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The Generalized Anxiety Disorder 7-item (GAD-7) scale in adolescents with generalized anxiety disorder: signal detection and validation

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Abstract

BACKGROUND—In pediatric patients with anxiety disorders, existing symptom inventories are either not freely available or require extensive time and effort to administer. We sought to evaluate a brief, self-report scale—the Generalized Anxiety Disorder 7-item Scale (GAD-7)—in adolescents with generalized anxiety disorder (GAD).

METHODS—The Pediatric Anxiety Rating Scale (PARS) and the GAD-7 were administered to youth with GAD (confirmed by structured interview). Relationships between the measures were assessed and sensitivity and specificity was determined with regard to a global symptom severity measure (Clinical Global-Impression-Severity).

RESULTS—In adolescents with GAD (N=40, mean age: 14.8±2.8), PARS and GAD-7 scores strongly correlated (R=0.65, p<0.001) and a main effect for symptom severity was observed (p<0.001). GAD-7 scores ≥11 and GAD-7 scores ≥17 represented the optimum specificity and sensitivity for the detection of moderate and severe anxiety, respectively.

CONCLUSIONS—The PARS and GAD-7 similarly reflect symptom severity and the GAD-7 is associated with acceptable specificity and sensitivity for detecting clinically-significant anxiety symptoms. GAD-7 scores may be used to assess anxiety symptoms and to differentiate between mild and moderate GAD in adolescents and may be more efficient than the PARS.

Keywords

GAD-7; PARS; generalized anxiety disorder; self-report; pediatric; anxiety

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INTRODUCTION

Anxiety disorders are among the most prevalent psychiatric conditions in children and adolescents and, in the United States, affect 15% of youth.[1] However, in the pediatric population, these disorders are often under-diagnosed and untreated.[2] In adult patients, a number of instruments are available to screen for anxiety disorders and to track anxiety symptoms.[3–5] These symptom inventories facilitate increased screening and the ability to monitor symptoms over time, in both clinical practice and in clinical research.[6] However, in youth, fewer instruments are available for the tracking of symptoms and self-report rating scales[7–9]—with several exceptions—are under-utilized by clinicians in child and adolescent populations.[10] Additionally, some scales that effectively assess anxiety symptoms in adults are difficult to use in pediatric patients. For example, the Hamilton Anxiety Rating Scale[4] may over-represent somatic symptoms (*e.g.*, autonomic, genitourinary, cardiovascular, sensory) that are less commonly reported in pediatric patients compared to adults[11] and may not fully assess cognitive aspects of anxiety in youth.[12]

Clinician-rated instruments that have been systematically evaluated in youth include the *Pediatric Anxiety Rating Scale*[9] which has been utilized as the primary outcome measure in the majority of psychopharmacologic treatment studies in youth with anxiety disorders.[13–16] This clinician-administered scale includes a 50 item symptom checklist which encompasses social anxiety/performance anxiety (9 items), separation anxiety (10 items), generalized anxiety (8 items), specific phobia (4 items), physical/somatic symptoms (13 items) as well as “other” items (6 items), The score, however, is determined from 7 severity and impairment items that are rated on a 6-point scale, with higher scores representing more severe symptoms and impairment. The PARS has established, acceptable, convergent validity with 3 anxiety rating scales although lower correlation coefficients have been observed between the PARS and self-report measures (e.g., *Multidimensional Anxiety Scale for Children* [MASC, R=0.22, p<0.05], *Screen for Child Anxiety Related Disorders*-Child [SCARED-Child, R=0.32, p<0.001], SCARED-Parent, R=0.46, p<0.001) relative to clinician-administered scales (*e.g.*, HAM-A, R=0.49, p<0.001).[9] Additionally, cutoffs have been established for response and remission.[17] However, this scale takes approximately 20 minutes to administer thus attenuating its practical utility in routine clinical practice, despite its excellent psychometric properties.[9]

In terms of self-report measures, the *Screen for Child Anxiety Related Disorders* (SCARED)[7,18] is frequently used to screen for anxiety disorders, assess a number of anxiety symptoms and is validated in pediatric populations. This instrument requires approximately 10 minutes to administer, includes 41 items and assesses symptoms of (1) panic disorder (or significant somatic symptoms); (2) generalized anxiety disorder symptoms; (3) social anxiety disorder symptoms; (4) separation anxiety symptoms and (5) significant school avoidance.[7] Finally, the *Multidimensional Anxiety Scale for Children* (MASC) is a self-report instrument that has been validated in youth 8–19 years of age and rates anxiety symptoms relative to aged norms. The MASC consists of 50 questions and is administered to both the pediatric patient and to his or her parent or caregiver.[8] This instrument includes scales related to separation anxiety/phobias, GAD, social anxiety, obsessions and compulsions and assesses physical symptoms/harm avoidance.

A decade ago, the GAD-7 was developed as a self-report screening tool for generalized anxiety symptoms in the primary care setting.[3] The scale was developed to address the limited number of anxiety measures in clinical problems and to address the common issue of symptom ratings seldom being used in clinical practice because of "their length, proprietary nature, lack of usefulness as a diagnostic and severity measure, and requirement of clinician administration rather than patient self-report."[3] As such, the GAD-7 has been successfully disseminated in adult primary care and psychiatric clinics and has been systematically evaluated in US and international samples.[19] The scale consists of 7 questions, requires approximately 1–2 minutes to administer and is sensitive to treatment-related changes in adults with generalized anxiety disorder. However, it has never been evaluated in adolescents with a primary diagnosis of generalized anxiety disorder. With this in mind, we sought to evaluate the GAD-7 in adolescents with GAD who participated in a double-blind, placebo-controlled treatment trial and to explore the relationship between the GAD-7 and the PARS with regard to one another and with regard to Clinical Global Impression-Severity (CGI-S) scores.[20] We hypothesized that GAD-7 scores would correlate with the PARS scores; that GAD-7 scores would be reflective of symptomatic/functional burden and that the GAD-7 would be sensitive/specific for differentiating mild from moderate-severe disease severity.

METHODS

This study was approved by the Institutional Review Board at the University of Cincinnati and written, informed consent and assent were obtained from parents/guardians and from patients, respectively before inclusion in the study.

Subjects

Study participants were outpatient youth aged 12 through 17 years who met *DSM-IV-TR* criteria for GAD, assessed by unstructured and semi-structured assessments by a board-certified child and adolescent psychiatrist (JRS). The diagnosis of GAD was confirmed with the *Anxiety Disorders Interview Schedule for DSM-IV* (*ADIS-IV*).[21] Demographic data including age, sex, and race/ethnicity were collected. Additionally, pubertal status was determined for 37 of the 40 patients using the Duke Self-Rated Tanner Scale (Self Report).[22]

Measures

To assess anxiety symptoms, the *Pediatric Anxiety Rating Scale* (PARS)[9] and GAD-7 served as screening and primary outcome measures. As described above, the *PARS* is a 50-item clinician-rated checklist of anxiety symptoms in children/adolescents in addition to 7 dimensional questions related to anxiety symptom severity (i.e., number of symptoms, severity of symptom distress, behavioral avoidance, functional interference at home, and functional interference outside of home) that are rated on a 6-point scale (0 = *none* to 5 = *extreme*). Higher scores represent higher levels of distress and anxiety.

The GAD-7 consists of 7 questions based in part on the *DSM-IV* criteria for GAD and reflects the frequency of symptoms during the preceding 2-week period. The GAD-7 requires approximately 1–2 minutes to administer and for each symptom queried provides

the following response options: “not at all,” “several days,” “over half the days” and “nearly every day” and these are scored, respectively, as 0, 1, 2 or 3.[3]

The CGI-S, a clinician-administered instrument, was administered by a board-certified child and adolescent psychiatrist with more than a decade of experience with the instrument. This scale, which is anchored with the question: “Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?” is rated on a seven-point scale. Scores of 1 reflect patients who are “normal, not at all ill;” scores of 2 reflect patients who are “borderline mentally ill;” scores of 3 describe patients who are “mildly ill;” scores of 4 reflect patients who are “moderately ill;” scores of 5 reflect patients who are “markedly ill;” and scores of 6 and 7 are associated with the descriptions “severely ill” and “among the most extremely ill patients,” respectively.[20] The rating—which is performed by a clinician—is based both on observed and reported symptoms, functional impairment and behavior over a 7 day period.

Statistical analysis

Relationships between the total GAD-7 score and total PARS score as well as relationships between individual items from the PARS and GAD-7 were evaluated with Spearman correlation coefficients. Additionally, the distribution of PARS scores and GAD-7 scores was evaluated descriptively with regard to CGI-S stratification (*e.g.,* CGI-S ≤3, CGI-S 4–5, CGI-S ≥6) and was statistically evaluated with an analysis of variance (ANOVA), as previously utilized in the comparison of symptom rating scales in pediatric patients with affective disorders.[23] Using receiver operating characteristic (ROC) methods[24,25] as previously employed to evaluate the PARS in youth with anxiety (Caporino et al. 2013), a vector matrix list of predicted disease severity (based on CGI-S score ≥4 and CGI-S score ≥6 for moderate and severe illness) was created in addition to a data frame containing the true labels for CGI-S classification (ROCR, *Predictions*, version 1.0–7). Cutoff-parameterized performance curves were then generated to evaluate the sensitivity and specificity of the GAD-7 score with regard to the detection of moderate (CGI-S 4–5) and severe (*i.e.*, CGI-S ≥6) severity anxiety symptoms. Finally, a confirmatory analysis was performed in which these cutoffs for GAD-7 scores were determined using optimal cutpoints methods.[27] Specifically, to maximize sensitivity and specificity, for each cutpoint, the minimum sensitivity and specificity were determined, where m_i represented the minimums across cutpoints. For the maximum of m_i (M), the cutpoint that maximized both sensitivity and specificity (and corresponded to the cutpoint that yielded M) was selected, as previously described.[28]

All analyses were conducted in *R* (version 3.3.2, “Sincere Pumpkin Patch”). *P*-values <0.05 were considered statistically significant and, given the exploratory nature of these analyses, no correction for multiple comparisons was made.

RESULTS

Participants

Forty PARS and GAD-7 assessments were performed in adolescents with GAD (n=40) of whom the majority were female (n=31, 77.5%) and Caucasian (n=34, 85%). The mean age of patients was 14.8±2.8 years and co-occurring anxiety disorders were common (Table 1). The modal self-rated Tanner score was 4 (45% of participants). Additional demographic and clinical characteristics are reported in Table 1.

Relationship between the PARS and GAD-7

Total PARS scores were highly correlated with total GAD-7 score (n=40, R=0.65, p<0.05). Among the individual components of the GAD-7, all items except irritability exhibited statistically significant correlations with the total PARS score and among specific GAD-7 items, the strongest correlations were noted for GAD-7 items 1 and 2: “feeling nervous, anxious or on edge” (R=0.57, p<0.05) and “worrying too much about different things” (R=0.54, p<0.05). Additional correlation coefficients for significant and non-significant relationships are shown in Figure 2.

Relationship of CGI-S with GAD-7 and PARS

Based on the CGI-S scores, patients were categorized as shown in Table 2 and statistically significant effects of symptom severity for the three CGI-S groups were observed for GAD-7 ($F_{2,37}$=26.83, p<0.001) and PARS ($F_{2,37}$=126.50, p<0.001) scores (Figure 1).

Sensitivity and specificity

Figure 3 depicts the sensitivity and specificity of GAD-7 scores relative to the CGI-S classification for “at least moderate” (*i.e.*, CGI-S ≥4) and “severe” (*i.e.,* CGI-S ≥6) illness. A GAD-7 score of ≥11 represents the optimal compromise between sensitivity (97%) and specificity (100%) (*AUC*=0.971, 95% confidence interval: 0.915–1.027) for diagnosis of at least “moderate” anxiety. In other words, 100% of patients classified as less than “moderately ill” had a GAD-7 score <11 and 97% of patients with a GAD-7 score ≥11 were classified as at least “moderately ill.” A GAD-7 score of ≥17 represents the optimal compromise between sensitivity (100%) and specificity (69%) for diagnosis of “severe” severity (*AUC*=0.84, 95% confidence interval: 0.694–0.987). As such, 69% of patients classified as less than “severly ill” had a GAD-7 score <17 and 100% of patients with a GAD-7 score ≥17 were classified as “severly ill.” Confirmatory analyses using a maximum sensitivity and specificity approach (MaxSpSe) for GAD-7 scores ≥11 was associated with a positive predictive value of >99% and a negative predictive value of 0.833. For GAD-7 scores ≥17 were associated with a positive predictive value of 0.266 and a negative predictive value of >99%.

DISCUSSION

This is, to our knowledge, the first report of GAD-7 in pediatric patients with GAD and provides preliminary data supporting the potential use of the GAD-7 as a simple, self-rated questionnaire in clinical practice and for clinical research. Moreover, GAD-7 scores which

may be rapidly obtained, strongly correlate with scores from the clinician-rated PARS, which is administered to both the parent and the child and requires approximately 30 minutes to administer.[9]

That some items on the GAD-7 are more weakly correlated with items on the PARS is important with regard to (1) the construction of the respective assessments and (2) the fact that the PARS represents an interview-based assessment whereas the GAD-7 is a self-report. In our sample, all PARS items significantly correlated with the total GAD-7 score; however, the PARS physical symptom item, the avoidance of anxiety-provoking situations and the interference with non-family relationships items exhibited relatively lower correlation coefficients. This is noteworthy in that the PARS assesses symptom severity, frequency and impairment whereas the GAD-7 assesses the frequency of GAD symptoms. While, in general, the frequency and disability of symptoms correlate, some patients may exhibit more discordance and this may be particularly relevant to pediatric patients. In this regard, family-related factors such as accommodation (*i.e.*, the degree to which a family system shifts family or parental behaviors to reassure the child or to assist a patient with the avoidance of symptom triggers) uniquely contribute to symptom severity and symptom burden in pediatric patients with anxiety disorders[29]. Thus, factors such as accommodation may moderate the relative dissociation of item-level relationships between impairment items on the PARS and symptom frequency on the GAD-7.

From a clinical trials standpoint, preliminary validation of an alternative scale for the assessment of GAD severity, which correlates with the PARS, may be helpful with regard to the development of inclusion criteria for clinical trials. In this regard, several recent studies in adults have noted that baseline score inflation, which may occur unintentionally, represents a significant contributor to placebo response, particularly given that patients with less severe symptomatology exhibit greater placebo responses[30] and that lower severity has been found to be associated with higher placebo response, a phenomenon which appears to be increasing over the last 30 years for psychopharmacologic trials in pediatric patients with anxiety disorders.[31] In studies of adults with anxiety and depressive disorders, computer-administered self-report data have recently been utilized[32] and alternative rating scales—as opposed to scores on the primary outcome measure—have been used for inclusion criteria. Thus, GAD-7 scores could represent an alternative entry criterion for inclusion in clinical trials of adolescents with GAD, particularly given that they both correlate with the PARS and that they have good sensitivity and specificity for detecting the severity level of GAD.

With regard to the use of the GAD-7 or other structured symptom-based assessments as a guide for treatment interventions, it has been suggested that the “uptake” of research findings in the clinic is related to the ability of clinicians to relate the clinical progress of their individual patients to the outcomes in clinical trials.[17] Thus if clinicians are able to relate GAD-7 scores—which are easily obtained in the clinic—to the PARS (*i.e.*, the primary or secondary outcome in the majority of psychopharmacologic trials in youth with anxiety disorders),[33] clinicians may be better able to apply clinical trials findings to their individual patients. Additionally, the American Academy of Child & Adolescent Psychiatry recommends “self-report measures for anxiety” in children >8 years of age as these instruments may “assist with screening and monitoring response to treatment”[34] and thus,

the GAD-7 may be easily implemented into clinical practice settings for the tracking of clinical response and, if subsequent studies confirm our findings related to the validity of the instrument with regard to the reflection of disease severity, scores could guide treatment decisions and planning. In this regard, it has been previously suggested that cut-offs may guide treatment planning in youth with anxiety disorders,[17] a suggestion that is of particular importance in that clinicians may not always reliably detect treatment failure and that "formal methods of identifying" non-response have been recommended by some.[35]

LIMITATIONS

While this is the first study to evaluate the GAD-7 in adolescents, there are a number of important limitations. First, the sample size is small and all patients were evaluated at a single site, thus potentially limiting generalizability. Second, healthy comparison subjects are not included in this sample and therefore GAD-7 scores in healthy adolescents who ostensibly would have lower CGI-S ratings remains unexplored and will be important to evaluate prior to the GAD-7 being utilized as a screening test. Third, the participants were all individuals who—with their families—were "treatment-seeking" and recognized, to some extent, the impairment associated with their symptoms. Thus, it remains possible that greater insight in this treatment-seeking population created a more "accurate" reporting of their symptoms on the GAD-7 thus increasing the likelihood of detecting changes.

CLINICAL SIGNIFICANCE

The results described herein suggest that the GAD-7, a self-rating scale, may reflect symptom severity in adolescents with GAD and that GAD-7 scores are highly correlated with clinician-administered ratings of anxiety symptoms. Taken together, these preliminary findings raise the possibility that this publically available rating, which may be completed by adolescents in <2 min, could be utilized by clinicians to assess anxiety symptom severity in youth with GAD.

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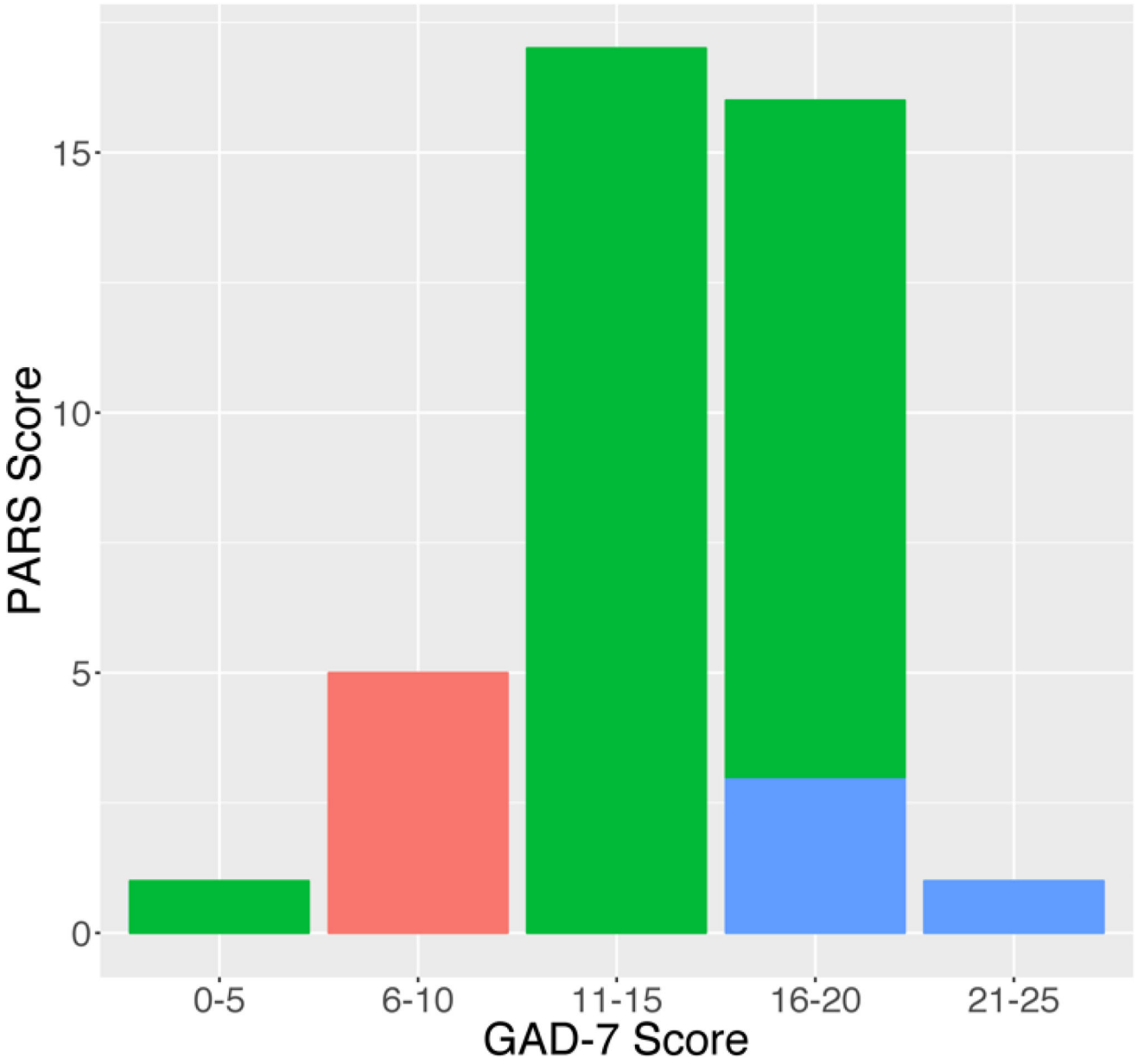

FIGURE 1. GAD-7 scores and Clinical Global Impression-Severity (CGI-S) scores

Frequency plots of GAD-7 scores with regard to Clinical Global Impression-Severity (CGI-S) scores in adolescents with GAD. Red bars indicate CGI-S scores of 1–3, green bars represent CGI-S scores of 4 and 5 and blue bars represent CGI-S scores of 6 and 7.

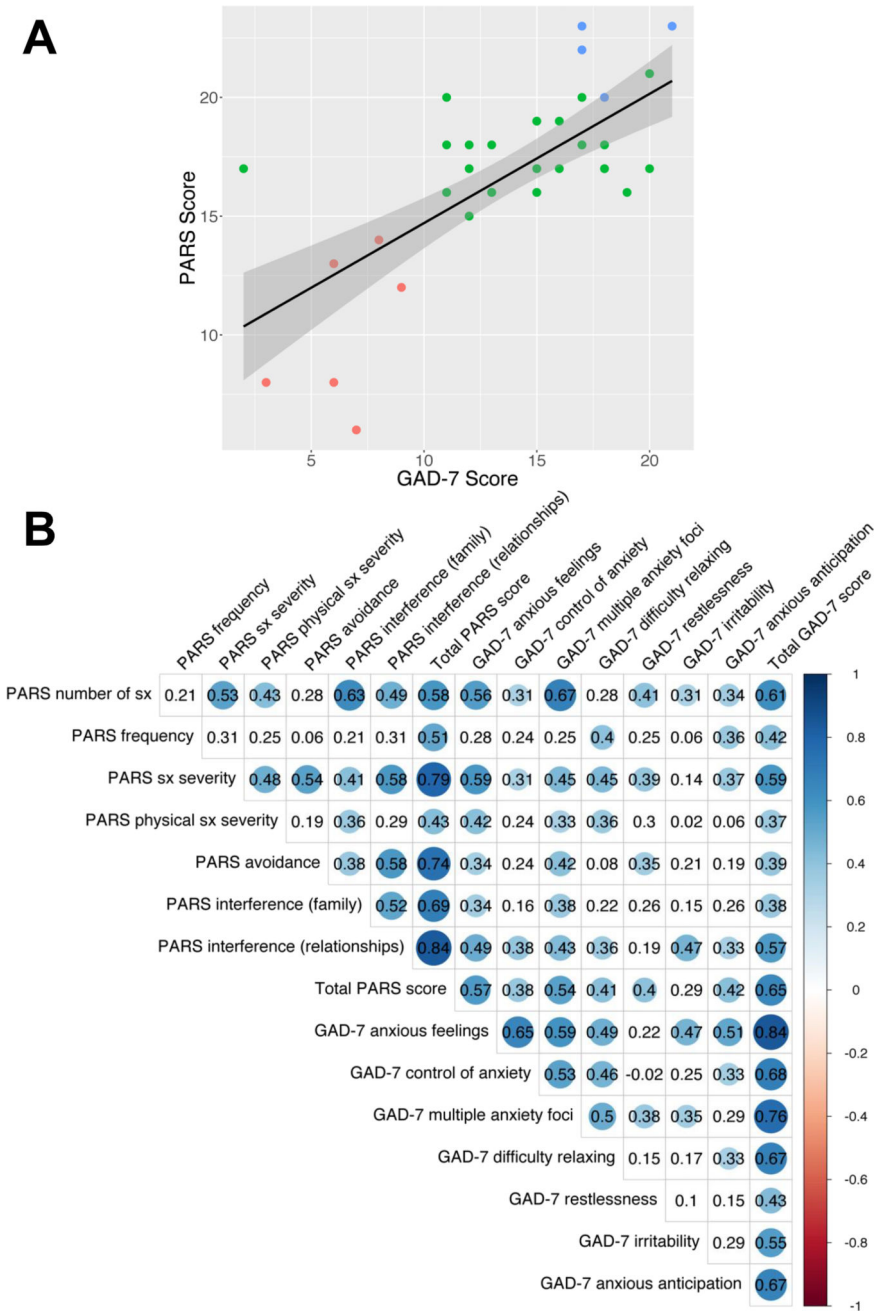

FIGURE 2. GAD-7 scores and Pediatric Anxiety Rating Scale (PARS) Scores

GAD-7 scores significantly and positively correlated with PARS scores (R=0.65, p<0.001). Clinical Global Impression-Severity (CGI-S) scores of 1–3 are denoted by red dots, scores of 4–5 are represented by green dots and scores of 6 and 7 are shown as blue dots (**A**). Additionally, individual correlation coefficients between GAD-7 items and PARS items are shown in a heat map with cooler colors reflecting larger correlation coefficients. Colored circles represent p-values <0.05 while white boxes reflect non-significant correlations (**B**).

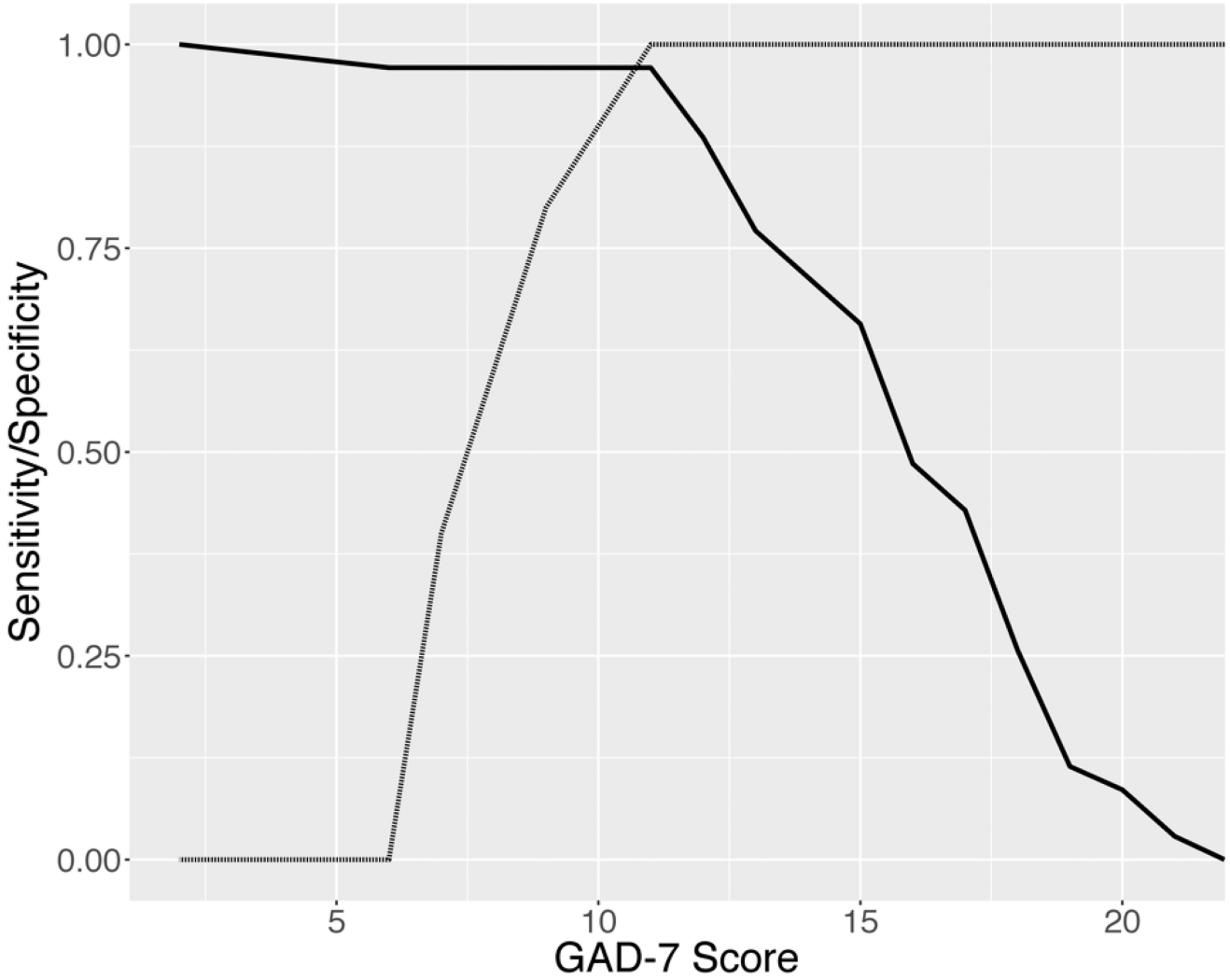

FIGURE 3. Sensitivity and specificity for the GAD-7 with regard to CGI-Severity Score ≤4 (moderate illness)

Solid and dashed lines represent sensitivity and specificity curves, respectively. A GAD-7 score of ≥11 represents the optimal compromise between sensitivity (97%) and specificity (100%) for classification of patients as at least “moderately ill.”

Table 1

Demographic and clinical characteristics of adolescents with generalized anxiety disorder (GAD).

Age, years, mean ± SD	14.8 ± 2.8
Male gender, n (%)	9 (22.5%)
Race, n (%)	
White	34 (85.0%)
Black or African American	2 (5.0%)
Multiracial	3 (7.5%)
Asian	1 (2.5%)
Ethnicity, n (%)	
Hispanic	3 (7.5%)
Non-Hispanic	37 (92.5%)
Current medical state, n (%)	
GAD	40 (100%)
Separation anxiety disorder	9 (22.5%)
Social anxiety disorder	19 (47.5%)
Specific phobia disorder	7 (17.5%)
Panic disorder	22 (55.0%)
ADHD	8 (20.0%)
PARS Score, mean ± SD	17.0 ± 3.3
CGI-S Score, mean ± SD	4.1 ± 1.2
GAD-7 Score, mean ± SD	14.1 ± 4.3
Tanner Score, n (%) *	
Stage III	5 (12.5%)
Stage IV	18 (45%)
Stage V	13 (32.5%)

ADHD, Attention-Deficity/Hyperactivity Disorder; PARS, Pediatric Anxiety Rating Scale; CGI-S, Clinical Global-Impression-Severity; GAD-7, Generalized Anxiety Disorder 7-item;

*data only collected for 37/40 patients

Table 2

PARS and GAD-7 scores of groups derived by CGI-S scores.

CGI-S Group	n	PARS score Mean ± SD (range)	GAD-7 score Mean ± SD (range)
1, 2, 3	5	10.6 ± 3.4(6–14)	7.2 ± 1.3 (6–9)
4, 5	31	17.4 ± 1.5 (15–21)	14.7 ± 3.6 (2–20)
6, 7	4	22.0 ± 1.4 (20–23)	18.3 ± 1.9 (17–21)
df		1, 39	1, 39
F		126.5	26.83
p		<0.001	<0.001

CGI-S, Clinical Global-Impression-Severity; PARS, Pediatric Anxiety Rating Scale; GAD-7, Generalized Anxiety Disorder 7-item;