes in their condition after a medical treatment 1 month after the baseline visit, indicating the possibility of using the administrative questionnaire to follow up IBS patients' health status after medical treatment. All results are shown in Table 4.

Relationships between IBS-SSS and population characteristics

Statistical analysis using MANOVA (Table 5) showed that there was a statistically significant interaction effect between health status and the IBS-SSS questionnaire total score: $F(2, 136)=87.99$, $P<0.001$, Wilks' $\Lambda=0.436$ (Fig. 1B). More specifically, subjects with IBS had higher IBS-SSS scores. In addition, with regard to other health and demographic factors, the analysis showed that there was a huge and statistically significant interaction effect between family status, smoking and alcohol consumption, and the IBS-SSS questionnaire total score: $F(2, 132)=16.18$, $P<0.001$, Wilks' $\Lambda=0.891$. In particular, with regard to family status, single participants (not married) who had high alcohol consumption and were smokers had higher IBS-SSS scores. Alcohol consumption appeared to affect IBS-SSS positively, as did smoking and family status, showing that these 3 variables, either separately or combined, affect the total IBS-SSS score. Furthermore, as expected, the IBS category also showed a statistically significant interaction effect on the total IBS-SSS score: $F(6, 272)=63.02$, $P<0.001$, Wilks' $\Lambda=0.416$.

Patients with IBS-C scored higher on the questionnaire. There was also a statistically significant interaction effect between age, weight and height, and the total IBS-SSS score: $F(2, 136)=1.106$, $P<0.001$, Wilks' $\Lambda=7.909$, $F(2, 136)=3.478$, $P<0.001$, Wilks' $\Lambda=2.512$, and $F(2, 136)=5.276$, $P<0.001$, Wilks' $\Lambda=4.421$, respectively. More specifically, subjects with lower height had higher IBS-SSS scores, as did those with greater weight. Moreover, older adults demonstrated higher IBS-SSS values. Additionally, as expected, there was a statistically significant interaction effect between the BMI and IBS-SSS, with a high BMI being associated with a higher total IBS-SSS score: $F(2, 125)=4.047$, $P=0.002$, Wilks' $\Lambda=1.913$. However, no statistically significant interaction effect was found between type of residence, occupation and education, and total IBS-SSS score.

Discussion

In this study, our primary objectives were to translate the IBS-SSS questionnaire and assess the measurement properties of the Greek version. As a secondary objective, we aimed to estimate the symptom severity of a multi-center cohort of individuals with IBS, as well as to assess any associations with the sociodemographic and clinical characteristics of our population.

The translation process of IBS-SSS followed the Rome Foundation's predefined criteria, and the evaluation of its

Table 5 MANOVA table reporting the results of a multivariate comparison evaluating the Irritable Bowel Syndrome-Severity Scoring System (IBS-SSS) and demographic factors

Source	Dependent variable	Type III sum of squares	df	Mean square	F	P-value
IBS-SSS	Sex	16.548	1	16.548	0.001	0.970
	Health status	2053652.346	1	2053652.346	176.216	<0.001
	Sex x Health status	286.591	1	286.591	0.025	0.876
	Error	1596619.088	137	11654.154		
	Total	8780300.000	141			
	Type of residence	31252.595	1	31252.595	1.157	0.284
	Education	124185.173	2	62092.586	2.299	0.104
	Occupation	24459.693	2	12229.847	0.453	0.637
	Type of residence x Education	16141.349	2	8070.674	0.299	0.742
	Type of residence x Occupation	13882.282	1	13882.282	0.514	0.475
	Education x Occupation	8425.506	2	4212.753	0.156	0.856
	Type of residence x Education x Occupation	8488.593	1	8488.593	0.314	0.576
	Error	3457157.427	128	27009.042		
	Total	8780300.000	141			
	Family Status	57324.012	1	57324.012	2.495	0.117
	Smoking	8442.481	1	8442.481	0.368	0.545
	Alcohol	4347.361	1	4347.361	0.189	0.664
	Family status x Smoking	118816.628	1	118816.628	5.172	0.025
	Family status x Alcohol	192777.917	1	192777.917	8.392	0.004
	Smoking x Alcohol	43569.868	1	43569.868	1.897	0.171
	Family status x Smoking x Alcohol	371742.902	1	371742.902	16.182	<0.001
	Error	3055302.904	133	22972.202		
	Total	8780300.000	141			
	IBS category	2144191.577	3	714730.526	63.026	<0.001
	Error	1553605.586	137	11340.187		
	Total	8780300.000	141			
	Age	106500.000	8	13312.500	1.10628	<0.001
	Weight	334866.667	8	41858.333	3.478	<0.001
	Height	190500.000	3	63500.000	5.277	<0.001
	Error	8.4248875	7	1.203E+00		
	Total	8780300.000	141			
	BMI	3591297.163	125	28730.377	4.047	0.002
	Error	106500.000	15	7100.000		
	Total	8780300.000	141			

BMI, body mass index

measurement properties was performed according to the COSMIN checklist [30,31]. During the cultural adaptation of IBS-SSS, the diverse social, economic and cultural features of Greece were not found to affect the original factorial structure proposed by the questionnaire's creators.

In line with studies conducted on other populations, the validity of the Greek version of the questionnaire was found to be high [11,32,33]. More specifically, the questionnaire was

found to allow clinicians to differentiate, not only between individuals with IBS and healthy controls, but also among IBS patients experiencing mild, moderate or severe symptoms. In addition, it was found that the questionnaire can detect with high sensitivity changes in the severity of IBS following therapeutic interventions, suggesting that the Greek version of IBS-SSS is a sensitive tool that could be used effectively in clinical trials.

With regard to IBS severity, our study yielded interesting results compared to previous studies conducted in other populations [11,32,33]. In particular, the majority of our IBS patients exhibited severe symptoms, whereas in studies including American and Japanese patients the majority of them had moderate symptoms. This was because, in our study, we included patients from tertiary referral centers rather than from the community; hence, these patients had greater symptom severity.

Among the different sociodemographic and clinical characteristics of our population, family status (single), alcohol consumption and obesity were the sole factors associated with greater symptom severity. Our study was the first that specifically sought to identify potential factors associated with greater symptom severity, and it can therefore be used as a reference study for future studies. It also highlighted a possible target group for future interventions.

Moreover, a recent systematic review [34] including 31 studies explored the potential association of both smoking and alcohol and their connection to IBS severity, yielding controversial results. Recent research studies also report a strong association between smoking [35] and alcohol consumption (even at low levels), and IBS [36]. In this common vein, the present validation study found a similar strong association between smoking and alcohol consumption, and IBS severity. In addition, recent research advances have shown that older adults and middle-aged adults, and more specifically those with frailty, have a significantly higher risk of developing IBS [37]. Similarly, our study results highlight the same relation, since older age was found to be highly positively associated with more severe IBS as graded by the questionnaire.

One potential limitation of our study is the absence of a gold standard method for comparing with IBS-SSS in the context of the evaluation of IBS symptom severity. However, in all studies where it was administered, such as ours, no such standard was used, as none exists [6]. Another possible limitation is recall bias. Although the COSMIN checklist suggested using a more than 10-day period to minimize recall bias, this time period is relatively long for individuals to precisely recall the intensity of their experienced symptoms. Therefore, we used a 24-h retest period, as used in the original study by the creators. Moreover, a future extension of the present study could consider administering the Greek version of IBS-SSS as part of a randomized clinical trial, in order to examine its potential ability to detect significant changes in IBS patients' health status following a particular medical treatment.

Overall, the Greek version of IBS-SSS was found to be a reliable and valid instrument for evaluating the severity of IBS; hence, it can be used in future studies. Alcohol consumption, smoking, obesity and family status (single) are associated with more severe symptoms, indicating specific population groups for future interventions.

Summary Box

What is already known:

- Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder affecting about 5-10% of the general population
- The IBS Severity Scoring system (IBS-SSS) is a valid questionnaire for assessing symptom severity and the clinical course of syndromes
- No similar questionnaire existed in the Greek language

What the new findings are:

- The Greek version of the IBS-SSS questionnaire is a valid and reliable tool for assessing the syndrome's severity, and is capable of categorizing patients into 4 severity groups)
- Alcohol consumption, smoking, obesity and older age are factors correlated with greater symptom severity

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Supplementary material



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April 19, 2021

Nikolaos Dimzas
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Re: Rome Foundation Approval of Translation

Dear Nikolaos,

We have received your documentation relating to the translation of the Rome Foundation's IBS-SSS into Greek for Greece.

Thank you for this excellent job and important contribution to the body of translated Rome Foundation material. We are pleased to extend official Rome Foundation approval of the translation.

The Rome Foundation maintains all copyrights for the translated document. This material cannot be used without its approval, including licensing and usage fees when applicable.

Sincerely,

A handwritten signature in black ink, appearing to read "Ami Sperber".

Ami D. Sperber, MD, MSPH
Head, Rome Translation Project

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