

Gastrointestinal Symptoms in Healthy, Full-Term Infants Under 7 Months of Age

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ARTICLE INFO

Article history:

Received 5 October 2019

Revised 20 March 2020

Accepted 21 March 2020

Keywords:

Gastrointestinal diseases

Infant

Newborn

Colic

Feeding

ABSTRACT

Purpose: To describe symptoms of gastrointestinal distress experienced by healthy, full-term infants in the first 7 months of life and test the psychometric properties of the Infant Gastrointestinal Symptoms Questionnaire (IGSQ).

Design and methods: Parents of infants <7 months ($n = 320$) completed the IGSQ, the Infant Gastroesophageal Reflux Questionnaire – Revised (I-GERQ-R), and the Neonatal Eating Assessment Tool (NeoEAT) – Breastfeeding and/or Bottle-feeding. Median and percentile scores were calculated for the IGSQ scores for each age group: 0–2, 2–4, 4–6, and 6–7 months. Change in IGSQ scores with age were evaluated using the Kruskal-Wallis test with Mann-Whitney U tests for post-hoc comparisons. Internal consistency reliability was assessed using Cronbach's alpha. Concurrent validity was tested using Spearman's rho between the IGSQ and the I-GERQ-R and NeoEAT.

Results: IGSQ scores decreased significantly with increased infant age, from a median of 28 at 0–2 months to 23 at 6–7 months old. The IGSQ had acceptable internal consistency reliability (Cronbach's alpha = 0.74). IGSQ total score was significantly correlated with I-GERQ-R total score (Spearman's rho (r_s) = 0.69, $p < .001$), NeoEAT – Breastfeeding: Gastrointestinal Function subscale score ($r_s = 0.46$, $p < .001$), and NeoEAT – Bottle-feeding: Gastrointestinal Tract Function subscale score ($r_s = 0.47$, $p < .001$).

Conclusions: Gastrointestinal symptoms decrease with increasing age in the first 7 months of life. The IGSQ has evidence of acceptable internal consistency reliability and concurrent validity.

Practice implications: These data can be used to guide IGSQ score interpretation.

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Introduction

Parents of young infants often express concern about their infant's gastrointestinal function and comfort, including concerns about symptoms of constipation, diarrhea, gas, irritability, gastroesophageal reflux, vomiting, and pain or straining with stooling (van Tilburg et al., 2015). For the pediatric healthcare provider, it can be difficult to determine whether an infant's gastrointestinal symptoms are within the range of what would be expected for their age, and likely to resolve spontaneously, or if the symptoms are more concerning and warrant further investigation of underlying pathology. Identification of the infant with significant gastrointestinal symptoms is critical to ensure that feeding and nutritional intake are not affected during this time of exponential brain growth (Georgieff, Brunette, & Tran, 2015).

Background

For young infants and children who are not able to report their own symptoms, parent-report assessment tools can complement a clinician's health history and physical assessment by providing additional information about the child's symptoms (Thoyre et al., 2014). While a clinician may be able to observe symptoms in the short period of time of a clinical visit, parent-report assessments can provide information about symptoms throughout the day and over the course of several days to weeks. Currently, the only published parent-report assessment that focuses specifically on gastrointestinal symptoms in infants is the Infant Gastrointestinal Symptoms Questionnaire (IGSQ) (Riley, Trabulsi, Yao, Bevans, & DeRusso, 2015). The IGSQ is a short, 13-item, parent-report measure of gastrointestinal symptoms in infants and has evidence of validity and reliability. The IGSQ can be used in clinical practice or research to describe the severity of an infant's gastrointestinal symptoms (Riley et al., 2015).

Understanding whether gastrointestinal symptoms fall within a range of what is expected for an infant's age or whether symptoms are more severe and warrant further investigation and management requires reference data from a large sample of healthy, full-term infants.

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To date, no studies have reported data on healthy, full-term infants that could be used for referencing. The purpose of this study was to describe the symptoms of gastrointestinal distress experienced by healthy, full-term infants in the first 7 months of life and test the psychometric properties of the Infant Gastrointestinal Symptoms Questionnaire (IGSQ).

Methods

The Institutional Review Boards at the University of North Carolina at Chapel Hill and Boston College approved this descriptive, cross-sectional study. This study was conducted through a web-based survey on the Qualtrics platform that included questions about the infant's medical history, symptoms of gastrointestinal distress (Infant Gastrointestinal Symptoms Questionnaire), gastroesophageal reflux (Infant Gastroesophageal Reflux Questionnaire – Revised), and feeding (Neonatal Eating Assessment Tool). Parents were also asked a set of questions about themselves and their families to describe the demographic characteristics of the sample. Participants were offered a \$10 USD e-gift card for completing the survey.

Sample

Primary caregivers (hereafter referred to as parents) of infants <7 months old were recruited to participate. To be eligible, the parent had to be at least 18 years old, self-report as being literate in English, and have access to the internet for the purposes of completing the survey. The target sample was approximately 50–100 parents of infants in each of the age groups: 0–2 months (i.e., birth to 2 months 0 days), 2–4 months (i.e., 2 months 1 day to 4 months 0 days), 4–6 months (i.e., 4 months 1 day to 6 months 0 days), and 6–7 months (i.e., 6 months 1 day to 7 months 0 days), with approximately equal distributions within age group by infant sex. Infants develop rapidly in the first 7 months of life. Intervals of 2 months were chosen up through 6 months to reflect this rapid development and expected changes in maturation of the brain and gastrointestinal tract. Introduction of complementary foods (i.e., “baby food”) is recommended by the American Academy of Pediatrics between 4 and 7 months of age (Kleinman, 2000), so the age groups 4–6 months and then 6–7 months likely reflect increasing proportions of infants exposed to small amounts of complementary foods which may impact gastrointestinal symptoms (Grummer-Strawn, Scanlon, & Fein, 2008). The selected age groupings are consistent with other published norm-reference studies for young infants (Pados, Park, & Thoyre, 2019a, 2019b).

The sample for this study was selected to reflect healthy, full-term (>37 weeks gestational age at birth) infants with no significant medical conditions. To be included in the study, parents had to indicate that the infant did not have any of the following conditions: a parent-identified or provider-diagnosed feeding problem, genetic disorder, cystic fibrosis, metabolic disorder, epilepsy, hearing or vision impairment, food allergy, developmental delay, chronic lung disease, congenital diaphragmatic hernia, congenital heart disease, structural abnormality involving the face, mouth, or gastrointestinal tract. Additionally, infants were excluded if they had ever needed feedings through a feeding tube.

In an effort to recruit a diverse sample in terms of geographic location, socio-economic status, and race-ethnic background, we recruited from multiple sources, both local and national. Participants were recruited from ResearchMatch.com, a national health volunteer registry supported by the United States National Institutes of Health as part of the Clinical and Translational Science Award (CTSA) program; Join the Conquest, a volunteer registry supported by the CTSA at the University of North Carolina; Qualtrics respondent panels; recruitment emails to the staff, faculty, and students at the University of North Carolina; and the outpatient primary care clinic at North Carolina Children's Hospital.

Measures

Infant Gastrointestinal Symptoms Questionnaire (IGSQ)

The IGSQ is a 13-item parent-reported measure of gastrointestinal symptoms for infants (Riley et al., 2015). Questions on the IGSQ ask about hard stools, difficulty passing stools, spitting up, arching back, crying and fussiness, difficulty soothing, and gassiness. Items on the IGSQ are scored such that higher scores indicate more gastrointestinal symptoms. Response options are assigned a value of 1 to 5, with the possible range of scores on the IGSQ being between 13 and 65. In work published by the developer of this instrument, the IGSQ was found to have acceptable internal consistency reliability (Cronbach's $\alpha = 0.72$), test-retest reliability ($r = 0.69$), inter-rater reliability, and known-groups validity (Riley et al., 2015). No norm-reference data has been published for the IGSQ.

Infant Gastroesophageal Reflux Questionnaire – Revised (I-GERQ-R)

The I-GERQ-R was chosen as an instrument to test the concurrent validity of the IGSQ. The I-GERQ-R is a 12-item parent-reported measure of symptoms of gastroesophageal reflux in infants (Kleinman et al., 2006; Orenstein, 2010; Orenstein, Cohn, Shalaby, & Kartan, 1993; Orenstein, Shalaby, & Cohn, 1996). Questions on the I-GERQ-R cover similar constructs to that on the IGSQ, but with more of a focus on gastroesophageal symptoms, such as spitting up, refusal to feed, and trouble breathing. Items on the I-GERQ-R are assigned scores that vary by question type, with some being Yes/No questions and some asking parents to rate severity of symptoms on a scale from Never to Always. The possible range of scores on the I-GERQ-R is 0 to 42, with higher scores indicating more symptoms of gastroesophageal reflux. In the development work of the I-GERQ-R, the developers have published evidence to support the psychometric properties of the tool. Internal consistency reliability has been reported as acceptable (Cronbach's $\alpha = 0.86$ – 0.87), as well as test-retest reliability (intra-class correlation coefficient = 0.85) and known-groups validity (Kleinman et al., 2006).

Neonatal Eating Assessment Tool (NeoEAT) – Breastfeeding and Bottle-Feeding versions

The NeoEAT is a parent-report measure of symptoms of problematic feeding in infants <7 months old and has a version for infants who are breastfeeding and a version for infants who are bottle-feeding (Pados et al., 2019a, 2019b; Pados, Estrem, Thoyre, Park, & McComish, 2017; Pados, Thoyre, Estrem, Park, & McComish, 2018a, 2018b). Each of these versions contains a subscale pertaining to symptoms of gastrointestinal function that was selected for testing the concurrent validity of the IGSQ. On the NeoEAT – Breastfeeding version, the Gastrointestinal Function subscale contains seven items that ask questions related to difficulty stooling, bloating, gassiness, diarrhea, discomfort after feeding, and hiccups. The full 62-item NeoEAT – Breastfeeding instrument has acceptable psychometric properties, with evidence of content validity, internal consistency reliability (Cronbach's $\alpha = 0.92$), test-retest reliability ($r = 0.91$), and known-groups validity ($p < .001$) (Pados et al., 2017; Pados et al., 2018b). The 7-item Gastrointestinal Function subscale has acceptable internal consistency reliability (Cronbach's $\alpha = 0.7$) and known-groups validity ($p < .05$) (Pados et al., 2018b). Scores on the NeoEAT – Breastfeeding Gastrointestinal Function subscale range from 0 to 35, with higher scores indicating more symptoms of problems related to gastrointestinal function.

On the NeoEAT – Bottle-feeding version, the relevant subscale for testing the concurrent validity of the IGSQ is called the Gastrointestinal Tract Function subscale. The Gastrointestinal Tract Function subscale of the NeoEAT – Bottle-feeding has 28 items that ask about symptoms related to dysfunction along the entire gastrointestinal tract, from mouth to anus. Overall, the 64-item NeoEAT –

Bottle-feeding instrument has evidence of content validity and acceptable internal consistency reliability (Cronbach's $\alpha = 0.92$), test-retest reliability ($r = 0.9$), and known-groups validity ($p < .001$) (Pados et al., 2017; Pados et al., 2018a). The 28-item Gastrointestinal Tract Function subscale has evidence of internal consistency reliability (Cronbach's $\alpha = 0.92$) and known-groups validity ($p < .01$) (Pados et al., 2018a). Scores on the NeoEAT – Bottle-feeding Gastrointestinal Tract Function subscale range from 0 to 140, with higher scores indicating greater symptoms of problematic gastrointestinal tract function.

Data cleaning and analysis

While online surveys provide an opportunity to collect data from large, national and even international samples, there are inherent risks of falsified or inaccurate data. Multiple strategies were used to ensure the validity of the data. Individualized links were sent, allowing for only one response per participant. Response time to the survey was recorded and participants who completed the survey in less than one third of the median time based on the first 10% of respondents were excluded; the speed at which these surveys were completed were not likely to reflect thoughtful and accurate responses. Additionally, attention check questions were placed throughout the survey. These types of questions instruct the respondent to answer the question a certain way (e.g., “Please select ‘Never.’”); participants who failed to respond appropriately to these attention check questions were exited from the survey. After the data were collected, responses to similar questions were compared for congruency and responses that were inconsistent were excluded. For example, participants who selected that their infant was in the 6–7 month age group, but provided a date of birth and due date that would indicate the infant was 2 weeks old, were excluded.

For the purposes of analysis, cases with missing data on the IGSQ were excluded since missing data would inadvertently lower the IGSQ total score. We first evaluated the IGSQ total score data for normal distribution using the Shapiro-Wilk test to determine whether parametric or non-parametric statistics would be most appropriate. The data for the IGSQ were not normally distributed (Shapiro-Wilk statistic = 0.94 ; $p < .001$), thus non-parametric statistics are warranted. Descriptive statistics were used to calculate the median and 25th, 50th, 75th, 90th, and 95th percentile scores. The Kruskal-Wallis test was used to evaluate the effect of infant age on IGSQ total score. Post-hoc multiple comparisons were made using the Mann-Whitney U test (two-tailed). A Bonferroni correction was applied to the p-value to account for multiple comparisons; a p-value of .01 was considered statistically significant for these tests.

Cronbach's alpha was calculated for the IGSQ total score for the full sample to test internal consistency reliability. Concurrent validity was tested using bivariate correlations (two-tailed) between the IGSQ and 1) the I-GERQ-R total score, 2) the NeoEAT – Breastfeeding Gastrointestinal Function subscale for breastfeeding infants, and 3) the NeoEAT – Bottle-feeding Gastrointestinal Tract Function subscale for bottle-feeding infants. These correlations were calculated for all age groups combined and then for each age group individually. A p-value of <.05 was defined as statistically significant for these tests.

Table 1
Age and sex distribution of infants in sample (N = 320).

Age group	Female (n)	Male (n)	Total (n)
0–2 months	60	50	110
2–4 months	46	40	86
4–6 months	45	38	83
6–7 months	20	21	41
Total: n (% of total)	171 (53.4%)	149 (46.6%)	320

Table 2
Demographic characteristics of sample (N = 320).

Variable of interest	n (%)
Respondent's relationship to child (n = 320)	
Mother	300 (93.8%)
Father	17 (5.3%)
Other primary caregiver	3 (0.9%)
Family type (n = 320)	
Two parent	287 (89.7%)
One parent	26 (8.1%)
Other family type	7 (2.2%)
Income (n = 320)	
<\$20,000	27 (8.4%)
\$20,000–39,999	72 (22.5%)
\$40,000–59,000	64 (20%)
\$60,000–79,000	50 (15.7%)
\$80,000–99,000	26 (8.1%)
>\$100,000	81 (25.3%)
Parent education (n = 320)	
High school or less	81 (25.3%)
Technical school or community college	35 (10.9%)
University	113 (35.3%)
Graduate school	91 (28.4%)
Child's race (n = 320)	
American Indian or Alaskan Native	1 (0.3%)
Asian	12 (3.8%)
Black or African American	16 (5.0%)
Hispanic or Latino	20 (6.3%)
Native Hawaiian or Pacific Islander	2 (0.6%)
White	216 (67.5%)
More than one race	49 (15.3%)
Other	4 (1.3%)

Results

Sample

There were 320 cases that were included in this analysis, with approximately equal distributions between male and female infants (Table 1). The age distributions of the sample are also presented on Table 1. Demographic characteristics of the sample are presented on Table 2. All but four of the respondents were from the United States. The respondents outside of the United States were from Canada (n = 2), Mexico (n = 1), and Turkey (n = 1). Within the United States, there were respondents from 39 states.

IGSQ total scores by age groups

The median, 25th, 50th, 75th, 90th, and 95th percentile scores for this norm-reference sample are presented by age group on Table 3. The change in median, 90th, and 95th percentile IGSG scores by age group are presented on Fig. 1. There was a statistically significant change in IGSG total score by age group ($\chi^2(3) = 23.516$, $p < .001$), with IGSG scores decreasing with increased age. Post-hoc comparisons revealed that the IGSG total score was not different between infants 0–2 months and 2–4 months ($U = 4143.5$, $p = .14$) and was also not

Table 3
IGSQ norm-reference values for infants less than 7 months (N = 320).

	Infant age			
	0–2 months (n = 110)	2–4 months (n = 86)	4–6 months (n = 83)	6–7 months (n = 41)
Median	28	27	24	23
25th PCTL	24	23	20	21
50th PCTL	28	27	24	23
75th PCTL	33	30	30	27
90th PCTL	38	36	32	31.8
95th PCTL	41.5	37	34.8	38.3

Note. PCTL = percentile. Possible range of scores: 13–65, with higher scores indicating more gastrointestinal symptoms.

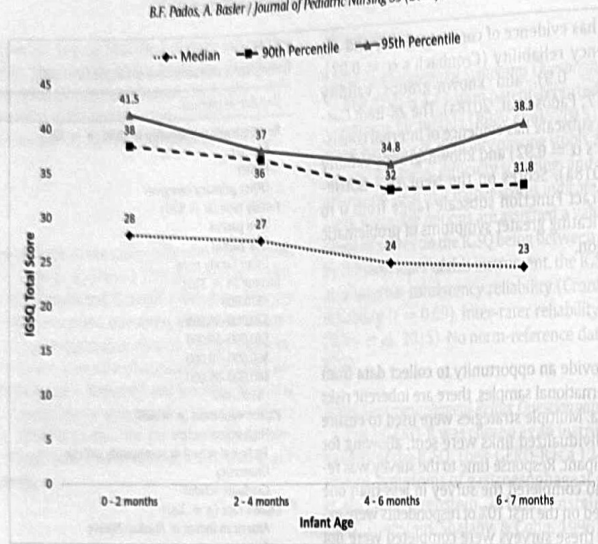


Fig. 1. IGSQ total score by infant age group.

different between infants 4–6 months and 6–7 months ($U = 1601.5$, $p = .6$). Significant differences were found between all other age group comparisons. IGSQ total score for infants 0–2 months was significantly higher than infants in the 4–6 month age group ($U = 3069$, $p < .001$) and significantly higher than infants in the 6–7 month age group ($U = 1383$, $p < .001$). IGSQ total score for infants 2–4 months was significantly higher than infants in the 4–6 month age group ($U = 2744$, $p < .01$) and also significantly higher than infants in the 6–7 month age group ($U = 1233.5$, $p < .01$).

Internal consistency reliability

The 13-item IGSQ had acceptable internal consistency reliability ($n = 320$; Cronbach's alpha = 0.74).

Concurrent validity

The IGSQ total score was significantly correlated with the I-GERQ-R total score for the full sample ($n = 318$; Spearman's rho (r_s) = 0.69, $p < .001$). This relationship was consistent within each age group. The IGSQ total score was significantly correlated with the I-GERQ-R total score for infants age 0–2 months ($n = 108$; $r_s = 0.71$, $p < .001$), 2–4 months ($n = 86$; $r_s = 0.58$, $p < .001$), 4–6 months ($n = 83$; $r_s = 0.69$, $p < .001$), and 6–7 months old ($n = 41$; $r_s = 0.59$, $p < .001$).

For breastfeeding infants, the IGSQ total score was also significantly correlated with the NeoEAT – Breastfeeding: Gastrointestinal Function subscale for the full sample ($n = 275$; $r_s = 0.46$, $p < .001$). This statistically significant relationship was upheld across the following age groups: 0–2 months ($n = 96$; $r_s = 0.4$, $p < .001$), 2–4 months ($n = 78$; $r_s = 0.41$, $p < .001$), 4–6 months ($n = 72$; $r_s = 0.4$, $p < .001$), and 6–7 months ($n = 29$; $r_s = 0.52$, $p < .001$).

For bottle-feeding infants, the IGSQ total score was significantly correlated with the NeoEAT – Bottle-feeding: Gastrointestinal Tract Function subscale score for the full sample ($n = 280$; $r_s = 0.47$, $p < .001$). This relationship was also statistically significant across the following age groups: 0–2 months ($n = 102$; $r_s = 0.37$, $p < .001$), 2–4 months ($n = 71$; $r_s = 0.34$, $p < .01$), 4–6 months ($n = 72$; $r_s = 0.5$, $p < .001$), and 6–7 months ($n = 35$; $r_s = 0.52$, $p < .01$).

Discussion

The IGSQ is a short, 13-item, questionnaire that can be completed by parents to evaluate the severity of gastrointestinal symptoms in young infants. This non-invasive, cost-effective, and low burden assessment may be useful to nurses working with young infants to determine whether the infant's gastrointestinal symptoms are outside of the range of normal and assess response to interventions. The data reported here can be used as reference data to guide interpretation of an infant's score in relation to a healthy, age-matched sample and decision-making about need for further assessment, intervention, and/or referral. Scores above the 90th percentile could be interpreted as symptom burden outside of the range of typical, with scores above the 95th percentile being even more concerning.

In this healthy sample, symptoms of gastrointestinal distress decreased significantly over time with increasing infant age in the first 7 months of life. At 0–2 months, the median IGSQ total score was 28 and by 6–7 months, the median IGSQ total score was 23. With the possible range of scores being 13 to 65, these median scores indicate that most healthy, full-term infants exhibit some symptoms of gastrointestinal distress, but these symptoms improve with maturation. Comparisons within age groups revealed a particular improvement in gastrointestinal symptoms after 4 months of age.

This study provides additional evidence for the psychometric properties of the IGSQ, including internal consistency reliability and concurrent validity with the I-GERQ-R and the NeoEAT subscales related to gastrointestinal function. Evidence of the validity and reliability of the IGSQ supports the use of this measure for evaluating infant gastrointestinal symptoms in both clinical practice and research. Researchers can use these data to categorize symptoms of gastrointestinal distress and to evaluate response to interventions.

Limitations

The primary limitation of this norm-reference sample was that, despite our efforts to recruit broadly, the respondents were primarily highly-educated White mothers from two-parent families. There was geographic and socio-economic diversity within the sample, but future studies need to target samples with greater racial-ethnic diversity. Although there are not specific reasons to suspect that gastrointestinal symptoms of infants would vary by race or ethnicity, future studies

interpretation of scores should be made with the understanding that this sample was limited in racial-ethnic diversity. Additionally, future studies should include larger sample sizes. There are no standards for sample size requirements for norm-reference studies for young infants, however the sample size in this study was consistent with that of Saccani, Valentini, and Pereira (2016) who included 63–116 infants per age group in their study to establish Brazilian norms for the Alberta Infant Motor Scale.

Conclusion

While many healthy, full-term infants exhibit some symptoms of gastrointestinal distress, these symptoms improve with increasing age in the first 7 months of life, with a particular reduction in symptoms occurring after 4 months. The IGSQ is a short, 13-item, parent-report assessment that was found in this study to have evidence of acceptable internal consistency reliability and concurrent validity, supporting its use in both clinical practice and research. The reference data provided in this manuscript can be used in both clinical practice and research to evaluate response to interventions and to guide interpretation of IGSQ scores and decision-making around need for further assessment, intervention, and referral.

CRediT authorship contribution statement

Britt Frisk Pados: Conceptualization, Data curation, Formal analysis, Funding acquisition, Methodology, Investigation, Project administration, Writing – original draft, Writing – review & editing. **Audrey Basler:** Writing – original draft, Writing – review & editing.

Declaration of competing interest

None.

Acknowledgements

This work was supported by the National Association of Neonatal Nurses (small grant awarded to Britt Pados) and Boston College faculty research funds.

Role of the funding sources

The funding sources had no role in the conduct of the study or the preparation of the manuscript.

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