The Pediatric Sleep Clinical Global Impressions Scale–A New Tool to Measure Pediatric Insomnia in Autism Spectrum Disorders

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ABSTRACT: ***Objective:*** **To pilot a clinician-based outcome measure that provides complementary information to objective measures and parent-based questionnaires for insomnia in children with autism spectrum disorders (ASD).** ***Method:*** **The authors developed a Pediatric Sleep Clinical Global Impressions Scale (CGI). Questions included (1) the child's ability to fall asleep and remain sleeping independently (i.e., apart from parents); (2) bedtime resistance; (3) sleep onset delay; (4) night awakening; (5) parental satisfaction with their child's current sleep patterns; (6) family functioning as affected by their child's current sleep patterns; and (7) clinician's overall concern with the child's sleep. After refining the instrument through the evaluation of vignettes by ASD and sleep experts, the authors piloted the Pediatric Sleep CGI in a 12-week randomized trial of iron supplementation in children with ASD. Clinicians completed Pediatric Sleep CGIs and structured sleep histories, parents completed the Children's Sleep Habits Questionnaire (CSHQ), and children wore actigraphy watches.** ***Results:*** **In repeated measures models, the Pediatric Sleep CGI and CSHQ were correlated for sleep onset delay ($r = .66$, $p < .001$), night wakings ($r = .40$, $p < .001$), and total score ($r = .29$, $p < .001$). The CGI-S sleep onset delay and actigraphy sleep onset delay scores ($r = .75$, $p = .0095$) were also correlated. The overall CGI-S showed improvement with therapy ($p = .047$).** ***Conclusion:*** **The Pediatric Sleep CGI shows promise in measuring clinician-rated outcomes in pediatric insomnia in children with ASD. Larger samples will be necessary to examine reliability, validity, and measure to change, as well as applicability to other populations with pediatric insomnia.**

*(J Dev Behav Pediatr 37:*370–376, 2016) **Index terms:** sleep, autism, CGI, Children's Sleep Habits Questionnaire, actigraphy.

Sleep disturbance is a common concern in pediatrics, especially among special populations, affecting 50% to 80% of children with autism spectrum disorders (ASD) compared with 20% to 50% of children with typical development.[1–3] One of the most common sleep concerns in pediatrics is insomnia, defined as difficulty in initiating or maintaining sleep, resistance in going to bed, or difficulty in sleeping without a parent or caregiver intervention, associated with daytime impairment, occurring at least 3 times a week, and present for at least 3 months.[4] Although parent-based questionnaires are valuable for documenting the presence of pediatric sleep concerns, they were not typically designed to evaluate the efficacy of potential treatments to improve sleep. In addition, clinician-based outcome measures provide important complementary information to parent questionnaires. For example, a clinician-based outcome measure allows the practitioner to assess a child's sleep across their experiences of caring for many children. It also allows for a more qualitative evaluation of the severity of sleep concerns. For example, although the Children's Sleep Habits Questionnaire[5] inquires whether a child falls asleep within 20 minutes after going to bed, and whether this is a problem, it does not differentiate the child who takes 45 minutes to fall asleep from the child who takes 2 hours. Clinician-based questionnaires can also provide information regarding the aspects of sleep when objective measures of sleep (actigraphy or

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Received August 2015; accepted March 2016.

Disclosure: The authors report no conflicts of interest or financial relationships relevant to this article. This research was conducted as part of a multicenter trial funded through the Autism Intervention Research Network on Physical Health (Cooperative agreement UA3 MC 11054 from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Maternal and Child Health Research Program, to the Massachusetts General Hospital) and the Autism Speaks Autism Treatment Network. The views expressed in this publication do not necessarily reflect the views of Autism Speaks, Inc. Additional support was provided by CTSA award numbers UL1TR000445, UL1 TR000042, and UL1 TR001082 from the National Center for Advancing Translational Sciences. Contents are solely the responsibility of the authors and do not necessarily represent official views of the National Center for Advancing Translational Sciences or the National Institutes of Health.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's Web site (www.jdbp.org).

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polysomnography) are not available or do not capture information about specific domains. These include bedtime resistance or how sleep affects the child and family. These questionnaires could serve as valuable assessment tools in clinical trials of the effects of interventions on sleep.

Our goal was to develop an instrument that captured both severity and clinician expertise in the interpretation of parent report of a child's sleep patterns, focusing on insomnia. Clinical Global Impressions Scales (CGIs) have been used in neuropsychiatric disorders[6,7] and have been recommended as outcome measures in autism clinical trials.[8] An autism CGI was used in a randomized clinical trial of education and parent training in children with ASD and behavior problems.[9] We developed a Pediatric Sleep CGI to provide a more comprehensive assessment of insomnia in intervention studies of autism and sleep. Furthermore, our instrument could be used by clinicians and sleep researchers to measure improvement in insomnia in children with ASD, and potentially in broader pediatric populations with insomnia. As an initial step, we piloted the Pediatric Sleep CGI in a trial of iron supplementation for children with ASD, low normal iron stores (serum ferritin between 17 and 49 ng/mL), and sleep onset delay or night waking.

METHODS

Description of Instrument

The Pediatric Sleep Clinical Global Impressions Scale (CGI) was developed based on review of existing CGIs in the literature, as well as consultation with clinicians within the Autism Speaks Autism Treatment Network (AS ATN). These clinicians included members of the AS ATN Sleep Committee and those who had developed the Ohio Autism Clinical Impressions Scale (OACIS), a CGI which focuses on autism symptoms that has been used in randomized clinical trials.[9] The AS ATN is a network of sites across North America dedicated to improving care for children with autism spectrum disorders (ASD) that includes standardized collection of data such as autism diagnosis, diagnostic history, and comorbid conditions associated with ASD.

Aspects of sleep included in the sleep CGI were (1) the child's ability to fall asleep and remain sleeping independently (e.g., apart from parents); (2) bedtime resistance; (3) sleep onset delay; (4) night awakening; (5) parental satisfaction with their child's current sleep patterns; (6) family functioning as affected by their child's current sleep patterns; and (7) clinician's overall concern with the child's sleep. These aspects are congruent with the elements of insomnia as defined by the International Classification of Sleep Disorders (difficulty in initiating or maintaining sleep, resistance in going to bed, or difficulty in sleeping without a parent or caregiver intervention, associated with daytime impairment).[4] The importance of focusing on these specific aspects was emphasized through input from clinicians and parents. The frequency of sleep concerns reported in the literature of children with ASD also supports these aspects. For example, sleep onset delay, night wakings, and children's unwillingness to sleep in their own bed are frequent parental sleep concerns.[10] We also believed that it is important to assess parental satisfaction with their children's sleep patterns and family functioning, as families tend to differ in their responses to a child's poor sleep.

There are 2 parts to the Pediatric Sleep CGI (Supplemental Digital Content 1, http://links.lww.com/JDBP/A103), following the work of the original CGI.[6] The first part is a severity scale (CGI-severity or CGI-S) in which each question was rated by the clinician on a scale of 1 to 7, with 1 representing no concerns and 7 among the highest level of concerns seen by the examiner. The second part is an improvement scale (CGI-improvement or CGI-I) in which each question was rated by the clinician on a scale of 1 to 7, with 1 representing "very much improved," 4 representing "no change," and 7 representing "very much worse." The 1 to 7 scales for the CGI-S and CGI-I were chosen based on the scales used in other CGIs.[6,9] To aid the clinician in completing the severity scale, we decided to include explicit anchors for several of the categories based on our concern that these anchors would be needed to limit subjectivity. For example, for bedtime resistance, "borderline to mild severity" (2 on a scale of 1–7) was defined as "talking," whereas "moderate to marked severity" (4 or 5 on a scale of 1–7) was defined as crying. The clinician was also asked to take into account the length of time and the number of nights each week the symptom occurred.

To allow for differentiation of the different aspects of sleep, each of the questions (A–F) of the sleep CGI (with the exception of Section G) was constructed to stand alone. For example, the clinician was asked to rate bedtime resistance independent of sleep onset delay. This allowed for differentiation of a child who took an hour to fall asleep, but lay quietly, from one who took an hour to fall asleep and was agitated and crying out in the hour before falling asleep. The ability of children to fall asleep on their own was rated separately from bedtime resistance, sleep onset delay, and night wakings as we recognized that cosleeping with a parent might lessen bedtime resistance, minimize sleep onset delay, and reduce the frequency or severity of night wakings. In this way, the sleep CGI allowed us to differentiate a child who had minimal bedtime resistance and was cosleeping from one who had minimal bedtime resistance and slept independently. To be sensitive to preferences regarding cosleeping and incorporate these preferences into the CGI, we also asked clinicians to indicate whether cosleeping was a parental preference. This was accomplished by making the first question "Does the child sleep in the same bed with the parent at any time?" A "no" answer to this question means that the child never sleeps with the parent, in which case the clinician was then instructed to skip to Section B. A "yes" answer to

this question means that the child sleeps with the parent, and the clinician was instructed to complete Section A with the exception that the clinician would also skip to Section B if the parent chose to cosleep. Given that some children cosleep all the time while others do so inconsistently, the clinician was guided to rate the concern related to cosleeping based on the number of nights a week cosleeping occurs and how much of the night it affects (e.g., falling asleep and staying asleep). The overall question regarding sleep (Section G) "How concerned are you with this child's sleep overall" on the severity scale and "Rate the total improvement in this child's sleep overall" on the improvement scale, did take into account the other scales. The clinician was asked to consider all the responses (A–F) on the severity and improvement scales, respectively, in rating these questions.

Refinement Through Vignettes

After the Pediatric Sleep CGI was drafted, we provided clinicians with several vignettes and asked them to complete the Pediatric Sleep CGI based on these vignettes. Scores were tabulated and in most cases, clinicians differed by no more than one number in a given category. The clinicians then met face-to-face to discuss their responses, paying particular attention to the responses in which clinicians differed by more than one number (1–7) in a given category. Through this discussion, the Pediatric Sleep CGI was refined further. For example, through consensus, agreement was reached on which anchors represented moderate bedtime resistance versus severe bedtime resistance. We also discussed at length how to provide the clinician some flexibility in rating a child's sleep, and how to best avoid overburdening the clinician with rules related to anchors, while at the same time ensuring uniformity in responses across children. For example, because of multiple factors to take into consideration when rating bedtime resistance (duration of crying, or how easily a parent might be able to comfort a child), we decided that anchors would not explicitly specify the length of time each night and the number of nights a week resistance occurred, but that clinicians would be asked to take these factors into account when making their ratings. In contrast, for sleep onset delay and night wakings, we did include specific information in the anchors related to length of time a child was awake and the number of nights per week that the concern occurred. After refining our Pediatric Sleep CGI and reviewing additional vignettes, we were able to achieve agreements by clinicians within one number on most categories.

Pilot Testing

We then pilot-tested our Pediatric Sleep CGI as a measure within a study of iron supplementation in children with ASD conducted at 3 sites within the AS ATN: University of Colorado, Vanderbilt University Medical Center, and University of Rochester Medical Center (Reynolds, submitted). The mean age (SD) of the 20 participants was 5.3 (2.9) years, with 86% male, 80% white, and 11% Hispanic. The children had low normal iron stores (serum ferritin between 17 and 49 ng/mL), and sleep onset delay or night waking. Low ferritin levels have been associated with poor sleep and restless legs syndrome[11,12] and thus may be an important remediable cause of insomnia in children with ASD.

The coordinating center at Massachusetts General Hospital and each site received Institutional Review Board/Research Ethics Board approval. To complete the Pediatric Sleep CGI, a structured sleep history was taken by the site investigators (clinicians with expertise in pediatric sleep or developmental medicine). See Supplemental Digital Content 1 (http://links.lww.com/JDBP/A104); any sleep history providing information to complete the CGI can be used. The structured sleep history covers the items from the CGI-S, including explicit questions about cosleeping, bedtime resistance, sleep onset delay, night wakings, parent satisfaction with their child's sleep, and how family functioning was affected by their child's sleep. Additional parent comments (which often arise naturally in the course of the evaluation) related to the frequency of cosleeping and where the child sleeps (in parent's bed, in the child's own bed in parent's room) were also used to complete the sleep CGI. Our structured sleep history, along with an initial medical evaluation, also included questions regarding sleep disorders or other medical conditions present that might be interfering with the child's sleep and warrant treatment before proceeding with the study (e.g., obstructive sleep apnea or gastroesophageal reflux disease).

Twenty participants who met inclusion criteria and whose insomnia did not respond to sleep education were randomized to 3 mg/kg/day of ferrous sulfate (n = 9) or placebo (n = 11) for 12 weeks. The Pediatric Sleep CGI (along with the structured sleep history) was initially collected at a screening visit and repeated at the randomization visit and again at monthly visits during the clinical trial (Weeks 4, 8, and 12).

Parents also completed the Children's Sleep Habits Questionnaire (CSHQ) at the screening, randomization, and monthly visits.[5] The CSHQ is a validated parentally completed questionnaire that has been used to examine sleep behavior in toddlers, preschool- and school-aged children with a variety of conditions, including ASD.[13–15] We used a shorter CSHQ version consisting of 33 items—this version contains the items that comprise the subscales. Subscales of the CSHQ measure insomnia-related dimensions such as bedtime resistance, sleep anxiety, sleep onset delay, sleep duration, and night wakings, as well as other dimensions such as daytime sleepiness, sleep disordered breathing, and parasomnias. Actigraphy watches were worn for 10 days before randomization and for 10 days at the end of Week 12 (posttreatment). To provide information about when the child first attempted to fall asleep (needed to calculate sleep onset delay) and any parentally reported night

wakings, as well as times the watch was removed, parents completed an actigraphy sleep diary form. Actigraphy devices (Philips Respironics Spectrum devices and Actiware version 5.7 software, Murrysville, PA) were worn on the nondominant wrist for 10 days to ensure 7 scorable days, with a 1-minute epoch length and a medium threshold used for data analysis. Parents were taught how to use actigraphy devices and to complete a sleep diary as described in a previous study of sleep education.[13] Children who were not able to tolerate the wrist device were given the opportunity to wear the device in a custom pocket on the shoulder of a shirt provided to the child. In a previous study, results from this modified placement were comparable with standard actigraphy.[16] Actigraphy data were interpreted at a central site (Vanderbilt University) in conjunction with sleep diaries documenting bedtime and wake time.

Analytic Plan

Histograms for each question of the Pediatric Sleep CGI severity scale (CGI-S) were plotted for each of the available visits to examine variability in the CGI scales. Repeated measures mixed effects regression models, including treatment and the treatment-visit interaction terms, were run to test the association between corresponding longitudinal sleep CGI-S and the CSHQ and actigraphy scores. CGI-S-visit interaction terms were also tested initially and included in the subsequent mixed effects regression models if the association with CSHQ was significant at the 0.05 level. The scores tested were bedtime resistance, sleep onset delay, night wakings, and overall sleep. Models used the initial in-person interview at screening, the randomization visit, and Weeks 4, 8, and 12 visit data. Given our small sample size, we did not examine the CGI-I. The study was also not designed to assess test-retest reliability.

RESULTS

Figure 1 shows the histograms for the Clinical Global Impressions severity score (CGI-S) at the screening visit in the pilot study, demonstrating that clinicians often (but not always) used the full range of CGI-S scores. Eighty-three percent of children were reported to sleep in their own beds. Only 1 child was reported to sleep with parents because of parental preference.

The relation of CGI-S and Children's Sleep Habits Questionnaire (CSHQ) did not differ by visit except for the night wakings question ($p = .0462$). The CGI-S night wakings-visit interaction term was therefore included in night wakings model. In the repeated measures models for sleep CGI-S (Table 1), there were significant associations between CGI-S and CSHQ in the following domains: sleep onset delay ($r = .659$; $p < .0001$), night wakings ($r = .401$; $p < .0001$), and overall ($r = .285$; $p < .0001$). For each unit increase in the corresponding CGI-S score, the CSHQ sleep onset delay score increased by approximately 0.259 units (95% CI, 0.162–0.355), night wakings score increased by approximately 0.647 units (95% CI, 0.382–0.912), and total score increased by approximately 2.558 units (95% CI, 1.572–3.544). There were no significant associations between the CGI-S and CSHQ bedtime resistance scores.

There were also significant associations between the CGI-S and actigraphy sleep onset delay scores ($r = .748$; $p = .0095$). For each unit increase in the CGI-S sleep onset delay score, the actigraphy score increased by approximately 6.923 minutes (95% CI, 1.961–11.884). There were no significant associations between the CGI-S night wakings and actigraphy wake time after sleep onset scores. Iron supplementation was associated with improvement on the overall CGI-S score (regression coefficient effect size $= -1.5$, $p = .047$).

To examine interobserver agreement, clinical cases based on 2 participants' sleep histories were reviewed by 5 clinicians (sleep specialists and a developmental pediatrician). See Supplemental Digital Content 3 (http://links.lww.com/JDBP/A105) for cases. For each question on the CGI-S and CGI-I, interobserver agreement, defined as being within one point of the median response, was 80% to 100% (Supplemental Digital Content 3, http://links.lww.com/JDBP/A105).

DISCUSSION

We report on a new clinician instrument, the Pediatric Sleep Clinical Global Impressions Scale (CGI), which was designed to measure response to an intervention to treat insomnia. The Pediatric Sleep CGI measures specific aspects of sleep that are common concerns in children with autism spectrum disorders (ASD), with a focus on aspects of insomnia. Insomnia is a very common concern in children with ASD, which was the motivation for the authors of this study to develop this instrument. However, our intent is that this instrument is also applicable to children without ASD, including those with other neurodevelopmental disorders.

The Pediatric Sleep CGI severity score (CGI-S) showed good convergent validity with the Children's Sleep Habits Questionnaire (CSHQ) for sleep onset delay and night wakings, as well as the overall score. Clinicians can use this instrument to calibrate the results of one child's sleep against that of others in their experience, measure responsiveness to interventions, and explicitly assess family functioning and parent satisfaction with a child's sleep. The sleep CGI-S for sleep onset delay also showed good convergent validity with actigraphic measurements of sleep onset delay. This has relevance to measurement of sleep onset insomnia in clinical trials, as well as in clinical practice. Although less intrusive and costly than polysomnography, actigraphy involves several steps that go beyond clinician report—configuring watches for children, parent education on how to collect the data in a reliable fashion, downloading of data, and scoring

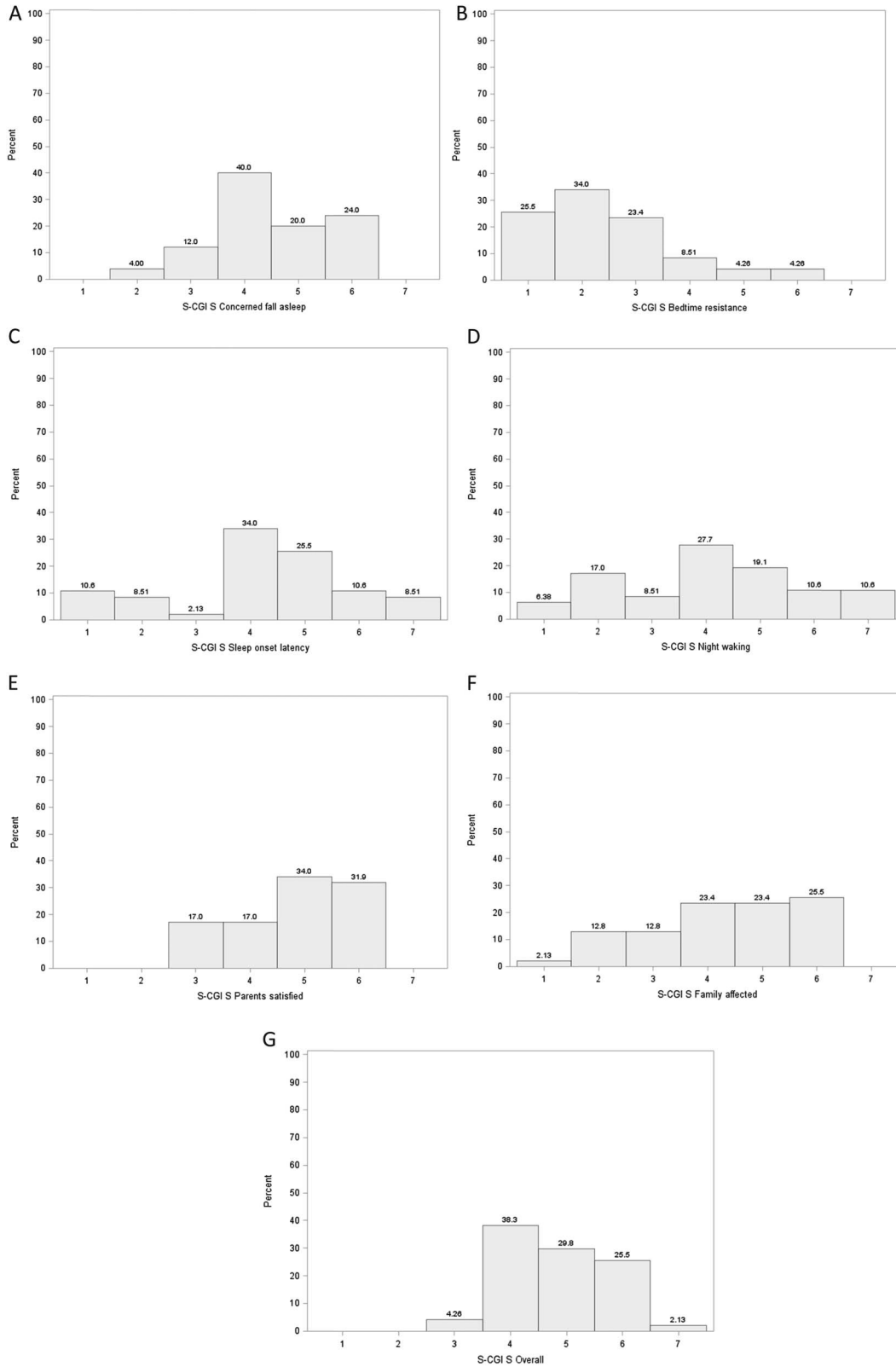

Figure 1. Histograms displaying the frequency of responses on the various Pediatric Sleep CGI subscales. A, Cosleeping, (B) bedtime resistance, (C) sleep onset latency, (D) night waking, (E) parents satisfied with child's sleep, (F) family affected by child's sleep, and (G) overall sleep. CGI-S, Clinical Global Impressions severity score.

by an experienced analyst. The Pediatric Sleep CGI may, therefore, provide an informative measure of sleep onset insomnia when actigraphy is not available.

Bedtime resistance did not show convergent validity with the CSHQ. This finding may have reflected a greater level of variability among clinicians in completing this

Table 1. Model Results for CSHQ and Actigraphy in Relation to Sleep CGI-S

Dependent Variable	Correlation Coefficient (r)	Estimate (β)	Standard Error	95% Confidence Interval	p
CSHQ bedtime resistance	−.105	0.029	0.146	−0.264 to 0.321	.844
CSHQ sleep onset delay	.659	0.259	0.048	0.162 to 0.355	<.0001
CSHQ night wakings	.401	0.647	0.132	0.382 to 0.912	<.0001
CSHQ overall	.285	2.558	0.486	1.572 to 3.544	<.0001
Actigraphy sleep onset delay	.748	6.923	2.328	1.961 to 11.884	.0095
Actigraphy WASO	−.379	0.614	1.784	−3.188 to 4.416	.736

CGI-S, Clinical Global Impressions severity score; CSHQ, Children's Sleep Habits Questionnaire; WASO, wake time after sleep onset.

scale (with fewer anchors for the bedtime resistance question). Alternatively, bedtime resistance on the CSHQ may have been measuring different constructs than the sleep CGI bedtime resistance question. In addition to "Struggles at bedtime," which reflects traditional bedtime resistance, other questions on the CSHQ bedtime resistance scale include less direct correlates of bedtime resistance such as "Goes to bed at the same time;" "Falls asleep in own bed"; "Falls asleep in other's bed"; "Needs parent in room to sleep"; and "Afraid of sleeping alone."

For night wakings, the sleep CGI-S did not show convergent validity with actigraphy measurements of wake time after sleep onset (WASO). We have shown similar dissonance in our work comparing actigraphy wake time after sleep onset with parent report of night wakings.[8] One possible contributor relates to differences in parent perception of night wakings from the amount of wake time that a child with ASD experiences, especially if a parent is not alerted to the child's awakening. It is also important to recognize that actigraphic measurements of WASO are based on movement, rather than actual waking. Children may lie quietly while awake, thereby underestimating WASO relative to wakefulness, whereas others may have restless sleep, thereby overestimating WASO relative to wakefulness. Although not systematically studied in ASD (to our knowledge), the repetitive behavior characteristics of ASD may result in higher levels of activity during wakefulness. Actigraphy and polysomnography have shown closer agreement with sleep onset than with WASO in previous studies in children.[17]

Our finding that an intervention was associated with improvement on the overall CGI-S supports that the CGI-S may be a useful instrument to measure change with interventions related to sleep.

We found the Pediatric Sleep CGI easy to complete and efficient in terms of time required. The use of anchors did require pairing of the sleep CGI with a structured sleep history, although one could also use the sleep CGI without anchors and increase efficiency even further. This would require further study to determine whether raters are consistent in their responses and whether convergent validity with parent-reported questionnaires such as the CSHQ is preserved even when anchors and a structured sleep history are not used. It may also be appropriate to provide training for individuals who will use the Pediatric Sleep CGI to rate children, especially if used in research studies.

This study has several limitations. Because of the small sample size, our findings are preliminary; the Pediatric Sleep CGI will require additional study in larger samples with attention to reliability, validity, and change with an intervention. We did not include a validated measure of family functioning in our study to compare with the Pediatric Sleep CGI. We did not quantify parent concern about cosleeping for those who cosleep out of parental preference; although cosleeping due to parent preference was uncommon in this small sample of children with ASD, it may be more common in larger and more heterogeneous samples. One concern raised by an astute reviewer of our work is that some children sleep in the same room with their parents but do not share a bed. We therefore modified the Pediatric Sleep CGI header for Question A to read "Does the child sleep in the same bed or room with the parent at any time?" In addition, although we assessed interobserver agreement, we did not assess interrater reliability. In future work, interrater and test-retest reliability of the Pediatric Sleep CGI, additional assessments of construct validity especially for questions related to cosleeping, parent satisfaction, and impact on the family will be necessary. In addition, ability to assess improvement with an intervention will need to be tested rigorously in future work. The use of the Pediatric Sleep CGI in primary care is also worthy of study—it would allow for collection of a clinician-based outcome measure based on parent input that may provide valuable information on treatment response. Although the CGI questions are relatively straightforward and therefore likely to be implemented easily by primary care physicians, it will be important to gain experience to ensure that this CGI is appropriate for use in primary care settings.

In summary, most current sleep questionnaires assess parent report of the presence or frequency of sleep problems, not the severity of sleep problems, and very few measures change.[18] Outcome measures sensitive to change are needed to evaluate efficacy of sleep interventions. The Pediatric Sleep CGI is a novel instrument that allows a clinician to assess the severity of pediatric sleep domains related to insomnia. Future work will be

needed to determine the usefulness of this instrument in larger populations of children with and without ASD, and its relationship to parent-reported questionnaires and objective measures of sleep.

ACKNOWLEDGMENTS

The following individuals assisted with development of the Pediatric Sleep CGI: Jennifer Accardo, MD, Robert Arendt, MD, and Eric Butter, MD. The following individuals assisted with study coordination: Susanna Burr, Sheryl Faut, Jennifer Foley, Stephanie Huston, Amy Wallace, and Deborah Wofford. We are also grateful to the families who participated in this study.

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