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Normative data for the Brief Symptom Inventory for patients with Crohn's disease

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ABSTRACT

Objective: The Brief Symptom Inventory (BSI) is a self-report measure of psychological symptoms in clinical and non-clinical populations. However, norms for BSI are lacking for patients with chronic illness, such as Crohn's disease (CD). This study aimed to provide BSI clinical norms using a cohort of CD patients.

Design: Adult Israeli CD patients (n = 430) completed questionnaires regarding clinical, demographic and psychological aspects of disease, including BSI. Their BSI data were compared with published norms from adult Israeli population and British psychiatric outpatients.

Results: CD patients in active disease state had higher levels of mental health symptoms than those in remission. Interestingly, levels of symptomatology did not differ with respect to disease duration. No significant sex differences in BSI dimensions were found, with the exception of somatization. Being younger than 60 years and having lower economic status were associated with more severe psychological symptoms. Psychological symptom levels in CD patients were high in comparison to the Israeli general population, but low compared to British psychiatric outpatients.

Conclusion: Results confirm the link between CD and elevated psychological symptoms. The findings highlight the need to use appropriate BSI norms when assessing clinically significant levels of psychological symptoms in non-psychiatric patients with chronic illness.

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Brief Symptom Inventory; Crohn's disease; normative study; psychological distress

1. Introduction

Psychological distress is highly prevalent in patients with chronic medical illness (Burke et al., 2015; Graff et al., 2009). One of the most common instruments for measuring psychological symptoms is the Brief Symptom Inventory (BSI; Derogatis & Spencer, 1983). The BSI is a cross-culturally validated and useful tool for measuring

psychological distress in healthy and clinical individuals (Moura-Ramos et al., 2012; Neuendorf et al., 2016). Despite the widespread use of this scale by researchers and clinicians, normative data do not exist for the BSI in patients with chronic medical conditions. Population norms for the BSI are currently available from general population studies in different countries or based on patients with psychiatric disorders (De Leo et al., 1993; Francis et al., 1990; Gilbar & Ben-Zur, 2002; Ryan, 2007). Thus, these norms may be of limited use as comparative data for identifying clinically significant psychopathology in individuals with chronic medical illnesses.

One such medical illness is Crohn's disease (CD) – a chronic inflammatory bowel disease, with rising incidence worldwide, and hitherto without known etiology or cure (Torres et al., 2017). Patients with CD suffer from relapsing and remitting episodes of abdominal pain, diarrhea and fatigue, requiring life-long therapy to control the course of the disease and prevent surgery (Torres et al., 2017). These often unpredictable symptoms impair their ability to perform activities of daily living and can lead to poor social and work functioning (Guthrie et al., 2002; Høivik et al., 2013).

It is, therefore, not surprising that previous research has found an increased prevalence of mental health symptoms in individuals with CD compared to the general population (Byrne et al., 2017; Mikocka-Walus et al., 2016; Neuendorf et al., 2016). Moreover, the severity of disease symptoms has been consistently associated with increased risk of depression and anxiety in Crohn's patients (Byrne et al., 2017; Graff et al., 2009; Neuendorf et al., 2016).

Therefore, the objectives of this study were as follows: (1) to provide adult clinical norms for the BSI using a cohort of CD patients where psychiatric disease was excluded; (2) to explore the relationships of BSI scores with sociodemographic and medical variables; (3) to compare the normative data of our sample with published norms from the adult general Israeli population (Gilbar & Ben-Zur, 2002) as well as adult British psychiatric outpatients (Ryan, 2007).

2. Methods

2.1. Design and study population

A cross-sectional study design was conducted to examine the psycho-social state of adult patients with CD (Sarid et al., 2018). Patients with a confirmed diagnosis of CD were informed of the study when presenting for follow-up or for acute (non-hospitalized) care at the outpatient Gastroenterology departments of five participating university-affiliated hospitals distributed in the north, center and south of Israel. Data collection took place from July 2013 through June 2016. Inclusion criteria were patients with a confirmed diagnosis of CD, aged 18 years and over. Exclusion criteria were history of psychiatric disease or taking medication for such disease.

Patients who consented to participate completed a questionnaire either on paper or online at their discretion. Patients completing the paper version of the questionnaire received a verbal explanation of the study and instructions for completion. They were encouraged to consult the study coordinator for any further clarification. Patients recruited online could avail themselves of the written explanation of the study and

instructions for completing the questionnaire at the web site. They were also provided with a telephone number of a staff member who could be contacted anonymously with any questions.

Of the 1,325 eligible patients that were approached, 596 consented to participate (response rate 45%). Of these, 442 had a confirmed diagnosis of CD and were included in the final analysis. Individuals with incomplete data on the BSI variables (see section 3.2.1. below) were excluded, reducing the final sample to 430 individuals. All participants provided informed consent and the study was approved by institutional review boards at each participating hospital.

2.2. Measures

Sociodemographic and clinical information were collected, including age, sex, marital status, years of education, employment status and time since diagnosis in years. Economic status was assessed by self-rated statement with five-point scale from very poor (= 1) to very good (= 5). For analysis purposes, these were collapsed into three categories: poor, medium and good.

2.2.1. Psychological symptoms (BSI)

The BSI consists of 53 items measuring nine dimensions of negative psychological symptoms (Derogatis & Melisaratos, 1983). In addition, a summary score is indicated by the Global Severity Index (GSI) and reflects overall distress. Participants rate the extent to which they have been distressed by each symptom in the preceding week on a five-point scale (0 = 'not at all', 1 = 'a little bit', 2 = 'moderately', 3 = 'quite a bit', 4 = 'extremely'). The nine BSI subscales are: anxiety, (e.g., 'nervousness or shakiness inside'), depression (e.g. 'feeling no interest in things'), somatization (e.g. 'faintness or dizziness'), hostility (e.g. 'feeling easily annoyed or irritated'), obsessive-compulsive (e.g. 'having to check and double check what you do'), phobic anxiety (e.g. 'feeling afraid in open spaces'), paranoid ideation (e.g. 'feeling that you are watched or talked about by others'), psychoticism (e.g. 'feeling that people are unfriendly or dislike you'). All nine subscales showed good reliability, with Cronbach's α coefficients exceeding .70 (Table 1).

In the depression subscale, one item about suicidal thoughts ('thoughts of ending your life') was highly skewed due an excessive number of zero responses (i.e. endorsement of no suicidality) and contributed to a reduced internal consistency of the scale; thus, this item was excluded from the depression scale. In the somatization subscale, one item – 'nausea or upset stomach'– overlaps with Crohn's disease symptoms (see section 3.2.2). Because the somatization subscale reflects emotional distress by *medically unexplained* somatic symptoms, this item was excluded from the current analysis.

For participants who had only one item missing on a given BSI subscale (n = 60), mean imputation was used on the subscale level. As noted above, nine participants with more than one missing item per subscale were excluded from the analysis leaving a sample of 430 patients.

Table 1. Sociodemographic characteristics of the sample (N = 430).

Variable	n (%)
Gender	
Male	182 (42)
Female	248 (58)
Age (mean ± SD) [†]	38.5 ± 14.4
Education (mean \pm SD) †	14.6 ± 3.0
Country of birth	
Israel	333 (79)
Europe	44 (10)
North America	22 (5)
Africa	22 (5)
Asia	1 (<1)
Marital status	
married	228 (55)
single	143 (35)
divorced	32 (8)
widowed	7 (2)
Economic status	
good	134 (32)
medium	203 (48)
poor	85 (20)
Employment status	
employed	278 (65)
unemployed	147 (35)
Illness duration $(mean \pm SD)^{\dagger}$	9.0 ± 6.1
Disease activity [‡]	
active disease	156 (36)
disease remission	274 (64)

[†]in years.

2.2.2. Disease activity (patient Harvey-Bradshaw index)

Disease activity (illness severity) was assessed using the Patient Harvey-Bradshaw Index (P-HBI; Evertsz et al., 2013; Sarid et al., 2017). The P-HBI is a patient-based guestionnaire which consists of four questions covering symptoms of CD during preceding 24 hours (general well-being, abdominal pain, diarrheal episodes and extraintestinal manifestations of CD). A disease activity score is generated by summing the scores for each item. A total P-HBI score of <4 indicates disease remission status whereas a P-HBI score >5 indicates an active disease state.

2.3. Statistical analyses

Data are presented as mean ± standard deviation for continuous variables and as frequencies and percentages for categorical variables. Given the large sample size, the normality of BSI scores was examined using skewness and kurtosis absolute values, with skewness of <2 and kurtosis of <7 indicating a normal distribution (Kim. 2013). All of the skewness and kurtosis values were below the cutoffs and therefore the assumption of normality was considered sufficient to warrant parametric tests. Thus, Pearson correlation coefficient was used to examine the relationships between CD patients' GSI scores and sociodemographic and clinical characteristics. We used the Welch's t-test to compare BSI scores in our sample against normative scores from the Israeli general population (Gilbar & Ben-Zur, 2002) or the British patient population (Ryan, 2007). Within the study sample of CD patients, BSI scores were compared by

[‡]based on scores on Patient Harvey-Bradshaw Index.

patient's sex, age, economic status and disease activity using the Welch's t-test or Analysis of Variance (ANOVA), depending on the number of groups. To account for multiple comparisons, statistical significance was set at p<.01.

3. Results

3.1. Sample characteristics

The socio-demographic characteristics of respondents are presented in Table 1. The sample include 430 participants, 58% women (n = 248), with an average age of 38.5 years (SD = 14.4, range = 18-79). Most participants (79%) were born in Israel, and their illness duration ranged from less than a year to 24 years, with a mean of 9.0 years (SD = 6.1). Based on P-HBI, 64% of patients were classified as being in disease remission, while 36% were considered in active disease state at the time of assessment. A physician reviewed participants' medical charts for evidence of psychological or psychiatric disorders. Fewer than 5% of these patients had a minor psychological comorbidity and none had a psychiatric disorder, as indicated in the inclusion criteria.

3.2. Description of psychological distress

Descriptive statistics for the nine BSI subscales and the GSI (global severity index of overall psychological distress) are presented in Table 2. The mean of total GSI score was 0.90 (out of 4.0, SD = 0.71, range = 0-3.35). The highest mean value was observed for the 'obsessive-compulsive' subscale (score = 1.11 out of 4), while the lowest was observed for 'psychoticism' (score = 0.60 out of 4). The correlations between the nine BSI subscales were high and statistically significant (p<.001), ranging between .59 (for the association between 'somatization' and 'interpersonal sensitivity') to .83 (for the association between depression and psychoticism').

3.3. BSI norms as a function of clinical variables

Patients with active CD scored higher on the GSI in comparison with those in remission (1.18 vs. 0.73, p<.001). Similarly, patients with active disease had significantly higher symptom levels than patients in remission on all nine BSI subscales (p<.001 for all; see Table 3). In contrast, disease duration was not associated with scores on the BSI subscales and GSI.

3.4. BSI norms as a function of sociodemographic variables

No statistically significant gender differences for the GSI or the BSI subscales, with the exception of somatization; women had higher levels of somatic symptoms compared with men (1.05 vs. 0.83, $t_{(417)}=2.583$, p=.010). Advance age correlated weakly but significantly with lower GSI scores when analyzed as a continuous variable (r=-.114, p=.018). Patient's age was further divided into three age groups: young (18–29 years; n=138), middle-aged (30 to 59 years; n=240) and elderly (over 60 years, n=52). An ANOVA examining GSI scores as a function of age group revealed a significant main

Table 2. Means, SDs, ranges and alphas of the BSI scales for Israeli CD patients ($N=$

Subscale	Mean	SD	Median	Range	Cronbach's α
Somatization [†]	0.95	0.89	0.67	0-3.83	.864 (no. items = 6)
Anxiety	1.09	0.86	0.83	0-3.67	.857 (no. items $= 6$)
Depression [†]	1.00	0.95	0.60	0-4.00	.871 (no. items $= 5$)
Obsessive-Compulsive	1.11	0.90	1.00	0-3.67	.836 (no. items $= 6$)
Hostility	0.80	0.78	0.60	0-4.00	.817 (no. items $= 5$)
Phobic Anxiety	0.70	0.78	0.40	0-4.00	.793 (no. items $= 5$)
Paranoid ideation	0.80	0.85	0.45	0-3.60	.823 (no. items $= 5$)
Psychoticism	0.60	0.73	0.30	0-3.25	.762 (no. items $= 5$)
Interpersonal sensitivity	0.84	0.88	0.50	0-3.75	.811 (no. items $= 4$)
GSI	0.90	0.71	0.72	0-3.35	.972 (no. items = 53)

[†]Somatization subscale including item #23 ('nausea or upset stomach'): mean = 1.09, SD = 0.89.

Table 3. Means and SDs of BSI scales as a function of disease activity.

	Active disea	se (<i>n</i> = 156)	In remission		
Subscale	Mean	SD	Mean	SD	t statistic
Somatization	1.38	0.95	0.71	0.75	7.60**
Anxiety	1.40	0.92	0.91	0.77	5.66**
Depression	1.30	1.00	0.83	0.87	4.86**
Obsessive-Compulsive	1.17	0.90	1.04	0.90	5.28**
Hostility .	0.79	0.76	0.81	0.81	3.42**
Phobic Anxiety	0.73	0.79	0.67	0.77	6.00**
Paranoid ideation	0.78	0.84	0.83	0.87	3.41**
Psychoticism	0.60	0.69	0.60	0.77	4.05**
Interpersonal Sensitivity	0.89	0.86	0.77	0.90	4.25**
GSI	0.92	0.68	0.86	0.74	6.37**

Note: GSI = Global Severity Index.

effect for participant's age ($F_{(2.427)} = 5.34$, p = .005). Bonferroni post hoc tests indicated CD patients aged >60 endorsed significantly lower GSI scores compared with younger age groups (0.60 vs. 0.94 for ages 30-59 and <30). Similar age differences were found on the subscales of 'depression', 'anxiety', 'phobic anxiety', 'interpersonal sensitivity' and 'psychoticism' (see Table 4). Finally, statistically significant differences were found between economic status categories in each of the BSI scales and the GSI score. Specifically, CD patients who reported poor economic status had more severe levels of psychological distress, followed by those with medium and then good economic status (1.43 vs. 0.85 vs. 0.61 for GSI scores, $F_{(2,421)} = 43.5$, p < .001).

3.5. BSI norms across populations

Table 5 presents the comparisons across populations in BSI norms. Compared with normative data from the general Israeli population (N = 510, women 51%, mean age 45.6 ± 8.6 years; Gilbar & Ben-Zur, 2002), CD patients reported higher general severity scores (0.90 vs. 0.72 out of 4-point scale, $t_{(429)} = 4.18$, p < .001). CD patients also endorsed higher levels of symptomatology than the general population across six dimensions of 'anxiety', 'depression', 'interpersonal sensitivity', 'obsessive-compulsive', 'phobic anxiety' and 'somatization'. In contrast, compared with psychiatric

[†]Depression subscale including item #9 ('thoughts of ending your life'): mean = 0.86, SD = 0.83; GSI = Global Severity Index.

^{**}*p*<.001.

Table 4.	Means an	d SDs of BS	I scales as	a function of	age group.

18–29 yrs (<i>n</i> = 138		(n = 138)	30–59 yrs	(n = 240)	≥60 yrs		
Subscale	Mean	SD	Mean	SD	Mean	SD	F statistic
Somatization	0.92 ^a	0.90	1.02 ^a	0.91	0.72 ^a	0.74	2.65
Anxiety	1.12 ^a	0.84	1.15 ^a	0.89	0.71 ^b	0.68	5.77*
Depression	1.13 ^a	0.99	1.01 ^a	0.94	0.60 ^b	0.73	6.17*
0-C	1.15 ^a	0.90	1.15 ^a	0.92	0.86 ^a	0.76	2.39
Hostility	0.84 ^a	0.89	0.82 ^a	0.75	0.56 ^a	0.56	2.76
Phobic anxiety	0.72 ^a	0.76	0.77 ^a	0.82	0.35 ^b	0.49	6.24*
PI	0.82 ^a	0.87	0.85 ^a	0.86	0.54 ^a	0.71	2.87
Psychoticism	0.66 ^a	0.72	0.64 ^a	0.77	0.30 ^b	0.43	5.18*
IS	0.92 ^a	0.91	0.87 ^a	0.90	0.50 ^b	0.58	4.64*
GSI	0.94 ^a	0.70	0.94 ^a	0.73	0.60 ^b	0.54	5.34*

Note: O-C = obsessive-compulsive, IS = interpersonal sensitivity; PI = paranoid ideation; GSI = Global Severity Index; values with different letters are significantly different according to Bonferroni test. **p* <.01.

Table 5. Comparison of Israeli Crohn patients' norms with Israeli general population norms and British psychiatric patients' norms.

	Israel CD	(N = 430)	lsr	Israel GP (N = 510)		U	JK CP (N=	= 378)
Subscale	Mean	SD	Mean	SD	t statistic	Mean	SD	t statistic
Somatization [¥]	0.95	0.89	0.62	0.68	6.29,	1.14	0.93	2.95,
Anxiety	1.09	0.86	0.85	0.71	p ≤ .001 4.61 ,	1.87	1.03	p = .003 11.59,
$Depression^{\psi}$	1.00	0.95	0.70	0.69	p ≤ .001 5.45 ,	1.99	1.10	p ≤ .001 13.60,
0-C	1.11	0.90	0.94	0.79	p ≤ .001 3.05 ,	2.03	1.02	p ≤ .001 13.51,
Hostility	0.80	0.78	0.72	0.70	p = .002 1.64	1.39	1.02	p ≤ .001 9.14 ,
Phobic Anxiety	0.70	0.78	0.46	0.61	5.18,	1.41	1.20	p ≤ .001 9.82,
Paranoid ideation	0.80	0.85	0.91	0.78	p ≤ .001 −2.05	1.54	1.08	p ≤ .001 10.72,
Psychoticism	0.60	0.73	0.57	0.62	0.67	1.45	0.97	p ≤ .001 13.92,
IS	0.84	0.88	0.68	0.71	3.03 , p = .003	2.08	1.22	p ≤ .001 16.37 ,
GSI	0.90	0.71	0.72	0.59	p = .003 4.18 , $p \le .001$	1.65	0.81	$p \le .001$ 13.91, $p \le .001$

[¥]This group difference in somatization between Israeli Crohn's patients vs. general population remained statistically significant when the item assessing nausea or upset stomach was included in the subscale. However, the difference in somatization between Israeli Crohn's patients and psychiatric patients was no longer statistically significant

outpatients in the UK (N = 378, women 67%, age 36.7 ± 11.7 years; Ryan, 2007), CD patients had significantly lower levels of mental health symptoms, shown by the general severity scores (1.65 vs. 0.90, $t_{(377)}$ =13.9, p<.001) and across all BSI subscales.

Of note, the Israeli general population norms were based on a narrower age range (35-65) than in our study. To rule out age as a confounding factor to the observed differences in the BSI subscales between the two studies, a re-analysis restricted to CD

 $^{^{\}psi}$ All group differences in depression remained statistically significant when the item assessing suicidal thoughts was included in the subscale. Israel CD=Israeli Crohn's patients; Israel GP= Israeli general population; UK CP= British psychiatric clinical population.

O-C = obsessive-compulsive, IS = interpersonal sensitivity; GSI = Global Severity Index.

patients within this age range was done (n = 182). This subsample also showed higher scores of 'somatization', 'anxiety', 'phobic anxiety' and GSI compared to the non-clinical Israeli population. However, group differences on 'depression', 'obsessive-compulsive' and 'interpersonal sensitivity' subscales were no longer statistically significant (see Supplementary Table S1).

4. Discussion

Population norms for measuring mental health symptomology using BSI have been established for US, Israeli, British and European non-clinical populations (Cochran & Daniel Hale, 1985; De Leo et al., 1993; Derogatis & Melisaratos, 1983; Francis et al., 1990; Gilbar & Ben-Zur, 2002; Loutsiou-Ladd et al., 2008; Pereda et al., 2007) and for psychiatric patients (Derogatis & Melisaratos, 1983; Ryan, 2007). Our study is the first to provide norms for the BSI in a cohort of patients with a chronic inflammatory illness in Israel. The current findings show that CD patients experience significantly higher rates of negative psychological symptoms compared to healthy individuals, but significantly lower than those of psychiatric outpatients. These results are in line with earlier studies showing excess of depression and anxiety symptoms in CD patients compared to healthy controls (see Mikocka-Walus et al., 2016, for review). Thus, the current study extends existing research by providing data comparisons based on population norms of CD patients compared with earlier studies in healthy controls and psychiatric outpatients. Furthermore, we extended the study beyond depression and anxiety symptoms to include other dimensions of negative psychological symptoms such as 'interpersonal sensitivity', 'paranoid ideation' and 'obsessive-compulsive' symptoms.

With respect to disease-related factors, higher levels of negative psychological symptoms were observed in CD patients in active state compared with patients in remission, and this difference was statistically significant across all nine subscales of psychological symptoms. This agrees with earlier results showing elevated depression and anxiety in patients with active compared with inactive Crohn's disease (Byrne et al., 2017; Graff et al., 2009; Mikocka-Walus et al., 2016; Neuendorf et al., 2016). These results suggest that when using BSI norms for patients with chronic inflammatory illness one should take into account the state of the disease.

As in other normative studies conducted in healthy and psychiatric patient populations (Gilbar & Ben-Zur, 2002; Ryan, 2007), we did not find sex differences in BSI global and subscale scores (with the exception of 'somatization'). This is also in line with previous studies reporting no differences between men and women with CD for anxiety and depression (Häuser et al., 2011; Nahon et al., 2012).

In chronic illness populations, somatization is defined as distress due to physical symptoms that cannot be medically explained by the underlying disease (Zijlema et al., 2013). As such, somatization may reflect a multifaceted concept that includes both physical and psychological components (Sitnikova et al., 2017). It is possible that women with CD are more hypervigilant to physical sensations for which they might be more inclined to interpret as indicative of flares (Polak et al., 2020; van Tilburg et al., 2013). Interestingly, we have shown in a previous paper (Regev et al., 2020), that although women report higher levels of 'somatization', the direct association

between 'somatization' and disease severity appears to be stronger for men. Thus, sex differences in this subscale could be an interesting research direction for future studies in patients coping with chronic disorders. Nevertheless, given the lack of sex differences in all other BSI dimensions and GSI, we would not recommend that sex be represented as a level in BSI norms.

In contrast, mental health symptoms seem to differ somewhat in relation to age group. Specifically, CD patients aged over 60 years endorsed significantly lower levels of psychological distress compared with CD patients aged 30 to 60 and those under 30 years. However, these age differences were statistically significant on only five of the nine BSI subscales. Additionally, these results are not in line with previous research reporting lack of association between GSI and age in the Israeli non-clinical population (Gilbar & Ben-Zur, 2002) or that older age is associated with worse depression in CD patients (Nahon et al., 2012). Therefore, future research among CD patients is needed to further examine whether different age groups vary in their vulnerability to psychological distress.

Our study has several strengths in providing normative information for the BSI. First, it includes a relatively large and diverse cohort of patients representing a wide range of disease severity and socio-demographic characteristics. Second, psychiatric disorders were strictly excluded through medical evaluations; thus, the normative data for BSI in CD are not likely to be confounded by comorbidities of psychiatric disorders. Some limitations should also be acknowledged. Firstly, this study is based on a selfselected population of CD patients seeking health care in outpatient clinics. Thus, very ill CD patients requiring admission to hospital were not likely to participate in this study. We were also unable to compare the characteristics of responders and non-responders in terms of demographics and health status – a common limitation in normative studies with patient populations (Mols et al., 2009; Pearman et al., 2014). Secondly, the generalizability of the results to other countries or populations of chronically ill patients with a different array of clinical symptoms might be limited. Therefore, future research is needed with other groups of medically ill patients to corroborate the current normative data. Thirdly, our measure of somatization excluded an item about gastrointestinal symptoms (i.e., "nausea or upset stomach"). Thus, our normative data for this subscale might be more suitable for patient populations with chronic inflammatory digestive diseases. Fourthly, we could not access endoscopic and radiological investigations of biochemical markers of disease activity, but all the patients had confirmed CD by accepted criteria (Lichtenstein et al., 2009). Finally, we used patient-reported outcome measures to assess symptom severity in CD and mental health. As with any self-report measure, these tools have a methodological limitation due to their inherent subjectivity. However, patient-reported measurements are relatively quick and cost effective (Williet et al., 2014). Moreover, many disease symptoms (e.g. abdominal pain and stool frequency) are in essence based on patient' report (Evertsz et al., 2013).

5. Conclusion

Psychological tests commonly utilize population-adjusted norms to increase screening and diagnostic utility. The current results suggest that the BSI, a widely used measure

of psychological distress, requires population-specific cut-off scores for patients with chronic medical conditions. Specifically, the BSI scores reported in this study for patients with CD are lower than those of the general population but higher than those of psychiatric patients. These data can be used by clinicians and researchers for identifying clinically significant levels of psychological symptoms in CD patients, particularly when disease is clinically active.

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Disclosure of interest

The authors report no conflict of interest.

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

References

Burke, A. L., Mathias, J. L., & Denson, L. A. (2015). Psychological functioning of people living with chronic pain: A meta-analytic review. The British Journal of Clinical Psychology, 54(3), 345-360. https://doi.org/10.1111/bic.12078

Byrne, G., Rosenfeld, G., Leung, Y., Qian, H., Raudzus, J., Nunez, C., & Bressler, B. (2017). Prevalence of anxiety and depression in patients with inflammatory bowel disease. Canadian Journal of Gastroenterology & Hepatology, 2017, 6496727. https://doi.org/10.1155/2017/ 6496727

- Cochran, C. D., & Daniel Hale, W. (1985). College student norms on the Brief Symptom Inventory. Journal of Clinical Psychology, 41(6), 777–779. https://doi.org/10.1002/1097-4679(198511)41:6
- De Leo, D., Frisoni, G. B., Rozzini, R., & Trabucchi, M. (1993). Italian community norms for the Brief Symptom Inventory in the elderly. The British Journal of Clinical Psychology, 32(2), 209-213. https://doi.org/10.1111/j.2044-8260.1993.tb01045.x
- Derogatis, L. R., & Melisaratos, N. (1983). The brief symptom inventory: An introductory report. Psychological Medicine, 13(3), 595-605. https://doi.org/10.1017/S0033291700048017
- Evertsz, F. B., Hoeks, C. C., Nieuwkerk, P. T., Stokkers, P. C., Ponsioen, C. Y., Bockting, C. L., & Sprangers, M. A. (2013). Development of the patient Harvey Bradshaw index and a comparison with a clinician-based Harvey Bradshaw index assessment of Crohn's disease activity. Journal of Clinical Gastroenterology, 47, 850-856. https://doi.org/10.1097/MCG.0b013e31828b2196
- Francis, V. M., Rajan, P., & Turner, N. (1990). British community norms for the Brief Symptom Inventory. British Journal of Clinical Psychology, 29(1), 115-116. https://doi.org/10.1111/j.2044-8260.1990.tb00857.x
- Gilbar, O., & Ben-Zur, H. (2002). Adult Israeli community norms for the brief symptom inventory (BSI). International Journal of Stress Management, 9(1), 1-10. https://doi.org/10.1023/ A:1013097816238
- Graff, L. A., Walker, J. R., & Bernstein, C. N. (2009). Depression and anxiety in inflammatory bowel disease: a review of comorbidity and management. Inflammatory Bowel Diseases, 15(7), 1105-1118. https://doi.org/10.1002/ibd.20873
- Guthrie, E., Jackson, J., Shaffer, J., Thompson, D., Tomenson, B., & Creed, F. (2002). Psychological disorder and severity of inflammatory bowel disease predict health-related quality of life in ulcerative colitis and Crohn's disease. The American Journal of Gastroenterology, 97(8), 1994–1999. https://doi.org/10.1016/S0002-9270(02)04198-9
- Häuser, W., Janke, K. H., Klump, B., & Hinz, A. (2011). Anxiety and depression in patients with inflammatory bowel disease: Comparisons with chronic liver disease patients and the general population. Inflammatory Bowel Diseases, 17(2), 621-632. https://doi.org/10.1002/ibd.21346
- Høivik, M. L., Moum, B., Solberg, I. C., Henriksen, M., Cvancarova, M., & Bernklev, T, & IBSEN Group (2013). Work disability in inflammatory bowel disease patients 10 years after disease onset: results from the IBSEN Study. Gut, 62(3), 368-375. https://doi.org/10.1136/gutjnl-2012-302311
- Kim, H. Y. (2013). Statistical notes for clinical researchers: Assessing normal distribution (2) using skewness and kurtosis. Restorative Dentistry & Endodontics, 38(1), 52-54. https://doi.org/10. 5395/rde.2013.38.1.52
- Lichtenstein, G. R., Hanauer, S. B., Sandborn, W. J, & Practice Parameters Committee of the American College of Gastroenterology (2009). Management of Crohn's disease in adults. The American Journal of Gastroenterology, 104(2), 465-483. https://doi.org/10.1038/ajg.2008.168
- Loutsiou-Ladd, A., Panayiotou, G., & Kokkinos, C. M. (2008). A review of the factorial structure of the Brief Symptom Inventory (BSI): Greek evidence. International Journal of Testing, 8(1), 90-110. https://doi.org/10.1080/15305050701808680
- Mikocka-Walus, A., Knowles, S. R., Keefer, L., & Graff, L. (2016). Controversies revisited: A systematic review of the comorbidity of depression and anxiety with inflammatory bowel diseases. Inflammatory Bowel Diseases, 22(3), 752-762. https://doi.org/10.1097/MIB.0000000000000620
- Mols, F., Pelle, A. J., & Kupper, N. (2009). Normative data of the SF-12 health survey with validation using postmyocardial infarction patients in the Dutch population. Quality of Life Research, 18(4), 403-414. https://doi.org/10.1007/s11136-009-9455-5
- Moura-Ramos, M., Gameiro, S., Canavarro, M. C., Soares, I., & Santos, T. A. (2012). The indirect effect of contextual factors on the emotional distress of infertile couples. Psychology & Health, 27(5), 533-549. https://doi.org/10.1080/08870446.2011.598231
- Nahon, S., Lahmek, P., Durance, C., Olympie, A., Lesgourgues, B., Colombel, J. F., & Gendre, J. P. (2012). Risk factors of anxiety and depression in inflammatory bowel disease. Inflammatory Bowel Diseases, 18, 2086-2091. https://doi.org/10.1002/ibd.22888



- Neuendorf, R., Harding, A., Stello, N., Hanes, D., & Wahbeh, H. (2016). Depression and anxiety in patients with inflammatory bowel disease: A systematic review. Journal of Psychosomatic Research, 87, 70-80. https://doi.org/10.1016/j.jpsychores.2016.06.001
- Pearman, T., Yanez, B., Peipert, J., Wortman, K., Beaumont, J., & Cella, D. (2014). Ambulatory cancer and US general population reference values and cutoff scores for the functional assessment of cancer therapy. Cancer, 120(18), 2902-2909. https://doi.org/10.1002/cncr.28758
- Pereda, N., Forns, M., & Peró, M. (2007). Dimensional structure of the Brief Symptom Inventory with Spanish college students. Psicothema, 19, 634-639.
- Polak, E. J., O'Callaghan, F., & Oaten, M. (2020). Perceptions of IBD within patient and community samples: A systematic review. Psychology & Health, 35(4), 425-448. https://doi.org/10.1080/ 08870446.2019.1662014
- Regev, S., Odes, S., Slonim-Nevo, V., Friger, M., Schwartz, D., Sergienko, R., Eliakim, R., & Sarid, O. (2020). Differential relationships of somatization, depression, and anxiety to severity of Crohn's disease. Journal of Health Psychology. https://doi.org/10.1177/1359105320909879
- Ryan, C. (2007). British outpatient norms for the Brief Symptom Inventory. Psychology and Psychotherapy, 80(Pt 2), 183–191. https://doi.org/10.1348/147608306X111165
- Sarid, O., Slonim-Nevo, V., Pereg, A., Friger, M., Sergienko, R., Schwartz, D., Greenberg, D., Shahar, I., Chernin, E., Vardi, H., Eidelman, L., Segal, A., Ben-Yakov, G., Gaspar, N., Munteanu, D., Rozental, A., Mushkalo, A., Dizengof, V., Abu-Freha, N., Fich, A., & Odes, S. (2017). Coping strategies, satisfaction with life, and quality of life in Crohn's disease: A gender perspective using structural equation modeling analysis. PloS One, 12(2), e0172779. https://doi.org/10.1371/journal.pone.0172779
- Sarid, O., Slonim-Nevo, V., Schwartz, D., Friger, M., Sergienko, R., Pereg, A., Vardi, H., Chernin, E., Greenberg, D., Singer, T., & Odes, S. (2018). Differing relationship of psycho-social variables with active ulcerative colitis or Crohn's disease. International Journal of Behavioral Medicine, 25(3), 341–350. https://doi.org/10.1007/s12529-018-9712-5
- Sitnikova, K., Dijkstra-Kersten, S. M., Mokkink, L. B., Terluin, B., van Marwijk, H. W., Leone, S. S., van der Horst, H., & van der Wouden, J. C. (2017). Systematic review of measurement properties of questionnaires measuring somatization in primary care patients. Journal of Psychosomatic Research, 103, 42-62. https://doi.org/10.1016/j.jpsychores.2017.10.005
- Torres, J., Mehandru, S., Colombel, J. F., & Peyrin-Biroulet, L. (2017). Crohn's disease. The Lancet, 389(10080), 1741–1755. https://doi.org/10.1016/S0140-6736(16)31711-1
- van Tilburg, M. A., Palsson, O. S., & Whitehead, W. E. (2013). Which psychological factors exacerbate irritable bowel syndrome? Development of a comprehensive model. Journal of Psychosomatic Research, 74(6), 486-492. https://doi.org/10.1016/j.jpsychores.2013.03.004
- Williet, N., Sandborn, W. J., & Peyrin-Biroulet, L. (2014). Patient-reported outcomes as primary end points in clinical trials of inflammatory bowel disease. Clinical Gastroenterology and Hepatology, 12(8), 1246-1256. https://doi.org/10.1016/j.cgh.2014.02.016
- Zijlema, W. L., Stolk, R. P., Löwe, B., Rief, W., White, P. D., Rosmalen, J. G, & BioSHaRE (2013). How to assess common somatic symptoms in large-scale studies: A systematic review of questionnaires. Journal of Psychosomatic Research, 74(6), 459–468. doi:10.1016/j.jpsychores.2